

REGISTRATION REPORT

Part B **Section 3** **Efficacy Data and Information** Concise summary

Product code: GF-3307
Product name(s): not assigned yet
Chemical active substances:
Fenpicoxamid, 50 g/L
Prothioconazole, 100 g/L

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT (authorization)

Applicant: Corteva Agriscience
Submission date: July 2021, updated May 2022
MS Finalisation date: August 2022 (initial Core Assessment)
January 2023 (final Core Assessment)

Version history

When	What
July 2021	Initial dRR – Corteva Agriscience
May 2022	<p>Updated by Applicant (orange text)</p> <p>The data in Preliminary Sections 3.2.1.10 and 3.2.1.11 has been removed due to concerns raised by the zRMS.</p> <p>In the efficacy section, 39 new trials have been added (24 on winter wheat, 1 on spring wheat, 2 on winter rye, 1 on winter triticale, 10 on winter barley and 1 on spring barley) and 4 two-dose trials have been removed (2 on winter wheat, 1 on winter triticale and 1 on winter barley). The additional trials from 2021 have bolstered data available for Fusarium and mildew in wheat in the NE EPPO and additional trials from 2021 to support the SE EPPO zone on a range of diseases. Generally there is a more complete package to fully support the GAP.</p> <p>A dose range of 1.0-1.5 L/ha has been proposed for use in the EPPO North-East zone for control of SEPTTR and ERYSGT on wheat and RHYNSE and PUCCHD on barley.</p> <p>The dose range of 1.0-1.5 L/ha on barley in the EPPO South-East zone now covers claims for control of RHYNSE.</p> <p>Update general EPPO standards in efficacy sections: Since these tables are in the "efficacy test" chapter, the EPPO standard PP 1/225 (Minimum effective dose) is removed and replaced by the EPPO standards PP 1/226 (Number of efficacy trials), PP 1/214 (Principles of acceptable efficacy) and PP 1/223 (Introduction to the efficacy evaluation of plant protection products).</p>
August 2022	<p>Initial zRMS assessment</p> <p>The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Data or text not agreed, or the information considered irrelevant by zRMS are struck through, but left in black font. On the contrary, the content removed by the applicant as the result of dossier updating described above, in May 2022, is left in place for completeness, but as the text struck through and faded.</p>
January 2023	<p>Final report (Core Assessment updated following the commenting period).</p> <p>Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is struck through and shaded.</p>

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3 Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

3.1 Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6) Abstract

Abstract by zRMS

Introduction

GF-3307 is a fungicide, the EC formulation of 50 g/L fenpicoxamid and 100 g/L prothioconazole. According to the information given by the applicant, “*GF-3307 is already approved for use in wheat, rye and triticale in Austria, UK, Ireland, France, Germany, Belgium, Netherlands, Serbia, Bulgaria with submissions for wheat, barley and oilseed rape under review in a number of countries*”. With the present submission the applicant is seeking approval for the use of GF-3307 in the control of foliar diseases in cereals, at the range of dose rates depending on disease complex, severity and zone location, with the maximum dose rate of 1.5 L/ha, applied once per growth season at BBCH 30-69, in the Czech Republic, Poland, Slovakia and Romania..

1) Information on the dossier update:

In May 2022 the applicant had delivered 39 new efficacy trials from 2021, the action accepted by the zRMS in the course of the pre-submission meeting held in April 2021. At the same time the applicant decided to remove 4 efficacy trials from the dataset submitted hitherto, based on their double-spray application scheme irrelevant for the present submission, and to withdraw 31 preliminary data trials (KCP 6.1 section) that had been previously submitted but are now declared irrelevant to the submission. Austria was removed from the GAP table as the cMS, although the trials carried out in this MS have been retained in the data set, being reportedly supportive for the FUSASP efficacy data for the SE EPPO zone. It has been revealed, in the course of the evaluation, that still 22 more efficacy trials from the data set were in fact never used by the applicant while producing the present dRR. These trials were delivered to zRMS along with the original submission, they have been evaluated by the zRMS, but they are not listed in the Appendix 1, neither in the original nor in the updated dRR or BAD. They are now listed by the zRMS, by the end of the Appendix 1.

The BAD and the dRR documents became updated accordingly, by highlighting majority of the added or altered content with the orange font. In the updated dRR file submitted in May 2022, the original dRR parts that were abandoned by the applicant have been removed permanently, making the rejected content invisible to the reader. Conversely, not all of the text amendments made by the applicant during the update (for instance, the tabulated info on the dose rates used) were highlighted by orange font colour, in the updated file.

As revealed during the inspection of the original submission versus the updated file, the extent of the unmarked amendments is considerable. Therefore the zRMS has additionally marked, by orange font, the parts amended but not marked as such by the applicant, and has restored the originally submitted but now abandoned dRR parts, along with the parts of the evaluation that were complete on the day of the update submission. These parts are now clearly marked by the ~~faded and struck-through font~~. They are more essential for the evaluator, than they are for the cMSs. Although reading them is not necessary for understanding the present submission, for the evaluator the content added and amended by the applicant in order to present and summarize the 2021 data is more comprehensible when accompanied by the old text and previous data summaries.

In the updated version, the new figures in summary tables replaced the former values without leaving the latter in faded and struck-through format, thus making extremely time-consuming any attempt to restore them one by one. In such cases the original tables are faded and struck through *en masse*, by the zRMS, and their updated versions are pasted below and are marked orange, *en masse* either. The same rule is also applied to the GAP table, of which the original, 5-paged version was replaced, on request of zRMS, with the extended form, displaying crops and target pathogens in separate rows, and to the the Appendix 1, *List of data considered in support of the evaluation*, of which the updated version is pasted following the full, original version. For clarity, both versions of Appendix 1 are indexed in the content table of dRR, in the preceding page.

The zRMS actions resulting from the evaluation alone (and not from the integration of the altered, added and removed content) are restricted to:

- 1) adding text under grey highlight, when necessary, including adding values or rows to original tables, the rows added are in such cases shaded grey completely. To avoid ambiguity, the omnipresent shading of selected table rows by the applicant was removed by zRMS,
 - 2) striking text through when necessary (~~in the original parts under black font and in those amended, marked with the orange font~~),
 - 3) adding commenting boxes.
- These actions refer exclusively to the proper dRR content, *i.e.* to the dossier in the updated shape, as submitted by the applicant in May 2022. In contrast, the text under ~~faded and struck through font~~ marks exclusively the action of the applicant: removal of some parts during the update.

2) The data set actually relied on for the evaluation

The dossier containing originally (July 2021) 232 efficacy trials from 2012-2020, is now supported by **267 trials** (232+39-4) from **2014-2021**, including 133 trials in wheat, 19 in rye, 32 in triticale and 83 in barley.

The preliminary tests and trials presented by the applicant support the co-formulation of the actives, their selected ratio in the product, the formulation type, as well as the efficacy claims based on control of example pathogens in wheat and barley.

Minimum Effective Dose

The zRMS summary of the MED data is located by the end of the MED chapter, in the page **284 285**.

Efficacy

Uses supported in the EPPO Maritime zone

In **winter**¹⁾ **wheat** in control of SEPTTR, PUCCRT, PUCGST, FUSASP, PYRNTR and ERYSGT¹⁾, at 1.5 L/ha, in **winter rye** in control of PUCCRE and RHYNSE, at 1.5 L/ha, in **winter triticale** in control of SEPTSP, ERYSGT and PUCGST, at 1.5 L/ha, in winter and spring **barley** in control of RAMUCC, RHYNSE, PUCCHD and ERYSGH, at 1.5 L/ha, in **winter barley** in control of PYRNTE, at 1.5 L/ha.

Uses supported in the EPPO North-Eastern zone

In winter and spring **wheat** in control of SEPTTR and ERYSGT, at 1.0-1.5 L/ha, in control of PUCGST and PYRNTR, at 1.2-1.5 L/ha, in **winter wheat** in control of PUCCRT at 1.2 – 1.5 L/ha and in control of FUSASP, at 1.5 L/ha, in **winter rye** in control of PUCCRE and RHYNSE at 1.2-1.5 L/ha, in **winter triticale** in control of SEPTSP, ERYSGT and PUCGST, at 1.2 - 1.5 L/ha, in **spring triticale** in control of PYRNTR and PUCCRT, at 1.2 - 1.5 L/ha, in winter and spring **barley** in control of RHYNSE and PUCCHD at 1.0 - 1.5 L/ha, and in control of PYRNTE and ERYSGH at 1.2 – 1.5 L/ha.

Uses supported in the EPPO South-Eastern zone

In **winter wheat** in control of SEPTTR at 1.0-1.5 L/ha, In **winter wheat** in control of PUCCRT, PUCGST, PYRNTR and ERYSGT¹⁾, at 1.2-1.5 L/ha, and in control of FUSASP - at 1.5 L/ha *, in winter and spring **barley** in control of RAMUCC **, PYRNTE and ERYSGH at 1.2-1.5 L/ha and in control of RHYNSE*** and PUCCHD at 1.0 - 1.5 L/ha.

*, **, ***, ¹⁾ - all details and additional necessary comments of zRMS are in the commenting box following the *Efficacy tests* chapter, page **480 485**.

Yield and quality

The test item GF-3307, when applied at all the proposed label rates of 1.0 - 1.5 L/ha across the EPPO Maritime, North-Eastern and South-Eastern climatic zones, had demonstrated positive effect on yield amount and quality in wheat, barley, triticale and rye crops. More details can be found in the commenting box page 479.

Risk of Resistance

Prothioconazole represents well known SBI Class I (DMI), FRAC group 3 (G1), while fenpicoxamid is relatively novel a compound, representing FRAC group 21 (C4), with the mode of action based on binding to the quinone inside site of mitochondrial electron transport complex III. Both prothioconazole and fenpicoxamid represent single-site mode of action, whereas some of the pathogens targeted by GF-3307, as ERYSGH and

RAMUCC, are considered as pathogens of high risk of resistance development. Following the scheme outlined in the EPPO guidance PP1 / 213 (4), the applicant characterized: 1) the resistance risk intrinsic in the key target pathogens (SEPTTR, PUCCTR, PYRNTE and RAMUCC) and 2) the one intrinsic in the actives – components of the GF-3307. The applicant has concluded that the unmodified risk of resistance resulting from the unrestricted use is medium to high for SEPTTR and RAMUCC, and low to medium for PUCCTR and PYRNTE. The risk of cross resistance, risk modifiers and label recommendations concerning risk management strategy are described in the commenting box following the resistance chapter, p. 523 530.

Adverse effects on the treated crops

Phytotoxic effects

Phytotoxicity symptoms were reported by none of the testing units in none of the **efficacy trials**, making the submission of the dedicated selectivity trials unnecessary, according to the PP 1/135(4) EPPO guidance. Some **selectivity** trials have been submitted nevertheless. No symptoms were seen in 5 dedicated selectivity trials in TRZAW, nor in 2 selectivity trials in TRZAS. A single, variety-screening selectivity study, based on double-application scheme was carried out in 2014 in the UK, testing 4 varieties of TTLWI, 2 – of SECCW, and 2 – of HORVW. No phytotoxicity symptoms were observed. No impact on germination ability of the seeds was reported from the selectivity trials in wheat, triticale and rye, nor from the efficacy trials in barley. The GF-3307 was not found to be affecting the baking or beer brewing processes, including the effect on the gustatory quality (in case of beer).

Impact on succeeding and adjacent crops

It may be broadly assumed that negative effects on succeeding crops are unlikely, following the application of GF-3307 at the dose rates up to 1.5 L/ha in cereals as the preceding crops. For details see the zRMS comments following the chapter 3.5.1. The same is essentially true for adjacent crops, but see also the zRMS comments after the respective chapter 3.5.2.1.

Tank cleaning

Standard triple rinsing of the sprayer tank with water volume of 10% total tank capacity is sufficient to avoid any negative impact of GF-3307 on any subsequently sprayed crops.

Rainfastness studies

In two studies, one in wheat (PUCCTR and SEPTTR) and one in barley (RHYNSE) no loss of control efficacy was observed after simulated rainfall of 10 mm or 30 mm respectively in wheat and barley. GF-3307 may be claimed rainfast after 1 hour time following its application.

GF-3307 is a new agricultural fungicide for the control of a range of important foliar diseases in wheat, rye, triticale and barley. The product is formulated as an emulsifiable concentrate (EC) containing 50 g/L fenpicoxamid and 100 g/L prothioconazole. GF-3307 is already approved for use in wheat, rye and triticale in Austria, UK, Ireland, France, Germany, Belgium, Netherlands, Serbia, Bulgaria with submissions for wheat, barley and oilseed rape under review in a number of countries.

This dossier is supported by 232 267 effectiveness trials (133 Wheat, 19 rye, 32 triticale, 83 barley) from across the EPPO Maritime, North-East and South-East climatic zone. It is considered that the proposed disease claims and dose rates are fully supported by these data and authorisation across the Central EU Authorisation zone can be recommended.

GF-3307 is pre-mixture of non-cross resistant fungicides (fenpicoxamid and prothioconazole). The resistance risk is considered low to high, depending on the target pathogen, and a number of modifiers (including a maximum of one application per season) have been proposed to restrict use to reduce risk of resistance developing. The applicant has established strong baselines for specific diseases is conducting and will conduct a resistance monitoring programme on a regular basis in order to detect the potential development of fungicide resistance within the target diseases in Europe. If this should occur, they provide recommendations in terms of chemical control and agronomic practices.

It considered that the use of GF-3307 as proposed will have no adverse effects on winter and spring wheat (including spelt and durum wheat), rye, triticale, winter and spring barley crops treated between

growth stage BBCH 30 (beginning of stem elongation) and up to and including the end of flowering (BBCH 69).

It is considered that the use of GF-3307 as proposed will have no undesirable or unintended side-effects on succeeding crops, adjacent crops or on beneficial and other non-target organisms.

This assessment is fully compliant with Uniform Principles.

Table 3.1-1: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

	2	3	4	5	6	7	8	9	10	11	12	13	14	
Use- No. ²⁸	Member state(s)	Crop and/ or situation (crop destination /purpose of crop)	F, Fn, FnP G, Gn, GnP or I ^{28,29}	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g-safener/-synergist per ha, other dose rate expression, dose range (min-max)	
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product /ha a) max. rate per appl. b) max. total rate per crop/season	g or kg ai/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW), Durum wheat (TRZDU), Spelt (TRZSP)	F	<i>Zymoseptoria tritici</i> (SEPTTR), <i>Puccinia recondita</i> (PUCCRT), <i>Puccinia striiformis</i> (PUCCST), <i>Fusarium</i> spp. (FUSASP), <i>Blumeria graminis</i> f. sp. <i>tritici</i> (ERYSGT), <i>Pyrenophora tritici- repentis</i> (PYRNTR)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	14	a) 1.5 L/ha b) 1.5 L/ha	a) 75 fenpicoxamid + 150 prothioconazole b) 75 fenpicoxamid + 150 prothioconazole	100-300	PHI F	Range 1.2-1.5 L/ha proposed (except <i>Fusarium</i> spp. (FUSASP))	
2	PL,	Winter triticale (TTLWI)	F	<i>Septoria</i> spp. (SEPTSP), <i>Puccinia striiformis</i> (PUCCST), <i>Blumeria graminis</i> f. sp. <i>tritici</i> (ERYSGT)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	14	a) 1.5 L/ha b) 1.5 L/ha	a) 75 fenpicoxamid + 150 prothioconazole b) 75 fenpicoxamid + 150 prothioconazole	100-300	PHI F	Range 1.2-1.5 L/ha proposed	
3	PL	Winter rye (SECCW)	F	<i>Rhynchosporium secalis</i> (RHYNSE), <i>Puccinia recondita</i> (PUCCRE)	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	14	a) 1.5 L/ha b) 1.5 L/ha	a) 75 fenpicoxamid + 150 prothioconazole b) 75 fenpicoxamid + 150 prothioconazole	100-300	PHI F	Range 1.2-1.5 L/ha proposed	
4	PL	Winter barley (HORVW)	F	<i>Ramularia collo- cygni</i> (RAMUCC), <i>Rhynchosporium secalis</i> (RHYNSE), <i>Pyrenophora teres</i> (PYRNTE),	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	14	a) 1.5 L/ha b) 1.5 L/ha	a) 75 fenpicoxamid + 150 prothioconazole b) 75 fenpicoxamid + 150 prothioconazole	100-300	PHI F	Range 1.2-1.5 L/ha proposed	

				<i>Puccinia hordei</i> (PUCCHD); <i>Blumeria graminis</i> f. sp. <i>hordei</i> (ERYSGH);										
5	PL	Spring-wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> (SEPTTR); <i>Puccinia recondita</i> (PUCCRT); <i>Puccinia striiformis</i> (PUC CST); <i>Fusarium</i> spp. (FUSASP); <i>Blumeria graminis</i> f. sp. <i>tritici</i> (ERYSGT); <i>Pyrenophora tritici-repentis</i> (PYRNTR)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a) 75-fenpicoxamid +150-prothioconazole b) 75-fenpicoxamid +150-prothioconazole	400-300	PHI-F	Range 1.2-1.5 L/ha proposed, except <i>Fusarium</i> spp. (FUSASP)	
6	PL	Spring-triticale (TTLSO)	F	<i>Septoria</i> spp. (SEPTSP); <i>Puccinia striiformis</i> (PUC CST); <i>Blumeria graminis</i> f. sp. <i>tritici</i> (ERYSGT)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a) 75-fenpicoxamid +150-prothioconazole b) 75-fenpicoxamid +150-prothioconazole	400-300	PHI-F	Range 1.2-1.5 L/ha proposed	
7	PL	Spring-rye (SECCS)	F	<i>Rhynchosporium secalis</i> (RHYNSE); <i>Puccinia recondita</i> (PUC CRE)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a) 75-fenpicoxamid +150-prothioconazole b) 75-fenpicoxamid +150-prothioconazole	400-300	PHI-F	Range 1.2-1.5 L/ha proposed	
8	PL	Spring-barley (HORVS)	F	<i>Ramularia collo-cygni</i> (RAMUCC); <i>Rhynchosporium secalis</i> (RHYNSE); <i>Pyrenophora teres</i> (PYRNTE); <i>Puccinia hordei</i> (PUCCHD); <i>Blumeria graminis</i> f. sp. <i>hordei</i> (ERYSGH);	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a) 75-fenpicoxamid +150-prothioconazole b) 75-fenpicoxamid +150-prothioconazole	400-300	PHI-F	Range 1.2-1.5 L/ha proposed	
9	AT, CZ	Winter-wheat (TRZAW); Durum-wheat	F	<i>Zymoseptoria tritici</i> (SEPTTR); <i>Puccinia recondita</i>	Tractor mounted spray	BBCH 30-69	a)-1	14	a)-1.5 L/ha	a) 75-fenpicoxamid +150-prothioconazole	400-300	PHI-F		

		(TRZDU), Spelt (TRZSP)		(PUCCRT), <i>Puccinia-striiformis</i> (PUCGST), <i>Fusarium</i> spp. (FUSASP), <i>Blumeria graminis</i> f. sp.-tritici (ERYSGT), <i>Pyrenophora tritici-</i> <i>repentis</i> (PYRNTR)			b)-1		b)-1.5 L/ha	b)-75 fenpicoxamid + 150-prothioconazole				
10	AT, CZ	Winter-tritiale (TTLWT)	F	<i>Septoria</i> spp. (SEPTSP), <i>Puccinia-striiformis</i> (PUCGST), <i>Blumeria graminis</i> f. sp.-tritici (ERYSGT)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid + 150-prothioconazole b)-75 fenpicoxamid + 150-prothioconazole	100-300	PHI-F		
11	AT, CZ	Winter-rye (SECCW)	F	<i>Puccinia-recondita</i> (PUCCRE), <i>Rhynchosporium</i> <i>secalis</i> (RHYNSE)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid + 150-prothioconazole b)-75 fenpicoxamid + 150-prothioconazole	100-300	PHI-F		
12	AT, CZ	Winter-barley (HORVW)	F	<i>Ramularia collo-</i> <i>cygni</i> (RAMUCC), <i>Rhynchosporium</i> <i>secalis</i> (RHYNSE), <i>Pyrenophora-teres</i> (PYRNTE), <i>Puccinia-hordei</i> (PUCCHD), <i>Blumeria graminis</i> f. sp.-hordei (ERYSGH).	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid + 150-prothioconazole b)-75 fenpicoxamid + 150-prothioconazole	100-300	PHI-F		
13	AT, CZ	Spring-wheat (TRZAS)	F	<i>Zymoseptoria-tritici</i> (SEPTTR), <i>Puccinia-recondita</i> (PUCCRT), <i>Puccinia-striiformis</i> (PUCGST), <i>Fusarium</i> spp. (FUSASP), <i>Blumeria graminis</i> f. sp.-tritici (ERYSGT), <i>Pyrenophora tritici-</i>	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid + 150-prothioconazole b)-75 fenpicoxamid + 150-prothioconazole	100-300	PHI-F		

				<i>repentis</i> (PYRNTR)										
14	AT, CZ	Spring-triticale (TFLSO)	F	<i>Septoria</i> spp. (SEPTSP); <i>Puccinia-striiformis</i> (PUC CST); <i>Blumeria graminis</i> f. sp.- <i>tritici</i> (ERYSGT)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid +150-prothioconazole b)-75 fenpicoxamid +150-prothioconazole	100-300	PHI F		
15	AT, CZ	Spring-rye (SECCS)	F	<i>Zymoseptoria-tritici</i> (SEPTTR); <i>Puccinia-recondita</i> (PUC CRT); <i>Puccinia-striiformis</i> (PUC CST); <i>Fusarium</i> spp. (FUSASP); <i>Blumeria graminis</i> f. sp.- <i>tritici</i> (ERYSGT); <i>Pyrenophora-tritici- repentis</i> (PYRNTR)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid +150-prothioconazole b)-75 fenpicoxamid +150-prothioconazole	100-300	PHI F		
16	AT, CZ	Spring-barley (HORVS)	F	<i>Ramularia-collo- cygni</i> (RAMUCC); <i>Rhynchosporium secalis</i> (RHYNSE); <i>Pyrenophora-teres</i> (PYRNTE); <i>Puccinia-hordei</i> (PUC CHD); <i>Blumeria graminis</i> f. sp.- <i>hordei</i> (ERYSGH);	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid +150-prothioconazole b)-75 fenpicoxamid +150-prothioconazole	100-300	PHI F		
17	SK, RO	Winter-wheat (TRZAW); Durum-wheat (TRZDU); Spelt (TRZSP)	F	<i>Zymoseptoria-tritici</i> (SEPTTR); <i>Puccinia-recondita</i> (PUC CRT); <i>Puccinia-striiformis</i> (PUC CST); <i>Fusarium</i> spp. (FUSASP); <i>Blumeria graminis</i> f. sp.- <i>tritici</i> (ERYSGT); <i>Pyrenophora-tritici- repentis</i> (PYRNTR)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid +150-prothioconazole b)-75 fenpicoxamid +150-prothioconazole	100-300	PHI F	Dose-range-proposed-from 1.0-1.5 L/ha-for-SEPTTR; 1.2-1.5 L/ha-for-other diseases, except <i>Fusarium</i> spp. (FUSASP). Lower doses-to-be-used-when lower-disease-pressure	

18	SK, RO	Winter barley (HORVW)	F	<i>Ramularia collo-cygni</i> (RAMUCC); <i>Rhynchosporium secalis</i> (RHYNSE); <i>Pyrenophora teres</i> (PYRNTE); <i>Puccinia hordei</i> (PUCCHD); <i>Blumeria graminis</i> f. sp. <i>hordei</i> (ERYSGH);	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid + 150 prothioconazole b)-75 fenpicoxamid + 150 prothioconazole	100-300	PHI-F	Dose-range proposed from 1.0-1.5 L/ha for PUCCHD; 1.2-1.5 L/ha for other diseases. Lower doses to be used when lower disease pressure	
19	SK, RO	Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> (SEPTTR); <i>Puccinia recondita</i> (PUCCRT); <i>Puccinia striiformis</i> (PUC CST); <i>Fusarium</i> spp. (FUSASP); <i>Blumeria graminis</i> f. sp. <i>tritici</i> (ERYSGT); <i>Pyrenophora tritici-repentis</i> (PYRNTR)	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid + 150 prothioconazole b)-75 fenpicoxamid + 150 prothioconazole	100-300	PHI-F	Dose-range proposed from 1.0-1.5 L/ha for SEPTTR; 1.2-1.5 L/ha for other diseases, except <i>Fusarium</i> spp. (FUSASP). Lower doses to be used when lower disease pressure	
20	SK, RO	Spring barley (HORVS)	F	<i>Ramularia collo-cygni</i> (RAMUCC); <i>Rhynchosporium secalis</i> (RHYNSE); <i>Pyrenophora teres</i> (PYRNTE); <i>Puccinia hordei</i> (PUCCHD); <i>Blumeria graminis</i> f. sp. <i>hordei</i> (ERYSGH);	Tractor mounted spray	BBCH 30-69	a)-1 b)-1	14	a)-1.5 L/ha b)-1.5 L/ha	a)-75 fenpicoxamid + 150 prothioconazole b)-75 fenpicoxamid + 150 prothioconazole	100-300	PHI-F	Dose-range proposed from 1.0-1.5 L/ha for PUCCHD; 1.2-1.5 L/ha for other diseases. Lower doses to be used when lower disease pressure	

Table 3.1-2: Acceptability of intended uses (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	PL	Winter wheat (TRZAW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
2	PL	Winter wheat (TRZAW)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
3	PL	Winter wheat (TRZAW)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
4	PL	Winter wheat (TRZAW)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
5	PL	Winter wheat (TRZAW)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
6	PL	Winter wheat (TRZAW)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
7	PL	Durum wheat (TRZDU)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
8	PL	Durum wheat (TRZDU)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
9	PL	Durum wheat (TRZDU)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
10	PL	Durum wheat (TRZDU)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
11	PL	Durum wheat (TRZDU)	F	PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
12	PL	Durum wheat (TRZDU)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		N Possible approv- al based on the art. 51 (minor crops).
13	PL	Spelt (TRZSP)	F	ERYSGR	Tractor mounted	BBCH 30-69	a) 1	-	a) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	N Possible approv-

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (6)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
					spray		b) 1		b) 1.5 L/ha	b) 75 Fenpicoxamid + 150 Prothioconazole				al based on the art. 51 (minor crops).
14	PL	Spelt (TRZSP)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
15	PL	Spelt (TRZSP)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
16	PL	Spelt (TRZSP)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
17	PL	Spelt (TRZSP)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
18	PL	Spelt (TRZSP)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		N Possible approv- al based on the art. 51 (minor crops).

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
19	CZ	Winter wheat (TRZAW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
20	CZ	Winter wheat (TRZAW)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
21	CZ	Winter wheat (TRZAW)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
22	CZ	Winter wheat (TRZAW)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
23	CZ	Winter wheat (TRZAW)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
24	CZ	Winter wheat (TRZAW)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
25	CZ	Durum wheat (TRZDU)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
26	CZ	Durum wheat (TRZDU)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
27	CZ	Durum wheat (TRZDU)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
28	CZ	Durum wheat (TRZDU)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
29	CZ	Durum wheat (TRZDU)	F	PUCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
30	CZ	Durum wheat (TRZDU)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
31	CZ	Spelt (TRZSP)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
32	CZ	Spelt (TRZSP)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
33	CZ	Spelt (TRZSP)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
34	CZ	Spelt (TRZSP)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
35	CZ	Spelt (TRZSP)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
36	CZ	Spelt (TRZSP)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
37	SK, RO	Winter wheat (TRZAW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
38	SK, RO	Winter wheat (TRZAW)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
39	SK, RO	Winter wheat (TRZAW)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
40	SK, RO	Winter wheat (TRZAW)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
41	SK, RO	Winter wheat (TRZAW)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
42	SK, RO	Winter wheat (TRZAW)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
43	SK, RO	Durum wheat (TRZDU)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
44	SK, RO	Durum wheat (TRZDU)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
45	SK, RO	Durum wheat (TRZDU)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	C
46	SK, RO	Durum wheat (TRZDU)	F	PUC CRT	Tractor mounted spray	BBCH 30-69	a) 1	-	a) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
							b) 1		b) 1.5 L/ha	b) 75 Fenpicoxamid + 150 Prothioconazole				
47	SK, RO	Durum wheat (TRZDU)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
48	SK, RO	Durum wheat (TRZDU)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
49	SK, RO	Spelt (TRZSP)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
50	SK, RO	Spelt (TRZSP)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
51	SK, RO	Spelt (TRZSP)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	C
52	SK, RO	Spelt (TRZSP)	F	PUC CRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
53	SK, RO	Spelt (TRZSP)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
54	SK, RO	Spelt (TRZSP)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
55	PL	Winter tritcale (TTLWI)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
56	PL	Winter tritcale (TTLWI)	F	SEPTSP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
57	PL	Winter tritcale (TTLWI)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
58	PL	Winter tritcale (TTLWI)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
59	CZ	Winter tritcale (TTLWI)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1	-	a) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
							b) 1		b) 1.5 L/ha	b) 75 Fenpicoxamid + 150 Prothioconazole				
60	CZ	Winter triticales (TTLWI)	F	SEPTSP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
61	CZ	Winter triticales (TTLWI)	F	PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
62	CZ	Winter triticales (TTLWI)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
63	PL	Winter rye (SECCW)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
64	PL	Winter rye (SECCW)	F	PUCCRE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
65	PL	Winter rye (SECCW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
66	CZ	Winter rye (SECCW)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
67	CZ	Winter rye (SECCW)	F	PUCCRE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
68	CZ	Winter rye (SECCW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
69	PL	Winter Barley (HORVW)	F	PUCCHD	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
70	PL	Winter Barley (HORVW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
71	PL	Winter Barley (HORVW)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
72	PL	Winter Barley (HORVW)	F	PYRNTE	Tractor mounted spray	BBCH 30-69	a) 1	-	a) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (f)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
							b) 1		b) 1.5 L/ha	b) 75 Fenpicoxamid + 150 Prothioconazole				
73	PL	Winter Barley (HORVW)	F	RAMUCC	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N
74	CZ	Winter Barley (HORVW)	F	PUCCHD	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
75	CZ	Winter Barley (HORVW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
76	CZ	Winter Barley (HORVW)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
77	CZ	Winter Barley (HORVW)	F	PYRNTE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
78	CZ	Winter Barley (HORVW)	F	RAMUCC	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
79	SK, RO	Winter Barley (HORVW)	F	PUCCHD	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	A
80	SK, RO	Winter Barley (HORVW)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
81	SK, RO	Winter Barley (HORVW)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	C
82	SK, RO	Winter Barley (HORVW)	F	PYRNTE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
83	SK, RO	Winter Barley (HORVW)	F	RAMUCC	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
84	PL	Spring wheat (TRZAS)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
85	PL	Spring wheat (TRZAS)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1	-	a) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		N

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (6)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
							b) 1		b) 1.5 L/ha	b) 75 Fenpicoxamid + 150 Prothioconazole				
86	PL	Spring wheat (TRZAS)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
87	PL	Spring wheat (TRZAS)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 15	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N
88	PL	Spring wheat (TRZAS)	F	PUC CST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
89	PL	Spring wheat (TRZAS)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
90	CZ	Spring wheat (TRZAS)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
91	CZ	Spring wheat (TRZAS)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
92	CZ	Spring wheat (TRZAS)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
93	CZ	Spring wheat (TRZAS)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
94	CZ	Spring wheat (TRZAS)	F	PUCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
95	CZ	Spring wheat (TRZAS)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
96	SK, RO	Spring wheat (TRZAS)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
97	SK, RO	Spring wheat (TRZAS)	F	FUSASP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
98	SK, RO	Spring wheat (TRZAS)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1	-	a) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
							b) 1		b) 1.5 L/ha	b) 75 Fenpicoxamid + 150 Prothioconazole				
99	SK, RO	Spring wheat (TRZAS)	F	PUCCRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
100	SK, RO	Spring wheat (TRZAS)	F	PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
101	SK, RO	Spring wheat (TRZAS)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
102	PL	Spring triticale (TTL SO)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N
103	PL	Spring triticale (TTL SO)	F	SEPTSP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N
104	PL	Spring triticale (TTL SO)	F	PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approval based on the art. 51 (PUCCST as minor use in

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
														TTLSO).
105	PL	Spring triticale (TTLSO)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N
106	CZ	Spring triticale (TTLSO)	F	SEPTTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
107	CZ	Spring triticale (TTLSO)	F	SEPTSP	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
108	CZ	Spring triticale (TTLSO)	F	PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
109	CZ	Spring triticale (TTLSO)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
110	PL	Spring rye (SECCS)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
111	PL	Spring rye	F	PUCCRE	Tractor	BBCH	a) 1	-	a) 1.5 L/ha	a) 75 Fenpicoxamid +	100-300	PHI F	Dose range requested	N

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (6)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		(SECCS)			mounted spray	30-69	b) 1		b) 1.5 L/ha	150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole			for PL, 1.2-1.5 L/ha	Possible approv- al based on the art. 51 (minor crops).
112	PL	Spring rye (SECCS)	F	PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
113	PL	Spring rye (SECCS)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N Possible approv- al based on the art. 51 (minor crops).
114	CZ	Spring rye (SECCS)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
115	CZ	Spring rye (SECCS)	F	PUCCRE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
116	CZ	Spring rye (SECCS)	F	PUCCST	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
117	CZ	Spring rye (SECCS)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid +	100-300	PHI F		C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
										150 Prothioconazole				
118	PL	Spring Barley (HORVS)	F	PUCCHD	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
119	PL	Spring Barley (HORVS)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
120	PL	Spring Barley (HORVS)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.0-1.5 L/ha	A
121	PL	Spring Barley (HORVS)	F	PYRNTE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
122	PL	Spring Barley (HORVS)	F	RAMUCC	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	N
123	CZ	Spring Barley (HORVS)	F	PUCCHD	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
124	CZ	Spring Barley	F	ERYSGR	Tractor	BBCH	a) 1	-	a) 1.5 L/ha	a) 75 Fenpicoxamid +	100-300	PHI F		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fpn G, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
		(HORVS)			mounted spray	30-69	b) 1		b) 1.5 L/ha	150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole				
125	CZ	Spring Barley (HORVS)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
126	CZ	Spring Barley (HORVS)	F	PYRNTE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		C
127	CZ	Spring Barley (HORVS)	F	RAMUCC	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F		A
128	SK, RO	Spring Barley (HORVS)	F	PUCCHD	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	A
129	SK, RO	Spring Barley (HORVS)	F	ERYSGR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
130	SK, RO	Spring Barley (HORVS)	F	RHYNSE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid +	100-300	PHI F	Dose range requested for SK and RO 1.0-1.5 L/ha	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: devel- opmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/synergist per ha (⁶)	zRMS Conclusion (efficacy)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
										150 Prothioconazole				
131	SK, RO	Spring Barley (HORVS)	F	PYRNTE	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	A
132	SK, RO	Spring Barley (HORVS)	F	RAMUCC	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for SK and RO 1.2-1.5 L/ha	C
133	PL	Spring triticale (TTL SO)	F	PYRNTR	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A
134	PL	Spring triticale (TTL SO)	F	PUC CRT	Tractor mounted spray	BBCH 30-69	a) 1 b) 1	-	a) 1.5 L/ha b) 1.5 L/ha	a) 75 Fenpicoxamid + 150 Prothioconazole b) 75 Fenpicoxamid + 150 Prothioconazole	100-300	PHI F	Dose range requested for PL, 1.2-1.5 L/ha	A

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

A	Acceptable
R	Acceptable with further restriction
C	To be confirmed by cMS
N	Not acceptable / evaluation not possible
n.r.	Not relevant for section 3

3.2 Efficacy data (KCP 6)

Introduction

This document summarises the information related to the efficacy data of the plant protection product GF-3307 containing the active substances fenpicoxamid + prothioconazole. The Dossier for approval of fenpicoxamid under Regulation EC 1007/2009 was submitted in December 2014 to the RMS UK, the coRMS France and to all member states; GF-2925 (130 g/L fenpicoxamid, SC) was the representative formulation. Fenpicoxamid active substance approval was in October 2018.

GF-3307 is a new agricultural fungicide for the control of a range of important foliar diseases in wheat (including durum wheat), spelt, rye, triticale and barley. The product is formulated as an emulsifiable concentrate (EC) containing 50 g/L fenpicoxamid and 100 g/L prothioconazole. **GF-3307 is already approved for use in wheat, rye and triticale in Austria, UK, Ireland, France, Germany, Belgium, Netherlands, Serbia, Bulgaria with submissions for wheat, barley and oilseed rape under review in a number of countries.**

Due to the ability of plant pathogenic fungi to develop fungicide resistance, the development of novel highly efficacious fungicides that lack cross resistance to currently used products is of considerable importance to growers. Fenpicoxamid with the ISO common name fenpicoxamid (commercial name Inatreq™) possesses these characteristics and is the first product under development from a novel picolinamide class of fungicides derived from the antifungal natural product UK-2A. This chemistry delivers a novel biochemical mode of action for the cereal fungicide market, involving inhibition of mitochondrial complex III *via* binding to the Q_i ubiquinone binding site rather than to the Q_o site targeted by the strobilurin class of fungicides and, as such, no target site-based cross resistance to strobilurin fungicides would be anticipated. Prior validation of the bc1 Q_i binding site as a commercially viable fungicide mode of action was provided by cyazofamid (ISK Biosciences Corp.), a structurally unrelated chemistry which uniquely binds to the Q_i site of Oomycete pathogens only. The novel chemistry and biochemical target site of fenpicoxamid, as well as its lack of cross resistance and strong efficacy against *Zymoseptoria tritici*, *Pyrenophora teres* and other pathogens, highlights the importance of fenpicoxamid as a new tool for controlling plant pathogenic fungi.

Fenpicoxamid (early stage coded X772777, XR-777, XDE-777 and DE-777) was discovered by Dow AgroSciences and is being co-developed by Meiji Seika Kaisha Limited.

This document supports the registration of GF-3307 in Poland (PL) as the zRMS, ~~Austria (AT)~~, the Czech Republic (CZ), Romania (RO) and Slovakia (SK).

The **Detailed summary** (Biological Assessment dossier/BAD) is located in the following report: Part B, Section 3 (Efficacy Data and Information) of the draft registration report (dRR) for GF-3307. The data presented in this dossier support label claims for the use of GF-3307 for the control of *Zymoseptoria tritici* (SEPTTR), *Puccinia recondita tritici* (PUCCTR), *Puccinia striiformis* (PUCST), *Fusarium* species (FUSASP), *Pyrenophora tritici-repentis* (PYRNTR) and *Blumeria graminis* f. sp. *tritici* (ERYSGT) in wheat; *Puccinia recondita* (PUCCRE) and *Rhynchosporium secalis* (RHYNSE) on rye; *Mycosphaerella* (*Septoria*) spp. (SEPTSP), *Blumeria graminis* f. sp. *tritici* (ERYSGT) and *Puccinia striiformis* (PUCST) on triticale; *Ramularia collo-cygni* (RAMUCC), *Rhynchosporium secalis* (RHYNSE), *Pyrenophora teres* (PYRNTE), *Puccinia hordei* (PUCCHD) and *Blumeria graminis* f. sp. *hordei* (ERYSGH) in barley.

For further physical-chemical properties reference should be made to Registration Report Part B Section 1: Identity, physical and chemical properties, other information.

Benefit statement for GF-3307

GF-3307 contains fenpicoxamid (XDE-777) which is a potent naturally derived novel fungicide active with translaminar properties and prothioconazole which is a broad-spectrum synthetic fungicide produced by Bayer CropScience of the triazolinthione family of compounds with curative, preventative with translaminar and systemic action. Fenpicoxamid binds very strongly to the cuticular layers of leaves and provides reliable long term protectant control of *Mycosphaerella* (*Septoria*) spp, *Ramularia collo-cygni* and other diseases such as *Puccinia* spp., *Pyrenophora* spp. or *Rhynchosporium*. It has also curativity (reach back) which allows the flexible use of fenpicoxamid for disease control based on integrated pest control principles. Fenpicoxamid builds stable deposits on the

treated foliage very quickly and therefore GF-3307 is rain fast ~~as soon as the spray cover has dried~~ **within an hour after application**. Fungi susceptible to prothioconazole include diseases caused by Ascomycetes, Basidiomycetes and Deuteromycetes. Prothioconazole is approved for use on wheat, barley and a range of other cereal crops.

GF-3307 can be used over a wide window of application from crop growth stage BBCH 30 up to BBCH 69 (wheat, rye, triticale and barley) with a high level of crop safety to all cereal varieties. GF-3307 has a very positive effect on yield amount and quality of the grain. Cereal pathogens such as *Zymoseptoria tritici* and *Ramularia collo-cygni* have adapted to many fungicides from different chemical groups such as the Methyl Benzimidazole Carbamates (MBCs), DMIs and strobilurin fungicides. There are also first indications towards adaptation to SDHI fungicides. Fenpicoxamid will be a novel target site fungicide in the cereal crop segment (assigned to FRAC group C4 #21) and does not show target site based cross resistance to any of the current commercial fungicides used in cereals. As a consequence, it will be an important additional tool for farmers in aiding the management of resistance risk to the limited number of effective fungicide options available in the future for control of diseases of cereal crops.

Fenpicoxamid is derived from a natural product, UK-2A, produced by a soil dwelling *Streptomyces* species belonging to the phylum Actinobacteria. The original strain was isolated from a soil sample collected at Osaka University in Japan. In the manufacturing of fenpicoxamid, UK-2A is first produced through a conventional fermentation process within a contained bioreactor. Afterward, a single (and reversible) chemical modification step is added to enhance molecule stability and performance in the field, without changing the active function of the natural substance. The fact that fenpicoxamid converts exactly back to the natural product UK-2A in the presence of carboxylase enzymes release by fungi and in plants makes the product a potential bio-control solution for growers.

Fenpicoxamid will bring a significant benefit for cereal growers as it **is** a new active substance of natural origin offering a new target site with no cross resistance to current chemistries.

Prothioconazole can be used as both a seed treatment and a foliar treatment. After absorption it moves into cells of the target organisms, ~~effecting~~ **affecting** sterol biosynthesis and thereby disrupting membrane structure. This ultimately affects hyphal growth and germ tube elongation. Prothioconazole is sold in combination with numerous other fungicides, including bixafen, spiroxamine, tebuconazole, fluoxastrobin, trifloxystrobin and fluopyram. Prothioconazole is one of the most effective triazole fungicides used in cereals. Although there have been shifts in triazole sensitivity for some diseases in the last decade, prothioconazole is still highly effective, especially in mixture with strong partners and brings as a mix partner robust activity against a wide range of cereal diseases such as rusts where reduced sensitivity is not an issue for triazole fungicides.

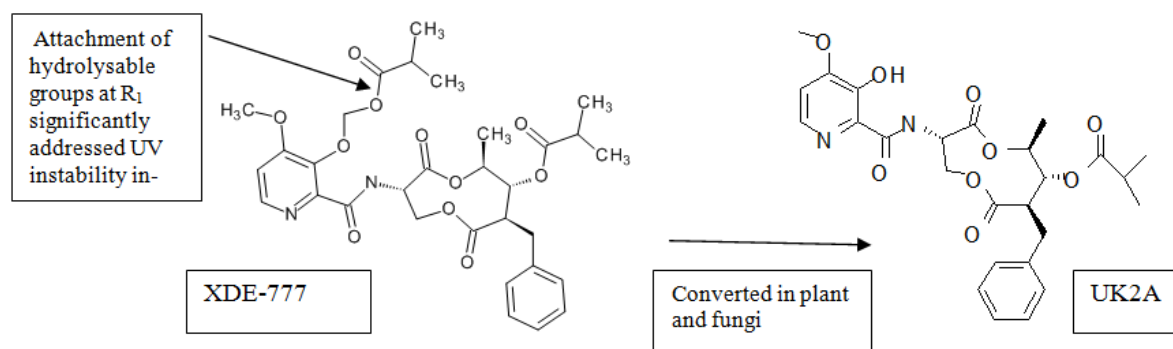
GF-3307 will offer broad spectrum control of diseases in all cereal crops and provide a new target site for resistance management. GF-3307 will be a vital tool for cereal growers to manage disease outbreaks in the next decade and especially at a period when resistance to existing solutions is an issue and many existing fungicide solutions may soon be exiting the market as a result of regulatory restrictions.

Description of active substances

The active substance fenpicoxamid (XDE-777) belongs to a proposed new family of Picolinamide type fungicides. Fenpicoxamid is based on the natural-product UK-2A which is produced through fermentation of *Streptomyces* sp. 517-02. In early stage testing, UV instability was found to be inherent in UK-2A and was clearly an issue for field performance of the natural product. In the period between 1997 and 2002, Dow AgroSciences committed considerable synthesis and biology resources to pursue both synthetic and semi-synthetic approaches for introducing structural variation in the UK-2A molecule. Finally, the semi synthetic approach was found to be most stable and successful approach to improve UV stability.

At manufacturing, through a single synthetic step, UK-2A is converted to fempicoxamid. When fempicoxamid is applied to the plant it is photostable on the leaf surface. Only in the presence of fungi *on the outside of the plant* is fempicoxamid rapidly activated to UK2A (see Figure 3.2-1) and becomes a potent inhibitor of mitochondrial electron transport and consequently fungal respiration. Conversely, when fempicoxamid disperses inside the leaf it is also rapidly converted to UK-2A and so becomes a potent fungicide inside the leaf. It is thought that carboxalyse enzymes released by the fungus and inside the plant, promote conversion of fempicoxamid to UK2A, though further detailed studies are ongoing.

Figure 3.2-1: Sites of structural modification to UK-2A to make fempicoxamid



Mode of action

Fempicoxamid when formulated as an EC formulation (as in GF-3307) is a protectant and curative fungicide for control of foliar diseases in cereal crops. Fempicoxamid is rapidly activated in the presence of fungi and inside plants to UK-2A which is a potent inhibitor of mitochondrial electron transport (MET). Previous biochemical studies on the mode of action of UK-2A have demonstrated binding to the Qi site of the cytochrome *bc1* (ubiquinone reductase) complex (complex III) in the electron transport chain, similar to the mechanism of the structurally related natural product antimycin A.

UK-2A inhibits respiration at complex III which likely represents the primary biochemical mode of action for this chemistry. The mode of action of fempicoxamid will be novel to the European cereal fungicide market and is assigned to Group C4, FRAC code 21 (FRAC Code List 2021, March 2021).

The cytochrome *bc1* complex (complex III) of the mitochondrial electron transport (MET) chain has two quinone binding sites known as the Qo and Qi sites. The Qo site is the target site of the strobilurin fungicides, which include many commercial products. Inhibitors of the Qi site are also known, although to date only the Oomycete-specific fungicides cyazofamid and amisulbrom (FRAC group 21) have been commercialized. Although the target site of activity is the same, fempicoxamid has no activity against Oomycete diseases, but has strong activity against cereal diseases such as *Zymoseptoria tritici* and *Ramularia collo-cygni*.

The MET III Qi site is quite distinct from the MET III Qo site with which the strobilurins interact, so that no cross-resistance of field isolates of *Zymoseptoria tritici* and *Ramularia collo-cygni* resistant to strobilurin fungicides has been observed or would be anticipated.

Prothioconazole

Prothioconazole is a broad-spectrum synthetic fungicide produced by Bayer CropScience of the triazolinthione family of compounds with curative, preventative and eradicated action. The mode of action of prothioconazole is as a Sterol Biosynthesis Inhibitor (SBI) class 1 DeMethylation Inhibitors (DMI) and it is classified in Group G1, FRAC code 3. It can be used as both a seed treatment and a foliar treatment. After absorption it moves into cells of the target organisms, affecting sterol biosynthesis and thereby disrupting membrane structure. This ultimately effects hyphal growth and germ tube elongation. Fungi susceptible to prothioconazole include diseases caused by ascomycetes, basidiomycetes and deuteromycetes. Prothioconazole is approved for use on barley, wheat (winter, spring, durum), oats, oilseed rape (winter), rye (winter) and triticale. Prothioconazole is sold in combination with numerous other fungicides, including bixafen, spiroxamine, tebuconazole,

fluoxastrobin, trifloxystrobin and fluopyram. Prothioconazole is one of the strongest triazole fungicides used in cereals. Although there have been some shifts in triazole sensitivity to a number of cereal disease in the last decade, prothioconazole is still highly effective against these diseases in many countries of the central administration zone. Prothioconazole is especially beneficial in mixture with strong partners and brings as a mix partner, robust activity against a wide range of cereal diseases including rusts where reduced sensitivity is not an issue for triazole fungicides.

Figure 3.2-2: Structural formula of prothioconazole

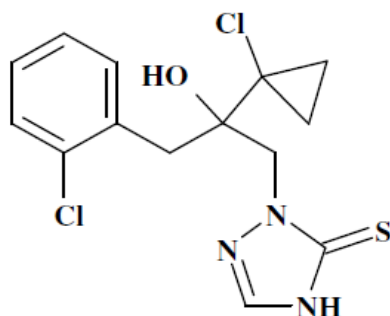


Table 3.2-1: Details of the active substances

Active substance	Fenpicoxamid	Prothioconazole
Concentration (Unit: g/kg or g/L...)	50 g/L	100 g/L
Chemical group	Picolinamide	Triazolinthione
IUPAC name (if applicable):	(3S,6S,7R,8R)-8-benzyl-3-[[[(4-methoxy-3-[[[(2-methylpropanoyl)oxy]methoxy} pyridin-2-yl)carbonyl]amino]-6-methyl-4,9-dioxo-1,5-dioxonan-7-yl-2-methylpropanoate	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-1H-1,2,4-triazole-3-thione
Active brand name	Inatreq™ active	Proline
ISO common name	Fenpicoxamid	Prothioconazole
CAS number	517875-34-2	178928-70-6
Molar weight g/mol	614.64	344.2594
Structural formula	 C ₃₁ H ₃₈ N ₂ O ₁₁	
Mode of action	Group C4, FRAC code 21 Inhibition of respiration at complex III (QiI fungicides)	Group G1, FRAC code 3 Sterol Biosynthesis Inhibitor (SBI) class 1 DeMethylation Inhibitors (DMI)
Biological action	Curative and Protectant foliar fungicide, contact/residual with translaminal properties for use on cereals. When sprayed onto foliage it provides long lasting protection and curative activity against a range of cereal diseases	

Description of the plant protection product

GF-3307 is an emulsifiable concentrate (EC) 50 g/L fenpicoxamid + 100 g/L prothioconazole. The data presented in this dossier are intended to support the label claim for GF-3307 for the control of foliar diseases in wheat, rye, triticale and barley as shown in Table 3.2-2. Further details are in the table “All intended uses” in Part B - Section 0.

Table 3.2-2: Simplified table of requested uses for GF-3307.

Uses		Member State	Requested individual rate	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
TRZAW TRZAS TRZDU TRZSP	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	PL	1.0-1.5 L/ha SEPTTR and ERYSGT 1.2-1.5 L/ha for PUCCST, PUCCRT and PYRNTR 1.2-1.5 L/ha (except FUSASP 1.5 L/ha) 1.5 L/ha for FUSASP	One application between BBCH 30-69
	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	AT , CZ	1.5 L/ha	
	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	RO, SK	1.0-1.5 L/ha SEPTTR 1.2-1.5 L/ha for all other diseases (except FUSASP 1.5 L/ha)	
TTLWI TTL SO	SEPTSP* PUCCST ERYSGT	PL	1.2-1.5 L/ha	One application between BBCH 30-69
	SEPTSP* PUCCST ERYSGT	AT , CZ	1.5 L/ha	
SECCW SECCS	PUCCRE RHYNSE	PL	1.2-1.5 L/ha	One application between BBCH 30-69
	PUCCRE RHYNSE	AT , CZ	1.5 L/ha	
HORVW, HORVS	RAMUCC, RHYNSE, PYRNTE, ERYSGH, PUCCHD	PL	1.0-1.5 L/ha RHYNSE and PUCCHD 1.2-1.5 L/ha for all other diseases 1.2-1.5 L/ha	One application between BBCH 30-69
	RAMUCC, RHYNSE, PYRNTE, ERYSGH, PUCCHD	AT , CZ	1.5 L/ha	
	RAMUCC, RHYNSE, PYRNTE, ERYSGH, PUCCHD	RO, SK	1.0-1.5 L/ha RHYNSE and PUCCHD 1.2-1.5 L/ha for all other diseases	

*in triticale different *Septoria* species (SEPTSP) are frequently present in mixture. The infection levels visually assessed in the efficacy trials was addressed as SEPTTR as the prevailing symptom.

Note: For authorisation in EPPO North-East Member States, ~~a lower dose of 1.2 L/ha is requested across all crops~~ lower doses of 1.0 L/ha (SEPTTR and ERYSGT on wheat and PUCCHD and RHYNSE on barley) and 1.2 L/ha (all other diseases, except FUSASP), are requested. ~~The trials on barley in this dossier are mostly based on a higher dose rate of 1.25 L/ha, instead of the proposed label dose of 1.2 L/ha. Some barley trials in this dossier are based on a dose rate of 1.25 L/ha, instead of the proposed 1.2 L/ha. As these doses are within 10% of each other (4% difference), it is considered that the results at 1.25 L/ha are fully supportive of the proposed 1.2 L/ha dose rate. This dose also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers. For wheat/SEPTTR/ERYSGT, much of the lower dose data is based on application at 0.9 L/ha, instead of the proposed 1.0 L/ha. As these doses are within 10% of each other (10% difference), it is considered that the results at 0.9 L/ha are fully supportive of the proposed 1.0 L/ha dose rate, which is a more practical dose rate for growers and avoids any potential pesticide wastage, as a 5 Litre pack size will treat multiples of 5 ha, at the 1.0 L/ha dose rate.~~

For authorisation in EPPO South-East Member States, lower doses of 1.0 L/ha (SEPTTR on wheat and PUCCHD on barley) and 1.2 L/ha (all other diseases, ~~except FUSASP~~), are requested. ~~The trials on barley in this dossier are mostly based on~~ Some barley trials in this dossier are based on a dose rate of 1.25 L/ha, instead of the proposed 1.2 L/ha. As these doses are within 10% of each other (4% difference), it is considered that the results at 1.25 L/ha are fully supportive of the proposed 1.2 L/ha dose rate. For wheat/SEPPTTR, much of the lower dose data is based on application at 0.9 L/ha, instead of the proposed 1.0 L/ha. As these doses are within 10% of each other (10% difference), it is considered that the results at 0.9 L/ha are fully supportive of the proposed 1.0 L/ha dose rate which is ~~an easier dose rate for growers to operate with in a practical situation~~ a more practical dose rate for growers and avoids any potential pesticide wastage, as a 5 Litre pack size will treat multiples of 5 ha, at the 1.0 L/ha dose rate. ~~The 1.2 L/ha dose also aligns with the label dose range proposed in wheat of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers. As growers in many South East EPPO zone countries cannot legally apply a lower dose than stipulated on the label it is important that a dose range is registered to offer flexibility so the correct dose can be applied for the specific agronomic conditions.~~

These amendments are proposed to ensure the dose rates are consistent for users across all target crops.

~~For constancy across the dossier, the 1.2 L/ha dose rate is specified in the text and summary tables and is highlighted in individual trials for barley diseases where 1.25 L/ha dose was used.~~

For constancy across the dossier, the dose rates used in the supporting trials (0.9, 0.9-1.0 or 1.0 L/ha, 1.2, 1.2-1.25 or 1.25 L/ha) are specified in the summary tables and the individual trials summaries in the BAD.

Description of the target pests

Table 3.2-3: Glossary of pests mentioned in the dossier

EPPO code	Scientific name	Common name
SEPTTR	<i>Zymoseptoria tritici</i>	<i>Septoria</i> leaf blotch on wheat
SEPTSP	<i>Septoria</i> spp.	<i>Septoria</i> species on triticale
PUCCRT	<i>Puccinia recondita tritici</i>	Brown rust on wheat
PUCCRE	<i>Puccinia recondita</i>	Brown rust on rye
PUCGST	<i>Puccinia striiformis</i>	Yellow rust or Stripe rust on wheat
PUCGST	<i>Puccinia striiformis</i>	Yellow rust or Stripe rust on triticale
RHYNSE	<i>Rhynchosporium secalis</i>	<i>Rhynchosporium</i> on rye, rye scald
FUSASP	<i>Fusarium</i> spp	<i>Fusarium</i> species in wheat
ERYSGT	<i>Blumeria graminis</i> f. sp. <i>tritici</i>	Powdery mildew in wheat

EPPO code	Scientific name	Common name
ERYSGT	<i>Blumeria graminis</i> f. sp. <i>tritici</i>	Powdery mildew in triticale
PYRNTE	<i>Pyrenophora tritici-repentis</i>	DTR / Tan Spot
RAMUCC	<i>Ramularia collo-cygni</i>	Ramularia leaf spot of barley
RHYNSE	<i>Rhynchosporium secalis</i>	Leaf scald of barley
PYRNTE	<i>Pyrenophora teres</i>	Net blotch of barley
PUCCHD	<i>Puccinia hordei</i>	Brown rust of barley
ERYSGH	<i>Blumeria graminis</i> f. sp. <i>hordei</i>	Powdery mildew of barley

SEPTTR

Septoria leaf blotch (SEPTTR) is caused by the fungus *Zymoseptoria tritici* which is a species of filamentous fungus, an ascomycete in the family *Mycosphaerellaceae*. It is a major wheat plant pathogen in Europe that is difficult to control due to resistance to multiple fungicides. *Mycosphaerella graminicola* is the name of the sexual stage (teleomorph) of the pathogen. The disease is more commonly referred to as *Septoria tritici* which is the name of its asexual stage (anamorph). The disease is widely distributed across the main wheat growing regions of the world. Yield losses in badly infected susceptible varieties can be major with reductions of up to 50% reported in the UK.

The disease is most damaging in regions where periods of rainfall and leaf wetness are common. Within the EU Central authorization zone the disease is more frequently damaging in the EPPO Maritime regions where it usually occurs first during the winter months. The initial infection arises from wind borne ascospores released from debris. Once a spore has landed on a new leaf, it is reported to take 12 hours for the spore to germinate; infection of the new leaf usually takes place within 24 hours of the spore being released. Wet conditions are required during this infection process. Leaf wetness can be caused by either rain or dew, so spore dispersal and infection can still take place even during dry weather spells. Symptoms do not appear immediately on a new leaf. The fungus grows undetected inside the leaf for a period of 2-4 weeks which is referred to as the latent phase. The speed of visible symptom development is linked to temperature so during the winter it can take a long time for symptoms to appear, while in the summer, symptoms can develop more rapidly. The existence of such a relatively long latent phase can make interpretation of results difficult as, for example, the effectiveness of fungicides with curative activity can be greatly reduced if applied during this phase.

The disease is most severe where these conditions are prevalent during the stem elongation phase of crop development. Further spread of the disease up the growing plant and onto the main yield producing higher leaf levels is primarily the result of the splash borne release of asexual pycniospores. Frequent cycles of infection can occur throughout the lifetime of the crop.

In triticale different *Septoria* species (SEPTSP) are frequently present in mixture including *Septoria nodorum* and *Septoria tritici*.

PUCCRT/PUCCRE

Brown (leaf) rust caused by *Puccinia recondita* is a fungal disease that affects cereals leaves and grains. In temperate zones it is destructive on winter wheat and other cereals because the pathogen overwinters. Infections can lead up to 5-20% yield loss exacerbated by dying leaves which fertilise the fungus but this can increase to 50% yield loss in severe infestations. It is the most prevalent of all the rust diseases, occurring in most wheat, barley and rye growing regions. Brown rust spreads via airborne spores. Five types of spores are formed in the life cycle. Uredospores, teleutospores, and basidiospores develop on cereal plants, whereas pycnidiospores and aeciospores develop on alternate hosts. The germination process requires moisture, and works best at 100% humidity. Optimum temperature for spore germination is between 15–20°C. Before sporulation, the cereal plants appear completely asymptomatic. Wheat, barley and rye brown rust pathogen is biotrophic and requires living plant cells to survive.

Symptoms are small, orange-brown pustules randomly scattered over leaves. It is common to see a yellowing of the leaf around the rust pustules. During autumn and winter symptoms are usually confined to older leaves. These winter symptoms are sometimes difficult to distinguish from those of

yellow rust. Late in the season brown rust can become very severe and result in leaf death. Leaf sheaths and ears sometimes become affected. Tiny black spore cases may be seen on diseased plant tissue, indicating a second developmental stage of the fungus (the teliospore stage). In high-risk situations typically, brown rust develops later in the summer than yellow rust, during warm, humid spells of weather. However, with higher than normal spring temperatures, the disease can develop much earlier in the season. Within the EU Central authorisation zone the disease is very damaging in the EPPO North-East, South-East as well as the Maritime regions which experience hot dry summers. Early-sown crops are at greater risk as they are more likely to become infected by wind-blown spores from infected wheat volunteers.

PUCCST

Yellow rust (*Puccinia striiformis*) is a primarily a disease on wheat and triticale occurring throughout Europe. It can cause severe infections in maritime climates such as Western Europe, and right across Europe to the Middle East. Yellow rust can occur on all aerial parts of the plant, but is most frequently seen on the leaves. The pathogen spreads by means of airborne uredospores. When spores land on wheat plants they germinate in high humidity, usually at temperatures of less than 15°C, and the germ tubes enter the leaves or other parts of the plant via the stomata. Once inside the leaf, haustoria are inserted into the mesophyll cells and the mycelium spreads along the leaf. In mature leaves it spreads longitudinally between the veins of the leaf. Lines of bright yellow new uredospores are produced and give the typical striped appearance on the leaves. The pustules are often arranged into conspicuous stripes and their linear orientation between vascular bundles can progress the length of the leaf blade. Damage is caused to the plant by extraction of nutrients via the haustoria of the pathogen and by disruption of the epidermis, which reduces the water retention capacity of the leaves. The major grain-producing parts of the wheat plant are the flag leaf and the ear, and severe infections on these parts of the plant may cause large reductions in yield. Greater reductions occurred with earlier infections, yields of susceptible cultivars could be reduced by 50% or more under severe and prolonged infection in the field.

The major method of control is the use of resistant cultivars. The development of systemic fungicides has led to the use of chemical control, particularly in areas where yields are high, as in Western Europe, where the cost of fungicide application is low in comparison with the value of the crop. Epidemics of yellow rust require appropriate weather conditions and the presence of susceptible cultivars. However, the repeated appearance of new yellow rust races continues to challenge varietal resistance, emphasising the importance of the balance between varieties and fungicides in managing the disease.

PUCCHD

Brown rust of barley is caused by the fungal disease *Puccinia hordei* (PUCCHD). In temperate zones it is destructive on winter crops because the pathogen overwinters on volunteers and early drilled crops. Brown rust spreads via airborne spores. Five types of spores are formed in the life cycle. Uredospores, teleutospores, and basidiospores develop on barley plants and pycnidiospores and aeciospores develop on the alternate hosts. Infections can lead to up to 5-20% yield loss exacerbated by dying leaves which fertilise the fungus, but this can increase to 50% yield loss in severe infestations.

The germination process requires moisture and works best at 100% humidity. Optimum temperature for germination is between 15–22°C. High-risk situations are therefore later in the summer, during warm, humid spells of weather. However, with higher than normal spring temperatures, the disease can develop much earlier in the season. Within the Central EU Authorisation zone, the disease is very damaging in the EPPO North-East and South-East, as well as the Maritime regions which can also experience hot, dry summers. Early-sown crops are at greater risk as they are more likely to become infected by wind-blown spores from infected volunteers.

Symptoms are small, orange-brown pustules randomly scattered over leaves. It is common to see a yellowing of the leaf around the rust pustules. During autumn and winter symptoms are usually confined to older leaves. Late in the season brown rust can become very severe and result in leaf

death. Leaf sheaths/stems and ears sometimes become affected. Tiny black spore cases may be seen on diseased plant tissue, indicating a second developmental stage of the fungus (the teliospore stage).

FUSASP

There are many species of *Fusarium* that affect wheat, barley, oats, triticale and grasses. These fungi form a complex of diseases on seeds, seedlings and adult plants. The seed-borne pathogen *Microdochium nivale* (formally known as *Fusarium nivale*) is also usually included in this group of fungi.

M. nivale is the primary pathogen in the group which causes seedling blight resulting in seedling death and thinning of the plant stand. Other species cause a range of symptoms including brown lesions on stem bases, often restricted to outer leaf sheath. *Fusarium* lesions often begin in the leaf sheath at the stem base where crown roots split the leaf sheath when emerging. This infection can then spread up the leaf sheath causing long dark brown streaks at the stem base. The most commonly seen symptom in the UK is the dark brown staining of the lower nodes. On older plants *Fusarium* infection can produce a true foot rot, where the stem base becomes brown and rotten, resulting in lodging and white-heads. This symptom is less common in the UK, although it can be found in very dry seasons.

Many of the *Fusarium* species cause a range of symptoms - often termed ear blights. *F. culmorum* and *F. graminearum* are the most commonly found species in the UK. Other species include *F. avenaceum*, *F. poae* and *F. langsethiae*. Infection frequently results in the whole or part of the ear becoming bleached. This symptom is seen when ears become infected during the early flowering stages. Later infections may result in infection of the grain but without obvious bleaching of the ears. The ear blight phase of the disease can cause yield loss but is most important as it can result in mycotoxin production in the grain. Mycotoxins are substances toxic to animals and humans. Levels in grain, flour and flour products for human and animal consumption are limited under EU legislation.

The most important source of *Fusarium* for wheat crops is the seed but the fungus can also survive on debris in the soil. In seasons where weather conditions are wet during flowering and grain formation, spores are splashed from lower in the canopy causing ear blights and seed-borne infection. In such seasons seed-borne infection can pose a serious threat to crop establishment unless seed is treated to control *Fusarium*. All the cereal *Fusarium* species are common in soil. Most have competitive saprophytic abilities which allow them to colonise debris and stubble in soil. Volunteers may also act as a source of inoculum.

Symptoms of *Fusarium* infection are common in wheat crops across the EU Central authorisation zone. When weather conditions are wet during flowering, high levels of ear blight can occur but their incidence is frequently over-estimated and losses are only rarely serious. Severe foot rotting is very rare in the UK and losses are generally very small. The seed-borne phase of the disease is potentially very damaging. Seed treatment plays a major role in preventing seedling losses in wheat. Seedling blight is rare in barley.

ERYSGR/ERYSGT/ERYSGH

Powdery mildew is a fungal disease that affects a wide range of plants. Powdery mildew diseases are caused by many different species of fungi in the order Erysiphales. *Blumeria graminis* f. sp. *tritici*, causes powdery mildew of wheat, whereas f. sp. *hordei* causes powdery mildew of barley. Powdery mildew is one of the easier plant diseases to identify, as its symptoms are quite distinctive. Infected plants display white powdery spots on the leaves and stems. The lower leaves are the most affected, but the mildew can appear on any above-ground part of the plant. As the disease progresses, the spots get larger and denser as large numbers of asexual spores are formed, and the mildew may spread up and down the length of the plant.

Powdery mildew grows well in environments with high humidity and moderate temperatures. In an agricultural setting, the pathogen can be controlled using chemical methods, genetic resistance, and careful farming methods. It is important to be aware of powdery mildew and its management as the resulting disease can significantly reduce crop yields. Powdery mildew fungi reproduce both sexually and asexually. Sexual reproduction is via chasmothecia (formerly cleistothecium), a type of ascocarp. Within each ascocarp are several asci. Over time, ascospores mature and are released to initiate new infections. Conditions necessary for spore maturation differ among species.

In an agricultural setting, the pathogen can be controlled using chemical methods, genetic resistance, and rotation. Chemical control is possible with fungicides such as triazoles.

PYRNTR/PYRNTE

Pyrenophora tritici-repentis (telomorph) and *Drehslera tritici-repentis* (anamorph) is a necrotrophic plant pathogen of fungal origin in the Phylum Ascomycota. The pathogen causes a disease commonly called tan spot, yellow leaf spot, yellow leaf blotch or helminthosporiosis. The tan spot fungus was first described in 1823 and was identified in Europe, the USA, and Japan in the early 1900s. The disease is one of the most important fungal diseases on wheat and the fungal pathogen is found to infect in all parts of the world wherever wheat and other susceptible host crops are found. *P. tritici-repentis* overwinters on stubble, and due to recent heavily no-till/residue retention cultural practices, increased incidence and yield loss of up to 49% has been witnessed if ideal conditions occur. It forms characteristic, dark, oval-shaped spots of necrotic tissue surrounded by a yellow ring. It is responsible for losses that account for up to 30% of the crop, due to its effects reducing photosynthesis. Pathogenesis and toxicity in *P. tritici-repentis* is controlled by a single gene, transformations of this gene cause the pathogen to become benign when interacting with wheat. This has major implications for those in agriculture seeking to combat the effects of this fungus.

Tan spot is found primarily on wheat, but is also found to infect other cereals and grasses including triticale, barley, and rye, but are less frequently affected. Lesions typically appear on both upper and lower leaf surfaces, and initially are tan to brown specks. Eventually, the tan to brown specks expand to larger irregular, oval, lens-shaped, ellipse, tan blotches with a yellow ring around them. The yellow ring is often referred to as a halo, yellow discoloration as chlorosis, and browning/death of leaf tissue as necrosis. The development of a dark brown to black spot in the centre the lesion is characteristic of the disease. If warmer temperatures and moist conditions persist, spores known as conidia will move up plant as secondary inoculum and can also infect head/spikes. Symptoms on the head are indistinct, but can cause brownish glumes, and grains can have a reddish appearance similar to the pathogen *Fusarium*. *P. tritici-repentis* survives/overwinters as pseudothecia on stubble from previous year's infected crop. The pseudothecia contain ascospores (sexual spores). Such ascospores produced are large and typically dispersed by wind but do not travel far due to their size. The ascospores land on leaf surfaces and will begin to produce lesions by infection from appressorium and infection peg. The lesions initially formed by ascospores, form conidia atop of conidiophores and can serve as primary inoculum to new plant/host via long distance wind dispersal. Conidia can also serve as primary inoculum via rain splash to further more up primary host and re-infect. During and after maturation of the wheat crop, fungus can grow saprophytically as mycelium from the infect leaf blade, down the leaf sheath and on to the stem where it will later form a pseudothecia. The disease develops over a wide temperature range, but is favourable of warmer temperatures along with or followed by long rains/dew or irrigation. The fungus requires 6-24+ hours of moisture in order to infect a leaf. This means that rain, significant dew or high canopy humidity are factors that can lead to infection. Optimal temperatures for symptom development range from 15.5-28°C.

Net blotch of barley (PYRNTE) is caused by *Pyrenophora teres f. teres*/*Drehslera teres* (net form) and *Pyrenophora teres f. maculata* (spot form). Infection is both seed borne or via infected trash, but the main infection is via air-borne spores and rain splash. 'Stripe' or 'netting' symptoms on leaves are most commonly seen, but the disease can also affect glumes and awns, producing dark brown flecking and striping. Yield losses from this disease can range between 10-40%.

High risk factors for this disease include infected barley trash and volunteers, susceptible varieties, high humidity and mild temperatures in spring and summer. Early drilled crops are also more susceptible due to infection developing over the winter into spring producing an early epidemic as the crop develops.

RHYNSE

Rhynchosporium secalis is one of the most important economical diseases of barley, rye and triticale which emerges particularly during wet seasons. The disease is referred to as 'Rhynchosporium' or 'scald' and is one of the most destructive pathogens which can greatly impact the yield and quality of grain. *Rhynchosporium* is polycyclic with the primary inoculum including conidia produced on crop

debris and infected seeds. No teleomorph has been associated with *R. secalis*. Secondary disease spread is primarily by splash dispersal of conidia produced on infected leaves, which may be symptomless early in the growing season. Symptoms first appear as chlorotic, irregular or diamond-shaped lesions. Later symptoms are typically blue-grey water-soaked lesions on leaves and leaf sheaths. Mature lesions become pale brown with a dark purple margin. As they grow, they merge forming large areas of dead tissue, even destroying the whole plant leaf.

RAMUCC

Ramularia leaf spot of barley (RAMUCC) is caused by the fungus *Ramularia collo-cygni*. It is an ascomycete in the family Ramularisphaerella. The primary source of infection is via infected seed, with secondary infection coming from airborne spores from crop debris/trash. It is not effectively controlled by seed treatments.

Ramularia leaf spot can be found on senescing leaves early in the season (BBCH 25-30). However, infected crops do not generally show symptoms until after flowering, when infection appears on the upper leaves. The symptoms (initial fine spots and later square spots between the leaf veins surrounded by a chlorotic halo), can often be mis-diagnosed for other barley disease such as net blotch or tan spot, or physiological spotting. The main period to protect crops is from BBCH 45-49, as it can cause extensive damage to the upper leaves of the crop and yield losses of 0.5-1.0 t/ha have been reported, particularly in susceptible varieties.

The disease is most damaging in regions where periods of rainfall and leaf wetness are common. Within the Central EU Authorization zone, the disease is more frequently damaging in the EPPO Maritime regions. However, the disease is widely distributed across the EU and over the past two decades has become a major barley plant pathogen. Resistance to a number of fungicides including strobilurins, azoles and SDHIs is increasing.

Information on wheat production in the Central Zone

Wheat is the most widely-grown crop in the world. Global harvests reached 765 million metric tonnes in 2019-2020. Within the EU, wheat advances from its world position of second most important food crop (after rice) to the status of most important cereal. In 2020 the various countries which comprise the EU produced over 125 million metric tonnes of wheat, which is comparable to that produced by China, 17% more than India and 2.5 times that produced by the USA. Of the various EU member states, France and Germany are the biggest wheat producers, harvesting circa 24% and 18% respectively of the EU total, with UK producing around 8.0%. Over the past 10 years, EU metric tonnage has increased by 23%, whilst, over the same period, US tonnages have fallen by around 8%. The EU currently exports up to 15% of its harvest and this figure is rising annually. Wheat grain grown in the EU provides calories for human foodstuffs (less than one third of harvest) and animal feed (circa two thirds of harvest). Wheat is also grown for alcohol distillation, as a raw material for biofuels and wheat straw is used for livestock bedding and fodder, roof thatching and basket-making. Such figures and statistics attest to the huge economic and social importance of wheat as an EU crop and commodity. It follows that losses to the wheat crop from attack by pests and infection by pathogens are of considerable concern. Of the various pathogens, the foliar disease of wheat, rusts, mildew and *Septoria tritici* are the most problematic in European wheat fields of the Central Zone. *S. tritici* flourishes in the humid climate that prevails in EPPO Maritime Zone, though it is widely present across Europe. Thus, the fungus pervades the major wheat growing regions of the EU. In fact, this persistent pathogen accounts for approximately 70% of annual fungicide usage in the EU. During severe epidemics losses of up to 50% of yield have been documented in fields planted with wheat cultivars susceptible to *S. tritici* (Fones & Gurr, 2015). Wheat production occurs in the whole Central Registration Zone which encloses three different EPPO zones of comparable climates: the Maritime Zone (Austria, Belgium, Czech Republic, Germany, Ireland, Luxembourg, The Netherlands and the United Kingdom), the North-East zone (Poland) and the South-East zone (Hungary, Romania, Slovenia and Slovakia.). The main countries for wheat production in the Central Zone are Germany, UK, Poland and Romania. The highest yield amounts are usually obtained in countries of the Maritime EPPO Zone such as Ireland, Netherlands, Belgium, Germany, United Kingdom, Denmark, France (North, maritime) and Sweden. De-

tailed information on wheat production is available from the [Eurostat](#) website on the following Tables. The importance of cereal crops within the Central Zone is demonstrated in Table 3.2-4.

Information on triticale production in the Central Zone

Triticale (\times *Triticosecale*), is a hybrid of wheat (*Triticum*) and rye (*Secale*). Commercially available triticale is almost always a second generation hybrid, i.e., a cross between two kinds of primary triticale. As a rule, triticale combines the yield potential and grain quality of wheat with the disease and environmental tolerance - including soil conditions - of rye. Depending on the cultivar, triticale can more or less resemble either of its parents. It is grown mostly for forage or fodder, although some triticale-based foods can be purchased at health food stores or are to be found in some breakfast cereals. Triticale production in the EU-28 amounted to 11.2 million tonnes in 2020. The primary producers of triticale in the EU-28 are Poland (5.1 million tonnes), Germany (2.0 million tonnes) and France (1.2 million tonnes). As a feed grain, triticale is already well established and of high economic importance. It also has received attention as a potential energy crop. Most wheat and rye diseases also occur on triticale. In comparison with wheat, some triticale varieties can have good resistance to several common wheat diseases including: rusts (*Puccinia* spp.), *Septoria* spp., scalds (*Rhynchosporium* sp.), smuts (*Ustilago* and *Urocystis* spp.), bunts (*Tilletia* sp.) or powdery mildew (*Blumeria graminis*). However, triticale has relatively greater susceptibility than wheat to diseases such as spot blotch (*Bipolaris sorokiniana*), scab (*Fusarium* spp.) and ergot (*Claviceps purpurea*).

Information on rye production in the Central Zone

Rye (*Secale cereale*) is a cereal crop grown extensively as a grain, a cover crop and as a forage crop. It is a member of the wheat tribe (Triticeae) and is closely related to barley (*Hordeum*) and wheat (*Triticum*). Rye grain is used for flour, rye bread, rye beer, crisp bread, some whiskeys, some vodkas, and animal fodder. It can also be eaten whole, either as boiled rye, or by being rolled, similar to rolled oats.

Rye grows well in much poorer soils than those necessary for most cereal grains. Thus, it is an especially valuable crop in regions where the soil has sand or peat. Rye plants withstand cold better than other small grains do. Rye will survive with snow cover that would otherwise result in winter-kill for winter wheat. Most farmers grow winter ryes, which are planted and begin to grow in autumn. In spring, the plants develop and produce their crop. Fall-planted rye shows fast growth. By the summer solstice, plants reach their maximum height of about a 120 cm while spring-planted wheat has only recently germinated. Vigorous growth suppresses even the most noxious weed competitors and rye can be grown without application of herbicides. Rye is grown primarily in Eastern, Central and Northern Europe. The main rye belt stretches from northern Germany through Poland, Ukraine, Belarus, Lithuania and Latvia into central and northern Russia. Rye is also grown in North America (Canada and the USA), in South America (Argentina, Brazil and Chile), in Oceania (Australia and New Zealand) in Turkey, in Kazakhstan and in northern China. Most rye is consumed locally or exported only to neighboring countries, rather than being shipped worldwide.

Information on barley production in the Central Zone

The harvested production of barley in the EU in 2020 was 57.7 million tonnes (around 20% of total cereal production in the EU). After wheat and grain maize, barley is the next most commonly grown cereal across the EU.

Barley (grain) is generally used for animal feed in the EU, but is also used for alcohol distillation, brewing and as a raw material for biofuels. The straw is used for livestock bedding and fodder, roof thatching and basket-making.

Detailed information on barley production by Member State is available from the [Eurostat](#) website and figures for countries where the data were generated are shown in Table 3.2-4 (area by EPPO zone), Table 3.2-7 (area by country) and Table 3.2-8 (average yield by country). It can be seen from these figures that the main countries for barley production in the Central EU Authorisation zone are Germany, the UK and Poland. The highest yield totals are usually obtained in countries of the EPPO Maritime climatic zone including Ireland, Netherlands, Belgium, Germany and the United Kingdom. The trials in this dossier have been generated in the main EU barley growing areas detailed in Table

3.2-6. A number of countries from outside the Central EU Authorisation zone are included as some data has been generated in these countries as they are in the relevant EPPO climatic zones (e.g. France, Denmark, Sweden, Latvia, and Bulgaria).

Table 3.2-4: The 30 most important field and vegetable crop species within the 3 EPPO climatic areas of the EU Central Zone¹

Maritime Zone		North-East Zone		South-East Zone	
	1000 ha		1000 ha		1000 ha
Common winter wheat	12048.1	Common winter wheat	2462.5	Grain maize	5757.6
Temporary grasses	6208.2	Spring barley	2105.9	Common winter wheat	5408.7
Winter rape	4087.3	Temporary grasses	1570.5	Sunflower seed	2373.2
Green maize	3917.0	Winter rye	1514.3	Winter rape	857.4
Winter barley	3528.6	grain other than maslin	1423.6	Winter barley	758.1
Spring barley	3124.7	Winter triticale	1295.9	Lucerne	646.8
Grain maize	2114.2	Oats	1045.7	Spring barley	482.5
Sugar beet	1217.8	Winter rape	852.7	Potatoes	458.8
Potatoes	947.3	Winter barley	815.0	Soya bean	353.2
Winter rye	920.1	Common spring wheat	797.0	Oats	334.9
Oats	842.6	Potatoes	649.5	Green maize	305.2
Winter triticale	789.5	Green maize	414.7	Clover and mixtures	253.0
Other annual fodder	565.3	Clover and mixtures	386.2	Other annual fodder	227.3
Sunflower seed	523.1	Grain maize	296.7	Winter triticale	191.4
Clovers	363.6	Spring rape	259.1	sainfoin, sweet clover	181.9
Common spring wheat	357.1	Sugar beet	254.1	Sugar beet	167.0
Lucerne	353.1	sainfoin, sweet clover	189.4	Temporary grasses	148.8
Field peas	336.4	Buckwheat	114.9	Winter rye	86.9
Broad bean, fields beans	265.3	Turnip rape	90.5	Officinal aromatic plants	67.5
Winter durum wheat	165.5	Other annual fodder	89.8	Cabbage (white)	66.4
Other oil seeds	120.8	Maslin	73.6	Water melons	58.4
grain other than maslin	107.5	Other dried pulses	58.2	Broad bean, fields beans	56.1
sainfoin, sweet clover	98.7	Lucerne	49.1	Onion	54.6
Spring rape	88.9	Lupins	40.5	Other oil seeds	50.2
Peas	87.7	Officinal, aromatic plants	37.7	Winter durum wheat	48.1
Flax (straw)	80.7	Cabbage (white)	35.5	Tobacco raw	47.1
Buckwheat	72.3	Fodder beet	35.1	Beans	45.1
Oil flax	70.4	Carrots	34.0	Field peas	42.3
Cauliflower	63.5	Onion	33.3	Kidney beans	41.7
Soya bean	63.4	Broad bean, fields beans	32.0	Peas	38.5

¹ Pierre HUCORNE, Centre Wallon de Recherches Agronomiques, 5030 Gembloux, BE: The actual distribution of crops in Europe. http://www.eppo.int/PPPRODUCTS/zonal_efficacy/12-18159_Distribution_of_crops_in_Europe.doc

Table 3.2-5: EU wheat growing area for selected countries (Eurostat)

Wheat (incl. spelt) growing area (1000 ha)	Year 2020
European Union (2020)	(27,799.9)
France	4261.5
Germany	2833.3
Poland	2471.6
Romania	2145.6
United Kingdom	1415.1
Hungary	933.5
Lithuania	891.6
Czech Republic	798.6
Denmark	502.6
Latvia	498.0
Sweden	450.4
Slovakia	387.1
Austria	279.0
Finland	198.8
Belgium	195.0
Estonia	168.0
Netherlands	108.9
Norway	67.6
Republic of Ireland	46.4
Luxembourg	11.9

Table 3.2-6: EU barley growing area for selected countries (Eurostat)

Barley growing area (1000 ha) in 2020*	Winter barley	Spring barley
European Union	4894.5	6380.6
France	1,283.5	638.9
Germany	1,311	367.0
United Kingdom	318.0	1096.1
Poland	239.7	738.0
Denmark	87.8	565.4
Romania	371.0	66.6
Czech Republic	114.6	217.3
Sweden	20.4	271.4
Hungary	235.0	24.6
Ireland	51.0	140.4
Lithuania	24.5	140.3
Austria	103.5	31.3
Slovakia	50.5	80.4
Bulgaria	127.7	3.2
Latvia	9.4	75.0
Belgium	39.9	4.1
Netherlands	9.6	28.8
Luxembourg	4.0	2.0

n/s = not significant. *2020 data used as this is the latest year with completed statistics
Ranked based on combined area for both winter and spring barley

Table 3.2-7: Typical yield amounts for winter barley for selected EU countries (Eurostat)

Winter barley yield (t/ha) in 2020*	Winter barley	Spring barley
European Union	n/r	n/r
Ireland	7.9	6.7
Belgium	7.7	4.7
Netherlands	7.4	6.1
Denmark	7.0	6.3
Austria	6.9	4.9
Germany	6.8	5.5
Sweden	6.5	5.1
United Kingdom	6.3	5.7
France	6.3	7.0
Czech Republic	6.1	5.2
Hungary	5.7	4.3
Slovakia	5.6	4.9
Luxembourg	5.5	5.5
Latvia	5.5	3.4
Lithuania	4.6	4.2
Poland	4.4	3.4
Bulgaria	4.3	3.2
Romania	2.7	2.1

n/s = not significant. *2020 data used as this is the latest year with completed statistics
Ranked based yield for winter barley

Table 3.2-8: Major / minor status of intended uses (for all cMS and zRMS)

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	Minor
Winter wheat TRZAW	PL, AT , CZ, SK, RO	-	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	-
Spring wheat TRZAS	PL, CZ, SK, RO	AT, CZ, SK, RO	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	-
Durum wheat TRZDU	-	CZ, PL, AT , CZ, SK, RO	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	-
Spelt TRZSP	-	CZ, PL, AT, CZ , SK, RO	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	SEPTTR PUCCST PUCCRT FUSASP ERYSGT PYRNTR	-
Winter rye SECCW	PL, AT	CZ	PUCCRE RHYNSE	PUCCRE RHYNSE	-
Spring rye SECCS	-	PL, AT CZ	PUCCRE RHYNSE	PUCCRE RHYNSE	-
Winter triticale TTLWI	PL	AT , CZ	SEPTSP PUCCST ERYSGT	SEPTSP PUCCST ERYSGT	-
Spring triticale TTLSO	PL	AT , PL , CZ	SEPTSP PUCCST ERYSGT	SEPTSP PUCCST ERYSGT	-
Winter barley HORVW	PL, AT , CZ, SK, RO	-	RAMUCC, RHYNSE, PYRNTE, ERYSGH, PUCCHD	RHYNSE, PYRNTE, ERYSGH, PUCCHD	RAMUCC
Spring barley HORVS	PL, AT CZ, SK, RO	-	RAMUCC, RHYNSE, PYRNTE, ERYSGH, PUCCHD	RHYNSE, PYRNTE, ERYSGH, PUCCHD	RAMUCC

Compliance with the Uniform Principles

This dossier is supplied in accordance with the requirements of the Annex to Commission Regulation (EU) No 545/2011, at the latest at the time of finalization of the evaluation for the purpose of decision-making, without prejudice, where relevant, to the provisions of Articles 33, 34 and 59 of Regulation (EC) No 1107/20. The data submitted are acceptable in terms of quantity, quality, consistency and reliability and sufficient to permit a proper evaluation of the dossier.

All field trials presented in this dossier to demonstrate the minimum effective dose, the efficacy at the proposed label rates, trials to evaluate crop selectivity and the impact on yield and yield quality were carried out by GEP certified testing organisations according to the relevant EPPO guidelines. The trials were carried out under a range of agricultural and environmental conditions across the EU, in areas or regions where the cereal crop species and varieties are commercially grown and where the diseases under investigation are prevalent. The primary guidelines used were the following:

- PP 1/26 Foliar and ear diseases on cereals (leading guideline and guidelines quoted therein)
- PP 1/225 Minimum effective dose
- PP 1/306(1) General principles for the development of co-formulated mixtures of plant protection products
- PP 1/214 (Principles of acceptable efficacy)
- PP 1/135 Phytotoxicity
- PP 1/152 Trial design
- PP 1/181 Conduct efficacy trial
- PP 1/278 Principles of Zonal Data Production and Evaluation
- PP 1/226 Number of Efficacy Trials
- PP 1/241 Guidance on Comparable Climates
- PP 1/214 Principles of Acceptable Efficacy
- PP 1/213 Resistance Risk Analysis
- PP 1/207 Effects of Succeeding Crops
- PP 1/256 Effects on Adjacent Crops
- PP 1/223 Introduction to the efficacy evaluation of plant protection products

Information on trials submitted (3.1 Efficacy data)

zRMS comments:

The following tables 3.2-9 – 3.2-12 have been corrected by zRMS based on the number of trial reports effectively submitted, on the 12th May 2022, the day of submission of the final updated BAD and dRR (excluding trials withdrawn, and trials not used by the applicant but submitted nevertheless – see Appendix 1). The tables 3.2-9 – 3.2-12 show frequency of data concerning particular targets and include many trials that report efficacy on more than one target. Tables 3.2-13-28 on the other hand, identify, by the report no., the trials that were indeed used by the applicant in compiling this dRR, with many of them listed in more than one table. As the result, the numbers in Tables 3.2-9 - 3.2-28 have little in common with the total number of trials submitted, that has been given by the applicant at the beginning of the present dRR.

Table 3.2-9: Presentation of MED and efficacy trials (wheat)

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
TRZAW	SEPTTR	Czech Republic	2014	P + MED + E	1	-	-	GEP	
			2015	E	3			GEP	
			2016	P + E	+ 2	-	-	GEP	
			2020	MED + E	- 3	-	-	GEP	
			2021	MED + E	2	-	-	GEP	
		Germany	2014	P + MED + E	- 5	-	-	GEP	1 MED, 1 P
			2015	MED + E	- 4	-	-	GEP	
			2016	E	1			GEP	
			2017	E	2	-	-	GEP	
			2019	E	1			GEP	
		Latvia	2014	P + MED + E	-	1	-	GEP	
			2015	P + MED + E	-	+ 2	-	GEP	
			2016	P + MED + E	-	2	-	GEP	1 P
		Poland	2014	P + MED + E	-	4 5	-	GEP	3 P
			2015	MED + E	-	2	-	GEP	1 MED
			2016	MED + E	-	+ 4	-	GEP	
			2020	MED + E	-	+ 2	-	GEP	
			2021	E		5		GEP	
		Bulgaria	2016	P + MED + E	-	-	2	GEP	
		Hungary	2014	MED + E	-	-	2	GEP	1 MED
			2015	P + MED + E	-	-	- 5	GEP	1 MED
			2016	E	-	-	+ 2	GEP	
		Romania	2016	E			1	GEP	

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
			2020	MED + E	-	-	6	GEP	2 MED
			2021	MED + E	-	-	+ 2	GEP	
		Slovakia	2021	MED + E			1		GEP
		Total (37 40)	2014-2020 2021	E (MED)	11 (6) 13 (8) 24	12 (11) 12 (10) 23	14 (8) 15 (9) 21	GEP	+0 +1 16 trials at 1.5 L/ha in S-E
TRZAS	SEPTTR	Poland	2016	E (MED)	-	1 (1)	-	GEP	
			2020	E (MED)	-	1 (1)	-	GEP	
		Total (2)				2		GEP	
TRZAW	PUCCRT	Austria	2015	MED + E	+ 2	-	-	GEP	
		Czech Republic	2015	MED + E	+ 2	-	-	GEP	
			2016	P + E	2	-	-	GEP	
			2018	E	1			GEP	
			2020	MED + E	3 4	-	-	GEP	
			2021	MED + E	2 3	-	-	GEP	
		Germany	2014	P + MED + E	2	-	-	GEP	1 P
			2015	MED + E	3	-	-	GEP	
			2017	E	1	-	-	GEP	
			2019	E	1			GEP	
		Poland	2014	P + MED + E	-	2 3	-	GEP	
			2015	MED + E	-	3	-	GEP	
			2016	E	-	2	-	GEP	
			2020	MED + E	-	+ 2	-	GEP	
			2021	MED + E	-	2	-	GEP	
		Bulgaria	2016	P + MED + E	-	-	2	GEP	
		Hungary	2014	MED + E	-	-	+ 0	GEP	
			2015	MED + E	-	-	4 5	GEP	2 MED
			2016	P + MED + E	-	-	4	GEP	3 MED, 3 P
			2017	E	-	-	1	GEP	
			2020	MED + E	-	-	1	GEP	
			2021	MED + E	-	-	1	GEP	
		Slovakia	2021	MED + E	-	-	1	GEP	
		Total (34 40)	2014-2020 2021	E (MED)	13 (9) 15 (11) 21	8 (6) 10 (8) 12	13 (9) 15 (8) 15	GEP	
		Total + neighbouring countries	2014-2020 2021	E (MED)	-	13 (6) -	-	GEP	DE trials support N-E

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
TRZAW	PUCST	Denmark	2016	P + MED + E	3	-	-	GEP	
		Germany	2014	P + MED + E	3 4	-	-	GEP	2 MED
			2016	P + MED + E	1	-	-	GEP	
			2017	E	1	-	-	GEP	
			2019	E	1	-	-	GEP	
		UK	2015	P + MED + E	2	-	-	GEP	1 P
		Czech Republic	2015	E	1			GEP	
			2016	E	1			GEP	
		Latvia	2016	P + MED + E	-	1	-	GEP	
		Poland	2016	MED + E	-	4	-	GEP	2 MED
			2020	MED + E	-	1	-	GEP	
			2021	MED + E	-	2	-	GEP	1 MED
		Hungary	2014	P + MED + E	-	-	2	GEP	1 MED
			2015	P + MED + E	-	-	1 2	GEP	
			2016	P + MED + E	-	-	2 3	GEP	1 P
		Romania	2016	E	-	-	1	GEP	
			2020	MED + E	-	-	1	GEP	
			2021	MED + E	-	-	1	GEP	
		Total (24 27 32)	2014-2020 2021	E (MED)	11 (8) 14	6 (4) 8 (5) 8	7 (5) 8 (5) 10	GEP	
		Total + neighbouring countries	2014-2020 2021	E (MED)	-	9 (7) 11 (8)	-	GEP	DE trials support N-E
TRZAS	PUCST	Poland (1)	2016	E (MED)	-	1 (1)	-	GEP	
TRZAW	FUSASP	Austria	2015	MED + E	1	-	-	GEP	
			2016	MED + E	2	-	-	GEP	
		Germany	2014	MED + E	1	-	-	GEP	
			2015	MED + E	1	-	-	GEP	
			2016	MED + E	2	-	-	GEP	
		Denmark	2016	MED + E	1	-	-	GEP	
		France	2016	MED + E	1	-	-	GEP	
		UK	2015	MED + E	1	-	-	GEP	
		Poland	2016	MED + E	-	1	-	GEP	
			2021	MED + E	-	6	-	GEP	

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
		Hungary	2021	MED + E	-	-	3	GEP	
		Total (11-20)	2014-2020 2021	E (MED)	10 (10)	1 (1) 7 (5)	3 (3)	GEP	
		Total + neighbouring countries	2014-2020 2021	E (MED)	-	5 (5) 11 (8)	4 (4) 11 (11)	GEP	DE trials support N-E, AT + PL trials support S-E
TRZAW	PYRNTR	Austria	2015	MED + E	1	-	-	GEP	
		Czech Republic	2020	MED + E	1	-	-	GEP	
			2021	MED + E	1	-	-	GEP	
		Germany	2014	MED + E	1	-	-	GEP	
			2015	MED + E	1	-	-	GEP	
			2016	MED + E	2	-	-	GEP	1 MED
			2017	E	1	-	-	GEP	
		Latvia	2014	MED + E	-	1	-	GEP	
			2015	E	-	2	-	GEP	
			2016	E		1		GEP	
		Poland	2014	MED + E	-	2 1	-	GEP	1 MED
			2016	E		1		GEP	
			2020	MED + E	-	1	-	GEP	
			2021	MED + E	-	1		GEP	
		Hungary	2014 2016	MED + E	-	-	1	GEP	
		Romania	2020	MED + E	-	-	5	GEP	2 MED
		Total (19-22)	2014-2020 2021	E (MED)	7 (6) 8	6 (3) 8	6 (3) 6	GEP	
		Total + neighbouring countries	2014-2020 2021	E (MED)	10 (6 7)	10 (7) 12 (9)	7 (7) 12 (9)	GEP	CZ + DE trials support N-E. AT + CZ + PL trials support S-E
TRZAS	PYRNTR	Latvia (1)	2014	E (MED)	-	1 (1)		GEP	
		Poland	2021	MED + E	-	1		GEP	
		Total (2)	2014-2021	E (MED)	-	2 (2)	-	GEP	
TRZAW	ERYSGT	Czech Republic	2015	MED + E	3	-	-	GEP	
			2018	MED + E	1	-	-	GEP	
			2020	MED + E	2	-	-	GEP	
		Germany	2017	E	1 2	-	-	GEP	
		Poland	2014	MED + E	-	1	-	GEP	

Crops*	Target(s)*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime Zone	North-East Zone	South-East Zone		
			2020	MED + E	-	1	-	GEP	
			2021	MED + E	-	4	-	GEP	
		Hungary	2017	E	-	-	2	GEP	
			2020	MED + E	-	-	3	GEP	
		Romania	2020	MED + E	-	-	2	GEP	1 MED
			2021	E			1	GEP	
		Total (16 21 22)	2014-2020 2021	E (MED)	7 (6) 8	2 (2) 6 (6)	7 (4) 8 (5)	GEP	
		Total + neighbouring countries	2014-2020 2021	E (MED)	10 (6) 13 (6)	6 (5) 10 (9)	9 (4) 10 (5)	GEP	PL trials support MAR, CZ + DE trials support N-E, CZ + trials support S-E
TRZAS	ERYSGT	Poland (1)	2020	E (MED)	-	1 (1)		GEP	
Grand Total (145# 172# 218)			2014-2020 2021	E (MED)	59 (45) 63 (50) 86	39 (31) 54 (43) 69	47 (29) 55 (33) 63	GEP	

*According to the GAP table. Timing of the application(s) can be added if relevant.

**P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

***GEP: Good Experimental Practices. Official: carried out by a national official organisation

#Dossier includes a total of 110 individual effectiveness trials on wheat (107 TRZAW and 3 TRZAS). Total of 145 trials in above table includes 31 trials that are used to support two or more diseases each.

zRMS comments:

The total of 132 trials in wheat (128 in TRZAW and 4 in TRZAS) contribute to the **overall count of 218 crop x pathogen x trial entries** reported in the last row of the Table 3.2-9 (**86+69+63**, Mar, NE, SE zone respectively). Majority of trials include data concerning more than one target pathogen.

Although no data is presented in spring wheat for control of Puccinia striiformis we believe that the comprehensive data set provided for control of this disease in winter wheat and winter rye supports the use as there is clear evidence of selectivity of GF-3307 in spring wheat and so read across should be possible from winter wheat to spring wheat.

No data is presented on durum wheat (TRZDU) and spelt (TRZSP) but as these are minor crops in EU countries in this submission, the extensive data provided for wheat should enable extrapolation to control of the same diseases in these other cereals crops. This argumentation has been accepted in other CZ member states where approval for GF-3307 has already been granted.

zRMS comments:

No extrapolation of Puccinia striiformis efficacy data is possible from TRZAW to TRZAS in Poland, without at least a single trial in TRZAS. It is not the matter of selectivity to the spring form, where the read-across approach would be adequate, but of the efficacy *per se*, where the extrapolation should be based on data and where, although limited compared to the winter form, some data is still needed. The same rule applies to durum wheat and to spelt wheat, if the approval is sought according to the art. 33.

The authorities of the other MSs concerned with the present submission may decide individually on their ap-

proval of the uses in TRZAS, TRZDU and TRZSP. In Poland, in the absence of data, the use in TRZAS (major crop) cannot be authorized, but the uses in TRZDU and TRZSP may be approved based on the art. 51 (minor crops).

Table 3.2-10: Presentation of preliminary, MED and efficacy trials (rye)

Crop(s)	Target(s)	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone	South-East climatic zone		
SECCW	PUCCRE	Germany	2015	MED + E	9	-	-	GEP	
			2016	MED + E	1	-	-		
			2017	E	2	-	-		
		Poland	2016	MED + E	-	3	-	GEP	
			2021	MED + E	-	2	-	GEP	2021
		Total (15 17)	2015-2017, 2021	E (MED)	12 (10)	3 (3) 5 (5)	-	GEP	
		Total + neighbouring countries	2015-2017, 2021	E (MED)	-	13 (13) 15 (13)	-	GEP	DE trials support N-E
SECCW	RHYNSE	Germany	2015	MED + E	7 8	-	-	GEP	
			2016	MED + E	1	-	-		
			2017	E	2	-	-		
		Poland	2016	MED + E	-	5	-	GEP	
			2021	MED + E	-	1	-	GEP	2021
		Total (15 16 17)	2015-2017, 2021	E (MED)	10 (8) 11	5 (5) 6 (6)	-	GEP	
		Total + neighbouring countries	2015-2017, 2021	E (MED)	-	13 (13) 14 (14)	-	GEP	DE trials support N-E
SECCW	All diseases	Total (30# 33# 34)	2015-2017, 2021	E (MED)	22 (18) 23	8 (8) 11 (11)	-	GEP	

**P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

***GEP: Good Experimental Practices. Official: carried out by a national official organisation

#Dossier includes a total of 17 individual SECCW effectiveness trials. Total of 30 trials in the above table includes 13 trials that are used to support two diseases each.

zRMS comments:

The total of 19 trials in winter rye contribute to the overall count of 34 crop x pathogen x trial entries reported in the last row of the Table 3.2-10 (23+11, Mar and NE zone respectively).

Table 3.2-11: Presentation of preliminary, MED and efficacy trials (triticale)

Crop(s)	Target(s)	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone	South-East climatic zone		
TTLWI	SEPTSP	Germany	2015	MED + E	4	-	-	GEP	
			2017	E	1	-	-	GEP	
			2018	E	1	-		GEP	
			2020	E	1	-	-	GEP	
		Poland	2016	MED + E	-	3	-	GEP	
			2018	E	-	1	-	GEP	
			2020 2019	E	-	2	-	GEP	
		Total (13)	2015-2020	E (MED)	7 (4)	6 (3)	-	GEP	
		Total + neighbouring countries	2015-2020	E (MED)	-	13 (7)	-	GEP	DE trials support N-E
TTLWI	ERYSGT	Germany	2015	MED + E	1	-	-	GEP	
			2017	E	1	-	-	GEP	
			2018	E	1	-	-	GEP	
			2020	E	2 1*	-	-	GEP	*Trial EA20F9B007F-DPE012 was withdrawn after the update May 2022
		Poland	2016	MED + E	-	3	-	GEP	
			2017	MED + E	-	1	-	GEP	
			2020	MED + E	-	1	-	GEP	
			2021	MED + E	-	1	-	GEP	
		Total (10)	2015-2020 2021	E (MED)	5 (1) 4 (1)	5 (5) 6 (6)	-	GEP	
		Total + neighbouring countries	2015-2020 2021	E (MED)	6 (10) 10 (7)	9 (6) 10 (7)	-	GEP	PL trials support MAR, DE trials support N-E
TTLWI	PUCCST	Germany	2015	MED + E	4	-	-	GEP	
			2018	E	1	-	-	GEP	
			2020	E	5	-	-	GEP	4 MED
		Poland	2016	MED + E	-	4 3	-	GEP	
			2018	E	-	3	-	GEP	
			2019	E	-	2	-	GEP	
			2020	MED + E	-	2	-	GEP	
		Total (18 20)	2015-2020	E (MED)	10 (8)	8 (3) 10	-	GEP	
		Total + neighbouring countries	2015-2020	E (MED)	-	16 (11)	-	GEP	DE trials support N-E

Crop(s)	Target(s)	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone	South-East climatic zone		
TTLWI	All diseases	Total (41#) 43	2015- 2020 2021	E (MED)	22 (13) 21 (13)	19 (14) 20 (15) 22	-	GEP	

**P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

***GEP: Good Experimental Practices. Official: carried out by a national official organisation

#Dossier includes a total of 32 individual TTLWI effectiveness trials. Total of 41 trials in the above table includes 11 trials that are used to support two diseases each.

zRMS comments:

The total of 32 trials in winter triticale contribute to the overall count of 43 crop x pathogen x trial entries reported in the last row of the Table 3.2-11 (21+22, Mar and NE zone respectively).

Although no data is presented in spring rye and spring triticale, these are regarded as minor crops when compared to winter varieties and the applicant believes that the comprehensive data provided for control of diseases in winter rye and triticale and the activity against similar pathogens in winter and spring wheat support read across the spring rye and triticale.

zRMS comments:

No extrapolation of efficacy data is possible from TTLWI to TTLSO in Poland, without at least a single trial in TTLSO, and the spring triticale is not a minor crop itself in Poland. However, the use in TTLSO in control of the yellow rust, *Puccinia striiformis*, may be approved in Poland based on the art. 51. The authorities of the other MSs concerned with the present submission may decide individually on their approval for the uses in TTLSO in general.

Table 3.2-12: Presentation of preliminary, MED and efficacy trials (barley)

Target(s)	Crops*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone	South-East climatic zone		
RAMUCC	HORVS	Denmark	2017	MED + E	2	-	-	GEP	
		Germany	2017	MED + E	2				
			2019	MED + E	1	-	-	GEP	
		Belgium	2019	E	1			GEP	
		UK	2019	E	1			GEP	
	HORVW	Denmark	2017	E	2			GEP	
		France	2018	E	1			GEP	
		Germany	2017	MED + E	2			GEP	
			2019	E	3	-	-	GEP	
		UK	2017	E	1			GEP	
			2019	E	1			GEP	
		Total (40 17)	2017-2019	E (MED)	10 (7) 17	-	-	GEP	

Target(s)	Crops*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone	South-East climatic zone		
	Total + neighbouring countries		2017-2019	E (MED)	-	8 (5)	5-8 (5) [§]	GEP	DE trials support S-E and N-E
RHYNSE	HORVS	Belgium	2019	MED + E	1			GEP	
		Germany	2019	E	1	-	-	GEP	
		UK	2017	MED + E	4 3	-	-	GEP	
			2019	P + MED + E	1	-	-	GEP	
		Poland	2019	MED + E	-	3 4	-	GEP	
			2018	MED + E		1		GEP	
			2020	MED + E	-	1	-	GEP	
	HORVW	Belgium	2019	P + MED + E	4	-	-	GEP	
		Germany	2018	P + MED + E	2	-	-	GEP	
			2019	E	4 2	-	-	GEP	
		France	2017	P + MED + E	2 3	-	-	GEP	1 P
			2018	P + MED + E	2	-	-	GEP	1 P
		UK	2017	P + MED + E	1	-	-	GEP	
			2019	E	1	-	-	GEP	
		Latvia	2017, 2019	MED + E	-	4	-	GEP	
		Latvia	2018	MED + E		1		GEP	
		Poland	2017	MED + E	-	1	-	GEP	
			2018	P + MED + E	-	2	-	GEP	
			2019	MED + E	-	1	-	GEP	
			2020	MED + E	-	1	-	GEP	
			2021	MED + E	-	1	-	GEP	
		Total (23-24) 29		2017- 2020 2021	E (MED)	13 (10) 16	10 (10) 11 (11) 13	-	GEP
	Total + neighbouring countries		2017- 2020 2021	E (MED)	-	12 (10) 13 (11)	9 (9) 10 (10)	GEP	DE trials support N-E, PL trials support S-E
PYRNTE	HORVS	Czech Republic	2018	MED + E	1			GEP	
		Germany	2017	MED + E	1			GEP	
		Denmark	2017	MED + E	1			GEP	
		Latvia	2017	MED + E	-	4 2	-	GEP	

Target(s)	Crops*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)	
					Maritime climatic zone	North-East climatic zone	South-East climatic zone			
			2019	P + MED + E	-	1	-	GEP		
		Poland	2018	MED + E		1		GEP		
			2019	MED + E	-	4	-	GEP		
			2020	MED + E	-	1	-	GEP		
		Slovakia	2018	MED + E			1	GEP		
		Hungary	2019	P + MED + E	-	-	2	GEP		
			2021	MED + E	-	-	1	GEP		
		HORVW	Austria	2017	MED + E	1	-	-	GEP	
				2018	P + MED + E	4 2	-	-	GEP	
			Belgium	2019	P + MED + E	1	-	-	GEP	
	France		2017	MED + E	3 6	-	-	GEP		
			2018	MED + E	1			GEP		
	Germany		2018	MED + E	4 2	-	-	GEP		
			2019	E	3	-	-	GEP		
	Bulgaria		2018	P + MED + E	-	-	2	GEP		
	Hungary		2019	P + MED + E	-	-	2	GEP		
			2020	MED + E	-	-	1	GEP		
			2021	MED + E	-	-	1	GEP		
	Romania		2021	MED + E	-	-	5	GEP		
	Latvia		2017	MED + E		2		GEP		
			2018	MED + E		1		GEP		
	Poland		2017	MED + E	-	1	-	GEP		
			2018	P + MED + E	-	2	-	GEP		
			2019	MED + E	-	1	-	GEP		
			2020	MED + E	-	1	-	GEP		
		2021	MED + E	-	2	-	GEP			
	Total (29-38) 53		2017-2020 2021	E (MED)	10 (7) 19	12 (12) 14 (14) 19	7 (7) 14 (14) 15	GEP		
	Total + neighbouring countries		2017-2020 2021	E (MED)	-	15 (12) 17 (14)	-	GEP	DE trials support N-E	
PUCCHD	HORVS	Czech Republic	2018	E	1	-	-	GEP		
		Denmark	2017	MED + E	2			GEP		

Target(s)	Crops*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone	South-East climatic zone		
		UK	2017	MED + E	2			GEP	
		Latvia	2017	MED + E	-	1	-	GEP	
			2019	E	-	1	-	GEP	
		Poland	2018	MED + E		1		GEP	
			2019	MED + E	-	2	-	GEP	
			2020	MED + E	-	2	-	GEP	
	HORVW	Slovakia	2017	MED + E	-	-	2	GEP	
		Austria	2018	E	1	-	-	GEP	
		Belgium	2019	MED + E	1	-	-	GEP	
		Denmark	2017	MED + E	2	-	-	GEP	
		France	2017	MED + E	1 2	-	-	GEP	
		Germany	2018	MED + E	2	-	-	GEP	1 MED
		Germany	2019	MED + E	2	-	-	GEP	
		UK	2017	E	3	-	-	GEP	
		Poland	2018	MED + E	-	1 2	-	GEP	
			2021	MED + E	-	1	-	GEP	
		Hungary	2019 2018	E	-	-	1	GEP	
			2021	MED + E	-	-	2	GEP	
		Romania	2021	MED + E			1	GEP	
	Romania	2021	MED + E	-	-	1	GEP	Romania	
	Total (21 25) 29		2017- 2020 2021	E (MED)	11 (5) 15	7 (6) 8 (7) 10	3 (2) 6 (5) 4	GEP	
	Total + neighbouring countries		2017- 2020 2021	E (MED)	-	8 (6) (9 (7)	8 (7) 12 (5)	GEP	DE trials support N-E, PL trials support S-E
ERYSGH	HORVS	Czech Republic	2018	MED + E	1			GEP	
		Germany	2017	MED + E	2	-	-	GEP	
			2019	MED + E	1	-	-	GEP	
		Denmark	2017	MED + E	1			GEP	
		Latvia	2017	MED + E	-	1	-	GEP	
			2019	MED + E	-	1	-	GEP	
		Poland	2018	MED + E	-	1	-	GEP	
			2020	MED + E	-	2	-	GEP	
		Hungary	2019	MED + E	-	-	1	GEP	
		Slovakia	2018	MED + E	-	-	1	GEP	
	HORVW	Belgium	2019	MED + E	1			GEP	

Target(s)	Crops*	Country	Years	Type of trial**	Number of valid trials			GEP, non-GEP, official***	Comments (any other relevant information)
					Maritime climatic zone	North-East climatic zone	South-East climatic zone		
		Denmark	2017	MED + E	1	-	-	GEP	
		France	2017	MED + E	1	-	-	GEP	
		Germany	2017	MED + E	1	-	-	GEP	
			2019	E	2	-	-	GEP	
		UK	2017	MED + E	1	-	-	GEP	
			2018	E	1	-	-	GEP	Trial GB18E7B007EB02C was withdrawn by the applicant as the result of dRR / BAD update in Maty 2022
		Latvia	2017	MED + E	-	2	-	GEP	
			2018	MED + E	-	1	-	GEP	
		Poland	2018	MED + E	-	1	-	GEP	
			2020	MED + E	-	1	-	GEP	
		Hungary	2021	MED + E	-	-	2 ³	GEP	
		Total (22 23 ²⁶)		2017- 2020 2021	E (MED)	10 ⁹ (7) 11	10 (10)	2 (2) 4 (4) ⁵	GEP
		Total + neighbouring countries		2017- 2020 2021	E (MED)	14 (7)	14 (10) 16 (10)	7 (7) 9 (4)	GEP DE trials support N-E, PL trials support S-E
All diseases	All crops	Total (105 120 [#]) 154	2017- 2020 2021	E (MED)	54 (36) 53 (36) 78	39 (38) 43 (42) 52	12 (11) 24 (23) 24	GEP	

**P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

***GEP: Good Experimental Practices. Official: carried out by a national official organisation

#Dossier includes a total of 73 individual effectiveness trials (45 HORVW, and 28 HORVS). Total of 105 trials in the above table includes 20 trials that are used to support two diseases each and 6 trials that supported three diseases each.

§ Number of trials differ for supporting 1.2 L/ha or 1.0 l/ha in South-East EPPO climatic zone + neighbouring countries

zRMS comments:

The total of **83 trials in barley** (including 54 in HORVW and 28 in HORVS) contribute to the overall count of **154 crop x pathogen x trial** entries reported in the last row of the Table 3.2-12 (**78+52+24**, Mar, NE and SE zone respectively).

Table 3.2-13 Presentation of 38 41 trials - Efficacy trials - Wheat - SEPTTR

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	SEPTTR	P + MED + E	Central	Maritime	Czech Republic	2014	CZ14E7B028PV01C	Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	P + E	Central	Maritime	Czech Republic	2016	CZ16E7B038PV02C	Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD056	Zkusebni stanice Nechanice, s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD058	Zemedelska zkusebni stanice Kujavy, s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Czech Republic	2021	EA21E7B058F-DQD032	Zkusebni stanice Nechanice, s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Czech Republic	2021	EA21E7B058F-DQD034	Ditana Spol. s.r.o.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2014	DE14E7B014FS01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Central	Maritime	Germany	2014	DE14E7B014WD01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2014	DE14E7B026UB01C	Biochem Agrar GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Germany	2015	DE15E7B014AS01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	Maritime	Germany	2015	DE15E7B014UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2017	DE17G1C012AS01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	Maritime	Germany	2017	DE17G1C012UB02C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Northern	North East	Latvia	2014	LV14E7B028MN02C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Northern	North-East	Latvia	2015	LV15E7B019MN03C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Northern	North-East	Latvia	2016	LV16E7B031KF01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Northern	North-East	Latvia	2016	LV16E7B031KF03C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Central	North East	Poland	2014	PL14E7B014AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	North East	Poland	2014	PL14E7B014AS03C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Central	North East	Poland	2014	PL14E7B028AS01C	IOR Sosnowice	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Central	North East	Poland	2014	PL14E7B028AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	North East	Poland	2015	PL15E7B041AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	North East	Poland	2015	PL15E7B041AS02C	IOR Sosnowice	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	North-East	Poland	2016	PL16E7B031AS03C	IOR Sosnowice	PP 1/26	GEP
TRZAS	SEPTTR	MED + E	Central	North-East	Poland	2016	PL16E7B031AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	North-East	Poland	2020	EA20E7B035F-DPF044	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Southern	South-East	Bulgaria	2016	BG16E7B030VA01C	ANADIAG Bulgaria Ltd	PP 1/26	GEP
TRZAW	SEPTTR	P + MED	Southern	South-East	Bulgaria	2016	BG16E7B030VA02C	ANADIAG Bulgaria Ltd	PP 1/26	GEP

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
		+ E								
TRZAW	SEPTTR	MED + E	Central	South East	Hungary	2014	HU14E7B014AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Hungary	2014	EA14E7B028AB01C	SynTech Research Hungary Kft.	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Central	South East	Hungary	2015	HU15E7B011AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Central	South East	Hungary	2015	HU15E7B011AB02C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	SEPTTR	P + MED + E	Central	South East	Hungary	2015	HU15E7B011LM01	Dow Agrosiences Hungary Kft	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South East	Hungary	2016	HU16E7B030LM03	Dow Agrosiences Hungary Kft	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Romania	2020	EA20E7B020F-DHT047	NARDI Fundulea	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Romania	2020	EA20E7B020F-DHT048	SC AgroProspect SRL	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Romania	2020	EA20E7B020F-DHT084	Eurofins Agricultural Services SRL	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	South-East	Romania	2020	EA20E7B035F-DHT074	SC AgroProspect SRL	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	South-East	Romania	2020	EA20E7B035F-DHT075	NARDI Fundulea	PP 1/26	GEP
TRZAW	SEPTTR	E	Central	South-East	Romania	2020	EA20E7B065F-DHT071	Eurofins Agricultural Services SRL	PP 1/26	GEP
TRZAW	SEPTTR	MED + E	Central	South-East	Romania	2021	EA21E7B059F-AMT049	SC AgroProspect SRL	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-14 Presentation of 34-40 trials - Efficacy trials - Wheat - PUCCRT

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	PUCCRT	MED + E	Central	Maritime	Austria	2015	DE15E7B014UB06C	Agro Trial Center GmbH	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Czech Republic	2015	CZ15E7B014PV01C	OSEVA PRO s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	P + E	Central	Maritime	Czech Republic	2016	CZ16E7B038PV01C	Ditana Spol. s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	P + E	Central	Maritime	Czech Republic	2016	CZ16E7B038PV02C	Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD055	Research Institute for Fodder Crops, Ltd	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD057	OSEVA PRO s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD058	Zemedelska zkusebni stanice Kujavy, s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Czech Republic	2021	EA21E7B058F-DQD032	Zkusebni stanice Nechanice, s.r.o	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Czech Republic	2021	EA21E7B058F-DQD034	Ditana Spol. s.r.o.	PP 1/26	GEP
TRZAW	PUCCRT	P + MED + E	Central	Maritime	Germany	2014	DE14E7B010WD01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	Germany	2014	DE14E7B026UB01C	Biochem Agrar GmbH	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Germany	2015	DE15E7B014AS01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Germany	2015	DE15E7B014UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	Maritime	Germany	2015	DE15E7B014UB04C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	Maritime	Germany	2017	DE17E7B016UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAW	PUCCRT	P + MED + E	Central	North-East	Poland	2014	PL14E7B010AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	P + MED + E	Central	North-East	Poland	2014	PL14E7B010AS02C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	North-East	Poland	2015	PL15E7B022AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	North-East	Poland	2015	PL15E7B022AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	North-East	Poland	2015	PL15E7B022AS03C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North-East	Poland	2016	PL16E7B038AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	North East	Poland	2016	PL16E7B046AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	North-East	Poland	2020	EA20E7B035F-DPF044	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	North-East	Poland	2021	EA21E7B054F-DPF031	IOR Sosnicowice	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	North-East	Poland	2021	EA21E7B054F-DPF033	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	PUCCRT	P + MED + E	Southern	South-East	Bulgaria	2016	BG16E7B030VA01C	ANADIAG Bulgaria Ltd	PP 1/26	GEP
TRZAW	PUCCRT	P + MED + E	Southern	South-East	Bulgaria	2016	BG16E7B030VA02C	ANADIAG Bulgaria Ltd	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	South-East	Hungary	2014	HU14E7B014AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2015	HU15E7B012AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	South-East	Hungary	2015	HU15E7B012AB02	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2015	HU15E7B012AB02C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	South-East	Hungary	2015	HU15E7B040AB02C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	PUCCRT	P + MED + E	Central	South-East	Hungary	2016	HU16E7B029AB04	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	P + MED + E	Central	South-East	Hungary	2016	HU16E7B029LM03	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	P + MED + E	Central	South-East	Hungary	2016	HU16E7B030AB01	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2016	HU16E7B046AB01C	BIOTEK Agriculture Hungary Kft.	PP 1/26	GEP
TRZAW	PUCCRT	E	Central	South-East	Hungary	2017	HU17E7B082AB01C	BIOTEK Agriculture Hungary Kft.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	South-East	Hungary	2020	EA20E7B035F-DHP069	Agropass Hungaria Kft.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	South-East	Hungary	2021	EA21E7B060F-EAN023	Agropass Hungaria Kft.	PP 1/26	GEP
TRZAW	PUCCRT	MED + E	Central	South-East	Slovakia	2021	EA21E7B060F-DQD24	FYSE s.r.o.	PP 1/26	GEP

⁽¹⁾ According to the GAP table. ⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-15 Presentation of 25-28 trials - Efficacy trials - Wheat - Puccst

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	Puccst	P + MED + E	Central	Maritime	Germany	2014	DE14E7B014WD01	Dow Agroscience GmbH	PP 1/26	GEP
TRZAW	Puccst	P + E	Central	Maritime	Germany	2014	DE14E7B026DD01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Central	Maritime	Germany	2014	DE14E7B028TS01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Central	Maritime	Germany	2016	DE16E7B027DD01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	Puccst	E	Central	Maritime	Germany	2017	DE17G1C012UB02C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TRZAW	Puccst	E	Central	Maritime	Germany	2019	EA19F9B017F-DPE01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Northern	Maritime	Denmark	2016	DK16E7B002KF01C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Northern	Maritime	Denmark	2016	DK16E7B002KF02C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Northern	Maritime	Denmark	2016	DK16E7B002KF03C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	Puccst	MED + E	-	Maritime	GB	2015	GB15E7B015EB01C	Armstrong Fisher Ltd	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	-	Maritime	GB	2015	GB15E7B015EB04C	Suffolk and Cambridge Crop Station Ltd	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Northern	North-East	Latvia	2016	LV16E7B031KF01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	Puccst	MED + E	Central	North-East	Poland	2016	PL16E7B031AS01C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	Puccst	MED + E	Central	North-East	Poland	2016	PL16E7B031AS03C	IOR Sosnicowice	PP 1/26	GEP
TRZAS	Puccst	MED + E	Central	North-East	Poland	2016	PL16E7B031AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TRZAW	Puccst	E	Central	North-East	Poland	2016	PL16E7B038AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	Puccst	E	Central	North East	Poland	2016	PL16E7B046AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	Puccst	MED + E	Central	North East	Poland	2020	EA20E7B035F-DPF045	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	Puccst	MED + E	Central	North East	Poland	2021	EA21E7B054F-DPF034	Poznan University of Life Sciences	PP 1/26	GEP
TRZAW	Puccst	E	Central	North East	Poland	2021	EA21E7B054F-DPF042	Anadiag Polska	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Central	South East	Hungary	2014	HU14E7B010AB01	SynTech Research Hungary Kft.	PP 1/26	GEP
TRZAW	Puccst	P + E	Central	South East	Hungary	2014	HU14E7B026LM01	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Central	South East	Hungary	2015	HU15E7B011LM01	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	Puccst	P + MED + E	Central	South-East	Hungary	2016	HU16E7B029AB04	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	Puccst	MED+ E	Central	South-East	Hungary	2016	HU16E7B029LM03	Dow Agrosciences Hungary Kft	PP 1/26	GEP
TRZAW	Puccst	E	Central	South East	Romania	2016	RO16E7B046AP01C	NARDI Fundulea	PP 1/26	GEP

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	PUCCST	MED+ E	Central	South East	Romania	2020	EA20E7B035F-DHT075	NARDI Fundulea	PP 1/26	GEP
TRZAW	PUCCST	E	Central	South East	Romania	2021	EA21E7B059F-AMT049	SC AgroProspect SRL	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-16 Presentation of 20 trials - Efficacy trials - Wheat – FUSASP

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	FUSASP	MED + E	Central	Maritime	Austria	2015	DE15E7B018UB02C	Agro Trial Center GmbH	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	Maritime	Austria	2016	DE16E7B032UB02C	Agro Trial Center GmbH	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	Maritime	Austria	2016	DE16E7B032UB03C	Agro Trial Center GmbH	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	Maritime	Germany	2014	DE14E7B023UB01C	Agrartest GmbH	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	Maritime	Germany	2015	DE15E7B018UB01C	Agrartest GmbH	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	Maritime	Germany	2016	DE16E7B032FS01	Dow Agrosiences GmbH	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	Maritime	Germany	2016	DE16E7B032UB01C	Agrartest GmbH	PP 1/26	GEP
TRZAS	FUSASP	MED + E	Northern	Maritime	Denmark	2016	DK16E7B032KF02C	Aarhus University Flakkebjerg	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Southern	Maritime	France	2016	FR16E7B035MC01C	Staphyt	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	Maritime	UK	2015	GB15E7B018EB01C	ADAS UK Ltd	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	North-East	Poland	2016	PL16E7B032AS01C	IOR Sosnowice	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	North-East	Poland	2021	EA21E7B130F-DPF059	SGS Polska Sp. z o.o.	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	North-East	Poland	2021	EA21E7B130F-DPF060	SGS Polska Sp. z o.o.	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	North-East	Poland	2021	EA21E7B130F-DPF061	Staphyt Sp. z o.o.	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	North-East	Poland	2021	EA21E7B130F-DPF063	Staphyt Sp. z o.o.	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	North-East	Poland	2021	EA21WBN66001F-DPF016	IOR Sosnowice	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	North-East	Poland	2021	EA21WBN66001F-DPF017	SGS Polska Sp. z o.o.	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	South-East	Hungary	2021	EA21WBN66001F-EAN009	CPR Europe Kft.	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	South-East	Hungary	2021	EA21WBN66001F-EAN010	Agrofil-SZMI Kft.	PP 1/26	GEP
TRZAW	FUSASP	MED + E	Central	South-East	Hungary	2021	EA21WBN66001F-EAN011	Dow Agrosiences Hungary Kft.	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-17 Presentation of 20 21 trials - Efficacy trials - Wheat – PYRNTR

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	PYRNTR	MED + E	Central	Maritime	Austria	2015	DE15E7B014UB07C	Agro Trial Center GmbH	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD055	Research Institute for Fodder Crops, Ltd	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	Maritime	Czech Republic	2021	EA21E7B058F-DQD029	Vyzkumny ustav picninarsky, spol. s r.o.	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	Maritime	Germany	2014	DE14E7B013UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	Maritime	Germany	2015	DE15E7B016FS01	Dow Agrosciences GmbH	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	Maritime	Germany	2016	DE16E7B004UB01C	Agrartest GmbH	PP 1/26	GEP
TRZAW	PYRNTR	E	Central	Maritime	Germany	2016	DE16E7B004UB02C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	Maritime	Germany	2017	DE17E7B016UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAS	PYRNTR	MED + E	Northern	North-East	Latvia	2014	LV14E7B012MN01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Northern	North-East	Latvia	2014	LV14E7B028MN02C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	PYRNTR	E	Northern	North-East	Latvia	2015	LV15E7B009MN04C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	PYRNTR	E	Northern	North-East	Latvia	2015	LV15E7B019MN03C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
TRZAW	PYRNTR	E	Central	North-East	Poland	2014	PL14E7B014AS02C	IOR Sosnowice	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	North East	Poland	2014	PL14E7B014AS03C	Staphyt Sp. z o.o.	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	North East	Poland	2020	EA20E7B035F-DPF045	Poznan University of Life Sciences	PP 1/26	GEP
TRZAS	PYRNTR	MED + E	Central	North East	Poland	2021	EA21E7B054F-DPF032	IOR Sosnowice	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	North East	Poland	2021	EA21E7B054F-DPF036	SGS Polska Sp. z o. o.	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	South-East	Hungary	2014	HU14E7B014AB01C	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	South-East	Romania	2020	EA20E7B035F-DHT072	Eurofins Agricultural Services SRL	PP 1/26	GEP
TRZAW	PYRNTR	MED + E	Central	South-East	Romania	2020	EA20E7B035F-DHT073	Eurofins Agricultural Services SRL	PP 1/26	GEP
TRZAW	PYRNTR	E	Central	South-East	Romania	2020	EA20E7B020F-DHT046	Eurofins Agricultural Services SRL	PP 1/26	GEP
TRZAW	PYRNTR	E	Central	South-East	Romania	2020	EA20E7B065F-DHT070	Eurofins Agricultural Services SRL	PP 1/26	GEP
TRZAW	PYRNTR	E	Central	South-East	Romania	2020	EA20E7B065F-DHT076	Eurofins Agricultural Services SRL	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-18 Presentation of 17 22 trials - Efficacy trials - Wheat – ERYSGT

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TRZAW	ERYSGT	MED + E	Central	Maritime	Czech Republic	2015	CZ15E7B010PV01C	Zemedelsky vyzkumny ustav Kromeriz, s.r.o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	Maritime	Czech Republic	2015	CZ15E7B041PV01C	Ditana Spol. s.r.o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	Maritime	Czech Republic	2015	CZ15E7B041PV03C	Vyzkumny ustav rostlinne Vyroby, v.v.i.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	Maritime	Czech Republic	2018	CZ18E7B017PV01C	Zemedelska zkusebni stanice Kujavy, s.r.o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD057	OSEVA PRO s.r.o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	Maritime	Czech Republic	2020	EA20E7B036F-DQD058	Zemedelska zkusebni stanice Kujavy, s.r.o.	PP 1/26	GEP
TRZAW	ERYSGT	E	Central	Maritime	Germany	2017	DE17E7B016UB02C	Agrartest GmbH	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	North-East	Poland	2014	PL14E7B028AS01C	IOR Sosnicowice	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	North-East	Poland	2020	EA20E7B035F-DPF043	IOR Sosnicowice	PP 1/26	GEP
TRZAS	ERYSGT	MED + E	Central	North-East	Poland	2020	EA20E7B035F-DPF047	Staphyt Sp. z o.o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	North East	Poland	2021	EA21E7B054F-DPF036	SGS Polska Sp. z o. o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	North East	Poland	2021	EA21E7B054F-DPF037	SGS Polska Sp. z o. o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	North East	Poland	2021	EA21E7B054F-DPF038	SGS Polska Sp. z o. o.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	North East	Poland	2021	EA21E7B054F-DPF039	Staphyt Sp. z o.o.	PP 1/26	GEP
TRZAW	ERYSGT	E	Central	South-East	Hungary	2017	HU17E7B082AB01C	BIOTEK Agriculture Hungary Kft.	PP 1/26	GEP
TRZAW	ERYSGT	E	Central	South-East	Hungary	2017	HU17E7B082AB02C	BIOTEK Agriculture Hungary Kft.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	South-East	Hungary	2020	EA20E7B035F-DHP066	BIOTEK Agriculture Hungary Kft.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	South-East	Hungary	2020	EA20E7B035F-DHP067	BIOTEK Agriculture Hungary Kft	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	South-East	Hungary	2020	EA20E7B035F-DHP069	Agropass Hungaria Kft.	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	South-East	Romania	2020	EA20E7B035F-DHT075	NARDI Fundulea	PP 1/26	GEP
TRZAW	ERYSGT	E	Central	South-East	Romania	2020	EA20E7B020F-DHT047	NARDI Fundulea	PP 1/26	GEP
TRZAW	ERYSGT	MED + E	Central	South-East	Romania	2021	EA21E7B059F-AMT051	Eurofins Agricultural Services SRL	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-19 Presentation of 15 17 trials - Efficacy trials - Rye - PUCCRE

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B002TS01	Dow Agrosciences GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B002UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B002UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B002UB03C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB03C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB04C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB05C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	Maritime	Germany	2016	DE16E7B019UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2017	DE17G1C012TS01	Dow Agrosciences GmbH	PP 1/26	GEP
SECCW	PUCCRE	E	Central	Maritime	Germany	2017	DE17G1C012UB03C	Eurofins Agroscience Services GmbH	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS03C	Poznan University of Life Sciences	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS05C	Staphyt Sp. z.o.o.	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	North-East	Poland	2021	EA21E7B056F-DPF057	SGS Polska Sp. z.o.o.	PP 1/26	GEP
SECCW	PUCCRE	MED + E	Central	North-East	Poland	2021	EA21E7B056F-DPF058	Staphyt Sp. z.o.o.	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-20 Presentation of 15 16 trials - Efficacy trials - Rye – RHYNSE

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2015	DE15E7B002UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2015	DE15E7B002UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2015	DE15E7B002UB03C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB02C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB04C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2015	DE15E7B033UB05C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	Maritime	Germany	2016	DE16E7B019UB01C	Agrartest GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2017	DE17G1C012TS01	Dow Agrosiences GmbH	PP 1/26	GEP
SECCW	RHYNSE	E	Central	Maritime	Germany	2017	DE17G1C012UB03C	Eurofins Agrosience Services GmbH	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS01C	IOR Sosnicowice	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS02C	IOR Sosnicowice	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS03C	Poznan University of Life Sciences	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	North-East	Poland	2016	PL16E7B019AS05C	Staphyt Sp. z.o.o.	PP 1/26	GEP
SECCW	RHYNSE	MED + E	Central	North-East	Poland	2021	EA21E7B056F-DPF058	Staphyt Sp. z.o.o.	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-21 Presentation of 13 trials - Efficacy trials - Triticale – SEPTSP

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TTLWI	SEPTSP	MED+ E	Central	Maritime	Germany	2015	DE15E7B003AS01	Dow AgroSciences GmbH	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	Maritime	Germany	2015	DE15E7B003UB01C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	Maritime	Germany	2015	DE15E7B034UB02C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	Maritime	Germany	2015	DE15E7B034UB04C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	Maritime	Germany	2017	DE17G1C012UB01C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	Maritime	Germany	2018	DE18F9B009AS01C	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	Maritime	Germany	2020	EA20F9B007F-DPE014	Agrartest GmbH	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS03C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TTLWI	SEPTSP	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS05C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	North-East	Poland	2018	PL18F9B009AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	North-East	Poland	2020	EA19F9B003F-DPF01	IOR Sosnowice	PP 1/26	GEP
TTLWI	SEPTSP	E	Central	North-East	Poland	2020	EA19F9B003F-DPF03	Staphyt Sp. z.o.o.	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-22 Presentation of 10 trials - Efficacy trials - Triticale – ERYSGT

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TTLWI	ERYSGT	MED+ E	Central	Maritime	Germany	2015	DE15E7B003AS01	Dow AgroSciences GmbH	PP 1/26	GEP
TTLWI	ERYSGT	E	Central	Maritime	Germany	2017	DE17G1C012UB01C	Agrartest GmbH	PP 1/26	GEP
TTLWI	ERYSGT	E	Central	Maritime	Germany	2018	DE18F9B009AS01C	Agrartest GmbH	PP 1/26	GEP
TTLWI	ERYSGT	E	Central	Maritime	Germany	2020	EA20F9B007F-DPE012	Dow AgroSciences GmbH	PP 1/26	GEP
TTLWI	ERYSGT	E	Central	Maritime	Germany	2020	EA20F9B007F-DPE014	Agrartest GmbH	PP 1/26	GEP
TTLWI	ERYSGT	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS01C	IOR Sosnicowice	PP 1/26	GEP
TTLWI	ERYSGT	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS02C	IOR Sosnicowice	PP 1/26	GEP
TTLWI	ERYSGT	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS04C	Staphyt Sp. z.o.o.	PP 1/26	GEP
TTLWI	ERYSGT	MED+ E	Central	North-East	Poland	2017	PL17E7B089RK01C	IOR Sosnicowice	PP 1/26	GEP
TTLWI	ERYSGT	MED+ E	Central	North-East	Poland	2020	EA20E7B018F-DPF025	IOR Sosnicowice	PP 1/26	GEP
TTLWI	ERYSGT	MED+ E	Central	North-East	Poland	2021	EA21E7B055F-DPF049	Poznan University of Life Sciences	PP 1/26	GEP
TTLSO	PUCCRT	E	Central	North-East	Poland		PL22G1C013F-ASF08C	Poznan University of Life Sciences	PP 1/26	Non GLP
TTLSO	PYRNTR	E	Central	North-East	Poland		EA21G1C004F-DPF006	IOR Sosnicowice	PP 1/26	Non GLP
TTLSO	PYRNTR	E	Central	North-East	Poland		EA21E7B055F-DPF048	IOR Sosnicowice	PP 1/26	Non GLP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-23 Presentation of 18 trials - Efficacy trials - Triticale – PUCCST

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2015	DE15E7B003WD01	Dow AgroSciences GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2015	DE15E7B034UB02C	Agrartest GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2015	DE15E7B034UB03C	Agrartest GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2015	DE15E7B034WD01	Dow AgroSciences GmbH	PP 1/26	GEP
TTLWI	PUCCST	E	Central	Maritime	Germany	2018	DE18F9B009AS03C	Eurofins Agrosience Services GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B018F-DNZ057	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B018F-DNZ058	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B068F-DNZ074	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	Maritime	Germany	2020	EA20E7B068F-DNZ075	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	E	Central	Maritime	Germany	2020	EA20F9B007F-DPE013	Trial-tec GmbH	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	North-East	Poland	2016	PL16E7B020AS03C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	E	Central	North-East	Poland	2018	PL18F9B009AS01C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	E	Central	North-East	Poland	2018	PL18F9B009AS02C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	E	Central	North-East	Poland	2018	PL18F9B009AS03C	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	E	Central	North-East	Poland	2019	EA19F9B003F-DPF02	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	E	Central	North-East	Poland	2019	EA19F9B003F-DPF03	Staphyt Sp. z.o.o.	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	North-East	Poland	2020	EA20E7B018F-DPF026	Poznan University of Life Sciences	PP 1/26	GEP
TTLWI	PUCCST	MED+ E	Central	North-East	Poland	2020	EA20E7B018F-DPF027	Staphyt Sp. z.o.o.	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-24 Presentation of 10 trials - Efficacy trials - Barley – RAMUCC

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
HORVS	RAMUCC	MED + E	Central	Maritime	DE	2017	DE17E7B045AS01	Dow AgroSciences GmbH	PP 1/26	GEP
HORVW	RAMUCC	MED + E	Central	Maritime	DE	2017	DE17E7B045UB03C	AGRARTEST GmbH	PP 1/26	GEP
HORVW	RAMUCC	MED + E	Central	Maritime	DE	2017	DE17E7B045UB11C	Staphyt GmbH	PP 1/26	GEP
HORVS	RAMUCC	MED + E	Central	Maritime	DE	2017	DE17E7B046UB04C	AgrarTest GmbH	PP 1/26	GEP
HORVS	RAMUCC	MED + E	Central	Maritime	DE	2019	EA19E7B004F-DPE01	Dow AgroSciences GmbH	PP 1/26	GEP
HORVW	RAMUCC	E	Central	Maritime	DE	2019	EA19F9B024F-DPE02	Dow AgroSciences GmbH	PP 1/26	GEP
HORVW	RAMUCC	E	Central	Maritime	DE	2019	EA19G1C044F-DNZ01	Trial-Tec GmbH	PP 1/26	GEP
HORVW	RAMUCC	E	Central	Maritime	DE	2019	EA19G1C044F-DNZ02	Trial-Tec GmbH	PP 1/26	GEP
HORVS	RAMUCC	MED + E	Central	Maritime	DK	2017	DK17E7B043KF04C	Aarhus University	PP 1/26	GEP
HORVS	RAMUCC	MED + E	Central	Maritime	DK	2017	DK17E7B043KF05C	Aarhus University	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-25 Presentation of 23 24 trials - Efficacy trials - Barley - RHYNSE

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
HORVW	RHYNSE	P + MED + E	Central	Maritime	BE	2019	EA19E7B004F-DYE02	Centre Wallon de Recherches Agronome	PP 1/26	GEP
HORVW	RHYNSE	P + MED + E	Central	Maritime	DE	2018	DE18E7B007TS01	Dow AgroSciences GmbH	PP 1/26	GEP
HORVW	RHYNSE	P + MED + E	Central	Maritime	DE	2018	DE18E7B007UB04C	Trial-Tec GmbH	PP 1/26	GEP
HORVW	RHYNSE	E	Central	Maritime	DE	2019	EA19F9B025F-DPE01	Trial-Tec GmbH	PP 1/26	GEP
HORVS	RHYNSE	E	Central	Maritime	DE	2019	EA19F9B025F-DNZ01	Dow AgroSciences GmbH	PP 1/26	GEP
HORVW	RHYNSE	P + MED + E	Southern	Maritime	FR	2017	FR17E7B041MC07C	Biotek Agriculture	PP 1/26	GEP
HORVW	RHYNSE	MED + E	Southern	Maritime	FR	2017	FR17E7B042MC12C	Biotek Agriculture	PP 1/26	GEP
HORVW	RHYNSE	P + MED + E	Southern	Maritime	FR	2018	FR18E7B006MC07C	Biotek Agriculture	PP 1/26	GEP
HORVW	RHYNSE	MED + E	Southern	Maritime	FR	2018	FR18E7B012MC03C	Cerestis	PP 1/26	GEP
HORVS	RHYNSE	MED + E	-	Maritime	UK	2017	GB17E7B045SD01	Dow AgroSciences Ltd	PP 1/26	GEP
HORVW	RHYNSE	P + MED + E	-	Maritime	UK	2017	GB17E7B049RH01	Dow AgroSciences Ltd	PP 1/26	GEP
HORVS	RHYNSE	P + MED + E	-	Maritime	UK	2019	EA19E7B004F-DIT02	OAT Ltd	PP 1/26	GEP
HORVW	RHYNSE	E	-	Maritime	UK	2019	EA19F9B025F-DEH01	Cropworks Ltd	PP 1/26	GEP
HORVW	RHYNSE	MED + E	Northern	North-East	LV	2018	LV18E7B011KF01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVW	RHYNSE	MED + E	Central	North-East	PL	2017	PL17E7B045AS01C	IOR Sosnicowice	PP 1/26	GEP
HORVW	RHYNSE	P + MED + E	Central	North East	PL	2018	PL18E7B009AS05C	Uniwersytet Przyrodniczy Poznan	PP 1/26	GEP
HORVW	RHYNSE	P + MED + E	Central	North East	PL	2018	PL18E7B009AS08C	SGS Polska Sp. z o.o.	PP 1/26	GEP
HORVS	RHYNSE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF03	Poznan University of Life Sciences	PP 1/26	GEP
HORVS	RHYNSE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF04	Poznan University of Life Sciences	PP 1/26	GEP
HORVW	RHYNSE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF05	STAPHYT Sp. z o.o.	PP 1/26	GEP
HORVS	RHYNSE	MED + E	Central	North East	PL	2019	EA19E7B003F-DPF06	STAPHYT Sp. z o.o.	PP 1/26	GEP
HORVS	RHYNSE	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF050	IOR Sosnicowice	PP 1/26	GEP
HORVW	RHYNSE	MED + E	Central	North East	PL	2020	EA20E7B037F-DPF051	Poznan University of Life Sciences	PP 1/26	GEP
HORVW	RHYNSE	MED + E	Central	North East	PL	2021	EA21E7B057F-DPF022	IOR Sosnicowice	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-26 Presentation of 29 38 trials - Efficacy trials - Barley - PYRNTE

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
HORVW	PYRNTE	MED + E	Central	Maritime	AT	2017	DE17E7B045UB09C	Agro Trials Center GmbH	PP 1/26	GEP
HORVW	PYRNTE	P + MED + E	Central	Maritime	AT	2018	DE18E7B007UB02C	STAPHYT GmbH	PP 1/26	GEP
HORVW	PYRNTE	P + MED + E	Central	Maritime	BE	2019	EA19E7B004F-DYE01	Centre Wallon de Recherches Agronome	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	Maritime	DE	2018	DE18E7B012UB05C	Quintus GmbH	PP 1/26	GEP
HORVW	PYRNTE	E	Central	Maritime	DE	2019	EA19F9B023F-DPE02	Quintus GmbH	PP 1/26	GEP
HORVW	PYRNTE	E	Central	Maritime	DE	2019	EA19G1C044F-DNZ01	Trial-Tec GmbH	PP 1/26	GEP
HORVW	PYRNTE	E	Central	Maritime	DE	2019	EA19G1C044F-DNZ02	Trial-Tec GmbH	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Southern	Maritime	FR	2017	FR17E7B042MC03C	STAPHYT	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Southern	Maritime	FR	2017	FR17E7B042MC09C	BIOTEK Agriculture	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Southern	Maritime	FR	2017	FR17E7B042MC13C	BIOTEK Agriculture	PP 1/26	GEP
HORVS	PYRNTE	MED + E	Northern	North-East	LV	2017	LV17E7B043KF01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVS	PYRNTE	P + MED + E	Northern	North-East	LV	2019	EA19E7B007F-DHW09	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	North-East	PL	2017	PL17E7B045AS01C	IOR Sosnicowice	PP 1/26	GEP
HORVW	PYRNTE	P + MED + E	Central	North-East	PL	2018	PL18E7B009AS02C	Staphyt Sp. z.o.o.	PP 1/26	GEP
HORVW	PYRNTE	P + MED + E	Central	North-East	PL	2018	PL18E7B009AS05C	Poznan University of Life Sciences	PP 1/26	GEP
HORVS	PYRNTE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF02	IOR Sosnicowice	PP 1/26	GEP
HORVS	PYRNTE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF03	Poznan University of Life Sciences	PP 1/26	GEP
HORVS	PYRNTE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF04	Poznan University of Life Sciences	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF05	STAPHYT Sp. z.o.o.	PP 1/26	GEP
HORVS	PYRNTE	MED + E	Central	North-East	PL	2019	EA19E7B003F-DPF06	STAPHYT Sp. z.o.o.	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF051	Poznan University of Life Sciences	PP 1/26	GEP
HORVS	PYRNTE	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF052	Poznan University of Life Sciences	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	North-East	PL	2021	EA21E7B057F-DPF022	IOR Sosnicowice	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	North-East	PL	2021	EA21E7B057F-DPF025	Poznan University of Life Sciences	PP 1/26	GEP
HORVW	PYRNTE	P + MED + E	Southern	South-East	BG	2018	BG18E7B004KP03C	Anadiag Bulgaria Ltd	PP 1/26	GEP
HORVW	PYRNTE	P + MED + E	Southern	South-East	BG	2018	BG18E7B004KP04C	Anadiag Bulgaria Ltd	PP 1/26	GEP
HORVW	PYRNTE	P + MED + E	Central	South-East	HU	2019	EA19E7B003F-DBI01	Dow AgroSciences Hungary	PP 1/26	GEP
HORVS	PYRNTE	P + MED + E	Central	South-East	HU	2019	EA19E7B003F-DBI02	Dow AgroSciences Hungary	PP 1/26	GEP

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
HORVW	PYRNTE	P + MED + E	Central	South-East	HU	2019	EA19E7B003F-DBI03	Dow AgroSciences Hungary	PP 1/26	GEP
HORVS	PYRNTE	P + MED + E	Central	South-East	HU	2019	EA19E7B003F-DBI04	Dow AgroSciences Hungary	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	South-East	HU	2020	EA20E7B037F-DHP064	BOITEK Agriculture Hungary Kft	PP 1/26	GEP
HORVS	PYRNTE	MED + E	Central	South-East	HU	2021	EA21E7B061F-EAN029	CPR Europe Kft.	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	South-East	HU	2021	EA21E7B061F-EAN032	BOITEK Agriculture Hungary Kft	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	South-East	RO	2021	EA21E7B061F-AMT054	AgroProspect SRL	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	South-East	RO	2021	EA21E7B061F-AMT055	AgroProspect SRL	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	South-East	RO	2021	EA21E7B061F-AMT056	Eurofins Agrosience Services S.R.L.	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	South-East	RO	2021	EA21E7B061F-AMT057	Eurofins Agrosience Services S.R.L.	PP 1/26	GEP
HORVW	PYRNTE	MED + E	Central	South-East	RO	2021	EA21E7B061F-AMT058	Eurofins Agrosience Services S.R.L.	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-27 Presentation of 24 25 trials - Efficacy trials - Barley - PUCCHD

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
HORVW	PUCCHD	E	Central	Maritime	AT	2018	DE18E7B007UB01C	Staphyt/ATC - Agro Trial Center GmbH	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Central	Maritime	BE	2019	EA19E7B004F-DYE01	Centre Wallon de Recherches Agronomue	PP 1/26	GEP
HORVS	PUCCHD	E	Central	Maritime	CZ	2018	CZ18E7B007PV02C	InTec Agro Trials	PP 1/26	GEP
HORVW	PUCCHD	E	Central	Maritime	DE	2018	DE18E7B007UB04C	trial-tec GmbH	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Central	Maritime	DE	2018	DE18E7B012UB05C	Quintus GmbH	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Northern	Maritime	DK	2017	DK17E7B043KF01C	Aarhus University	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Northern	Maritime	DK	2017	DK17E7B043KF02C	Aarhus University	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Southern	Maritime	FR	2017	FR17E7B041MC04C	BIOTEK Agriculture	PP 1/26	GEP
HORVW	PUCCHD	E	-	Maritime	UK	2017	GB17E7B045JK02	Dow Agrosciences Ltd	PP 1/26	GEP
HORVW	PUCCHD	E	-	Maritime	UK	2017	GB17E7B046RH01	Dow Agrosciences Ltd	PP 1/26	GEP
HORVW	PUCCHD	E	-	Maritime	UK	2017	GB17E7B049RH02	Dow Agrosciences Ltd	PP 1/26	GEP
HORVS	PUCCHD	MED + E	Central	North East	LV	2017	LV17E7B043KF02C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVS	PUCCHD	E	Central	North East	LV	2019	EA19E7B007F-DHW09	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Central	North East	PL	2018	PL18E7B009AS05C	Uniwersytet Przyrodniczy Poznan	PP 1/26	GEP
HORVS	PUCCHD	MED + E	Central	North East	PL	2019	EA19E7B003F-DPF02	IOR Sosnowice	PP 1/26	GEP
HORVS	PUCCHD	MED + E	Central	North East	PL	2019	EA19E7B003F-DPF06	STAPHYT Sp. z o.o.	PP 1/26	GEP
HORVS	PUCCHD	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF050	IOR Sosnowice	PP 1/26	GEP
HORVS	PUCCHD	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF052	Poznan University of Life Sciences	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Central	North-East	PL	2021	EA21E7B057F-DPF022	IOR Sosnowice	PP 1/26	GEP
HORVW	PUCCHD	E	Central	South East	HU	2018	HU18F9B029AB01C	BIOTEK Agriculture Hungary Kft	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Central	South-East	HU	2021	EA21E7B061F-EAN030	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Central	South-East	HU	2021	EA21E7B061F-EAN031	AGROPASS Hungaria Kft.	PP 1/26	GEP
HORVW	PUCCHD	MED + E	Central	South-East	RO	2021	EA21E7B061F-AMT055	AgroProspect SRL	PP 1/26	GEP
HORVS	PUCCHD	MED + E	Central	South East	SK	2018	SK18E7B008PV01C	Gemerprodukt Valice	PP 1/26	GEP
HORVS	PUCCHD	MED + E	Central	South East	SK	2018	SK18E7B008PV02C	FYSE Ltd	PP 1/26	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Table 3.2-28 Presentation of 22 23 trials - Efficacy trials - Barley - ERYSGH

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Type of trial ⁽²⁾	Registration zone	EPPO climatic zone ⁽³⁾	Country	Year	Trial code	Testing facilities / Organisation	Leading EPPO Guideline	Trial Status ⁽⁴⁾
HORVS	ERYSGH	MED + E	Central	Maritime	DE	2017	DE17E7B045UB05C	AgrarTest GmbH	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Central	Maritime	DE	2017	DE17E7B045UB11C	Staphyt GmbH	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Central	Maritime	DE	2017	DE17E7B046UB04C	AgrarTest GmbH	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Central	Maritime	DE	2019	EA19E7B004F-DPE01	Dow AgroSciences GmbH	PP 1/26	GEP
HORVW	ERYSGH	E	Central	Maritime	DE	2019	EA19F9B023F-DPE01	Hetterich Fieldwork GbR	PP 1/26	GEP
HORVW	ERYSGH	E	Central	Maritime	DE	2019	EA19F9B025F-DPE01	Trial-Tec GmbH	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Northern	Maritime	DK	2017	DK17E7B043KF02C	Aarhus University	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Southern	Maritime	FR	2017	FR17E7B042MC11C	BIOTEK Agriculture	PP 1/26	GEP
HORVW	ERYSGH	MED + E	-	Maritime	UK	2017	GB17E7B046RH02	Dow AgroSciences Limited	PP 1/26	GEP
HORVW	ERYSGH	E	-	Maritime	UK	2018	GB18E7B007EB02C	Cropworks Ltd	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Northern	North-East	LV	2017	LV17E7B039KF01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Northern	North-East	LV	2017	LV17E7B043KF02C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Northern	North-East	LV	2017	LV17E7B043KF03C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Northern	North-East	LV	2018	LV18E7B011KF01C	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Northern	North-East	LV	2019	EA19E7B007F-DHW09	Latvian Plant Protection Research Centre, LAAPC	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Central	North-East	PL	2018	PL18E7B009AS02C	Staphyt Sp. z.o.o.	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Central	North-East	PL	2018	PL18E7B009AS04C	IOR Sosnicowice	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF050	IOR Sosnicowice	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF051	Poznan University of Life Sciences	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Central	North-East	PL	2020	EA20E7B037F-DPF052	Poznan University of Life Sciences	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Central	South-East	HU	2019	EA19E7B003F-DBI04	Dow AgroSciences Hungary	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Central	South-East	HU	2021	EA21E7B061F-EAN030	Agrofil Szaktanacsado Mernoki Iroda Kft.	PP 1/26	GEP
HORVW	ERYSGH	MED + E	Central	South-East	HU	2021	EA21E7B061F-EAN031	AGROPASS Hungária Kft.	PP 1/26	GEP
HORVS	ERYSGH	MED + E	Central	South-East	SK	2018	SK18E7B008PV01C	Gemerprodukt Valice OVD	PP 1/26	GEP

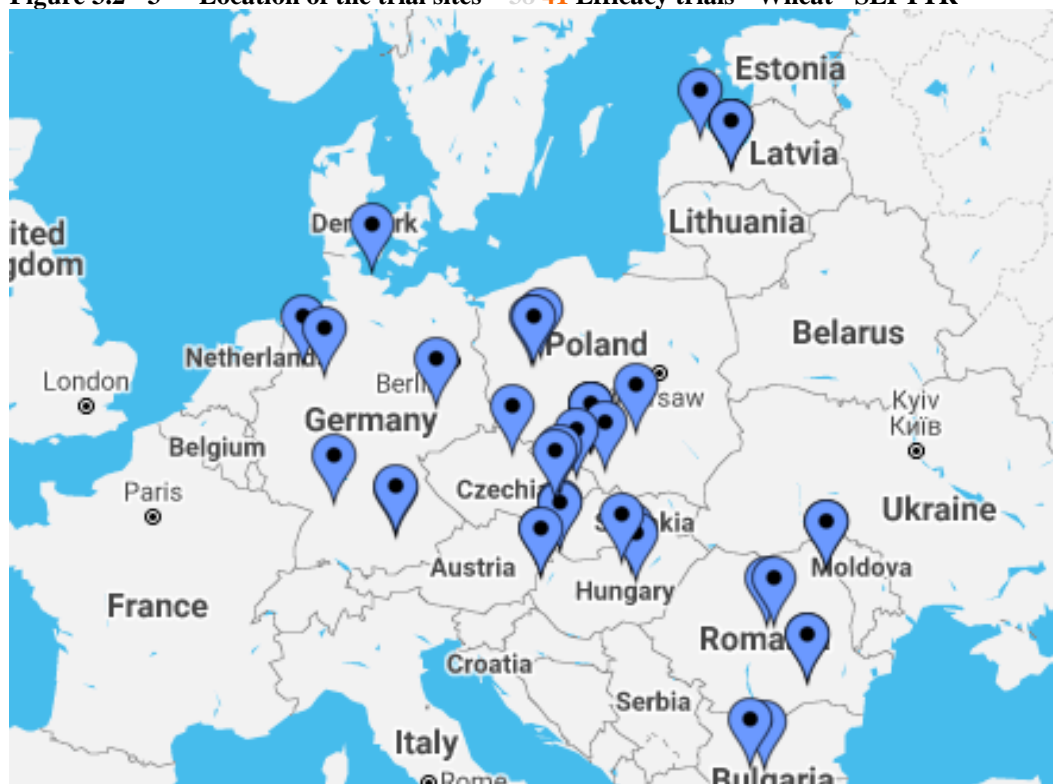
⁽¹⁾ According to the GAP table.

⁽²⁾ P= Efficacy trials used in preliminary part - MED: Efficacy trials used in Minimum effective dose - E = Efficacy trial

⁽³⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

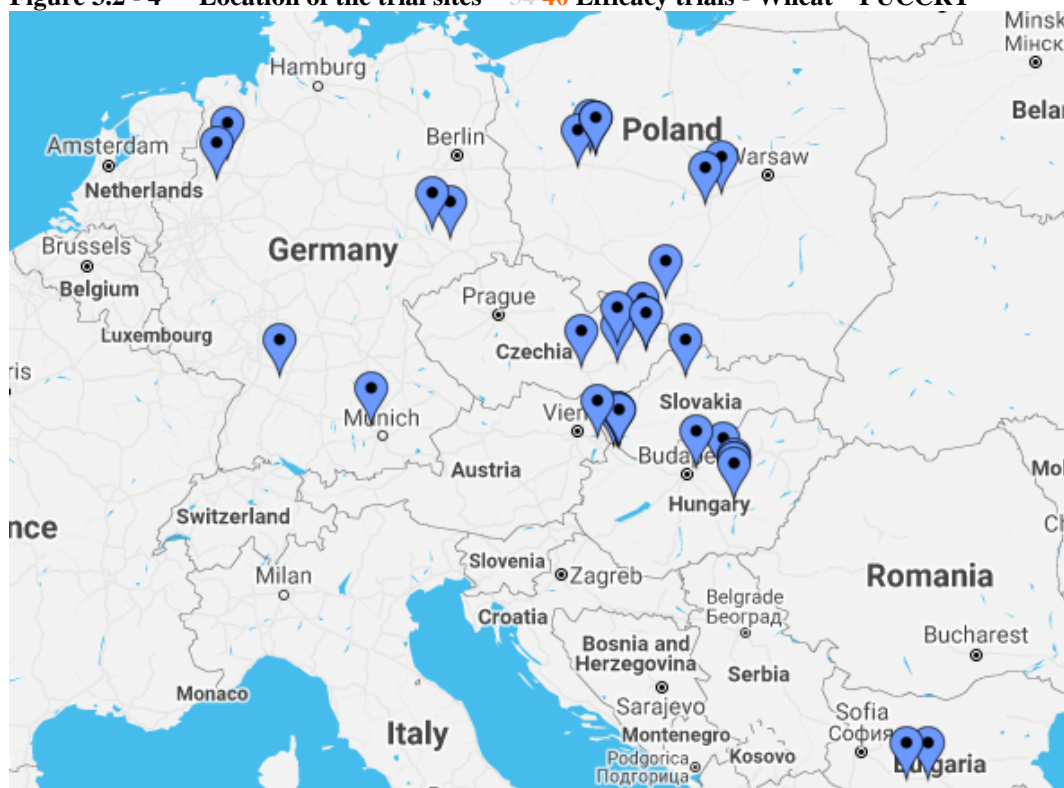
⁽⁴⁾ GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Figure 3.2 - 3 Location of the trial sites – 38 41 Efficacy trials - Wheat - SEPTTR



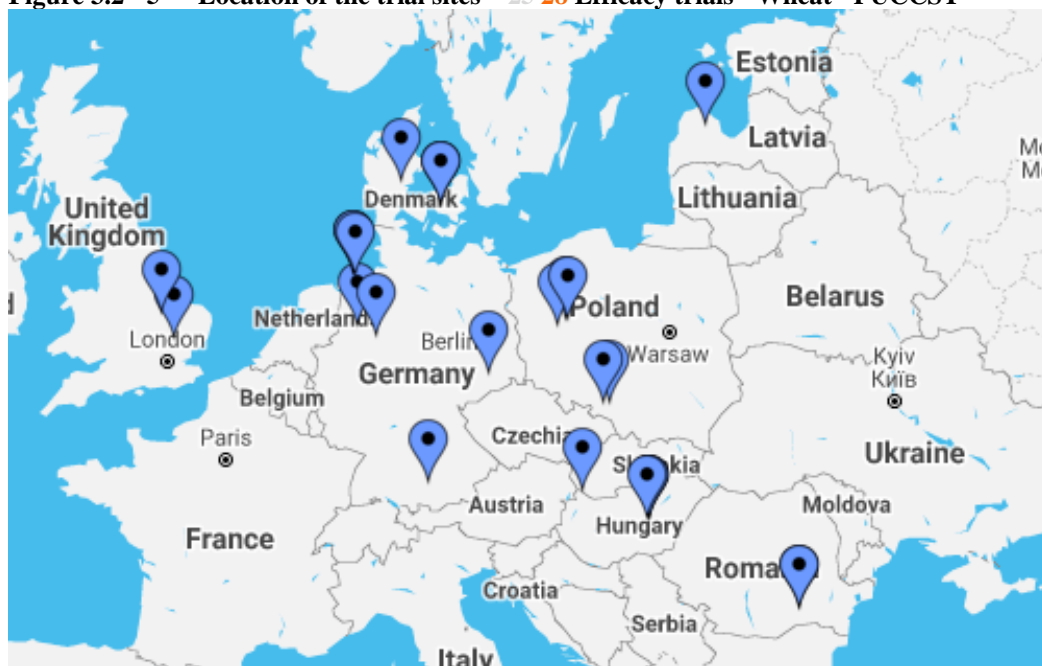
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 4 Location of the trial sites – 34 40 Efficacy trials - Wheat – PUCCRT



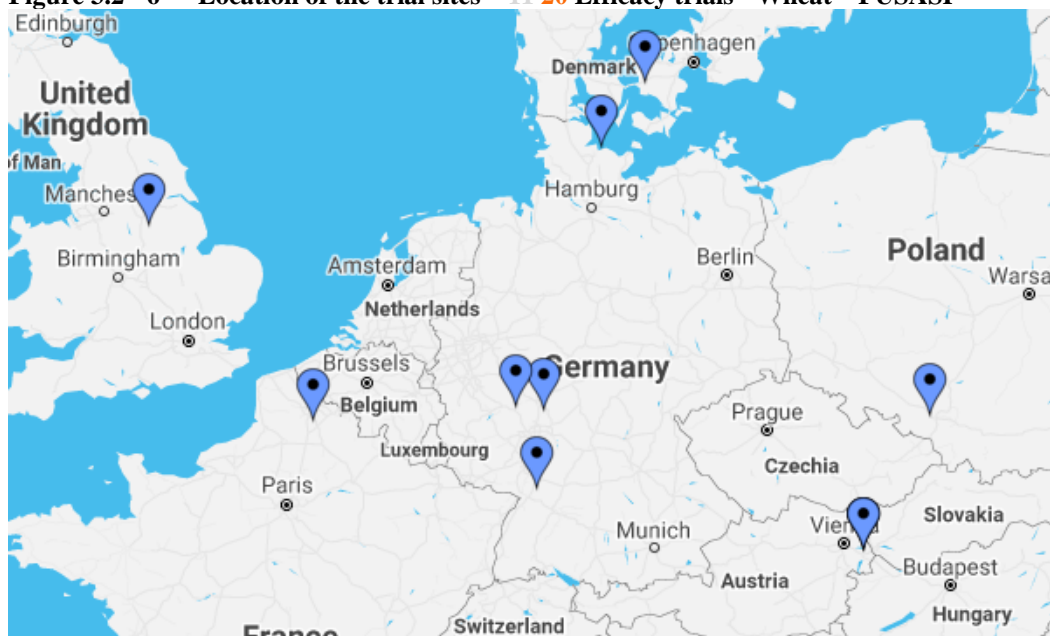
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 5 Location of the trial sites – 25 28 Efficacy trials - Wheat - PUCST



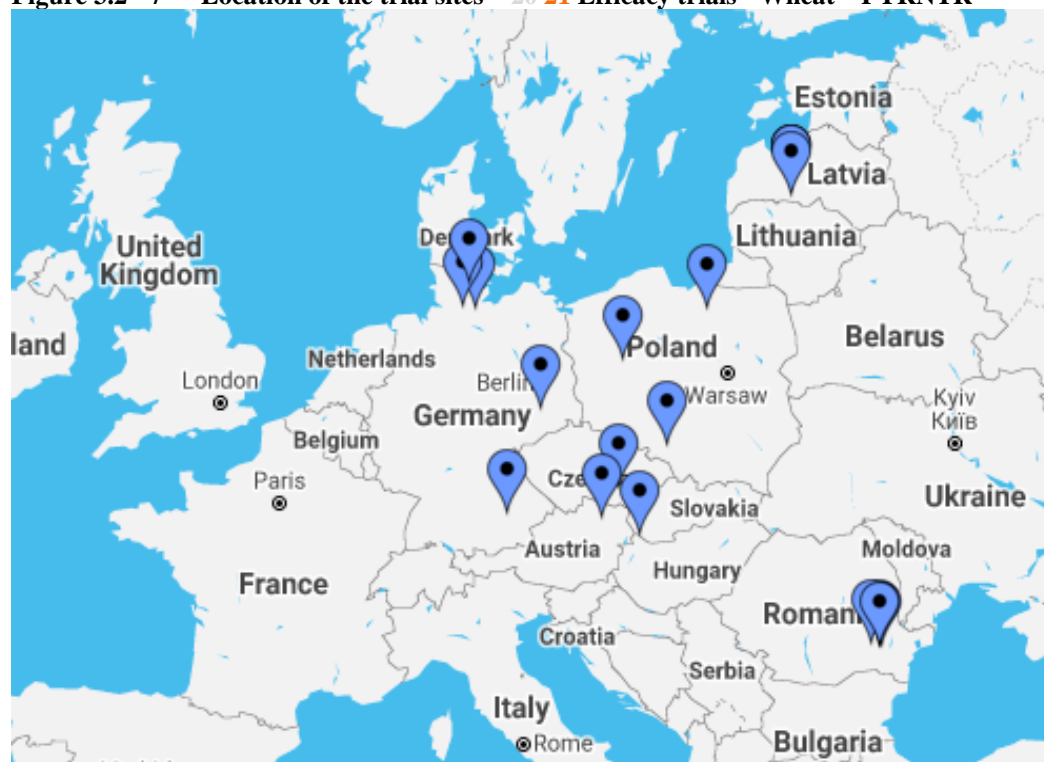
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 6 Location of the trial sites – 11 20 Efficacy trials - Wheat – FUSASP



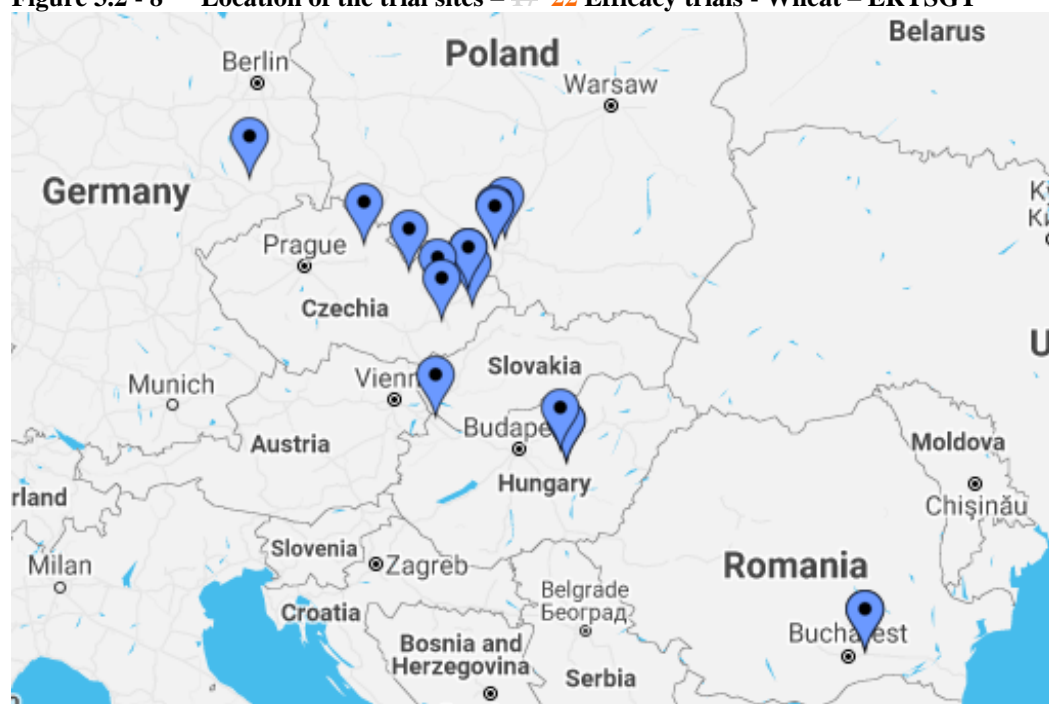
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 7 Location of the trial sites – 20 21 Efficacy trials - Wheat – PYRNTR



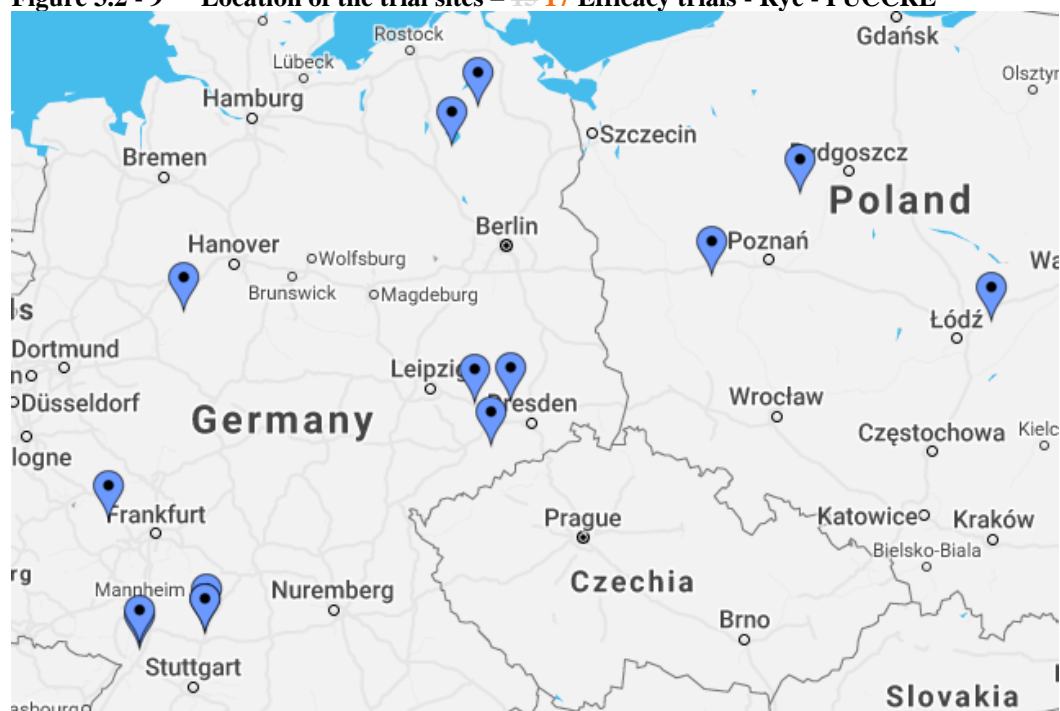
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 8 Location of the trial sites – 17 22 Efficacy trials - Wheat – ERYSGT



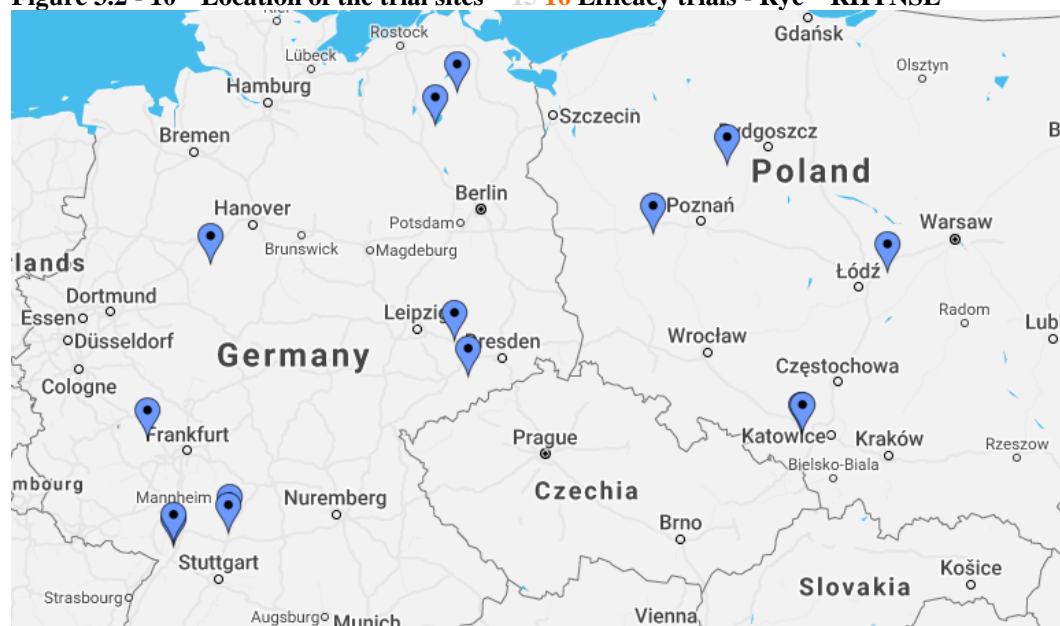
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 9 Location of the trial sites – 15 17 Efficacy trials - Rye - PUCCRE



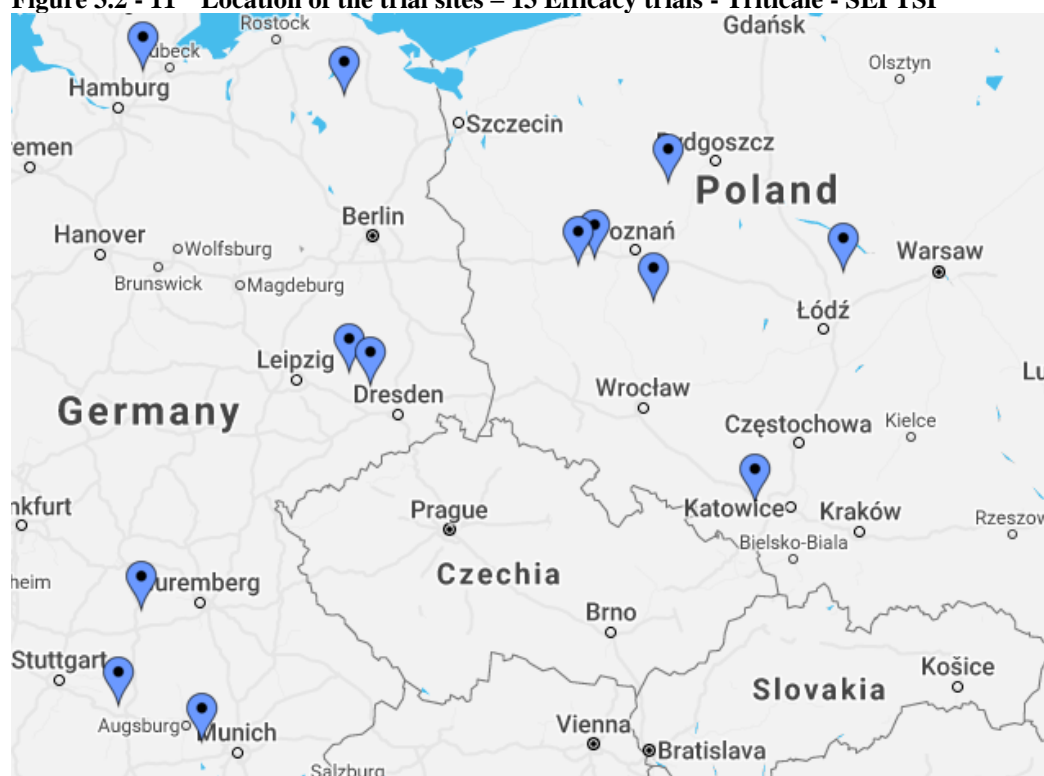
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 10 Location of the trial sites – 15 16 Efficacy trials - Rye – RHYNSE



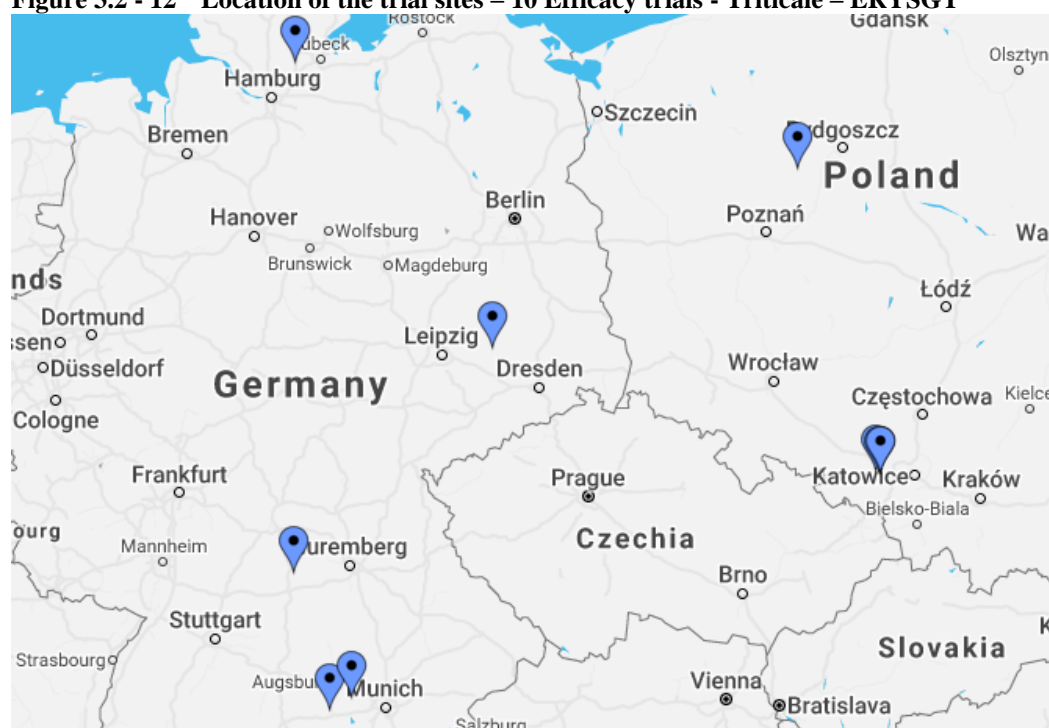
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 11 Location of the trial sites – 13 Efficacy trials - Triticale - SEPTSP



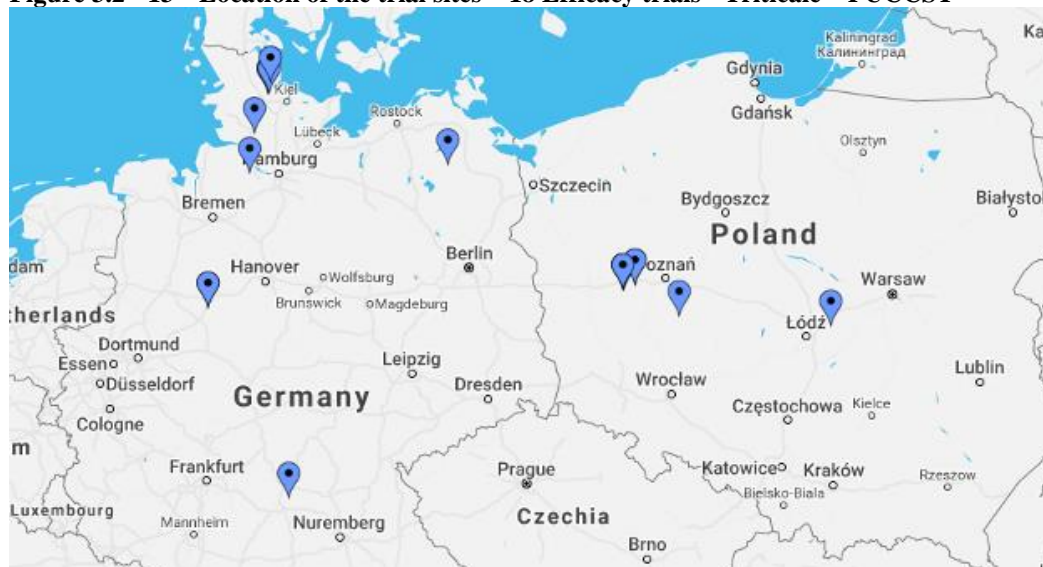
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 12 Location of the trial sites – 10 Efficacy trials - Triticale – ERYSGT



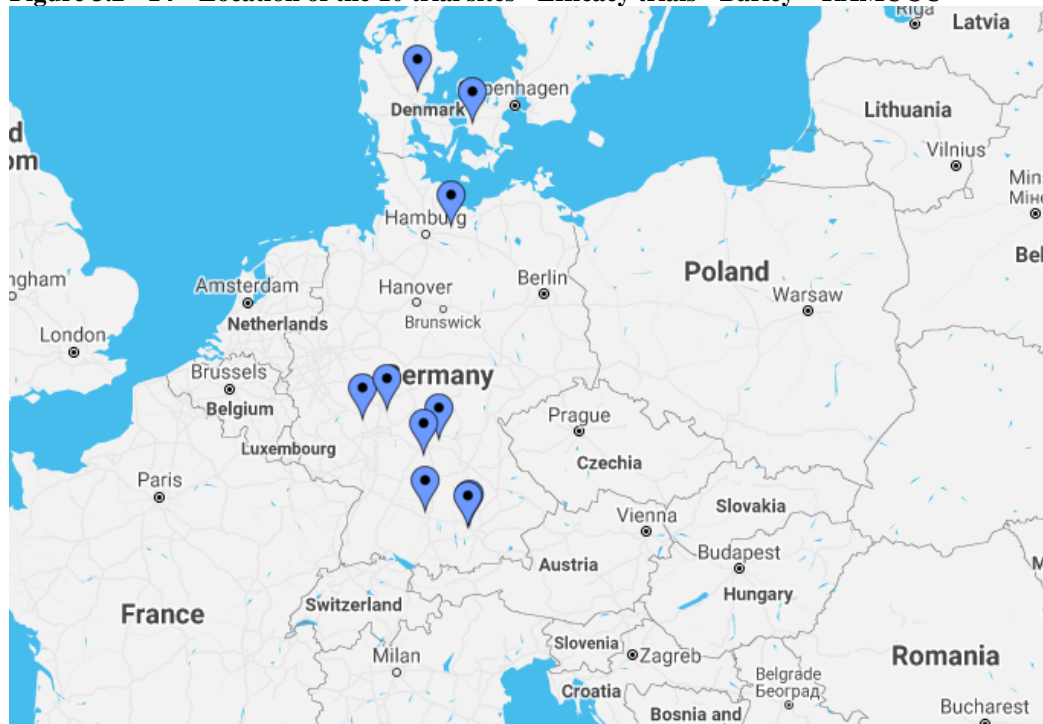
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 13 Location of the trial sites – 18 Efficacy trials - Triticale – PUCST



Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 14 Location of the 10 trial sites - Efficacy trials - Barley – RAMUCC



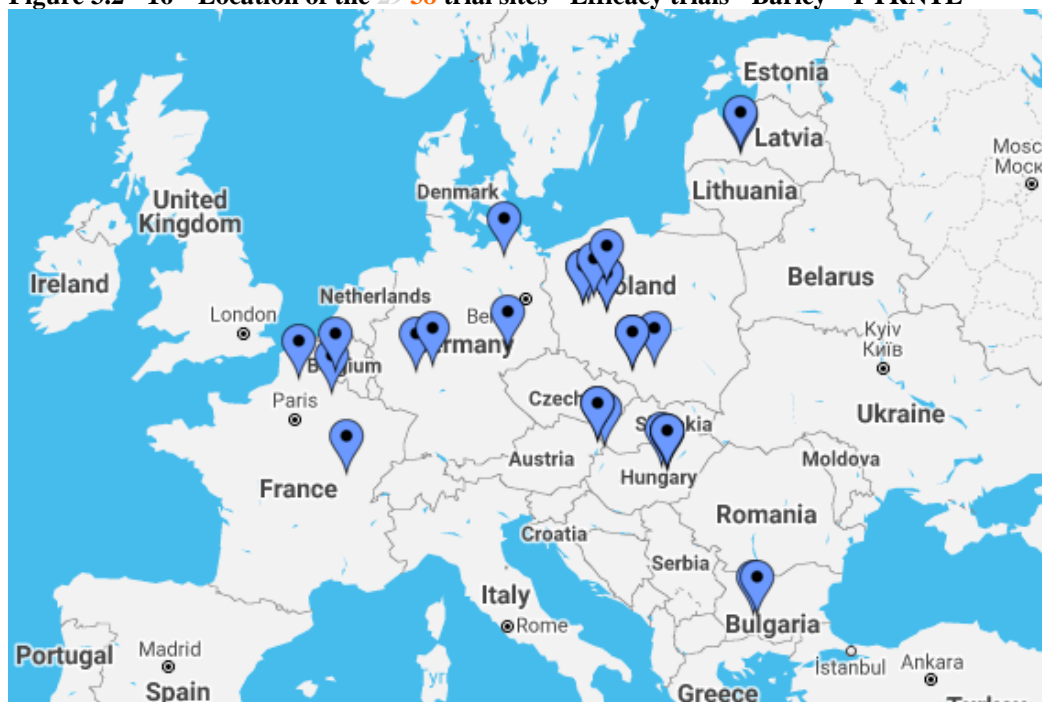
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 15 Location of the 23 24 trial sites - Efficacy trials - Barley - RHYNSE



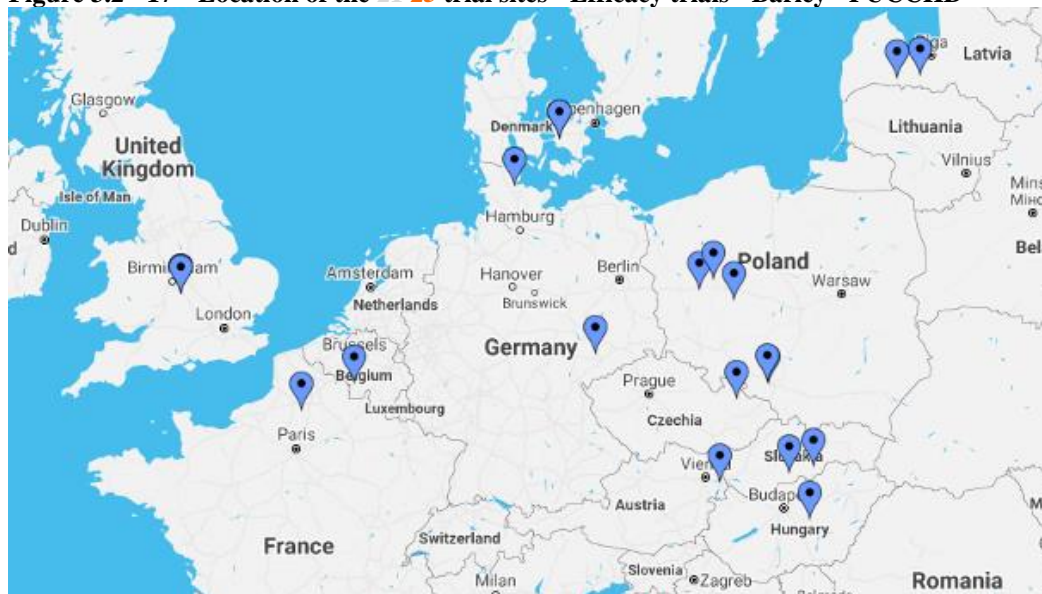
Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 16 Location of the 29 38 trial sites - Efficacy trials - Barley – PYRNTE



Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 17 Location of the 24 25 trial sites - Efficacy trials - Barley - PUCCHD



Note: Some markers may be for multiple sites in close proximity

Figure 3.2 - 18 Location of the 22 23 trial sites - Efficacy trials - Barley – ERYSGH



Note: Some markers may be for multiple sites in close proximity

Wheat (TRZAW and TRZAS)

To facilitate comparison of data produced in different conditions the same reference products have been used in the majority of trials (see Table 3.2-29), in line with EPPO PP 1/278 *Principles of Zonal Data Production and Evaluation*. The product Proline (275 g/L prothioconazole or 250 g/L prothioconazole) and bixafen + prothioconazole product Aviator Xpro (75 g/L bixafen + 150 g/L prothioconazole) have been chosen as the representative standards across the countries, as at least one of these products (or a related product) is authorised in all countries. In some trials other standards have been used (Vertisan (200 g/l penthiopyrad), Librax (45 g/l fluxapyroxad + 62.5 g/l metconazole), Input (160 g/l prothioconazole + 300 g/L spiroxamine) or Zantara (50 g/L bixafen + 166 g/L tebuconazole)) and where these have been used, it is detailed in the relevant section. Some trials included other standards, but these have not been listed as they are not referenced in this dossier.

Table 3.2-29: Presentation of reference standards used in wheat MED and efficacy trials

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Content of a.s.			
TRZAW	Proline 275	UK	MAPP 14790	prothioconazole	EC	275 g/ L	0.72 L/ha	0.72 L/ha	
	Proline 275	DK	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	CZ	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	DE	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	LV	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	PL	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250-300 g/l products registered
	Proline 275	HU	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	BG	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 250	CZ	4523-1	prothioconazole	EC	250 g/L	0.8 L/ha	0.6 L/ha	
	Proline	FR	n/a	prothioconazole	EC	250 g/L	n/a	0.8 L/ha	250 g/l product registered
	Proline	PL	n/a	prothioconazole	EC	250 g/ L	n/a	0.6 L/ha	250-300 g/l products registered
	Proline	HU	n/a	prothioconazole	EC	250 g/ L	n/a	0.6 L/ha	250 g/l product registered
	Proline	RO	n/a	prothioconazole	EC	250 g/ L	n/a	0.6 L/ha	250 g/l product registered
	Aviator XPRO 225 EC	AT	3053	bixafen + prothioconazole	EC	75+150 g/L	1.25 L/ha	1.25 L/ha	
	Aviator XPRO 225 EC	DE	006764-00	bixafen + prothioconazole	EC	75+150 g/L	1.25 L/ha	1.25 L/ha	
	Aviator XPRO 225 EC	CZ	5635-0	bixafen + prothioconazole	EC	75+150 g/L	0.8-1.0 L/ha	1.25 L/ha	
	Aviator XPRO 225 EC	PL	R-11/2013	bixafen + prothioconazole	EC	75+150 g/L	0.8-1.0 L/ha	1.25 L/ha	
	Aviator XPRO 225 EC	RO	352PC/29.11.2017	bixafen + prothioconazole	EC	75+150 g/L	0.8-1.0 L/ha	1.25 L/ha	
	Librax	DE	007969-00	fluxapyroxad + metconazole	EC	45 + 62.5 g/l	2.0 L/ha	2.0 L/ha	

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Content of a.s.			
	Vertisan	PL	n/a	penthiopyrad	EC	200 g/l	n/a	1.0 L/ha	Other 200 g/l product registered
	Vertisan	HU	n/a	penthiopyrad	EC	200 g/l	n/a	1.0 L/ha	Other 200 g/l product registered
	Vertisan	RO	n/a	penthiopyrad	EC	200 g/l	n/a	1.0 L/ha	Other 200 g/l product registered
	Input	RO	n/a	prothioconazole + spiroxamine	EC	160 g/l + 300 g/l	n/a	1.0 L/ha	
	Zantara	HU	04.2/7234-1/2011	bixafen + tebuconazole	EC	50 g/L + 166 g/L	0.75-1.5	1.0 L/ha	
TRZAS	Proline 275	LV	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	PL	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250-300 g/l products registered

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.)

n/a = not currently authorised/registered in 2021

Winter rye (SECCW) and winter triticale (TTLWI)

To facilitate comparison of data produced in different conditions the same reference products have been used in the majority of trials on rye and triticale (see Table 3.2-30), in line with EPPO PP 1/278 *Principles of Zonal Data Production and Evaluation*. The prothioconazole product Proline 275 (275 g/L prothioconazole) has been chosen as the representative standard across the majority of trials, as this product or similar prothioconazole products are authorised in all countries. In two German rye trials Aviator Xpro (75 g/L bixafen + 150 g/L prothioconazole) was the representative standard. In a number of triticale trials the product Prosaro (125 g/L prothioconazole + 125 g/L tebuconazole) was the reference standard and in one Polish trial, Wirtuoz 520 EC (320 g/L prochloraz + 160 g/L tebuconazole + 40 g/L proquinazid) in sequence with Artea (80 g/L cyproconazole + 250 g/L propiconazole) was used as the reference standard.

Table 3.2-30: Presentation of reference standards used in MED and rye and triticale efficacy trials

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Content of a.s.			
SECCW	Proline 275	DE	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	PL	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250-300 g/l product registered
	Proline 250	PL	n/a	prothioconazole	EC	250 g/ L	n/a	0.72 L/ha	250-300 g/l product registered
	Aviator XPRO 225 EC	DE	006764-00	bixafen + prothioconazole	EC	75+150 g/L	1.25 L/ha	1.25 L/ha	
TTLWI	Proline 275	DE	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250 g/l product registered
	Proline 275	PL	n/a	prothioconazole	EC	275 g/ L	n/a	0.72 L/ha	250-300 g/l product registered
	Proline 250	PL	n/a	prothioconazole	EC	250 g/ L	n/a	0.72-0.8 L/ha	250-300 g/l product registered
	Prosaro	DE	025662-00	tebuconazole + prothioconazole	EC	125+125 g/L	1.0 L/ha	1.0 L/ha	
	Prosaro	PL	R-261/2017	tebuconazole + prothioconazole	EC	125+125 g/L	1.0 L/ha	1.0 L/ha	
	Wirtuoz 520 EC	PL	R-70/2012 R-618/202d	prochloraz + tebuconazole + proquinazid	EC	320 + 160 + 40 g/l	0.75-1.25 L/ha	1.0 L/ha	Used in sequence with Artea
	Artea 330	PL	273/2015 R	cyproconazole + propiconazole	EC	80+250 g/L	0.5 L/ha	0.5 L/ha	Used in sequence with Wirtuoz

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.)

n/a = not currently authorised/registered in 2021

Barley (HORVW and HORVS)

To facilitate comparison of data produced in different conditions the same reference products have been used in the majority of trials on barley (see Table 3.2-31), in line with EPPO PP 1/278 *Principles of Zonal Data Production and Evaluation*. The prothioconazole product Proline (250 g/L prothioconazole) has been chosen as the representative standard across the majority of trials, as this product or similar prothioconazole products are authorised in all countries. In one Hungarian trial only results from Delaro containing (175 g/L prothioconazole + 150 g/L trifloxystrobin) as the reference standard are available and in four German trials the bixafen + prothioconazole product Aviator Xpro (75 g/L bixafen + 150 g/L prothioconazole) was the only representative standard.

Table 3.2-31: Presentation of reference standards used in MED and barley efficacy trials

Crop(s)	Reference standard	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Content of a.s.			
HORVW, HORVS	Proline	AT	3771-0	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline	BE	9805P/B	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline	BG	n/a	prothioconazole	EC	250 g/L	n/a	0.8 L/ha	250 g/l product registered
	Proline	CZ	4523-1	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline	DE	025287	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline EC 250	DK	18-473	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline	FR	n/a	prothioconazole	EC	250 g/L	n/a	0.8 L/ha	250 g/l product registered
	Proline	HU	n/a	prothioconazole	EC	250 g/L	n/a	0.6-0.8 L/ha	250 g/l product registered
	Proline	RO	n/a	prothioconazole	EC	250 g/L	n/a	0.72 L/ha	250 g/l product registered
	Proline	LV	0637	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline	PL	n/a	prothioconazole	EC	250 g/L	n/a	0.6-0.8 L/ha	250-300 g/l product registered
	Proline	SK	06-02-0768	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Proline	UK	MAPP 12084	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha	
	Aviator Xpro	DE	006764-00	bixafen + prothioconazole	EC	75+150 g/L	1.0 L/ha	1.0 L/ha	
	Prosaro	PL	R-261/2017	teboconazole + prothioconazole	EC	125+125 g/L	0.75-1.0 L/ha	0.75 L/ha	
HORVW	Delaro	HU	0.42/9998-1/2015	prothioconazole + trifloxystrobin	SC	175 + 150 g/L	0.7-1.0 L/ha	0.75 L/ha	

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.)

n/a = not currently authorised/registered in 2021

3.2.1 Preliminary tests (KCP 6.1)

Introduction

From this point on in this dossier fenpicoxamid may also be referred to as XDE-777 (and early stage coded X772777 or XR-777). Fenpicoxamid has been tested extensively in preliminary laboratory and field tests which demonstrated efficacious activity and appropriate crop safety of this novel fungicide active. Fenpicoxamid is a protectant and curative foliar applied fungicide for the control of a range of diseases frequently damaging cereal crops in countries of the European Union.

In glasshouse preliminary studies and efficacy trials across Europe, GF-3307 has strong curative and lasting protectant activity against SEPTTR, Puccst, Puccrt, PYRNTR, LEPNOD, ERYSGT, and FUSASP in wheat, against SEPTTR, Puccst, Puccrt, ERYSGR and FUSASP in triticale, and against RHYNSE, FUSASP, Puccst, ERYSGT and Puccre in rye. In preliminary glasshouse trials on barley, GF-3307 demonstrated strong efficacy against RHYNSE and ERYSGH. Additional diseases that could not be tested in the glasshouse include RAMUCC, PuccHD and PYRNTE, where GF-3307 has shown very good activity in the field and a clear benefit of using the combination of prothioconazole and fenpicoxamid. Very good field activity against MONGNI and PSDCHE in wheat has been observed in field trials, though there is not the correct number of trials to support a label claim at this time.

3.2.1.1 Early Stage Screening

The non-GEP/GLP early stage screening tests were carried out in the laboratories and glasshouses on the premises of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, Indiana 46268, USA.

In vitro fungi toxicity

Early stage biological evaluation of Fenpicoxamid included *in vitro* fungi toxicity testing across five pathogens and using eight dose rates expressed in ppm. Fungi toxicity assays were carried out in 96-well plates, each well containing a total assay volume of 200 µl. The growth media employed were yeast extract-malt extract-peptone agar for *Septoria nodorum* (LEPTNO), *S. tritici* (SEPTTR), *Pyricularia oryzae* (PYRIOR) & *Ustilago maydis* (USTIMA), a synthetic growth medium was used for *Phytophthora infestans* (PHYTIN).

Serial dilutions of picolinamides UK-2A and Fenpicoxamid were prepared using stock solutions in DMSO and 2 µl aliquots added to the wells to give the required 8 rate dose response (8.3 to 0.003 ppm) and a consistent final DMSO concentration of 1%. After addition of spore suspensions, initial readings of cell density were determined using a BMG NepheloStar nephelometer. Plates were subsequently placed in a shake incubator set at 90 rpm. SEPTTR was incubated at 22 °C for 72 hours, LEPTNO and PYRIOR at 22 °C for 48 hours, PHYTIN at 20 °C for 48 hours, and USTIMA at 24 °C for 48 hours respectively, and then read in the NepheloStar a second time to assess growth.

Growth inhibition in percent (%) was calculated by reference to control wells containing only growth media and inoculum. Data presented in Table 3.2-32 below show the compelling *in vitro* potency of this chemistry across the Ascomycetes (LEPTNO, SEPTTR & PYRIOR) and, to a lesser extent the Basidiomycete (USTIMA), as well as inactivity against Oomycete pathogens represented by PHYTIN. With the possible exception of USTIMA, the data also indicate relatively modest differences in growth inhibition between Fenpicoxamid and UK-2A. The implication is that the fungal pathogens are able to rapidly 'activate' Fenpicoxamid by blocking group removal to form UK-2A.

Reference report: Owen, W. J; Yao, C; Myung, K; Young, D; Meyer, S; Correa, O, XR-777 Discovery Advancement Report, Dow AgroSciences, unpublished report number 2009830; 2011.

Table 3.2-32: Dose response of UK-2A and Fenpicoxamid (XDE-777) for *in vitro* fungal growth inhibition

Test conc. ppm a.s.	Test pathogen, % control									
	LEPTNO		PHYTIN		PYRIOR		SEPTTR		USTIMA	
	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid	UK-2A	Fenpicoxamid
8.3	100	100	20	0	90	90	100	100	90	50
2.8	100	100	20	10	90	90	100	100	100	50
0.93	100	100	10	0	90	90	100	100	100	50
0.31	100	100	0	0	90	90	100	100	80	40
0.1	100	90	0	0	90	90	100	100	40	10
0.033	100	70	0	0	90	80	100	90	20	0
0.01	90	50	0	0	80	70	90	60	10	0
0.003	70	30	0	0	60	50	70	30	0	0

Insecticide activity

Fenpicoxamid was evaluated for insecticidal activity in high throughput insecticide screens against beet armyworm (*Spodoptera exigua*, LAPHEG), corn earworm (*Helicoverpa zea*, HELIZE), the green peach aphid (*Myzus persicae*, MYZUPE) and the yellow fever mosquito (*Aedes aegypti*, AEDSAE). The level 1 assays are designed to give the test compound the best chance of causing insect mortality. The high concentration of compound, combined with prolonged insect exposure to the test compound and the possibility of ingestion, increase the likelihood of observing insecticidal activity if it exists at all.

In addition to the high throughput screens, Fenpicoxamid was evaluated in more stringent single-dose screens against LAPHEG, MYZUPE and the cabbage looper (*Trichoplusia ni*, TRIPNI). Fenpicoxamid was either inactive or had limited activity against the species tested and is not considered to have significant insecticidal activity at practical use rates proposed.

Reference report: Wessels, F., Owen, J. Insecticidal Activity of XDE-777. Dow AgroSciences, unpublished report # DAI 1101, January 2013.

Herbicide activity

Fenpicoxamid was evaluated for herbicidal activity in level 2 herbicide screens. The screen included the two broadleaf species *Ipomea hederaceae* (morning-glory) & *Helianthus annuus* (sunflower) and the four grasses *Avena fatua* (wild oat), *Echinochloa crus-galli* (barnyard grass), *Setaria faberii* (giant foxtail) & *Alopecurus myosuroides* (black grass). The data indicate that Fenpicoxamid applied at 4000 g as/ha was inactive as an herbicide regardless of whether the treatment was made pre- or post-emergence.

Reference report: Parker C. L; Owen, J. Herbicide Activity of XDE-777. Dow AgroSciences, unpublished report # DAI 1177, ~~January 2013~~ November 11, 2015.

zRMS comments

on the preliminary testing of fungicidal, insecticidal and herbicidal activity of XDE-777:

The studies noted and considered valid. XDE-777 has neither insecticidal nor herbicidal activity of practical value.

3.2.1.2 Initial Lab Tests For formulation development of fenpicoxamid straight and mixture formulations against PUCCRT and SEPTTR

Introduction

During early formulation development it was found that addition of adjuvants increased curative and residual efficacy of fenpicoxamid (XDE-777) against *Puccinia recondita* (PUCCRT) and *Zymoseptoria tritici* (SEPTTR). Initial product concepts being considered for use in cereals include pre-mix formulations of fenpicoxamid plus prothioconazole or pyraclostrobin. The objective of this study was to determine the efficacy of emulsifiable concentrate (EC), suspension concentrate (SC) and

suspo emulsion (SE) formulations of fenpicoxamid applied alone or with prothioconazole or pyraclostrobin with or without adjuvants on Puccin and Septoria as either 3 day curative or 1 day protectant treatments.

Materials And Methods

Plant Material and inoculation. Winter wheat (*Triticum aestivum* (Yuma)) seeds were planted in two inch square pots containing an artificial soil mix. Seedlings were grown in a greenhouse maintained at 20 C until treatment. The seedlings were treated with fungicide formulations when the second true leaf was fully expanded. Two sets of pots were sprayed with the compounds for each treatment. One set of pots was inoculated with an aqueous suspension of Puccin and the second set inoculated with Septoria. A total of 3 to 4 replicate pots were sprayed per timing / pathogen/treatment. Inoculation occurred as either a 3-day curative (3DC) and 1-day protectant (1DP). Plants inoculated with Puccin were placed in a dark dew chamber maintained at 22 C and 99% relative humidity for 24 hours and then moved to a greenhouse held at 24-26 C. Disease severity on seedlings inoculated with Puccin was evaluated 7 to 8 days after inoculation. Plants inoculated with Septoria were placed in a dew chamber without illumination at 20-22 C for a 24-hour period after inoculation, then moved to an illuminated dew chamber held at 20-22 C for 48 hr, and finally moved to a greenhouse maintained at 20-22 C. Seedlings were evaluated for disease severity 16 to 20 days after inoculation. A visual rating of percent leaf area affected by disease was determined and percent disease control calculated by comparing the amount of disease on the treated plants to the untreated diseased plants which were considered to have zero control (Percent control=(1-disease in treated plants/disease in untreated plants)*100). Several fungicide formulation and adjuvant combinations were evaluated (Table 3.2-33 and Table 3.2-34). Serial dilutions of the compounds were made and compounds applied to wheat with a low volume track sprayer delivering 200 l/ha. The rate of the lead fungicide fenpicoxamid was always (121, 40.3, 13.3 and 4.5 g ha), with the companion fungicide being applied in the same rate as the mixture ratio. Data were analysis with statistics based on a factorial analysis across four rates of application P<0.05.

Table 3.2-33: Fungicide Formulations

Formulation #	Formulation Type	Fungicide (g ai/L)	
		fenpicoxamid	Prothioconazole
GF-2925	SC	130	-
GF-3135	EC	50	-
GF-2984	SC	92.6	138.9
GF-3134	EC	48.7	73

EC=emulsifiable concentrate, SC=suspension concentrate

Table 3.2-34: Adjuvants tested.

Adjuvant	DAS code	Final use rate (% v/v) in the tank mix.
Beep	0.5 % bis (2-ethylhexyl)-2-ethylhexyl phosphonate (BEEP)	0.12
Break-Thru S-233	Polyether modified polysiloxane	0.12
Agnique SBO- 10 E	Ethoxylated Soybean Oil (POE 10) Trycol 5941.	0.10

Results

Final percent disease control was influenced by formulations and adjuvants. Formulations applied without an adjuvant provided control that were inferior (P<0.05) to the same formulations applied with an adjuvant. The SC formulation of fenpicoxamid (GF-2925) with no adjuvant was the least effective of all formulations and clearly inferior to the equivalent EC formulation GF-3135 also with no adjuvant. The EC formulations without adjuvant for all mixtures was superior to the SC mixture formulations. The addition of adjuvants improved curative activity compared to the same formulations applied without an adjuvant and especially enhanced rust activity.

Table 3.2-35: Disease control of different fenpicoxamid containing formulations in combination with various adjuvants for control of SEPTTR and PUCCRT of wheat in two application timings, three day curative (3DC) one protectant (1DP).

Formulation Type/active ingredient	Adjuvant / Concentration (% v/v)	% Disease Control			
		SEPTTR 3DC	SEPTTR 1DP	PUCCRT 3DC	PUCCRT 1DP
GF-2925 SC/ (fenpicoxamid)	No adjuvant	27 f	75 de	0 g	33 h
GF-3135 EC/ (fenpicoxamid)	Beep (0.15)	100 a	94 ab	89 abc	92 abcde
	No adjuvant	80 c	92 ab	54 de	88 abcde
	BEEP (0.12)	100 a	95 ab	99 a	100 a
GF-3134 EC/ (fenpicoxamid + Prothioconazole)	Breakthru S233 (0.12)	97 a	98 ab	86 abc	95 abcd
	No adjuvant	83c	95 ab	92 ab	85 abcde
	SBO 10-E (0.1)	60 d	87 bcd	70 cd	77 def
GF-2984 SC/ (fenpicoxamid + Prothioconazole)	No adjuvant	53 de	71 e	73 bcd	65 fg

Statistics based on the factorial analysis across four rates of application P<0.05

Means values within each column are significantly (P<0.05) different where the letters are not the same.

Conclusions

1. The formulation type and composition had an effect on the final efficacy.
2. The EC formulations provided control superior to the SC formulations. The fenpicoxamid EC (GF-3135) was superior to the SC (GF-2925), fenpicoxamid and the mixture with Prothioconazole EC (GF-3134) was superior to the SC (GF-2984). (Table 3.2-35).
3. The addition of adjuvants enhanced curative activity on SEPTTR and efficacy against PUCCRT.

Reference report: Mathieson T; Correa da Silva. O; Kemmitt. G: Effect of formulation type and adjuvants on efficacy of XDE-777 containing formulations. Dow AgroSciences, unpublished report # SAGE 2020479, November 2013.

zRMS comments on the preliminary formulation and mixture testing: The study and the respective conclusions noted and recognized as valid: Emulsion superior to suspension, the use of adjuvants justified.

3.2.1.3 Protectant and curative properties of fenpicoxamid straight formulations in a glasshouse test

Three different formulation concentrates of fenpicoxamid, GF-2925 (130 g as/L) SC, GF-3135 (50 g as/L EC), and GF-3311 (66.7 g as/L EC) were compared in glasshouse studies. The formulation matrix used in GF-3311 is identical to the straight fenpicoxamid EC formulation GF-3308 (50 g as/L) and the mixture formulations GF-3307 and GF-3309.

Materials And Methods

Wheat plant seedlings (variety ‘Yuma’) were prepared. Number of plants was 8-12 per pot for efficacy evaluation. Aliquots of three formulation concentrates (GF-2925, GF-3135, and GF-3311) were mixed with 30 mL of water to prepare solutions containing 650 ppm fenpicoxamid. Ten millilitre of the solutions were sequentially mixed with 20 mL of water to perform three-fold dilutions. The formulation solutions were applied to the plants with a spray volume of 200 L/ha, using a track sprayer

equipped with a Tee Jet 8003E spray nozzle operating at 32 psi. The track speed was 2.9 km/hr, and distance between nozzle and bench was 63.5 cm.

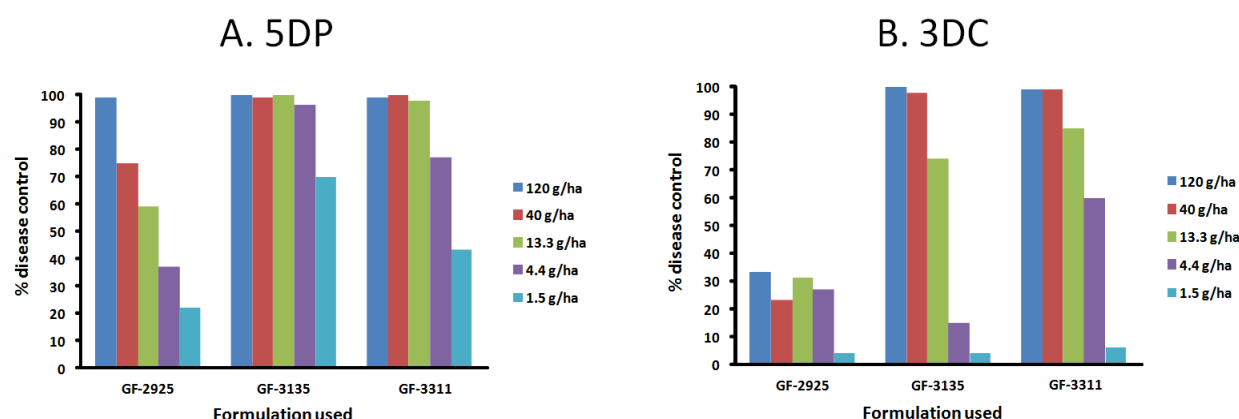
Test plants were inoculated with SEPTTR spores either 3 days prior to (3-day curative test, 3DC) or 5 days after (5-day protectant test, 5DP) fenpicoxamid application. The spore suspension (1 x 10⁶ spores/mL), which was prepared and applied to plants in a fine mist using a DeVilbiss sprayer connected to an air supply line with a pressure setting at 10 psi. After inoculation, the plants were kept at 100% relative humidity (one day in a dark dew chamber followed by two days in a lighted mist chamber) to permit spores to germinate and infect host leaves. The plants in 5DP tests were directly moved to a greenhouse after inoculation, while plants in curative tests were sprayed with formulations prior to moving to the greenhouse. Test plants were kept in a greenhouse set at 20°C until disease was fully expressed on untreated plants. Infection levels on the primary leaves were visually assessed on a scale of 0 to 100 percent disease severity. Percent disease control was calculated using the ratio of disease severity on treated plants relative to untreated plants. All the experiments were conducted with four replications, unless otherwise indicated.

Results and Discussion

SEPTTR wheat leaf blotch control of GF-2925, GF-3135 and GF-3311 in the 5 days protectant and 3 days curative test are shown in Figure 3.2-19. For the 5DP timing, GF-2925 completely controlled SEPTTR at a rate of 120 g/ha, but SEPTTR control was reduced as application rate decreased. In contrast, both GF-3135 and GF-3311 EC formulations provided excellent SEPTTR disease control (70-100% disease control) at rates as low as 4.4 g/ha, and delivered 40-70% disease control even at a rate of 1.5 g/ha. As 3DC treatments, GF-2925 failed to control SEPTTR at the highest rate used in this study, while both GF-3135 and GF-3311 provided more than 70% disease control at rates above 13.3 g/ha. At 4.4 g/ha, the 3DC activity by GF-3311 was better than that by GF-3135.

Overall, our greenhouse test results correlate with the enhancement of efficacy of fenpicoxamid seen in the field with EC matrix formulations (GF-3135 and GF-3311), compared to the SC formulation (GF-2925) and the ability to reduce the dose of fenpicoxamid when applied as an EC matrix formulation. However, it is commonly accepted that the rates tested and efficacy levels found in glasshouse studies do not translate 1:1 to results found under field conditions.

Figure 3.2-19: 5-day protectant (A) and 3-day curative (B) control of SEPTTR wheat leaf blotch by fenpicoxamid in different formulations (GF-2925, GF-3135, and GF-3311).



Reference report: Myung, K et al. Effects of different formulations on retention, surface coverage, and uptake of XDE-777 in wheat plants. Dow AgroSciences, SAGE report # 2026067, February 2015.

zRMS comments: The study noted and recognized as valid. Next to coverage and retention, the study also tested control of SEPTTR in wheat.

3.2.1.4

Protectant and curative properties of GF-3308 and GF-3307 in a

glasshouse test for the control of SEPTTR and Puccrt

Introduction

As demonstrated in the previous chapter, EC formulation matrices of fenpicoxamid proved to be more efficacious in controlling SEPTTR than SC based formulation types. In order to obtain a better understanding of how GF-3308 and GF-3307 as optimized formulation of fenpicoxamid compared to leading cereal reference products, a series of tests were completed to evaluate the protectant and curative properties of GF-3308 and GF-3307 for the control of Puccrt (GF-3308 only) and SEPTTR of wheat.

Materials and Methods

Testing facilities involved

This study (non GEP/non GLP) was carried out in the laboratories and glasshouses of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN., 46268, USA in 2018.

Experimental details

The experiment used a randomized complete block design with 3 replications per treatment. The test with both SEPTTR and Puccrt was carried out using wheat plant seedlings cv. Yuma which were raised in pots grown up to BBCH 12. GF-3308 and the reference products were applied to the plants prior (protectant) or after (curative) inoculation of the disease under investigation using a water volume of 150 L/ha. The track sprayer was equipped with a Tee Jet 8003E spray nozzle operating at 2.2 bar (32 psi).

For the evaluation against Puccrt the wheat seedlings were inoculated with a suspension of uredospores either 1 day prior to (1-day curative test, 1DC) or 1 day after (1-day protectant test, 1DP) the application of test products. After inoculation and application of products the wheat plants were transferred to a greenhouse kept at 24 °C for 7-8 days until the final efficacy assessment was made.

For SEPTTR the wheat plants were inoculated with a suspension of micro conidia either 3 days prior to (3-day curative test, 3DC) or 1 days after (1-day protectant test, 1DP) the application of products. The efficacies of products were evaluated 18 to 21 days after inoculation. The SEPTTR isolate used in the study was a wild type unselected strain with original sensitivity collected from the state of Indiana.

Formulations and rates used in the 1 day curative and 1 day protectant test against Puccrt

Test product	Formulation type	Active substance	Rate g as/ha
GF-3308	50 g/L EC	fenpicoxamid	25, 50, 75, 100
Comet	200 g/L EC	Pyraclostrobin	50, 100, 125, 200
Proline 275	275 g/L EC	Prothioconazole	50, 100, 150, 200

Formulations and rates used in the 3 day curative and 1 day protectant test against SEPTTR

Test product	Formulation type	Active substance	Rate g as/ha
GF-3308	50 g/L EC	fenpicoxamid	50, 75, 100
GF-3307	150 g/L EC	fenpicoxamid + prothioconazole	150, 225, 300
Imtrex	62.5 g/L EC	Fluxapyroxad	62.5, 93.8, 125
Proline 275	275 g/L EC	Prothioconazole	100, 150, 200

Assessments

The visual assessments for % infected leaf area were made 8 days after inoculation for Puccrt and 16 days after inoculation for SEPTTR using a scale of 0 to 100% (where 0 was no disease and 100 complete coverage with disease). Numbers were then converted to represent the percent disease control relative to the untreated check (% Abbott).

Results

In both the 1 day curative and 1 day protectant test with PUCCRT all treatments with Proline 275, Comet and GF-3308 provided equivalent control with the corresponding rates of compounds used in these test (see Table 3.2-36 and Table 3.2-37).

In the curative test for the control of SEPTTR, GF-3308, GF-3307 and Imtrex gave equivalent control of the fungus with Proline 275 being slightly inferior to GF-3308 (see Table 3.2-36).

In the 1-day protectant test with SEPTTR, GF-3308, GF-3307 and Imtrex were equivalent, whereby Proline was less efficacious against SEPTTR (see Table 3.2-37).

Table 3.2-36: 1-day curative efficacy of GF-3308 against PUCCRT

Formulation	Rate g as/ha	% control of PUCCRT			
		rep 1*	rep 2	rep 3	Average
GF-3308	100	100	100	100	100
GF-3308	75	100	100	100	100
GF-3308	50	100	100	100	100
GF-3308	25	99	99	100	99
Comet	200	100	100	100	100
Comet	125	100	100	100	100
Comet	100	100	100	100	100
Comet	50	99	99	100	99
Proline 275	200	100	100	100	100
Proline 275	150	100	100	100	100
Proline 275	100	100	100	100	100
Proline 275	50	100	100	100	100

* rep = replicate

Table 3.2-37: 1-day protectant efficacy of GF-3308 against PUCCRT

Formulation	Rate g as/ha	% control of PUCCRT			
		rep 1	rep 2	rep 3	Average
GF-3308	100	94	69	81	81
GF-3308	75	100	75	81	85
GF-3308	50	100	75	81	85
GF-3308	25	75	50	75	67
Comet	200	96	75	94	88
Comet	125	94	74	99	89
Comet	100	88	75	44	69
Comet	50	25	50	50	42
Proline 275	200	94	88	50	77
Proline 275	150	96	94	75	88
Proline 275	100	98	98	38	78
Proline 275	50	69	25	25	40

Table 3.2-38: 3-day curative efficacy of GF-3308 against SEPTTR

Formulation	Rate g as/ha	% control of SEPTTR			
		rep 1	rep 2	rep 3	Average
GF-3308	100	100	100	100	100
GF-3308	75	100	100	100	100
GF-3308	50	96	100	100	99
GF-3307	300	100	100	100	100
GF-3307	225	100	96	98	98
GF-3307	150	96	96	100	97
Imtrex	125	100	98	100	99
Imtrex	93.8	100	100	96	99
Imtrex	62.5	100	100	100	100
Proline 275	200	98	96	100	98
Proline 275	150	90	90	42	74
Proline 275	100	81	98	4	61

Table 3.2-39: 1-day protectant efficacy of GF-3308 against SEPTTR

Formulation	Rate g as/ha	% control of PUCCRT			
		rep 1	rep 2	rep 3	Average
GF-3308	100	100	99	95	98
GF-3308	75	99	98	97	98
GF-3308	50	98	97	99	98
GF-3307	300	99	100	97	98
GF-3307	225	100	100	91	97
GF-3307	150	99	100	98	99
Imtrex	125	98	97	98	97
Imtrex	93.75	89	94	86	90
Imtrex	62.5	94	83	86	88
Proline 275	200	66	86	77	77
Proline 275	150	55	72	77	68
Proline 275	100	66	43	55	55

Conclusions

This glasshouse study clearly demonstrated that fenpicoxamid formulations GF-3308 and GF-3307 do provide both, curative and protectant control of important cereal diseases such as SEPTTR and PUCCRT at levels that compare well to the efficacies shown by leading reference products Proline 275 (DMI), Imtrex (SDHI) or Comet (QoI).

Reference Report: Mathieson, T; Leader, A, 2018: How does the efficacy of Inatreq formulation GF-3307 (a combination) and GF-3308 (solo) compare to market references when tested against *Septoria tritici* (SEPTTR) and *Puccinia recondita* (PUCCRT) in greenhouse conditions? Dow AgroSciences internal report #169514.

zRMS comments on testing efficacy against SEPTTR and PUCCRT in greenhouse: The study and conclusions considered valid.

3.2.1.5 Preventive properties of GF-3307 in a glasshouse test for the control of *Rhynchosporium secalis* in barley

Introduction

In order to obtain a better understanding of how GF-3307, as an optimized formulation of fenpicoxamid + prothioconazole, compared to leading cereal reference products, a series of tests were

conducted to evaluate the preventive properties of GF-3307, for the control of RHYNSE in barley.

Materials and Methods

A greenhouse bioassay² was conducted to characterize the efficacy of GF-3307 for controlling *Rhynchosporium secalis* (RHYNSE) following a 1-day protectant application on 9-day-old barley plants. The efficacy of GF-3307 was compared to GF-3308 (containing fenpicoxamid), Imtrex (containing fluxapyroxad) and Proline (containing prothioconazole). The maximum dose of GF-3307 (300 g a.s./ha) chosen, reflects the maximum dose proposed in Europe for winter wheat. The ¾ dose of GF-3307 (225 g a.s./ha) represents the proposed registration dose of 1.5 L/ha on barley, in some EU Member States.

Fungicides were applied to 9-day-old barley plants using a Generation III Research Track Sprayer (DeVries Manufacturing) using an 8002E TwinJet flat fan nozzle with a spray arm speed of 2.14 km/h and a spray pressure of 220 kPa. Pots of barley plants were placed in the spray chamber such that their mid-canopy was 50 cm below the spray nozzle. Fungicides were applied to barley seedlings at their maximum registerable rates, also ¾ rate, ½ rate and ¼ rate, of their maximum registerable rates, simulating a spray volume of 200 L/ha. (Table 3.2-40).

Table 3.2-40: Fungicide products and rates used in preventive studies against *Rhynchosporium secalis* (RHYNSE) in barley

Formulation	Active substance	g a.s./L	Rates tested (g a.s./ha)			
			Max reg rate	3/4 max rate	1/2 max rate	1/4 max rate
GF-3307	fenpicoxamid + prothioconazole	50 + 100	300	225	150	75
GF-3308	fenpicoxamid	50	100	75	50	25
Imtrex	fluxapyroxad	62.5	125	93.75	62.5	31.25
Proline	prothioconazole	275	200	150	100	50

Rhynchosporium secalis (RHYNSE) spores were harvested from 10-day-old RHYNSE cultures grown on Yeast Malt Agar (YMA) plates. One day after application (1-day preventive study), barley seedlings were sprayed to run-off with a RHYNSE spore suspension using a compressed air spray gun. The spore suspension was filtered through two layers of cheesecloth and adjusted to 4 x 10⁶/ml. To the final suspension, 3 drops of Tween 20 per 100 ml of inoculum were added. Inoculated plants were placed in a dark ‘dew room’ (100% RH, 22°C) for 48 hours. Inoculated plants were then transferred to a greenhouse with a suitable environment for disease development.

Plants were evaluated for disease approximately two weeks after application (16 DAA). The percent disease control was calculated relative to the untreated inoculated control. Pots were arranged in a randomized complete block design with four replications.

Results

The percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application is presented in Table 3.2-41.

Table 3.2-41: Percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application at four rates. Results of two trials (n=8) assessed 16 DAA.

Products	Rates (g a.s./ha)							
	Max reg rate ^y		3/4 of reg rate ^y		1/2 of reg rate ^y		1/4 of reg rate ^y	
GF-3307	99.6	c	97.0	bc	95.8	ab	92.8	b
GF-3308	90.8	ab	86.7	ab	81.0	ab	83.2	ab
Imtrex	99.4	c	99.4	c	99.4	b	97.1	b
Proline	97.9	c	97.4	bc	92.7	ab	91.8	b
P value	<0.05		<0.05		<0.05		<0.05	

^z Percentage control values were calculated for each treatment within a rep according to the formula: [(SC – ST)/SC]*100 where SC is the severity on the untreated inoculated control and ST is the severity on the treatment.

² Vriesman, M, Leader, A, Diehl, C., Wineglass, A., Loeffler, J., 2019; Evaluate and compare Dow agrosiences™ products Questar (GF-3308), Univoq (GF-3307), Adavelt (GF-3840), and XDE-481 (GF-4319) for control of barley scald (*Rhynchosporium secalis*) following a preventive application - Dow agrosiences internal report (GL19E7B006F-DYC24 and GL19E7B006F-DYC25)

^y Values are the means of two independent trials with four replications each; means followed by the same letter within a column are not significantly different at P value <0.05 . Means were separated using Tukey's mean comparison test. The maximum registered dose is based on the maximum registration dose proposed in wheat.

GF-3307 applied at the maximum registerable rate achieved 99.6% control of RHYNSE. No significant differences in RHYNSE control (16 DAA) were observed between GF-3307, Imtrex and Proline treatments tested (Figure 3.2 - 20).

GF-3307 applied at the 3/4 of maximum registerable rate achieved 97% control of RHYNSE. No significant differences in RHYNSE control (16 DAA) were observed between GF-3307, Imtrex and Proline (Figure 3.2 - 21).

GF-3307 applied at the 1/2 of max registerable rate achieved 96% control of RHYNSE. Imtrex provided $>99\%$ control at this rate; Proline provided $>90\%$ control. However, no significant differences in RHYNSE control (16 DAA) were observed between GF-3307, Imtrex and Proline (Figure 3.2 - 22).

GF-3307 applied at the 1/4 of max registerable rate achieved 93% control of RHYNSE similar to Imtrex (97% control) and Proline (92% control). No significant differences in RHYNSE control (16 DAA) were observed between GF-3307, Imtrex and Proline (Figure 3.2 - 23).

Figure 3.2 - 20 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application at the max registerable rate. Results of two trials (n=8) assessed 16 DAA

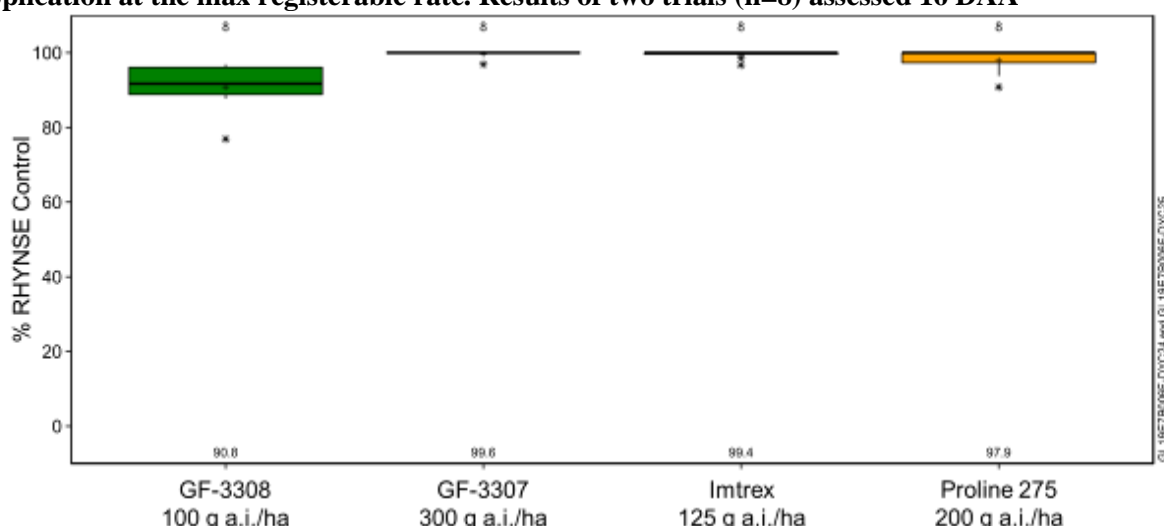


Figure 3.2 - 21 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application at 3/4 of the max registerable rate. Results of two trials (n=8) assessed 16 DAA

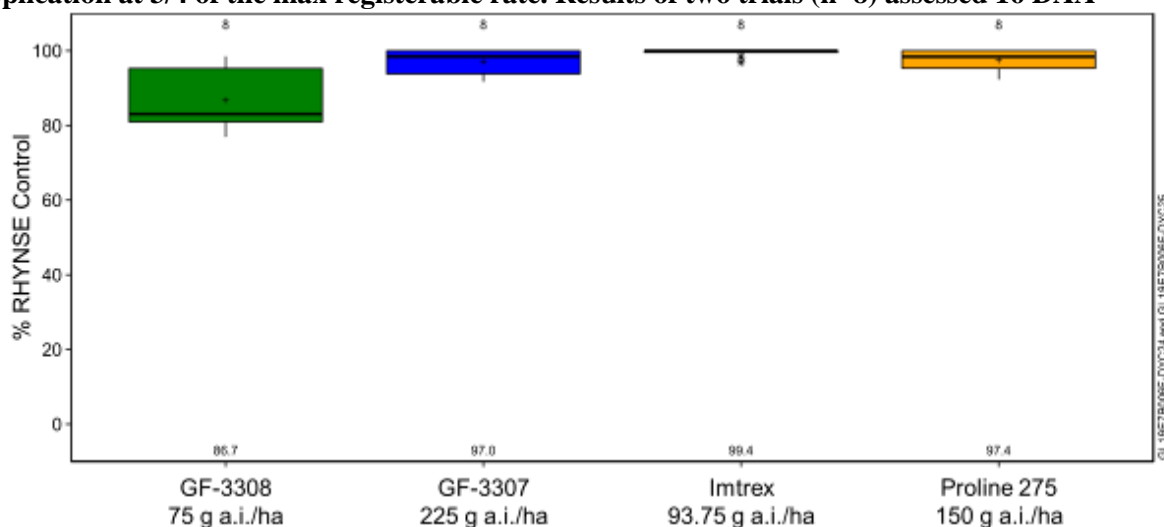


Figure 3.2 - 22 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application at 1/2 of the max registerable rate. Results of two trials (n=8) assessed 16 DAA

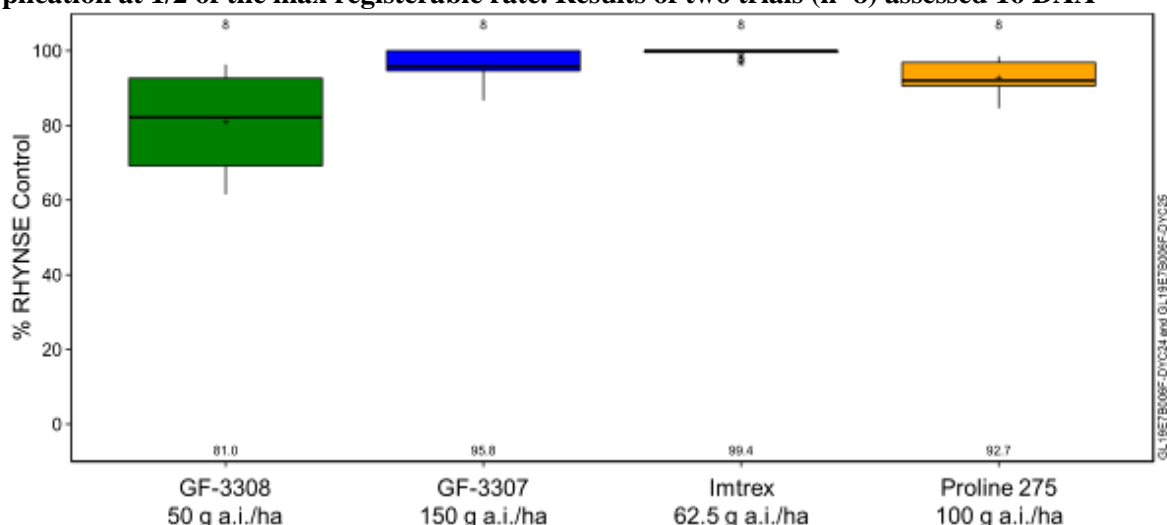
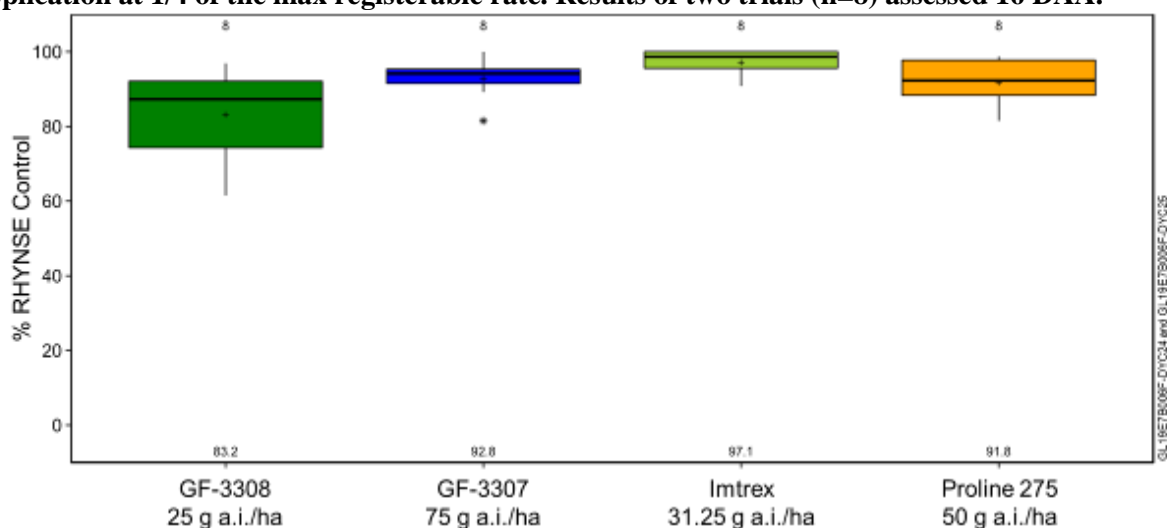


Figure 3.2 - 23 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application at 1/4 of the max registerable rate. Results of two trials (n=8) assessed 16 DAA.



Conclusions

The percentage control of barley leaf scald (RHYNSE) was high (>90%) using GF-3307, and the levels of control were not statistically different to that from those of the standards Imtrex and Proline, at the equivalent maximum registerable rates, 3/4, 1/2, and 1/4 of the maximum registerable rates.

This glasshouse study clearly demonstrated that GF-3307 provides preventive control of RHYNSE at levels that compare well to the levels of control shown by leading reference products, Proline (DMI) and Imtrex (SDHI). Inatreq (GF-3308) provides 80-90% control from 1/4 to full dose and would be an additional protectant partner to prothioconazole for resistance management and to broaden spectrum on other diseases including *Ramularia*.

zRMS comments on the preventive properties against *Rhynchosporium secalis* in barley as based on glass-house test: The study noted and the conclusions from it considered valid.

3.2.1.6 Curative properties of GF-3307 in a glasshouse test for the control of *Rhynchosporium secalis* in barley

Introduction

In order to obtain a better understanding of how GF-3307 as an optimized formulation of fenpicoxamid + prothioconazole, compared to leading cereal reference products, a series of tests were completed to evaluate the curative properties of GF-3307 for the control of RHYNSE of barley.

Materials and Methods

A greenhouse bioassay³ was conducted to characterize the efficacy of GF-3307 for controlling *Rhynchosporium secalis* (RHYNSE) following a 3-day curative application on 9-day-old barley plants. The efficacy of GF-3307 was compared to GF-3308 (containing fenpicoxamid), Imtrex (containing fluxapyroxad), Proline (containing prothioconazole) and Aviator Xpro (containing bixafen + prothioconazole). The maximum dose of GF-3307 (300 g a.s./ha) chosen, reflects the maximum dose proposed in Europe (for winter wheat).

Fungicides were applied to 9-day-old barley plants using a Generation III Research Track Sprayer (DeVries Manufacturing) using an 8002E TwinJet flat fan nozzle with a spray arm speed of 2.14 km/h and a spray pressure of 220 kPa. Pots of barley plants were placed in the spray chamber, such that their mid-canopy was 50 cm below the spray nozzle. Fungicides were applied to barley seedlings at their maximum registerable rates, also ½ rate, ¼ rate and 1/16 rate, of their maximum registerable rates, simulating a spray volume of 200 L/ha (Table 3.2-42).

Table 3.2-42: Fungicide products and rates used in curative studies against *Rhynchosporium secalis* (RHYNSE) in barley

Formulation	Active substance	g a.s./L	Rates tested (g a.s./ha)			
			Max reg rate	1/2 max rate	1/4 max rate	1/16 max rate
GF-3307	fenpicoxamid + prothioconazole	50 + 100	300	150	75	18.75
GF-3308	fenpicoxamid	50	100	50	25	6.25
Imtrex	fluxapyroxad	62.5	125	62.5	31.25	7.81
Proline	prothioconazole	275	200	100	50	12.5
Aviator Xpro	bixafen + prothioconazole	75 + 160	293.8	146.9	73.4	18.4

Rhynchosporium secalis (RHYNSE) spores were harvested from 10-day-old RHYNSE cultures grown on Yeast Malt Agar (YMA) plates. Three days before application (3-day curative study), barley seedlings were sprayed to run-off with a RHYNSE spore suspension using a compressed air spray gun. The spore suspension was filtered through two layers of cheesecloth and adjusted to 4 x 10⁶/ml. To the final suspension, 3 drops of Tween 20 per 100 ml of inoculum were added. Inoculated plants were placed in a dark ‘dew room’ (100% RH, 22°C) for 48 hours. Inoculated plants were then transferred to a greenhouse with a suitable environment for disease development.

Plants were evaluated for disease approximately two weeks after application (12-14 DAA). Percent disease severity was averaged from ten leaves per pot on a 0-100% scale. The percent disease control was calculated relative to the untreated inoculated control. Pots were arranged in a randomized complete block design with four replications.

Results

The percentage control of *Rhynchosporium secalis* (RHYNSE) after 3-day curative application is presented in Table 3.2-43.

³ Vriesman, M, Leader, A, Diehl, C., Wineglass, A., Loeffler, J., 2019; Evaluate and compare Dow agrosiences™ products Questar (GF-3308), Univog (GF-3307), Adavelt (GF-3840), and XDE-481 (GF-4319) for control of barley scald (*Rhynchosporium secalis*) following a curative application - Dow agrosiences internal report (GL19E7B006F-DYC102 - GL19E7B006F-DYC103)

Table 3.2-43: Percentage control of *Rhynchosporium secalis* (RHYNSE) after 3-day curative application. Results of two trials (n=8) assessed 12-14 DAA.

Products	Rates (g a.s./ha)							
	Max reg rate ^y		1/2 of reg rate ^y		1/4 of reg rate ^y		1/16 of reg rate ^y	
GF-3307	99.8	a	98.9	b	97.7	b	75.4	c
GF-3308	91.3	a	82.5	a	38.3	a	11.0	a
Imtrex	99.3	a	100.0	b	99.6	b	86.2	c
Proline	98.5	a	98.0	b	96.2	b	84.8	c
Aviator Xpro	99.3	a	99.8	b	100.0	b	88.1	c
P value	>0.05		<0.05		<0.05		<0.05	

^z Percentage control values were calculated for each treatment within a rep according to the formula: $[(SC - ST)/SC]*100$ where SC is the severity on the untreated inoculated control and ST is the severity on the treatment.

^y Values are the means of two independent trials with four replications each; means followed by the same letter within a column are not significantly different at P value <0.05. Means were separated using Tukey's mean comparison test. The maximum registered dose is based on the maximum registration dose proposed in wheat.

GF-3307 applied at the maximum registerable rate achieved >90% control of RHYNSE. No significant differences in RHYNSE control 12-14 DAA were observed between GF-3307, Imtrex, Proline and Aviator Xpro (Figure 3.2 - 24).

GF-3307 applied at the 1/2 of maximum registerable rate also achieved >90% control of RHYNSE. No significant differences in RHYNSE control 12-14 DAA were observed between GF-3307, Imtrex, Proline, and Aviator Xpro (Figure 3.2 - 25).

GF-3307 applied at the 1/4 of maximum registerable rate always achieved >90% control of RHYNSE. Imtrex and Aviator Xpro provided >99% control at this rate; Proline provided >90% control. However, no significant differences in RHYNSE control 12-14 DAA were observed between GF-3307, Imtrex, Proline, and Aviator Xpro (Figure 3.2 - 26). A clear benefit was seen with the addition of prothioconazole to fenpicoxamid at this lower dose for curative activity against RHYNSE (as fenpicoxamid has little curative activity against RHYNSE at this dose, when applied alone in GF-3308), whilst this was not as evident in the protectant activity test. A 1/16 of the maximum registerable rate of GF-3307 achieved >75% control of RHYNSE, whilst Imtrex, Proline, and Aviator Xpro all provided >80% control at this 1/16 rate. However, no significant differences in RHYNSE control 12-14 DAA were observed between GF-3307, Imtrex, Proline, and Aviator Xpro (Figure 3.2 - 27) at this 1/16 dose rate. Again, there was a clear benefit of the addition of prothioconazole to fenpicoxamid at this lowest dose for curative activity against RHYNSE (as fenpicoxamid has virtually no curative activity against RHYNSE at this dose, when applied alone in GF-3308), whereas this was not as evident in the protectant activity test.

Figure 3.2 - 24 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 3-day curative application at the max registerable rate. Results of two trials (n=8) assessed 12-14 DAA

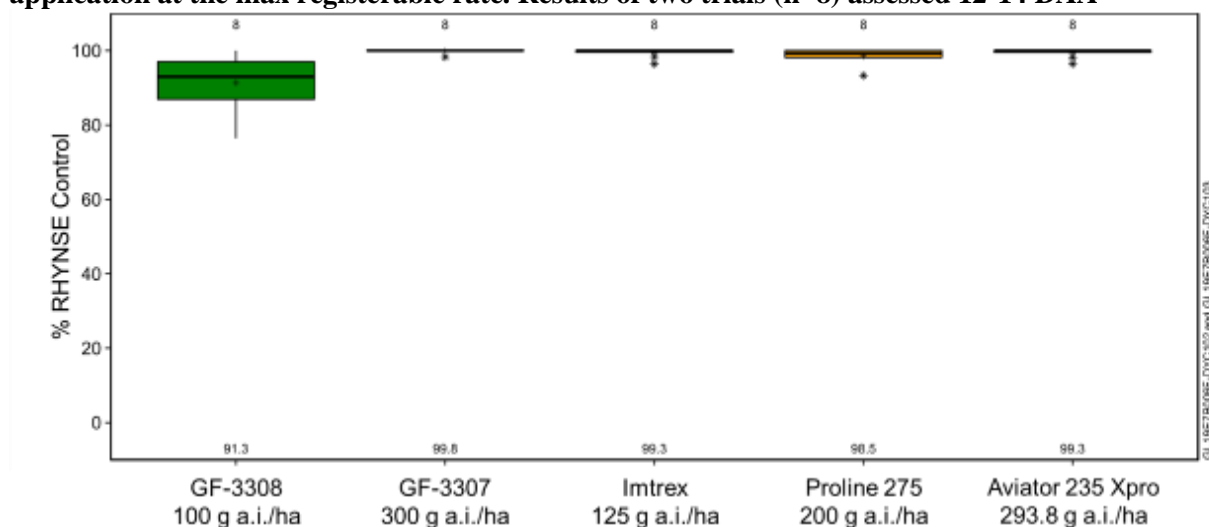


Figure 3.2 - 25 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 3-day curative application at 1/2 of the max registerable rate. Results of two trials (n=8) assessed 12-14 DAA

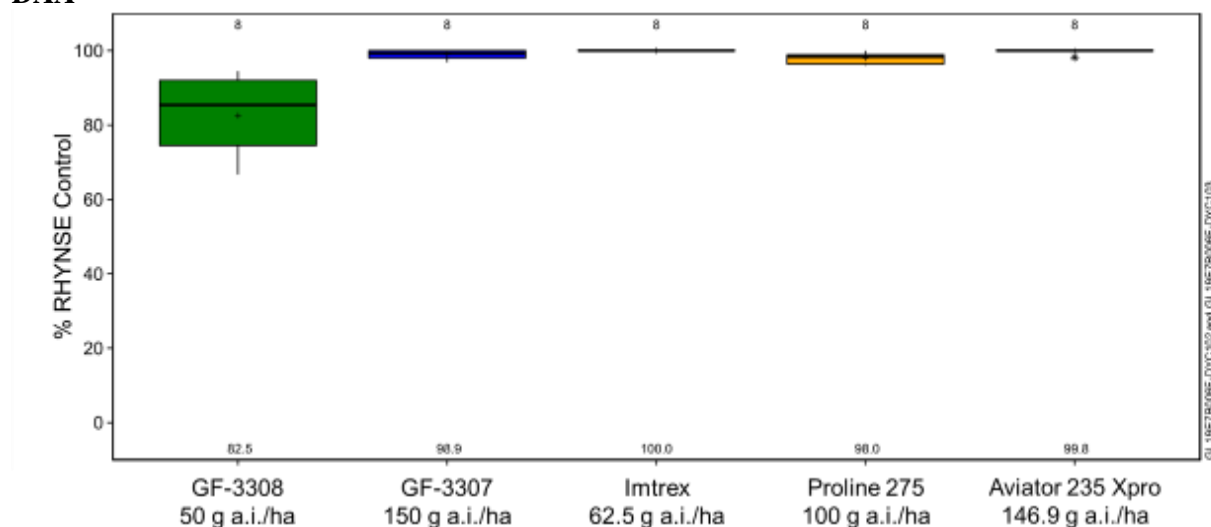


Figure 3.2 - 26 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 3-day curative application at 1/4 of the max registerable rate. Results of two trials (n=8) assessed 12-14 DAA

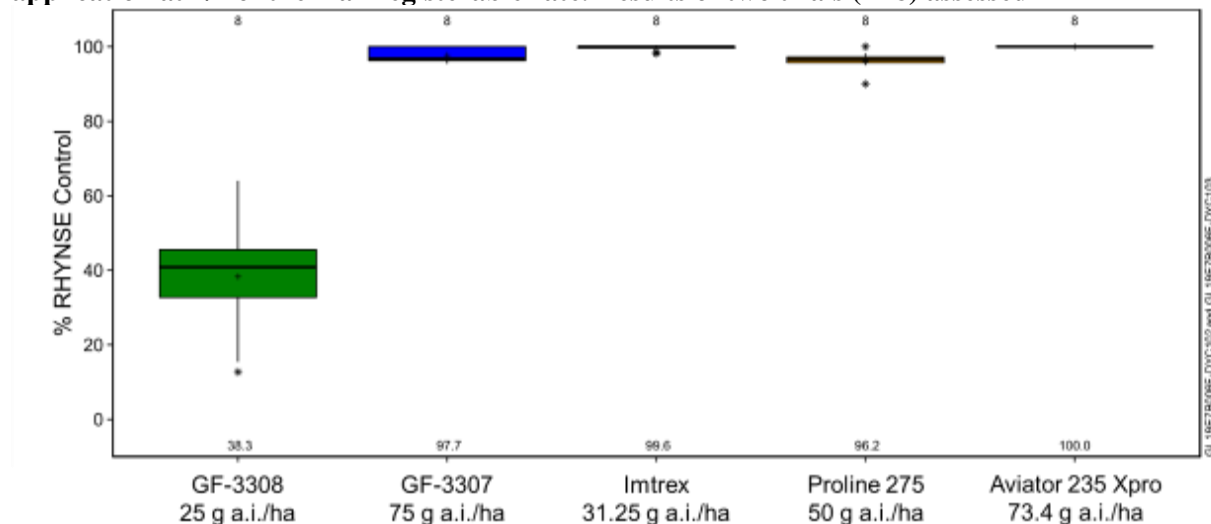
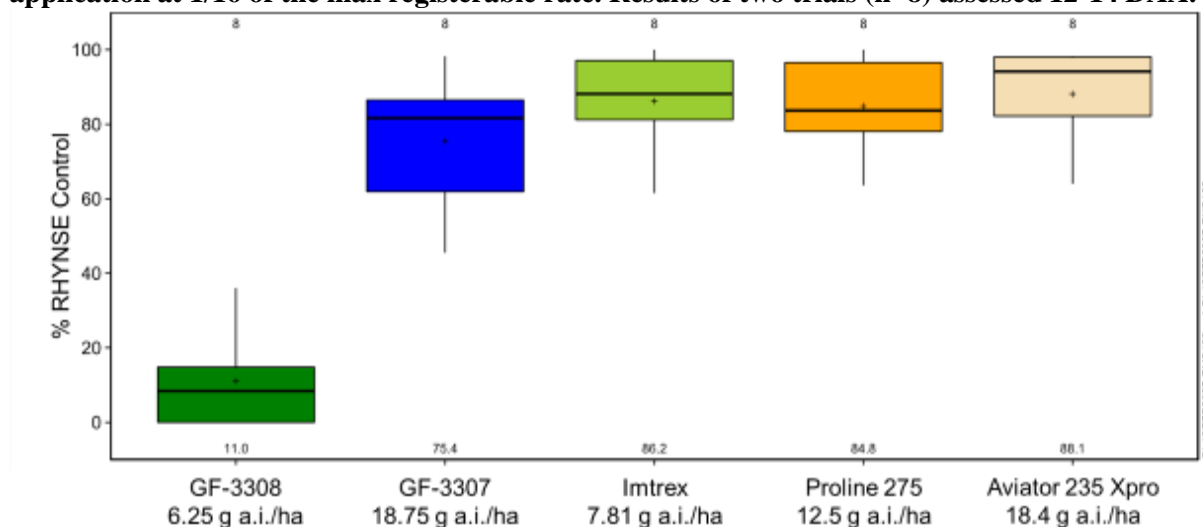


Figure 3.2 - 27 Percentage control of *Rhynchosporium secalis* (RHYNSE) after 3-day curative application at 1/16 of the max registerable rate. Results of two trials (n=8) assessed 12-14 DAA.



Conclusions

The percentage control of RHYNSE was high (>90%) using GF-3307, and statistically similar to that of standards Imtrex, Proline, and Aviator Xpro at the maximum registerable rates, also at 1/2, 1/4 and 1/16 of the maximum registerable rates, respectively.

This glasshouse study clearly demonstrated that GF-3307 provides curative control of RHYNSE at levels that compare well to the levels of control shown by leading reference products, Proline (DMI), Imtrex (SDHI) and Aviator Xpro (SDHI).

zRMS comments on the curative properties against *Rhynchosporium secalis* in barley as based on glass-house test: The study and its conclusions noted and recognized as valid.

3.2.1.7 Volatile properties of GF-3307 in a glasshouse test for the control of *Blumeria graminis* f. sp. *hordei* in barley

Introduction

In order to obtain a better understanding of how GF-3307, as an optimized formulation of fenpicoxamid + prothioconazole, compared to leading cereal reference products, a series of tests were conducted to evaluate the volatile properties of GF-3307, when used for the control of ERYSGH of barley.

Materials and Methods

Three growth chamber bioassays⁴ were conducted to characterize the efficacy and rainfastness of GF-3308 and GF-3307 for controlling *Blumeria graminis* f. sp. *hordei* (ERYSGH) following a 1-day protectant application and rain simulation 30 minutes or 1 hour after application on 9-day-old barley plants. The inoculation of these three trials were unsuccessful. The potential effects of the volatility of these fungicides on the disease expression was considered a hypothesis and tested as follows. A growth chamber bioassay was conducted to characterize the volatility of GF-3308 and GF-3307 for controlling barley powdery mildew (ERYSGH) following a 1-day protectant application on 9-day-old barley plants. The efficacy of GF-3307 was compared to that of Proline and Aviator Xpro.

Fungicides were applied to 9-day-old barley seedlings using a Generation III Research Track Sprayer (DeVries Manufacturing) using an 8002E TwinJet flat fan nozzle with a spray arm speed of 2.14 km/h and a spray pressure of 220 kPa. Pots of barley seedlings were placed in the spray chamber such that

⁴ Vriesman, M., Karaiskou, G., Leader, A., Diehl, C., Wineglass, A., Loeffler, J., 2020; Volatility of GF-3308, GF-3307, Proline, and Aviator 235 Xpro for control of barley powdery mildew (*Blumeria graminis* f. sp. *hordei*) on barley following a preventive application - Dow agrosiences internal report (GL20E7B002F-DYC007)

their mid-canopy was 50 cm below the spray nozzle. Fungicides were applied to barley seedlings at different rates (Table 3.2-44), simulating a spray volume of 150 L/ha.

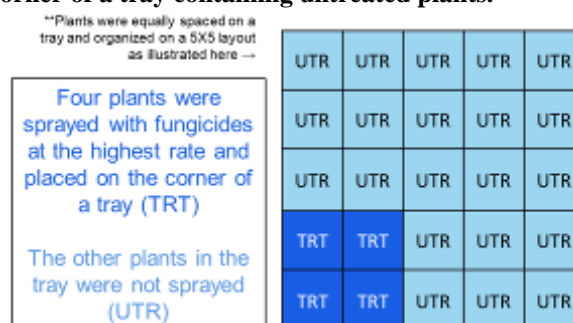
A total of four seedlings were sprayed with each fungicide. One day after application, treated plants were placed on the corner of a tray (65 x 65 cm) containing untreated plants, totalling 25 plants per tray. Pots in each tray were organized in a 5x5 layout, and the distance between the centres of each pot was 15 cm (

Figure 3.2 - 28).

Table 3.2-44: Fungicide products and rates used in volatility studies against *Blumeria graminis* f. sp. *hordei* (ERYSGH) in barley

Formulation	Active substance	g a.s./L	Rates tested (g a.s./ha)
GF-3307	fenpicoxamid + prothioconazole	50 + 100	300
GF-3308	fenpicoxamid	50	100
Proline	prothioconazole	275	200
Aviator Xpro	bixafen + prothioconazole	75 + 160	293.8

Figure 3.2 - 28 Schematic organization of treated (TRT) and untreated (UTR) plants per tray. Treated plants were placed on the corner of a tray containing untreated plants.



Fungicide-free barley seedlings of the same variety were used to generate ERYSGH inoculum. Inoculum was generated by dusting inoculated barley seedlings over non-inoculated seedlings. One day after application (1-day preventive study), twelve barley seedlings were used to inoculate a tray containing treated and untreated plants (n = 25). A tray containing 25 untreated plants was used as control. Inoculated plants were kept in a growth chamber with a suitable environment for disease development. Growth chamber was set at 20°C and 16-hr photoperiod; relative humidity was variable as the chamber was unable to control it.

Plants were evaluated for disease approximately two weeks after inoculation (14 DAI). Percent disease severity was averaged per pot on a 0-100% scale. The percent disease control was calculated relative to the untreated inoculated control. Trays were randomly arranged in the growth chamber. Each tray was replicated only once in this initial study.

Results

The percentage control of *Blumeria graminis* f. sp. *hordei* (ERYSGH) after 1-day preventive application and on untreated plants placed adjacent to treated plants is presented in Figure 3.2 - 29. 100% ERYSGH control was observed with GF-3307, Proline and Aviator Xpro, 14 DAI (

Figure 3.2 - 30).

Concerning the effect of volatility, ERYSGH control on untreated plants placed adjacent to treated plants was observed with GF-3307, Proline, and Aviator Xpro. ERYSGH control on untreated plants placed next to GF-3307 varied between 71.4 - 100.0%. ERYSGH control on untreated plants placed next to Proline varied between 52.4 - 100.0%. ERYSGH control on untreated plants placed next to Aviator Xpro varied between 88.1 - 100.0% (

Figure 3.2 - 31).

Figure 3.2 - 29 Percentage control of *Blumeria graminis* f. sp. *hordei* (ERYSGH) after 1-day preventive application and on untreated plants placed adjacent to treated plants. Results of one trial (n = 4) assessed 14 DAI (days after inoculation)

Percent ERYSGH control					Percent ERYSGH control					Percent ERYSGH control					Percent ERYSGH control				
4.8	0.0	16.7	16.7	16.7	100.0	97.6	88.1	76.2	81.0	96.4	95.2	57.1	52.4	64.3	97.6	97.6	97.6	100.0	97.6
16.7	0.0	0.0	0.0	0.0	100.0	100.0	95.2	88.1	71.4	97.6	90.5	71.4	57.1	71.4	100.0	100.0	97.6	100.0	97.6
40.5	0.0	28.6	28.6	0.0	100.0	100.0	81.0	85.7	92.9	100.0	95.2	76.2	71.4	57.1	100.0	100.0	97.6	92.9	92.9
57.1	64.3	16.7	33.3	16.7	100.0	100.0	95.2	88.1	85.7	100.0	100.0	90.5	76.2	76.2	100.0	100.0	95.2	92.9	88.1
76.2	88.1	28.6	0.0	4.8	100.0	100.0	100.0	97.6	90.5	100.0	100.0	88.1	81.0	76.2	100.0	100.0	100.0	97.6	88.1
4 plants treated with GF-3308 (100 g a.i./ha)					4 plants treated with GF-3307 (300 g a.i./ha)					4 plants treated with Proline 275 (200 g a.i./ha)					4 plants treated with Aviator 235 Xpro (293.8 g a.i./ha)				

Figure 3.2 - 30 *Blumeria graminis* f. sp. *hordei* (ERYSGH) on untreated plants (UTR - inoculated, four representative plants) and on the four plants treated with fungicide products. Photographs of one trial (n = 4) at 14 DAI.

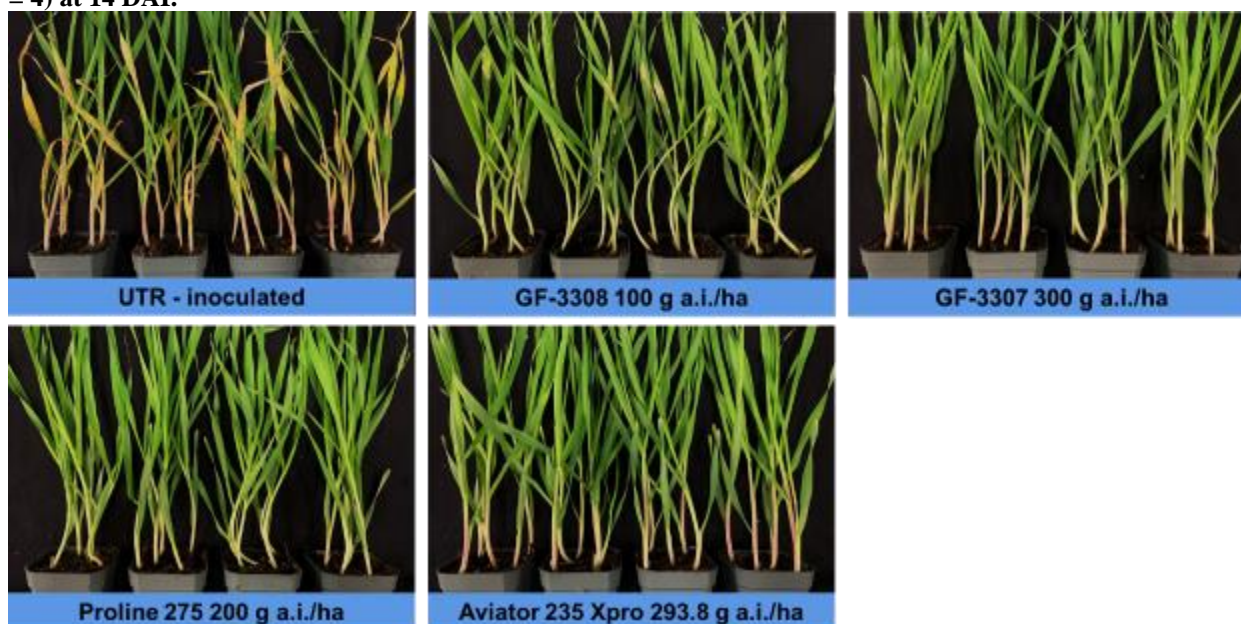
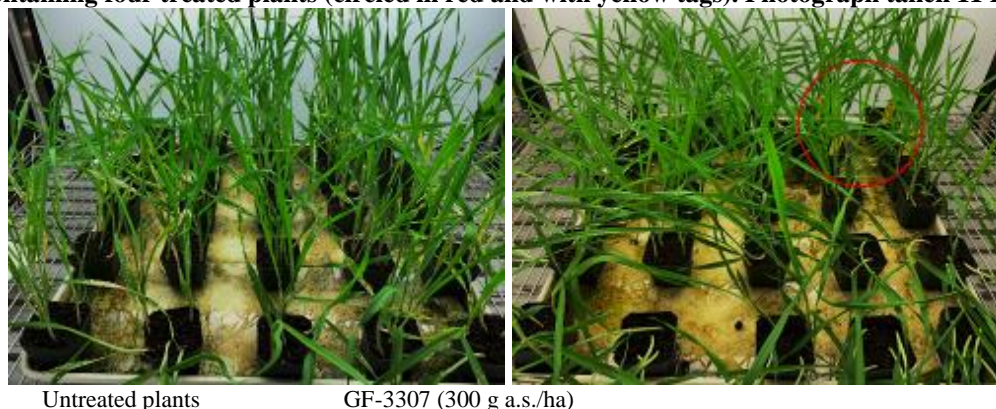
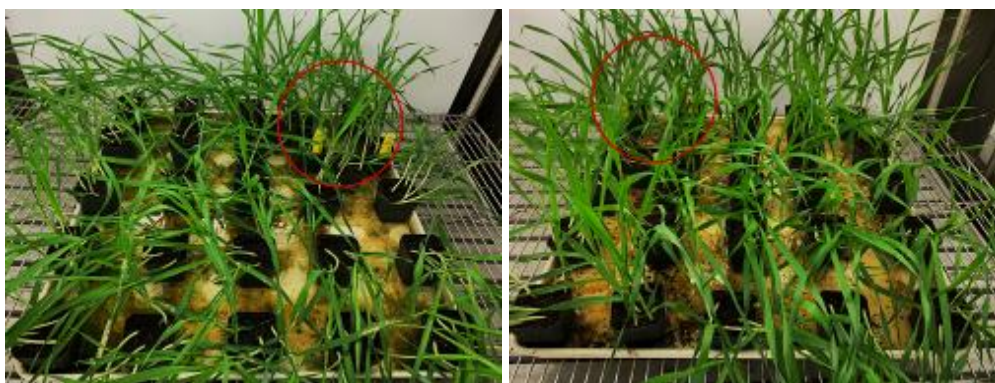


Figure 3.2 - 31 *Blumeria graminis* f. sp. *hordei* (ERYSGH) on a tray containing 25 untreated plants and on a tray containing four treated plants (circled in red and with yellow tags). Photograph taken 11 DAI.



Untreated plants

GF-3307 (300 g a.s./ha)



Proline (200 g a.s./ha)

Aviator Xpro (293.75 g a.s./ha)

Conclusions

100% control was observed with GF-3307 (300 g a.s./ha), Proline (200 g a.s./ha), and Aviator Xpro (293.75 g a.s./ha) after 1-day preventive application and at 14 DAI (days after inoculation). The effect of fungicide volatility on controlling ERYSGH on adjacent untreated plants was observed with GF-3307 and shows the clear benefit of the addition of prothioconazole to fenpicoxamid for mildew control. Volatility effect was also observed with Proline and Aviator Xpro, which is likely to also be because of the benefit of prothioconazole.

zRMS comments on the effect of volatility on the control of *Blumeria graminis* f.sp. *hordei* on adjacent plants, as based on a growth chamber test: The study and its conclusions noted and recognized as valid.

3.2.1.8 Uptake and foliar movement

Foliar Mobility

Foliar movement of fenpicoxamid was assessed in simple drop line tests based on regular disease bioassays. Mobility is an important measure of fungicide performance. Mobility is defined as the ability of a fungicide to redistribute within the plant to areas not covered by the spray application. Fungicide formulation also influences mobility and efficacy. Performance of 5 formulations of the fungicide fenpicoxamid (GF-3307 (50 g as/L fenpicoxamid +100 g as/L prothioconazole), GF-3312 (66.7 g as/L fenpicoxamid + 83.33 g as/L Pyraclostrobin), GF-3308 (50 g as/L EC), GF-3311 (66.7 g as/L EC) and GF-2925 (130 g as/L SC)) were compared to current cereal fungicide standards using a mobility bioassay to determine effect of formulation on *Puccinia recondita* (PuccRT) control on wheat in a glasshouse test.

Seeds of the 'Yuma' wheat were planted in an artificial growing media (Metro mix 360®) and grown for 7 days. The fungicides were applied at growth stage BBCH-12. The growth media Metro-mix 360 consists of formulated Canadian sphagnum peat moss, coarse perlite, bark ash, a starter nutrient charge (with gypsum), a slow-release nitrogen and dolomitic limestone. Each pot contained three wheat seedlings and three pots were used as replications for each treatment. Pots used were 5.5 x 6.5 x 5.5 cm. Seedlings were all marked 5 centimetres from the tip of the primary leaf with a pen to designate the point of fungicide application.

Fungicides were applied to the leaf tissue in a 2 ul droplet containing the recommended concentration of fungicide to be added to 150 litres of water (Table 3.2-45). The droplet was applied to the adaxial surface of wheat seedlings 5 cm below the tip of the leaf. At the time of fungicide application the leaf was maintained in a horizontal position to allow for optimum contact and absorption of the compounds.

Wheat seedlings were inoculated with the PuccRT 24 hours after application of the fungicides. Seedlings were inoculated with a suspension containing Tween 20 and 1 X 10⁶ urediospores/ml. After inoculation, seedlings were placed in a dew room for 24 hours with no light, 22 C, and 99% relative humidity and then moved to a greenhouse for the remainder of the experiment.

Wheat seedlings were evaluated 8 to 9 days after inoculation. Each leaf dosed with a fungicide was evaluated to determine the disease free distance from the point of application to the area containing the

first signs of disease caused by Puccinia. The percent disease-free area was calculated by determining the distance in centimetres from the point of fungicide application to the first pustules and multiplying by 20. The distance from the point of application to the leaf tip was 5 centimetres. A score of 5 cm would indicate 100% disease free zone from the application point to the tip of the leaf. If the leaf was disease free on the adaxial surface the fungicide was considered to be translaminar.

Table 3.2-45: Fungicide movement, disease-free, and translaminar activity.

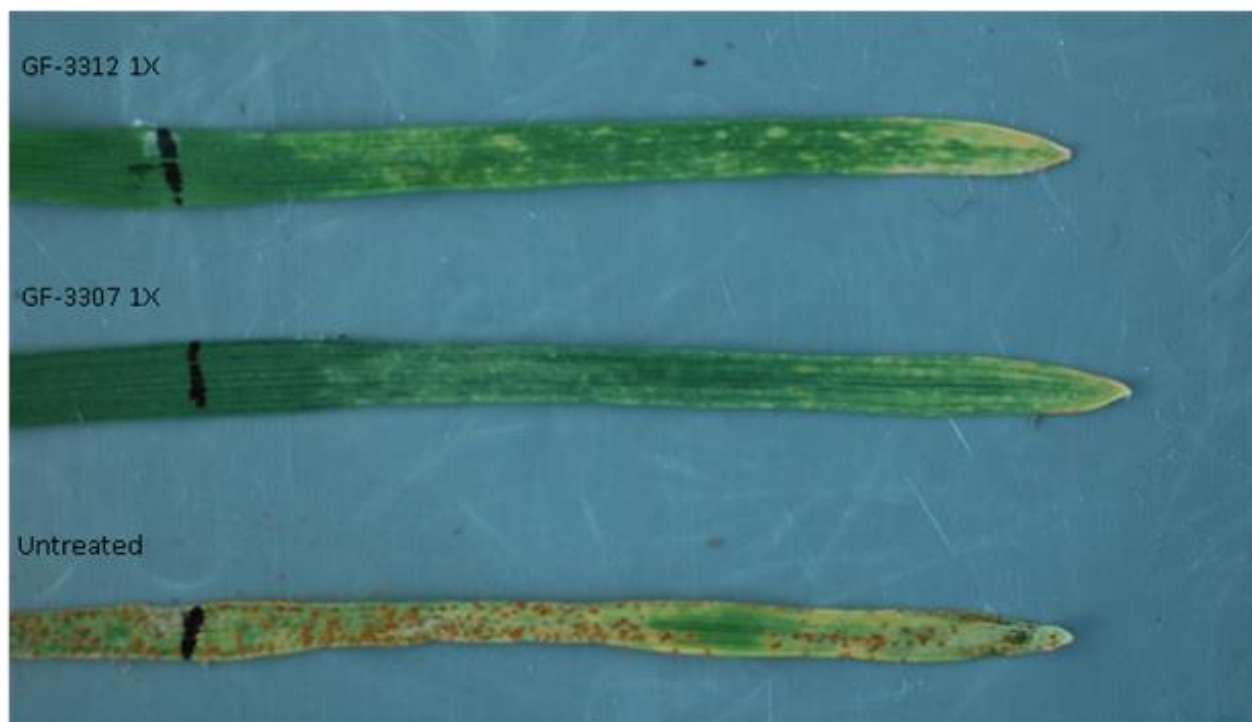
Treatment	Use rate	Average distance moved (cm)	Disease free area (%)	Translaminar activity
Untreated	0	0.0 c ^{1,2}	0	no
GF-2925 (fenpicoxamid)	130 g as/ha	3.0 b	60	yes
GF-3308 (fenpicoxamid)	130 g as/ha	5.0 a	100	yes
GF-3311 (fenpicoxamid)	130 g as/ha	4.3 a	86	yes
GF-3307 (fenpicoxamid + prothioconazole)	200+100 g as/ha	4.9 a	98	yes
GF-3312 (fenpicoxamid + Pyraclostrobin)	125+100 g as/ha	4.8 a	96	yes
Adexar (Epoconazole + Fluxapyroxad)	125+125 g as/ha	4.7 a	94	yes
Aviator Xpro (Prothioconazole + Bixafen)	200+94 g as/ha	5.0 a	100	yes
Bravo (Weather stik)	1.25 Kg as/ha	0.3 c	36	yes
Ignite (Epoconazole)	125 g as/ha	4.9 a	98	yes

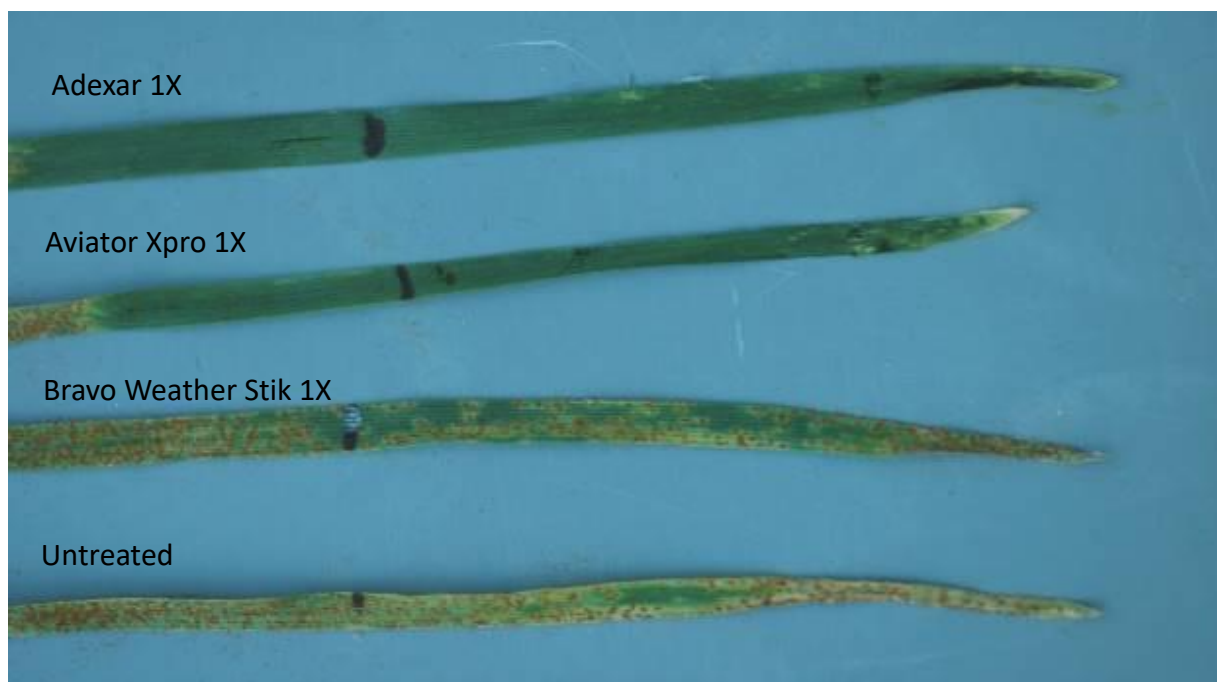
¹Means not followed by the same letter are significantly different at P<0.05.

²Distance measured in cm from point of application to the first disease symptom.

Both Bravo and GF-2925 were less mobile than the other fungicide formulations. These formulations are suspension concentrates (SC) and as a result may not have been able to penetrate the leaf tissue as effectively or redistribute as readily across leaf surface. Conversely, additional organic solvents and emulsifiers in the emulsifiable concentrate (EC) matrix formulations may help dissolve epicuticular waxes and promote fungicide uptake resulting in superior performance. All fungicides were translaminar at the point of application. Only Bravo had a disease-free area directly below the point of application. It may appear that Bravo was translaminar; however, Bravo may have penetrated the leaf, the fungus came in contact with the fungicide and growth was inhibited. No upward disease-free zone was observed with Bravo. All the compounds which were found to be disease-free on the upper side of the leaf were also found to be disease-free on the lower side of the leaf. Fenpicoxamid applied as GF-3308 and GF-3311 had similar mobility and translaminar movement and were statistically similar to mobile standards Ignite, Adexar and Aviator XPro and superior to GF-2925.

fenpicoxamid EC matrix formulations provided excellent Puccinia control and both GF-3308 and GF-3311 provided Puccinia control similar to the standards with the exception of Bravo and GF-2925, which provided control which was statistically inferior. The mixtures GF-3307 and GF-3312 were tested in the same EC matrix to determine if fenpicoxamid was compatible with prothioconazole or pyraclostrobin. All the mixtures containing fenpicoxamid were found to be safe to use with no loss of activity compared to fenpicoxamid applied alone as GF-3308.





Reference report: Mathieson, T. Comparative mobility of three XDE-777 formulations and commercial standards as measured by glasshouse bioassay with *Puccinia recondita* on wheat. Dow AgroSciences, SAGE report # 2024367, October 2014.

zRMS comments on the bioassay of foliar mobility of fenpicoxamid: The study and conclusions noted and recognized as valid.

Uptake and dispersion of fenpicoxamid in wheat plants

Materials and Methods

To evaluate the distribution of fenpicoxamid in wheat plants four different formulations of radiolabeled material were prepared from ^{14}C -labeled fenpicoxamid:

Test product	Formulation type	Active substance	Active g as/L	
NMP-based	EC	fenpicoxamid	65	Lab formulation based on <i>N</i> -methyl pyrrolidone (NMP)
GF-2925	SC	fenpicoxamid	130	
GF-3311	EC	fenpicoxamid	67.5	
GF-3135	EC	fenpicoxamid	50	

Solutions of formulations GF-2925, GF-3311 and GF-3135 each with ^{14}C -labeled fenpicoxamid were prepared at the concentration of 650 ppm, equivalent to target field rate of 130 g/ha. One 2 μL drop of the solutions was applied to a line, marked at 4 cm from the leaf tip, on the ad axial surface of the primary leaf. The droplets were allowed to dry for 30 min prior to sampling. At each sampling time (0.5 or 24 h after application), two plants per treatment were harvested. The plants were freeze-dried for 2 days and then exposed to phosphor screens (Molecular Dynamics) for a week. Images of plant samples were produced using a Storm 860 scanner and ImageQuant software (Molecular Dynamics).

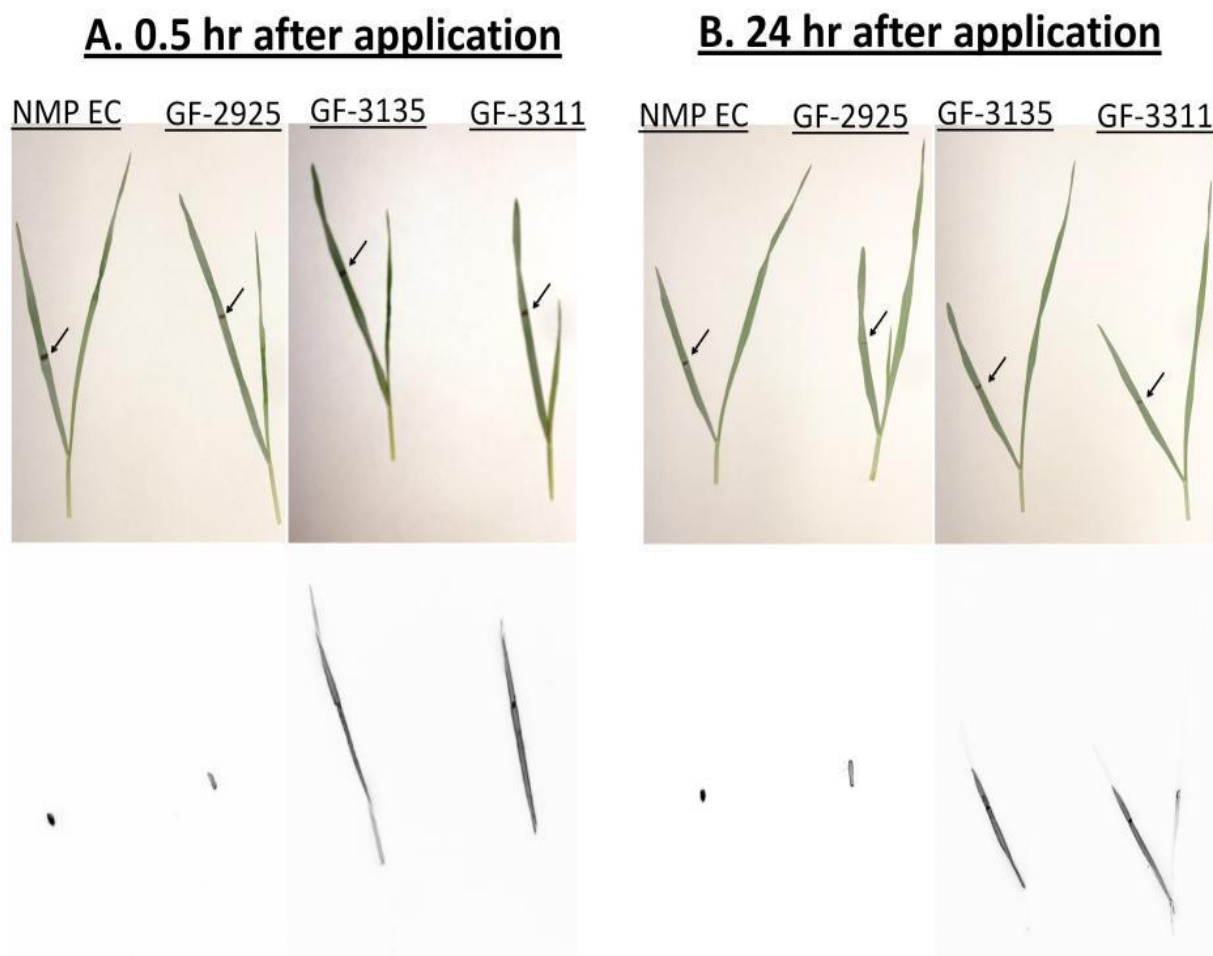
Results

When NMP-based EC formulation and SC based GF-2925 were applied to wheat leaves, most of the fenpicoxamid signal was detected at the application site without any noticeable movement out of the application zone up to 24 h after application.

In contrast, fenpicoxamid EC based formulations GF-3135 or GF-3311 became dispersed some 4-5 cm from the application site in both acropetal and basipetal directions within seconds (data not shown), giving rise to the significant dispersion shown on plants sampled 0.5 h after application. The recovery of radioactive fenpicoxamid in the EC matrix formulations GF-3311 and GF-3135 was four times greater than recovered from the NMP and GF-2925 SC formulations 48 h after application which provided evidence of increased uptake of fenpicoxamid in GF-3311 and GF-3135 formulations.

Noticeably, the phosphor images of 24 h samples, specifically for GF-3311, showed the presence of fenpicoxamid derived radioactivity in the second leaf implying fenpicoxamid dispersal down to the leaf axil area, and subsequent xylem movement into the untreated second leaf (see Figure 3.2-33). It was difficult to detect acropetal movement of fenpicoxamid in GF-2925, likely due to low foliar uptake of the active in this formulation. On the contrary, when GF-3135 and GF-3311 EC matrix formulations were applied, radioactivity of fenpicoxamid was clearly seen throughout the treated leaves, showing that surface dispersion of fenpicoxamid was mirrored by a parallel distribution of fenpicoxamid within the leaf tissue. These results further suggest that by using the EC matrix formulations, improved redistribution of compounds into the leaf tissue can be attained through increased surface spreading and penetration through the cuticle.

Figure 3.2-33: Unwashed Plants. Distribution of ^{14}C -labeled fencixoxamid in four different formulations.



Mounted plants (above) and phosphor images (below). Arrows indicate the application sites

Reference report: Myung, K [et al.](#) Effects of different formulations on retention, surface coverage, and uptake of XDE-777 in wheat plants. Dow AgroSciences, SAGE report # 2026067, February 2015.

zRMS comments on the bioassay of uptake and dispersion: The study noted and recognized as valid, it has been already used by the applicant in 3.2.1.3.

Conclusions

The series of studies revealed that different formulations can significantly affect retention, surface distribution and coverage, and uptake of fenpicoxamid in wheat plants. Fenpicoxamid formulated as a matrix EC in GF-3135 and GF-3311 showed significantly better retention and surface coverage on the plants than fenpicoxamid formulated as an SC in GF-2925. In addition, the study clearly demonstrated remarkable dispersion of fenpicoxamid on leaf surface with GF-3135 and GF-3311, which differed from a generic NMP-based EC formulation and GF-2925, for which such spreading was not observed. Furthermore, fenpicoxamid in GF-2925 and the NMP-based EC formulation had limited penetration into wheat leaf tissue, while uptake of the compound in GF-3135 and GF-3311 was 3-4 fold higher (24-48 Hr). The greater retention, surface redistribution, and uptake of fenpicoxamid could be key attributes for GF-3135 and GF-3311, EC matrix formulations contributing to the improved curative SEPTTR control and greatly enhanced rust activity compared to SC formulations. The exceptional spreading ability of fenpicoxamid in the EC matrix formulations is particularly interesting and this had been followed up with specific spray droplet application test at Silsoe research, UK comparing application through conventional flat fan and low drift nozzles presented in section 3.6.2.

As the application of GF-3307 would be required to be made through 3 star low drift nozzles, droplet deposition with these nozzles have been tested compared to standard flat fan at 100-200 L/ha with varying forward speeds of 8-14 KPH and 75% and 90% DRT with no impact observed upon deposition regardless of situation. These data along with efficacy field trials showing comparable levels of control between 3 star and conventional flat fan nozzles are presented in section 3.6.2.

Reference report: Butler Ellis, C *et al*, Characterisation Of Sprays And Visualisation Of Deposits On Surfaces. Contract report S0140/1, June 2016 and Butler Ellis, C *et al*, Characterising deposits on plants for a range of formulations and application conditions. Contract report S0181, July 2017.

zRMS comments: The study (Butler *et al*. 2017) (KCP 3.6/04) noted and recognized as valid. It is discussed by the applicant in section 3.6.2.

Mode of action of the active substance

Fenpicoxamid is a protectant and curative fungicide for control of foliar diseases in cereal crops. Fenpicoxamid is rapidly activated in the presence of fungi and inside plants to UK-2A which is a potent inhibitor of mitochondrial electron transport (MET). Previous biochemical studies on the mode of action of UK-2A have demonstrated binding to the Q_i site of the cytochrome *bc*1 (ubiquinone reductase) complex (complex III) in the electron transport chain, similar to the mechanism of the structurally related natural product antimycin A. UK2A inhibits respiration at complex III which likely represents the primary biochemical mode of action for this chemistry. The mode of action of fenpicoxamid will be novel to the European cereal fungicide market and will be assigned to FRAC group C4#21.

The cytochrome *bc*1 complex (complex III) of the mitochondrial electron transport (MET) chain has two quinone binding sites known as the Q_o and Q_i sites. The Q_o site is the target site of the strobilurin fungicides, which include many commercial products. Inhibitors of the Q_i site are also known, although to date only the Oomycete-specific fungicides cyazofamid and ambisulbrom (FRAC group 21) have been commercialized. Although the target site of activity is the same, fenpicoxamid has no activity against Oomycete diseases but has strong activity against cereal diseases such as SEPTTR.

The MET III Q_i site is distinct from the MET III Q_o site with which the strobilurins interact, so that no cross-resistance of field isolates of *Septoria* resistant to strobilurin fungicides has been observed or would be anticipated.

3.2.1.9 First field testing of EC formulation

The first field test of the new EC formulation GF-3135 was carried out in Italy against SEPTTR in durum wheat in 2013 in an especially curative situation. Both SC (GF-2925) and EC (GF-3135) formulations were evaluated with a clear benefit observed between the two formulation types. The trial comprised a single application at BBCH 35-39 (01/05/2013) ~~and compared to a sequential application at BBCH 31-32 (11/04/2013) and then BBCH 45 (08/05/2013).~~ The reference products included were Bravo (chlorothalonil) applied at 750 g as/ha ~~in the single application or 500 + 750 g as/ha as a sequential application~~ and Proline (prothioconazole) applied at 200 g as/ha in a corresponding single ~~or two~~ spray programme. Table 3.2-46 below shows the trial from Italy (IT13E7B0012DC01) where an assessment was made on leaf 1 (~~Flag~~ **Flag leaf**) at 26 days after single application spray ~~and 19 days after the second application in the sequential application~~ and the corresponding yield relative to the untreated. There was no visible disease present on leaf 1 at the time of application and so this was true curative situation. This trial not only showed the benefit of formulation but the corresponding impact on yield and provided the first field evidence of the impact of formulation on the activity of fenpicoxamid. **The final formulation GF-3307 was developed in 2014 as a result of formulation work with GF-3135.**

zRMS comments: The study (IT13E7B0012DC01) noted and recognized as valid. Conclusion on the higher efficacy of GF-3135 (EC formulation) compared to GF-2925 (SC formulation) are valid; the Table 3.2-46 can be seen in the next page.

Table 3.2-46 — Early field testing with SC formulation GF-2925 compared to EC formulation GF-3135 against SEPTTR in durum wheat. IT13E7B012DC01, Italy 2013. Assessment 26 days after application 1 and 19 days after application 2.

Single spray B35-39 Repeat spray B31/32 and B45		Leaf 1 % infection SEPTTR (%) at a single (x1) or at repeated (x2) applications							
		fenpicoxamid g as/ha				chlorothalonil g as/ha		prothioconazole g as/ha	
Leaf level evaluated	Untreated % infection	GF-2925 1 x 130	GF-2925 2 x 130	GF-3135 1 x 130	GF-3135 2 x 130	Bravo 1 x 750	Bravo 500/750	Proline 275 1 x 200	Proline 275 2 x 200
Leaf 1	59.1	29.2 (50.6%) abe	22.3 (62.4%) abe	13.3 (77.5%) be	6.5 (89.0%) e	26.8 (54.7%) abe	28 (52.7%) abe	20.8 (64.9%) abe	6.8 (88.6%) e
% Relative yield (Untreated t/ha)	4 t/ha	124 def	133 cd	144 b	160 a	117 f	128 e f	121 def	161 a

Leaf 1 efficacy assessment statistics: SD 9.43 Tukey's HSD P=.05 24.01

Table 3.2-47 Early field testing with SC formulation GF-2925 compared to EC formulation GF-3135 against SEPTTR in durum wheat. IT13E7B012DC01, Italy 2013. Assessment 26 days after one application

Single spray B35-39 Repeat spray B31/32 and B45		Leaf 1 % infection SEPTTR (%) at a single (x1) application			
		Fenpicoxamid g as/ha		Chlorothalonil g as/ha	Prothioconazole g as/ha
Leaf level evaluated	Untreated % infection	GF-2925 1 x 130	GF-3135 1 x 130	Bravo 1 x 750	Proline 275 1 x 200
Leaf 1	59.1	29.2 (50.6%) abc	13.3 (77.5%) bc	26.8 (54.7%) abc	20.8 (64.9%) abc
% Relative yield (Untreated t/ha)	4 t/ha	124 def	144 b	117 f	121 def

Leaf 1 efficacy assessment statistics: SD 9.43 Tukey's HSD P=.05 24.01

Reference report: Crestani D, Besco V: Evaluation of XDE-777 (GF-2925 & GF-3135) applied for the control of SEPTTR in wheat in Southern Europe. 2013. Dow AgroSciences, ARM report # IT13E7B012DC01, November 2013.

3.2.1.10 Preliminary range finding studies for ratio setting of GF-2800 and prothioconazole:

During the course of the evaluation of this dossier it was noted by the zRMS that the data in this section was mostly based on results after two applications and using an earlier SC formulation. This was the intended GAP for fenpicoxamid containing products when the studies used in this section were generated (2012), during early pre-development using an earlier SC formulation. However, as the GAP for GF-3307 has now been revised to one application per crop and the GF-3307 formulation is radically different from these earlier SC formulations, it is considered that this section is no longer relevant to the proposed use of GF-3307. As a result, the information in this section has been removed. Full justification for the proposed mixture of the two fungicides in GF-3307 (fenpicoxamid and prothioconazole), based on the proposed GAP and formulation, can be found in sections 3.2.1.12 to 3.2.1.14.

zRMS comments on the original submission and its updating:

The two sections removed by the applicant as the result of the present update (in May 2022) include altogether **31 trials** carried out during the preliminary phase of GF-3307 development, that had already been evaluated by zRMS at the time when the zRMS contacted the applicant.

The zRMS communication with the applicant concerned the double application scheme observed in those trials, as well as the final statement of the applicant, the one closing this chapter, 3.2.1.10: *“As diseases often occur as complexes of several pathogens [...] 1 to 2 application(s) of [the test item] should therefore be used to efficiently control [...]”* as contradicting the claim that one application per season was to be authorized.

To the opinion of zRMS, sufficient a response would be to correct the GAP table, in which the 14-day interval was left at that time, as if there should have been >1 application, and to remove the above statement from the present chapter. Instead, the applicant declared that this part of the dossier had little relevance to the GF-3307 formulation and decided to remove the content of the chapters 3.2.1.10 – 11 completely. Nevertheless, as the GF-3307 is a new product, the zRMS decided to retain the content dealing with the preliminary trials (even though ~~faded and struck through~~), as for a diligent reader it may be interesting to know the story as complete as originally submitted.

Since the removed part of the original dossiers includes 4 tables, the table numbering has been changed, but the updated table references also correspond to the present numbering.

Introduction

~~Preliminary range finding studies were carried out in 2012 to determine the the most effective ratio of fenpicoxamid and prothioconazole when applied together in mixture. 20 trials were conducted against target diseases SEPTTR (6 trials), Puccst (5 trials) and Puccrt (9 trials) in Maritime and Mediterranean EPPO zones. Fenpicoxamid was applied as an SC formulation coded GF 2800 which contained 89 g as/L of fenpicoxamid and was applied alone at 100 and 130 g as/ha which represented proposed doses supported for the active substance. The mix partner was an in-house formulated SC of prothioconazole as GF 2979 which contained 150 g as/L was applied at 112.5, 150 and 195 g as/ha. Mixtures of the two actives were then evaluated at 75+112.5 g as/ha, 75+150 g as/ha, 100+112.5 g as/ha, 100+150 g as/ha and 100+195 g as/ha and 130+195 g as/ha. According to the presented results, in Table 3.2 50 the application of GF 2800 at 100 g as/ha + prothioconazole at 195 g as/ha provided effective control against SEPTTR and much better control than GF 2800 alone against Puccst and Puccrt.~~

~~The reference product included in the SEPTTR trials was Proline 275 applied at 0.71 L/ha (195 g as/ha prothioconazole, EC) and in the Puccst and Puccrt trials Ignite (83 g as/L epoxiconazole) was applied at 1.5 L/ha (125 g as/ha epoxiconazole, EC).~~









~~The trials were carried out by Dow AgroSciences, contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). Refer to Table 3.2 49 for more details. The trials were conducted in Denmark (2), France (7), Germany (5), the United Kingdom (4), Republic of Ireland (1) and Italy (1) in 2012.~~

On the basis of the EPPO standard 1/241 ‘Guidance on comparable climates’, the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region.

5 trials are included from the Mediterranean EPPO Zone (S. France 4, N. Italy 1) against Puccrt. These are included as it is considered that disease pressure in this area is very high and so provides the worst case for the performance of a plant protection product.

Materials and Methods

Table 3.2-48: Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB (20)
	Plot size	18-36 m ²
	Number of replications	4 (20)
Crop	Trials per crop	Winter wheat (19)  Durum wheat (1) 
	Varieties per crop	Winter wheat: Biscay, Cubus, Hereford, Istabraq, KWS Sterling, Einstein, Baltimor, Altigo, Robigus, Oakley (2), Dekan, Skater, Tommi, Miradoux (3), Aubusson, Bologna Durum wheat: Orobel 
Application	Crop stage (BBCH)* at application	Winter wheat: BBCH 31–65 Durum wheat: BBCH  56–58 
	Timing Pest stage at application (1)	For the control of <i>S. tritici</i> the 1 st application was due when there was a risk of infection with SEPTTR or when the disease started to develop on the lower leaf levels. For Puccst and Puccrt application was made when the first pustules were visible.
	Number of applications	Winter wheat: 1 (7), 2 (12)  Durum wheat: 1 (1) 
	Spray volumes	200–250 L/ha 
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2–3 weeks after application and/or at BBCH 75 in winter wheat and 3–5 and 6–8 weeks after application in spring wheat.
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection
	e.g. Field / Greenhouse...	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR/Puccst/Puccrt is an abundant disease.

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-23 below.

Table 3.2-49 Testing facilities involved by EPPO Zone in 2012 preliminary range finding studies

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	EPPO Guideline	Trial Status
Central	Maritime	Germany	2012	DE12E7B013FS01	Dow AgroSciences, DE	PP 1/26	GEP

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	EPPO Guideline	Trial Status
Central	Maritime	Germany	2012	DE12E7B013UB01C	Agrartest, DE	PP 1/26	GEP
Northern	Maritime	Denmark	2012	DK12E7B013MN01C	Flakkebjerg	PP 1/26	GEP
Southern	Maritime	France	2012	FR12E7B013MC02C	Phyliae, FR	PP 1/26	GEP
-	Maritime	UK	2012	GB12E7B013SE01C	Eurofins Agroscience Services Ltd, UK	PP 1/26	GEP
Central	Maritime	Ireland	2012	IE12E7B013SE02C	Teagasc	PP 1/26	GEP
Central	Maritime	Denmark	2012	DK12E7B014MN01C	Flakkebjerg	PP 1/26	GEP
Southern	Maritime	France	2012	FR12E7B014MC03C	Anadiag France	PP 1/26	GEP
-	Maritime	UK	2012	GB12E7B014KS01	Dow AgroSciences, UK	PP 1/26	GEP
-	Maritime	UK	2012	GB12E7B014SD01	Dow AgroSciences, UK	PP 1/26	GEP
-	Maritime	UK	2012	GB12E7B014SE01C	Eurofins Agroscience Services Ltd, UK	PP 1/26	GEP
Central	Maritime	Germany	2012	DE12E7B015DD01	Dow AgroSciences, DE	PP 1/26	GEP
Central	Maritime	Germany	2012	DE12E7B015ML01	Dow AgroSciences, DE	PP 1/26	GEP
Central	Maritime	Germany	2012	DE12E7B015TS01	Dow AgroSciences, DE	PP 1/26	GEP
Southern	Mediterranean	France	2012	FR12E7B015CR01	Dow AgroSciences, FR	PP 1/26	GEP
Southern	Mediterranean	France	2012	FR12E7B015JG02	Dow AgroSciences, FR	PP 1/26	GEP
Southern	Mediterranean	France	2012	FR12E7B015MC03C	SRF, FR	PP 1/26	GEP
Southern	Mediterranean	France	2012	FR12E7B015MC04C	Anadiag France	PP 1/26	GEP
Southern	Mediterranean	France	2012	FR12E7B015MC05C	SRF, FR	PP 1/26	GEP
Southern	Mediterranean	Italy	2012	IT12E7B015DC01	Dow AgroSciences, Italia	PP 1/26	GEP

* Mediterranean EPPO zone, TRZDU trials

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR, PUCCST and PUCCRT are abundant diseases. For further trial site and application details see Table 3.2 49 [REDACTED]. The following map in Figure 3.2 34 provides an overview on the geographical distribution of the efficacy trials across the EU countries involved.

Figure 3.2 34: — Geographical distribution of the 20 preliminary range finding studies conducted in 2012 for the control of SEPTTR/PUCCST/PUCCRT in winter wheat



Formulations applied and rates

Test-product	Formulation-type	Active-substance	Rate product L/ha	Rate g as/ha
GF-2800	SC	fenpicoxamid (89 g as/L)	0.84-1.12-1.46	75-100-130
GF-2979	SC	Prothioconazole	0.75-1.0-1.3	112.5-150-195
Proline-275	EC	Prothioconazole	0.71	195
Ignite	EC	Epoxiconazole	0.51	125

Experimental details

All 20 dose ratio trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 18 m² and 36 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 250 L/ha.

GF-2800 (fenpicoxamid, SC) and GF-2979 (prothioconazole, SC) at the rates tested and the reference products Proline and Ignite were applied at a single or split application timing dependent upon disease target. Applications against SEPTTR were typically between BBCH 31 and BBCH 33 of winter wheat followed by a second timing between BBCH 39 and BBCH 41. The treatments were typically applied when SEPTTR had established on the lower leaves to stop the disease from further establishing. Against Puccst applications were timed to coincide with the first pustules visible, typically BBCH 31 to BBCH 33 with the second application between BBCH 39 to BBCH 59. Finally against Puccrt the application was a single application between BBCH 39 and BBCH 61 with the later timings accounting for the later disease presence of this pathogen. One trial in France had a split application at

BBCH 49 and then BBCH 59. For further application details see Table 3.2-24 below. **Further details available in Table 3.2-49 page 95, BAD.**

Assessments for efficacy (% infection) were aimed at the timing application, 2-3 weeks, 4-6 weeks after application and/or at BBCH 75. Depending on the temperature SEPTTR has an incubation period of circa 2-4 weeks until first symptoms appear on the leaves. Therefore assessments made 2-4 weeks after application are not differentiating as the product as not kicked in yet. Assessments against PUCST and PUCRT were tailored according to the disease progression in the knowledge that the pathogen can cycle very quickly. As such assessments were made at least every 2 weeks—less if necessary.

The final assessments for efficacy summarized in this chapter of the documents were made approximately 6-9 weeks after application when differences between treatments with GF-2800 and GF-2979 and/or the reference products and the untreated control were most obvious. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTTR or leaves which were fully senesced in treated and untreated plots were excluded from summarization and leaves showing less than 10% PUCST or PUCRT were excluded from the analysis.

Statistical analysis

The tabulated efficacy data presented in this section of the biological dossier are showing the treatment means of the percentage control relative to the untreated. Instead of statistical tests across trials the minimum and maximum means of percentage infection or control of the individual trial means are presented in the summary tables.

Results

Table 3.2-50 — Efficacy of active substance components in GF-2800 (89g a.s./L fenpicoxamid, SC) and GF-2979 (150g a.s./L prothioconazole, SC)

Target	Number of trials	Infestation of the untreated control (unit)		% control					
				GF-2800 + GF-2979 100 g a.s./ha + 195 g a.s./ha		fenpicoxamid as GF-2800 100 g a.s./ha		Prothioconazole as GF-2979 195 g a.s./ha	
		Mean	Min. & Max.	Mean	Min. & Max.	Mean	Min. & Max.	Mean	Min. & Max.
SEPTTR	6	61.7%	26.5-100%	82.2%	69.4-95.6%	66.4%	52.7-80.87%	65.1%	44.4-85.5%
PUCST	5	30.7%	10.3-48.8%	84.5%	68.9-98%	44.4%	13.1-66.3%	80.5%	69.3-97.8%
PUCRT	9	35.4%	6.5-84.1%	89.7%	72.6-98.2%	51%	15.1-86%	77.7%	36.2-98.2%

Preliminary range finding studies were carried out in 2012 in which 20 trials were conducted against target diseases SEPTTR (6 trials), PUCST (5 trials) and PUCRT (9 trials). Fenpicoxamid as GF-2800 was applied alone at 100 and 130 g a.s./ha whilst prothioconazole as GF-2979 was applied alone at 112.5, 150 and 195 g a.s./ha. Mixtures of the two actives were then evaluated at 75+112.5 g a.s./ha, 75+150 g a.s./ha, 100+112.5 g a.s./ha, 100+150 g a.s./ha and 100+195 g a.s./ha and 130+195 g a.s./ha. The ratio data summarised in the BAD shows that the most effective ratio of fenpicoxamid (GF-2800) and prothioconazole (GF-2979) was 100+195 g a.s./ha and a higher dose of 130 g a.s./ha of fenpicoxamid provided no additional benefits in mixture and a lower dose of 150 g a.s./ha prothioconazole was not as effective. According to the presented results summarised in Table 3.2-50 with SEPTTR, PUCST and PUCRT based on data in the BAD, the application of GF-2800 at 100 g a.s./ha + prothioconazole at 195 g a.s./ha provided effective control against SEPTTR superior to the reference Proline 275 and GF-2800 or prothioconazole (GF-2979) applied alone. A similar trend was apparent when control of PUCST and PUCRT was observed and although the levels of control were slightly lower than the reference Ignite at 125 g a.i./ha they clearly were commercially acceptable exceeding 80% control.

As diseases often occur as complexes of several pathogens throughout a season, 1 to 2 application(s) of fenpicoxamid + prothioconazole at 100 g a.s./ha + 200 g a.s./ha should therefore be used to efficiently control all pathogens claimed on the label leading to greater than 80% mean control across the trials and pathogens.

3.2.1.11 Preliminary range finding studies for co-formulated products and comparing EC vs SC co-formulations fenpicoxamid + prothioconazole

During the course of the evaluation of this dossier it was noted by the zRMS that the data in this section was mostly based on results after two applications and using an earlier SC formulation. This was the intended GAP for fenpicoxamid containing products when the studies used in this section were generated (2013), during early pre-development using an earlier SC formulation. However, as the GAP for GF-3307 has now been revised to one application per crop and the GF-3307 formulation is radically different from these earlier SC formulations, it is considered that this section is no longer relevant to the proposed use of GF-3307. As a result, the information in this section has been removed. Full justification for the proposed mixture of the two fungicides in GF-3307 (fenpicoxamid and prothioconazole), based on the proposed GAP and formulation, can be found in sections 3.2.1.12 to 3.2.1.14.

Introduction

The fenpicoxamid + prothioconazole tank mixture ratio trials established in 2012 clearly demonstrated that the rate ratio of 100 g as/ha fenpicoxamid + 195 g as/ha of prothioconazole was the most suitable across the target fungal species. Moving forward into 2013, new EC and SC co-formulated products were tested with an the aim of taking fenpicoxamid + prothioconazole 100 g as/ha + 195 g as/ha dose ratio as confirmed in 2012 and further refining against key targets and as a formulated product. Eleven trials were conducted against target diseases SEPTTR (7 trials), Puccst (3 trials) and Puccrt (1 trial). In Can formulations of fenpicoxamid + prothioconazole were applied as both EC formulations (GF 3134 and GF 3126) and SC formulations (GF 2984 and GF 3128).

Fenpicoxamid + prothioconazole was applied as EC formulations GF 3134 (125 g as/ha fenpicoxamid + 188 g as/ha prothioconazole, EC) and GF 3126 (100 g as/ha fenpicoxamid + 200 g as/ha prothioconazole, EC) and SC formulations GF 2984 (125 g as/ha fenpicoxamid + 188 g as/ha prothioconazole, SC) and GF 3128 (100 g as/ha fenpicoxamid + 200 g as/ha prothioconazole, EC) so that there were two rate ratios for each formulation. According to the results, presented in the BAD, the application of EC formulation, GF 3126 (fenpicoxamid at 100 g as/ha + prothioconazole at 200 g as/ha) provided the most effective control across all diseases tested.

The reference product included in the trials was Aviator Xpro 225EC (75 g as/L bixafen + 150 g as/L prothioconazole, EC) applied at 0.75 L/ha in the SEPTTR and Puccst trials and 1.0 L/ha in the Puccrt trials.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (1), France (5), Germany (2) and the United Kingdom (3) in 2013.

On the basis of the EPPO standard 1/241 'Guidance on comparable climates', the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region.

One trial was included from the Mediterranean Zone (S. France) against Puccrt. This was included as it is considered that disease levels in this area are very high and so worst case for the performance of a plant protection product.

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB (11)
	Plot size	20-37.5 m ²
	Number of replications	4 (11)
Crop	Trials per crop	Winter wheat (11)
	Varieties per crop	Winter wheat: JB Asano (2), Aldric, Cordiale, Istabraq, Consort, Santiago, Miradoux, Baltimor, Altigo, Torch
Application	Crop stage (BBCH)* at application	Winter wheat: BBCH 30–52
	Timing Pest stage at application (1)	For the control of <i>S. tritici</i> the 1 st application was due when there was a risk of infection with SEPTTR or when the disease started to develop on the lower leaf levels. For PuccST and PuccRT application was made when the first pustules were visible.
	Number of applications	Winter wheat: 1 (1), 2 (10)
	Spray volumes	150–220 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area.
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2–3 weeks after application and/or at BBCH 75 in winter wheat and 3–5 and 6–8 weeks after application in spring wheat.
Other relevant information	e.g. Natural / artificial inoculation...	Natural infection
	e.g. Field / Greenhouse...	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR/PuccST/PuccRT is an abundant disease.

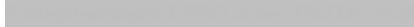
Materials and Methods

Testing facilities or organisations

Table 3.2-51 — Testing facilities involved by EPPO Zone in 2013 formulation comparison studies

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	EPPO Guideline	Trial Status
Central	Maritime	Germany	2013	DE13E7B022AS01	Dow AgroSciences, DE	PP 1/26	GEP
Central	Maritime	Germany	2013	DE13E7B022DD01	Dow AgroSciences, DE	PP 1/26	GEP
Southern	Maritime	France	2013	FR13E7B022MC01	Dow AgroSciences, FR	PP 1/26	GEP
Southern	Maritime	France	2013	FR13E7B022MC02C	Staphyt	PP 1/26	GEP
Southern	Maritime	France	2013	FR13E7B022MC03C	Phyliae, FR	PP 1/26	GEP
-	Maritime	UK	2013	GB13E7B022JF01	Dow AgroSciences, UK	PP 1/26	GEP
-	Maritime	UK	2013	GB13E7B022SE01C	ADAS-UK Ltd	PP 1/26	GEP
Southern	Mediterranean	France	2013	FR13E7B025MC02C	Anadiag France	PP 1/26	GEP
Northern	Maritime	Denmark	2013	DK13E7B028MN01C	DIAS – Danish Institute of	PP 1/26	GEP

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	EPPO Guideline	Trial Status
					Agricultural Sciences		
Southern	Maritime	France	2013	FR13E7B028MC01C	Anadiag France	PP 1/26	GEP
-	Maritime	UK	2013	GB13E7B028SE01C	Armstrong Fisher Ltd, UK	PP 1/26	GEP



Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR, PUCST and PUCRT are an abundant disease. For further trial site and application details see the BAD. The following map in Figure 3.2 35 provides an overview on the geographical distribution of the efficacy trials across the EU countries involved.

Figure 3.2 35: Geographical distribution of the 11 formulation comparison studies conducted in 2013



Formulations applied and rates

Test-product	Formulation type	Active-substance	Rate product L/ha	Rate gas/ha
GF-3134	EC	fenpicoxamid + prothioconazole	2.5	313
GF-3126	EC	fenpicoxamid + prothioconazole	2.0	300
GF-2984	SC	fenpicoxamid + prothioconazole	1.25	313
GF-3128	SC	fenpicoxamid + prothioconazole	1.25	300
Aviator Xpro 225EC	EC	Bixafen + prothioconazole	0.75-1.0	169-225

Experimental details

All 11 formulation comparison trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 20 m² and 37.5 m². The treatments in all trials were applied using self-propelled, or bicycle or knapsack precision plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 150 and 220 L/ha.

The formulations at the rates tested and the reference product Aviator Xpro 225EC were applied as a single or split application timing dependent upon disease target. Applications against SEPTTR were typically between BBCH 30 and BBCH 32 of winter wheat followed by a second timing between BBCH 35 and BBCH 52. The treatments were typically applied when SEPTTR had established on the lower leaves to stop the disease from further establishing. Against PuccST applications were timed to coincide with the first pustules visible, typically BBCH 30 to BBCH 32 with the second application between BBCH 37 to BBCH 41. Finally against PuccRT the application was a single application with a later timing accounting for the later disease presence of this pathogen. The single trial in France had application at BBCH 49. For further application details see the BAD.

Assessments for efficacy (% infection) were aimed at the timing application, 2-3 weeks, 4-6 weeks after application and/or at BBCH 75. Depending on the temperature SEPTTR has an incubation period of circa 2-4 weeks until first symptoms appear on the leaves. Therefore assessments made 2-4 weeks after application are not differentiating as the product as not kicked in yet. Assessments against PuccST and PuccRT were tailored according to the disease progression in the knowledge that the pathogen can cycle very quickly. As such assessments were made at least every 2 weeks – less if necessary.

The final assessments for efficacy summarized in this chapter of the documents were made approximately 6-9 weeks after application when differences between formulations and/or the reference products and the untreated control were most obvious. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTTR or leaves which were fully senesced in treated and untreated plots were excluded from summarization and leaves showing less than 10% PuccST or PuccRT were excluded from the analysis.

Statistical analysis

The tabulated efficacy data presented in this section of the biological dossier are showing the treatment means of the percentage control relative to the untreated. Instead of statistical tests across trials the minimum and maximum means of percentage infection or control of the individual trial means are presented in the summary tables.

Results

The eleven trials evaluated the performance of EC formulations versus SC formulations. According to the results, presented in the BAD [REDACTED], the application of EC formulation, GF 3126 (fenpicoxamid at 100 g as/ha + prothioconazole at 200 g as/ha) provided the most effective control across all diseases tested*. This trial series demonstrated the benefit of the EC delivery system and further confirmed that the 100 g as/ha fenpicoxamid + 200 g as/ha prothioconazole rate was the most effective dose ratio as shown in the 2012 dose ratio justification trials in the BAD [REDACTED]. As such the EC formulation GF 3126 was further enhanced with the addition of in-can wetting agents and coded GF 3307 which is the lead formulation containing** 100 g as/ha fenpicoxamid + 200 g as/ha prothioconazole.

zRMS comments:

*According to the BAD the efficacy in control of SEPTTR is concluded from 7 Maritime zone trials, in control of PuccST from 3 Maritime trials, and in control of PuccRT from 1 Mediterranean trial in TRZDU. The EC formulation performed on average 3 or 5 % higher compared to SC, in control of *Puccinia* or *Septoria*, respectively. The infection level in the untreated plots was on average 43%(25-77%, SEPTTR), 24%(12-43%, PuccST) and 100% (1 trial, PuccRT).

The applicant probably means that GF 3307 **delivers (and not: “contains”) 100 + 200 g fenpicoxamid + prothioconazole *per* 1 ha, when applied at 2.0 L/ha dose rate, as at that point (2013) the prototype GF 3126 used

in preliminary trials already contained the actives at the concentrations and ratio present in the test item GF 3307 actually submitted for authorization: 50 + 100; fenpicoxamid + prothioconazole.
For GF 3126 see also the non-numbered table *Formulations applied and rates*, in the preceding page.

3.2.1.12 Mix partner justification for fenpicoxamid + prothioconazole in the final formulation GF-3307 against *Septoria* and *Puccinia* in wheat

Introduction

GF-3307 has been developed in line with the guidance in EPPO standard PP1/306 (1) '*General principles for the development of co-formulated mixtures of plant protection products*'. The proposed combination of fenpicoxamid and prothioconazole in GF-3307 is intended to improved effectiveness of broad spectrum cereal disease control over products containing the single active substances and to bolster with resistance management. FRAC resistance management recommendations for both active substances (SBI (DMI) fungicides^[1] and fenpicoxamid^[2]) recommend applying both active substances in mixture (co-formulation) with a partner from a different cross-resistance group as a modifier to reduce the risk of resistance developing. This is discussed further in section 3.3.

The 1:2 ratio of fenpicoxamid and prothioconazole is already determined as the formulation GF-3307 and is authorised for use on wheat in UK, Germany, France, Belgium, Netherlands, Bulgaria with other registrations imminent and in future will be authorised for use on barley and oilseed rape. This is considered to be a favourable ratio for the formulated product showing no antagonism or phytotoxicity and to be used in a range of combinable crops to offer broad spectrum control. In addition to the above benefits of combining these two active substances in GF-3307, this co-formulation ratio also allows the dose rate of each active substance to be reduced when compared to products applied alone, while still maintaining effective control (See MED section 3.2.2). This complies with the advantages of a combined product detailed in EPPO Standard PP1/306 (1), which states that when using active substances in combination, whether against a single pest or a pest complex, lower rates may sometimes be used compared with when using solo products. The proposed maximum dose rate of 1.5 L/ha (5 g of fenpicoxamid/ha + 150 g of prothioconazole/ha) delivers lower doses of both active substances if applied alone because there are clear benefits of the combination (See MED section 3.2.2).

To demonstrate the benefit of combining the active substances and to justify the co-formulation, field trial data are presented in this section.

Field trials used in this section (14 trials on SEPTTR, 10 trials on PUCCRT and 13 trials on PUC CST trials) are those used in the effectiveness efficacy sections 3.2.3.1 to 3.2.3.3 in which the formulated product GF-3307 (50 g/L fenpicoxamid + 100 g/L prothioconazole) was tested at a comparable dose rate to the component active substances - fenpicoxamid (as the product GF-3308/GF-3311) and prothioconazole (as the product Proline 275). GF-3308 (50 g/L fenpicoxamid) was applied at 2.0 L/ha, or GF-3311 (66.7 g/L fenpicoxamid) was applied at 1.5 L/ha, to deliver 100 g of fenpicoxamid/ha, which was the dose rate proposed for fenpicoxamid when the trials were set up. Proline 275 (275 g/L prothioconazole) was applied at 0.72 L/ha in all trials, delivering 198 g of prothioconazole/ha, which is the authorized dose rate for this product on wheat, across the EU.

To enable a direct comparison to be made, the 2.0 L/ha dose rate of GF-3307 has been used in this section for wheat as it equates to the component products (100 g of fenpicoxamid/ha + 200 g of prothioconazole/ha) used at their maximum label dose in Europe so the benefits of the mixture are clear. Only wheat trials that included all three products at these dose rates are included. For barley the 1.5 L/ha dose rate has been used (75g/ha fenpicoxamid + 150 g/ha prothioconazole) as this represented the proposed maximum label dose supported in this dossier and fenpicoxamid will not be registered as a solo product in barley. **Note:** The proposed dose rate ranges from 1.0 to 1.5 L/ha (50-75 g of fenpicoxamid/ha + 100-150 g of prothioconazole/ha) depending on the country/EPPO climatic

[1] <https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>

[2] [https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-\(c4\)--fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2](https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-(c4)--fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2)

zone and the pest **this** offers growers flexibility to adjust dose to the conditions which supports resistance management and sustainable use of pesticides. This is especially critical to have a dose range in SE EPPO where growers cannot apply doses lower than the label dose.

SEPTTR in wheat

For SEPTTR, 14 trials were conducted in the Czech Republic (2), Germany (1), Latvia (3), Poland (3), Bulgaria (2) and Hungary (3) in the EPPO Maritime, North-East and South-East climatic zones, between 2014 and 2016. All trials were based on a single application (or assessment before a second application was applied). To be a robust test of the relative effectiveness of the products, only trials with >10% disease in the untreated have been used.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-13.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 3 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	fenpicoxamid + prothioconazole	2.0	300 (100+200)
GF-3308	EC	fenpicoxamid	2.0	100
GF-3311	EC	fenpicoxamid	1.5	100
Proline 275	EC	prothioconazole	0.72	198

Experimental details

The 14 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 300 L/ha.

GF-3307 was applied as a single application at BBCH 31-51 of winter wheat. The treatments were typically sprayed when SEPTTR had established on the lower leaves, to stop further disease development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 10% infection with SEPTTR or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were generally conducted on Leaf 1, with one on Leaf 2 and Leaf 3 and one on the whole plant.

Results

Across the 14 trials conducted in the EPPO Maritime, North-East and South-East climatic zones, the benefit of combining the active substances fenpicoxamid and prothioconazole in the product GF-3307

is clearly evident. The straight fenpicoxamid products applied at a dose rate of 100 g as/ha achieved 85.7% mean overall control of SEPTTR (range 70.7-97.2%) and the straight prothioconazole product applied at a dose rate of 198 g as/ha (0.72 L/ha of Proline 275) achieved 82.7% overall control (range 69.5-96.7%). GF-3307 applied at 2.0 L/ha (100 g as/ha fenpicoxamid + 200 g as/ha prothioconazole) achieved control above the two components at 92.8% (range 79.5-99.7%) Comparable results were reflected across all three EPPO zones.

Across these trials GF-3307 applied at BBCH 31-51 achieved control of SEPTTR significantly higher than straight fenpicoxamid in three trials, and significantly higher than straight prothioconazole in six trials. All other results were not significantly different, although the percentage control achieved by GF-3307 was higher than or equal to both straight fenpicoxamid and straight prothioconazole, in all trials.

The results are summarised in Table 3.2-52 below. The results of the individual trials are detailed in the BAD.

Table 3.2-52 Mix partner justification of GF-3307 applied for the control of SEPTTR in winter wheat in comparison to straight fenpicoxamid and straight prothioconazole. Summary of data from 14 trials conducted in the EPPO Maritime, North-East and South-East climatic zones. Assessment at 27-42 days after one application

Assessment at 27-42 days after one application											
EPPO zone	Number of trials	Application timing (BBCH)	Untreated: SEPTTR % infection		% control of SEPTTR						Significantly >, =, < Standards
					GF-3307 300 g as/ha		Proline 275 198 g as/ha		GF-3308/GF-3311 100 g as/ha		
			Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
All zones	14	31-51	30.9	11.3-61.0	92.8	79.5-99.7	82.7	69.5-96.7	85.7	70.7-97.2	6 >, 8 = P 3 >, 11 = F
Maritime	3	31-51	43.3	11.3-61.0	95.5	88.5-99.7	90.8	82.3-96.7	86.8	70.7-97.2	1 >, 2 = P 1 >, 2 = F
North-East	6	31-49	24.7	15.0-49.1	95.0	86.5-98.2	82.7	69.5-94.3	87.3	74.2-96.4	3 >, 3 = P 2 >, 4 =F
South-East	5	37-49	31.0	24.1-51.3	88.6	79.5-98.4	77.8	75.1-84.9	83.1	76.0-94.8	2 >, 3 = P 5 = F

P = Proline/prothioconazole, F = GF-3308/GF-3311/fenpicoxamid

Puccin on wheat

For Puccin, 10 trials were conducted in the Czech Republic (2), Germany (1), Poland (2), Bulgaria (2) and Hungary (3) in the EPPO Maritime, North-East and South-East climatic zones, between 2014 and 2016. All trials were based on a single application (or assessment before a second application was applied). To be a robust test of the relative effectiveness of the products, only trials with >10% disease in the untreated have been used. The trials were carried out by Dow AgroSciences, contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-14.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where Puccin is a prevalent disease. Puccin is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details, see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 4

provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	fenpicoxamid + prothioconazole	2.0	300 (100+200)
GF-3308	EC	fenpicoxamid	2.0	100
GF-3311	EC	fenpicoxamid	1.5	100
Proline 275	EC	prothioconazole	0.72	198

Experimental details

The 10 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 20m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 300 L/ha.

GF-3307 was applied as a single application at BBCH 37-61 of winter wheat. The treatments were typically sprayed when Puccrt had established on the lower leaves, to stop further disease development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 10% infection with Puccrt or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were all conducted on Leaf 1.

Results

Across the 10 trials conducted in the EPPO Maritime, North-East and South-East climatic zones, the benefit of combining the active substances fenpicoxamid and prothioconazole in the product GF-3307 is clearly evident. The straight fenpicoxamid products applied at a dose rate of 100 g as/ha achieved 74.9% mean overall control of Puccrt (range 33.3-100%) and the straight prothioconazole product applied at a dose rate of 198 g as/ha (0.72 L/ha of Proline 275) achieved 79.7% overall control (range 63.9-99.4%). GF-3307 applied at 2.0 L/ha (100 g as/ha fenpicoxamid + 200 g as/ha prothioconazole) achieved control above the two components at 92.0% (range 75.0-1007%) Comparable results were reflected across all three EPPO zones.

Across these trials GF-3307 applied at BBCH 37-61 achieved control of Puccrt significantly higher than straight fenpicoxamid in five trials, and significantly higher than straight prothioconazole in four trials. All other results were not significantly different, although the percentage control achieved by GF-3307 was higher than or equal to both straight fenpicoxamid and straight prothioconazole, in the majority of trials.

The results are summarised in Table 3.2-48 below. The results of the individual trials are detailed in the BAD.

Table 3.2-48 Mix partner justification of GF-3307 applied for the control of PuccST in winter wheat in comparison to straight fenpicoxamid and straight prothioconazole. Summary of data from 10 trials conducted in the EPPO Maritime, North-East and South-East climatic zones. Assessment at 23-42 days after one application

after one application											
EPPO Zone	Number of trials	Application timing (BBCH)	Untreated: PuccRT % infection		% control of PuccRT						Significantly >, =, < Standards
					GF-3307 300 g as/ha		Proline 275 198 g as/ha		GF-3308/GF- 3311 100 g as/ha		
			Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
All zones	10	37-61	33.6	11.9- 72.5	92.0	75.0- 100	79.7	63.9- 99.4	74.9	33.3- 100	4 >, 6 = P 5 >, 5 = F
Maritime	3	39-61	17.3	11.9- 22.5	91.1	89.7- 92.4	81.5	67.2- 99.4	63.2	33.3- 100	1 >, 2 = P 2 >, 1 = F
North- East	2	47-61	37.7	32.2- 43.1	96.6	95.3- 97.8	85.9	76.8- 95.0	89.3	82.6- 95.9	1 >, 1 = P 1 >, 1 = F
South- East	5	37-39	41.7	18.0- 72.5	90.7	75.0- 100	76.2	63.9- 92.3	76.1	55.3- 91.4	2 >, 3 = P 2 >, 3 = F

P = Proline/prothioconazole, F = GF-3308/GF-3311/fenpicoxamid

PuccST in wheat

For PuccST, 13 trials were conducted in Germany (4), Denmark (3), the UK (1), Latvia (1) and Hungary (4) in the EPPO Maritime, North-East and South-East climatic zones, between 2014 and 2016. All trials were based on a single application (or assessment before a second application was applied). To be a robust test of the relative effectiveness of the products, only trials with >10% disease in the untreated have been used.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-15.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PuccST is a prevalent disease. PuccST is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 5 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	fenpicoxamid + prothioconazole	2.0	300 (100+200)
GF-3308	EC	fenpicoxamid	2.0	100
GF-3311	EC	fenpicoxamid	1.5	100
Proline 275	EC	prothioconazole	0.72	198

Experimental details

The 13 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design

with 4 replicates and plot sizes ranging between 12m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 300 L/ha.

GF-3307 was applied as a single application at BBCH 31-45 of winter wheat. The treatments were typically sprayed when Puccst had established on the lower leaves, to stop further disease development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 10% infection with Puccst or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were generally conducted on Leaf 1, with a few on Leaf 2.

Results

Across the 13 trials conducted in the EPPO Maritime, North-East and South-East climatic zones, the benefit of combining the active substances fenpicoxamid and prothioconazole in the product GF-3307 is clearly evident. The straight fenpicoxamid products applied at a dose rate of 100 g as/ha achieved 71.1% mean overall control of Puccst (range 33.8-100%) and the straight prothioconazole product applied at a dose rate of 198 g as/ha (0.72 L/ha of Proline 275) achieved 89.0% overall control (range 73.7-100%). GF-3307 applied at 2.0 L/ha (100 g as/ha fenpicoxamid + 200 g as/ha prothioconazole) achieved control above the two components at 97.1% (range 91.2-100%) Comparable results were reflected across all three EPPO zones.

Across these trials GF-3307 applied at BBCH 31-45 achieved control of Puccst significantly higher than straight fenpicoxamid in five trials, and significantly higher than straight prothioconazole in two trials. All other results were not significantly different, although the percentage control achieved by GF-3307 was higher than or equal to both straight fenpicoxamid and straight prothioconazole, in all trials.

The results are summarised in Table 3.2-49 below. The results of the individual trials are detailed in the BAD.

Table 3.2-49 Mix partner justification of GF-3307 applied for the control of Puccst in winter wheat in comparison to straight fenpicoxamid and straight prothioconazole. Summary of data from 13 trials conducted in the EPPO Maritime, North-East and South-East climatic zones. Assessment at 27-42 28-49 days after one application

Days after one application											
EPPO Zone	Number of trials	Application timing (BBCH)	Untreated: PUCGST % infection		% control of PUCGST						Significantly >, =, < Standards
					GF-3307 300 g as/ha		Proline 275 198 g as/ha		GF-3308/GF-3311 100 g as/ha		
			Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
All zones	13	31-45	37.1	11.3-65.0	97.1	91.2-100	89.0	73.7-100	71.1	33.8-100	2 >, 11 = P 5 >, 8 = F
Maritime	8	31-45	30.6	12.6-65.0	97.0	91.2-100	90.5	81.9-98.0	77.9	33.3-95.8	1 >, 7 = P 2 >, 6 = F
North-East	1	37	40.6	-	100	-	99.8	-	80.0	-	1 = P 1 = F
South-East	4	39-45	49.1	11.3-63.8	96.6	94.1-100	83.3	73.7-100	55.4	44.1-77.9	1 >, 3 = P 3 >, 1 = F

P = Proline/prothioconazole, F = GF-3308/GF-3311/fenpicoxamid

3.2.1.13 Mix partner justification for fenpicoxamid + prothioconazole in the final formulation GF-3307 against *Rhynchosporium secalis* in barley.

Introduction

GF-3307 has been developed in line with the guidance in EPPO standard PP1/306 (1) '*General principles for the development of co-formulated mixtures of plant protection products*'. The proposed combination of fenpicoxamid and prothioconazole in GF-3307 is intended to improved effectiveness of broad spectrum cereal disease control over products containing the single active substances and to bolster with resistance management. FRAC resistance management recommendations for both active substances (SBI (DMI) fungicides^[1] and fenpicoxamid^[2]) recommend applying both active substances in mixture (co-formulation) with a partner from a different cross-resistance group as a modifier to reduce the risk of resistance developing. This is discussed further in section 3.3.

The 1:2 ratio of fenpicoxamid and prothioconazole is already determined as the formulation GF-3307 and is authorised for use on wheat in UK, Germany, France, Belgium, Netherlands, Bulgaria with other registrations imminent and in future will be authorised for use on barley and oilseed rape. This is considered to be a favourable ratio for the formulated product showing no antagonism or phytotoxicity and to be used in a range of combinable crops to offer broad spectrum control. In addition to the above benefits of combining these two active substances in GF-3307, this co-formulation ratio also allows the dose rate of each active substance to be reduced when compared to products applied alone, while still maintaining effective control (See MED section 3.2.2). This complies with the advantages of a combined product detailed in EPPO Standard PP1/306 (1), which states that when using active substances in combination, whether against a single pest or a pest complex, lower rates may sometimes be used compared with when using solo products. The proposed maximum dose rate of 1.5 L/ha (5 g of fenpicoxamid/ha + 150 g of prothioconazole/ha) delivers lower doses of both active substances if applied alone because there are clear benefits of the combination (See MED section 3.2.2).

To demonstrate the benefit of combining the active substances and to justify the co-formulation, field trial data are presented in this section. Field trials used in this section (9 trials) are the same as those in section 3.2.2.13 (RHYNSE) in which the formulated product GF-3307 (50 g/L fenpicoxamid + 100 g/L prothioconazole) was tested at a comparable dose rate to the component active substances - fenpicoxamid (as the product GF-3308) and prothioconazole (as the product Proline). GF-3308 (50 g/L fenpicoxamid) was applied at 1.5 L/ha in all trials (75g of fenpicoxamid/ha). Proline (250 g/L prothioconazole) was applied at 0.6 L/ha in all trials (150 g of prothioconazole/ha).

To enable a direct comparison to be made, the 1.5 L/ha dose rate of GF-3307 has been used in this section as it equates to the component products (75 g of fenpicoxamid/ha + 150 g of prothioconazole/ha), and only trials that included all three products at these dose rates are included. The trials were conducted in Belgium (1), France (2), Germany (2) and the UK (2) in the EPPO Maritime climatic zone and Poland (2) in the EPPO North-East climatic zone, between 2017 and 2019.

Materials and Methods

Trials were carried out by the testing facilities as listed in Table 3.2-25. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 15 provides an overview on the geographical distribution of the trials across the EU countries and Table 3.2-113 details the trial methodologies.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
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[1] <https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>

[2] [https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-\(c4\)--fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2](https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-(c4)--fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2)

GF-3307	EC	Fenpicoxamid + Prothioconazole	1.5	75 + 150
GF-3308	EC	Fenpicoxamid	1.5	75
Proline	EC	Prothioconazole	0.6	150

Experimental details

The 9 trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 19.5 m² and 36.0 m². Seven trials were carried out on winter barley and three on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha. All trials were based on a single application.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were senesced to a high degree in treated and untreated plots were excluded from the summary tables. Assessments used were Leaf 1, Leaf 2 or Leaf 3, as the highest assessed leaf in the trial or the leaf with high levels of disease.

Results

Across the 9 trials conducted in the EPPO Maritime and North-East climatic zones, the benefit of combining the active substances fenpicoxamid and prothioconazole in the product GF-3307 is clearly evident. The straight fenpicoxamid product applied at a dose rate of 75 g as/ha (1.5 L/ha of GF-3308) achieved 74.9% mean overall control of RHYNSE (range 40.0-3.5-93.4%) and the straight prothioconazole product applied at a dose rate of 150 g as/ha (0.6 L/ha of Proline) achieved 78.3% overall control of RHYNSE (range 49.1-100%). GF-3307 applied at 1.5 L/ha (75 g as/ha fenpicoxamid + 150 g as/ha prothioconazole) achieved control of RHYNSE above the two components at 88.4% (range 75.1-100%). Comparable results were reflected across both EPPO zones.

Across these trials GF-3307 applied at BBCH 31-51 achieved control significantly higher than straight fenpicoxamid and straight prothioconazole in one trial. All other results were not significantly different. The percentage control achieved by GF-3307 was higher than both straight fenpicoxamid and straight prothioconazole, in the majority of trials.

The results are summarised in Table 3.2-0 below. The results of the individual trials are detailed the BAD.

Table 3.2-50 Mix partner justification of GF-3307 applied for the control of RHYNSE in barley in comparison to straight fenpicoxamid (GF-3308) and straight prothioconazole (Proline). Summary of data from 9 trials conducted in the EPPO Maritime and North-East climatic zones. Assessment at 17-34 DAA

From 9 trials conducted in the EUO Maritime and North-East climatic zones. Assessment at 17-54 DAA											
EPPO Zone	Number of trials	Application timing (BBCH)	Untreated: RHYNSE % infection		% control of RHYNSE						Significantly >, =, < Standards
					GF-3307 1.5 L/ha		Proline 0.6 L/ha		GF-3308 1.5 L/ha		
			Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
All zones	9	31-51	14.6	7.6-32.5	88.4	75.1-100	78.3	49.1-100	74.9	40.0-93.4	1 >, 8 = P 1 >, 8 = F
Maritime	7	31-51	14.7	7.6-32.5	88.2	75.1-100	83.1	60.1-100	74.5	40.0-93.4	7 = P 7 = F
North-East	2	32-51	14.2	12.5-15.9	89.2	88.7-89.6	61.4	49.1-73.6	76.3	68.6-84.0	1 >, 1 = P 1 >, 1 = F

P = Proline/prothioconazole, F = GF-3308/fenpicoxamid

3.2.1.14 Mix partner justification for fenpicoxamid + prothioconazole in the final formulation GF-3307 against *Pyrenophora teres* in barley.

Introduction

GF-3307 has been developed in line with the guidance in EPPO standard PP1/306 (1) '*General principles for the development of co-formulated mixtures of plant protection products*'. The proposed combination of fenpicoxamid and prothioconazole in GF-3307 is intended to improved effectiveness of broad spectrum cereal disease control over products containing the single active substances and to bolster with resistance management. FRAC resistance management recommendations for both active substances (SBI (DMI) fungicides^[1] and fenpicoxamid^[2]) recommend applying both active substances in mixture (co-formulation) with a partner from a different cross-resistance group as a modifier to reduce the risk of resistance developing. This is discussed further in section 3.3.

The 1:2 ratio of fenpicoxamid and prothioconazole is already determined as the formulation GF-3307 and is authorised for use on wheat in UK, Germany, France, Belgium, Netherlands, Bulgaria with other registrations imminent and in future will be authorised for use on barley and oilseed rape. This is considered to be a favourable ratio for the formulated product showing no antagonism or phytotoxicity and to be used in a range of combinable crops to offer broad spectrum control. In addition to the above benefits of combining these two active substances in GF-3307, this co-formulation ratio also allows the dose rate of each active substance to be reduced when compared to products applied alone, while still maintaining effective control (See MED section 3.2.2). This complies with the advantages of a combined product detailed in EPPO Standard PP1/306 (1), which states that when using active substances in combination, whether against a single pest or a pest complex, lower rates may sometimes be used compared with when using solo products. The proposed maximum dose rate of 1.5 L/ha (5 g of fenpicoxamid/ha + 150 g of prothioconazole/ha) delivers lower doses of both active substances if applied alone because there are clear benefits of the combination (See MED section 3.2.2).

To demonstrate the benefit of combining the active substances and to justify the co-formulation, field trial data are presented in this section. Field trials used in this section (11 trials) are the same as those in section 3.2.2.14 (PYRNTE) in which the formulated product GF-3307 (50 g/L fenpicoxamid + 100 g/L prothioconazole) was tested at a comparable dose rate to the component active substances - fenpicoxamid (as the product GF-3308) and prothioconazole (as the product Proline). GF-3308 (50 g/L fenpicoxamid) was applied at 1.5 L/ha in all trials (75g of fenpicoxamid/ha). Proline (250 g/L prothioconazole) was applied at 0.6 L/ha in all trials (150 g of prothioconazole/ha).

To enable a direct comparison to be made, the 1.5 L/ha dose rate of GF-3307 has been used in this section as it equates to the component products (75 g of fenpicoxamid/ha + 150 g of prothioconazole/ha), and only trials that included all three products at these dose rates are included. The trials were conducted in Austria (1), Belgium (1) in the EPPO Maritime climatic zone, Latvia (1) and Poland (2) in the EPPO North-East climatic zone and Bulgaria (2) and Hungary (4) in the EPPO South-East climatic zone, between 2018 and 2019.

Materials and Methods

Trials were carried out by the testing facilities as listed in Table 3.2-26. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 16 provides an overview on the geographical distribution of trials across the EU countries involved and Table 3.2- details the trial methodologies.

^[1] <https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>

^[2] [https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-\(c4\)--fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2](https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-(c4)--fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2)

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	Fenpicoxamid + Prothioconazole	1.5	75 + 150
GF-3308	EC	Fenpicoxamid	1.5	75
Proline	EC	Prothioconazole	0.6	150

Experimental details

The 11 trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 25 m² and 30 m². Eight trials were carried out on winter barley and three on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha. All trials were based on a single application. Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were senesced to a high degree in treated and untreated plots were excluded from the summary tables. Assessments used were Leaf 1, Leaf 2 or Leaf 3, as the highest assessed leaf in the trial or the leaf with high levels of disease.

Results

Across the 11 trials conducted in the EPPO Maritime, North-East and South-East climatic zones, the benefit of combining the active substances fenpicoxamid and prothioconazole in the product GF-3307 is clearly evident. The straight fenpicoxamid product GF-3308 applied at a dose rate of 75 g as/ha (1.5 L/ha of GF-3308) achieved 59.7% mean overall control of PYRNTE (range 30.0-78.1%) and the straight prothioconazole product applied at a dose rate of 150 g as/ha (0.6 L/ha of Proline) achieved 70.4% overall control of PYRNTE (range 44.8-91.0%). GF-3307 applied at 1.5 L/ha (75 g as/ha fenpicoxamid + 150 g as/ha prothioconazole) achieved control of PYRNTE above the two components at 85.3% (range 80.3-91.6%). Comparable results were reflected across all EPPO zones.

Across these trials GF-3307 applied at BBCH 32-49 achieved control significantly higher than straight fenpicoxamid (GF-3308) in 9 trials, and significantly higher than straight prothioconazole in six trials. All other results were not significantly different. The percentage control achieved by GF-3307 was higher than both straight fenpicoxamid and straight prothioconazole, in all trials.

The results are summarised in Table 3.2-531 below. The results of the individual trials are detailed in the BAD.

Table 3.2-531 Mix partner justification of GF-3307 applied for the control of PYRNTE in barley in comparison to straight fenpicoxamid (GF-3308) and prothioconazole (Proline). Summary of data from 11 trials conducted in the EPPO Maritime, North-East and South-East climatic zones. Assessment at 17-43 DAA

DAA											
EPPO Zone	Number of trials	Application timing (BBCH)	Untreated: PYRNTE % infection		% control of PYRNTE						Significantly >, =, < Standards
					GF-3307 1.5 L/ha		Proline 0.6 L/ha		GF-3308 1.5 L/ha		
			Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
All zones	11	32-49	29.5	15.0-70.0	85.3	80.3-91.6	70.4	44.8-91.0	59.7	30.0-78.1	6 > P, 5= P 9 > F, 2 = F
Maritime	2	39-49	43.6	17.1-70.0	86.0	83.7-88.3	71.6	71.1-72.0	45.6	43.4-47.7	1 > P, 1= P 1 > F, 1 = F
North-East	3	32-49	20.2	16.1-25.0	84.2	80.3-88.0	53.0	44.8-69.1	70.1	54.7-78.1	3 > P 2 > F, 1 = F
South-East	6	37-49	29.4	15.0-40.0	85.6	81.1-91.6	78.7	71.2-91.1	59.3	30.0-68.8	2 > P, 4= P 6 > F

P = Proline/prothioconazole, F = GF-3308/fenpicoxamid

Summary and conclusions on the preliminary trials

GF-3307 is a formulation combining two active substances with different modes of action. Prothioconazole is a DMI fungicide, part of the SBI mode of action group, and fenpicoxamid is a picolinamide fungicides, part of the QII mode of action group. The combined product complies with the FRAC resistance management recommendations for both SBI (DMI) fungicides⁵ and fenpicoxamid⁶ which recommend applying both active substances in mixture (co-formulation) with a partner from a different cross-resistance group as a modifier to reduce the risk of resistance developing.

The combination of fenpicoxamid and prothioconazole in GF-3307 is an effective formulation for control of a wide range of foliar diseases in cereals, with clear benefits over the component active substances when used alone.

Glasshouse studies on SEPTTR, PUCCRT, RHYNSE and ERYSGH demonstrate that the formulation delivers preventative and curative control of these diseases that is comparable to or better than the component active substances.

For wheat (Table 3.2-52), field studies demonstrate that GF-3307 delivers a significant benefit over products containing the component active substances on SEPTTR, PUCCRT and PUCST, which are the three most important target diseases for GF-3307 on wheat. The combined product was the only product that consistently demonstrated over 90% control across all diseases. The results from these field trials are summarised in the following table:

Table 3.2-542 Summary of the mix partner justification trials (wheat, all EPPO Zones)

Target (EPPO code)	Number of trials	Untreated:% infection		% control					
				GF-3307 300 g as/ha		Proline 275 198 g a/ha		GF-3308/GF-3311 100 g as/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	14	30.9	11.3-61.0	92.8	79.5-99.7	82.7	69.5-96.7	85.7	70.7-97.2
PUCCRT	10	33.6	11.9-72.5	92.0	75.0-100	79.7	63.9-99.4	74.9	33.3-100
PUCST	13	37.1	11.3-65.0	97.1	91.2-100	89.0	73.7-100	71.1	33.8-100

It is therefore considered that for disease control in wheat, the combination of fenpicoxamid and prothioconazole in GF-3307 at a dose rate equivalent to the authorised dose rates of the component active substances, is fully justified.

Further studies in section 3.2.2 establish that the dose rate for GF-3307 can be further reduced to 1.0 to 1.5 L/ha (50-75 g of fenpicoxamid/ha + 100-175 g of prothioconazole/ha) and still provide the required levels of control of a wide range of foliar diseases in wheat.

For barley (Table 3.2-53), field studies demonstrate that GF-3307 at a dose rate of 1.5 L/ha delivers a significant benefit over products containing the component active substances at equivalent dose rates, on RHYNSE and PYRNTE, which are the two most important target diseases for GF-3307. The combined product was the only product that consistently demonstrated over 80% control across all trials. The results from these field trials are summarised in the following table:

Table 3.2-553 Summary of the mix partner justification trials (barley, all EPPO Zones)

Target (EPPO code)	Number of trials	Untreated:% infection		% control					
				GF-3307 225 g as/ha		Proline 250 150 g a/ha		GF-3308 75 g as/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RHYNSE	9	14.6	7.6-32.5	88.4	75.1-100	78.3	49.1-100	74.9	40.0-93.4
PRYNTE	11	29.5	15.0-70.0	85.3	80.3-91.6	70.4	44.8-91.0	59.7	30.0-78.1

⁵ <https://www.frac.info/frac-teams/working-groups/sbi-fungicides/recommendations-for-sbi>

⁶ [https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-\(c4\)--fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2](https://www.frac.info/docs/default-source/modes-of-action-without-recommendations-by-frac/group-21-(c4)--fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=20bd489a_2)

It is therefore considered that for disease control in barley, the combination of fenpicoxamid and prothioconazole in GF-3307 at the proposed maximum dose rate of 1.5 L/ha (equivalent to the dose rates of the component active substances: 75 g/ha fenpicoxamid + 150 g/ha prothioconazole), is fully justified.

Further studies in section 3.2.2 establish that the dose rate for GF-3307 can be further reduced to 1.0 to 1.5 L/ha (50-75 g of fenpicoxamid/ha + 100-175 g of prothioconazole/ha) and still provide the required levels of control of a wide range of foliar diseases in barley.

zRMS comments on the preliminary data set:

The preliminary tests and trials presented by the applicant do support the co-formulation of the actives, their selected ratio in the product, the formulation type, as well as the efficacy claims based on control of example pathogens in wheat and barley.

3.2.2 Minimum effective dose tests (KCP 6.2)

This chapter covers the minimum effective dose tests of GF-3307 for the control of foliar diseases in wheat, rye, triticale and barley. Data are presented across a range of diseases in wheat, rye, triticale and barley based on a single application of GF-3307 applied between BBCH 30-65.

The data in this section relate to the proposed claims for use of GF-3307:

- a dose of 1.5 L/ha in the EPPO Maritime countries of the Central EU Authorisation zone across all crops and targets,
- a dose rate range of 1.2-1.5 L/ha in the EPPO North-East countries of the Central EU Authorisation zone across all crops ~~(rate-target specific)~~ (lower dose of 1.0 L/ha on specific target diseases/crop),
- ~~a dose rate range of 1.0-1.5 L/ha in the EPPO South-East countries of the Central EU Authorisation zone on wheat and barley~~ a dose rate range of 1.2-1.5 L/ha in the EPPO South-East countries of the Central EU Authorisation zone on wheat and barley (lower dose of 1.0 L/ha on specific target diseases/crop)

For the proposed dose rates in the EPPO North-East and South-East, some barley trials in this dossier (and 2021 FUSASP trials on wheat) are based on a dose rate of 1.25 L/ha, instead of the proposed 1.2 L/ha. As these doses are within 10% of each other (4% difference), it is considered that the results at 1.25 L/ha are fully supportive of the proposed 1.2 L/ha dose rate. For wheat/SEPTTR/ERYSGT, much of the lower dose data is based on application at 0.9 L/ha, instead of the proposed 1.0 L/ha. As these doses are within 10% of each other (10% difference), it is considered that the results at 0.9 L/ha are fully supportive of the proposed 1.0 L/ha dose rate, which is a more practical dose rate for growers and avoids any potential pesticide wastage, as a 5 Litre pack size will treat multiples of 5 ha, at the 1.0 L/ha dose rate.

For constancy across the dossier, the dose rates used in the supporting trials (0.9, 0.9-1.0 or 1.0 L/ha, 1.2, 1.2-1.25 or 1.25 L/ha) are specified in the summary tables and individual trials summaries.

In some wheat trials a dose of 2.0 L/ha GF-3307 was included in the treatment list, but is not included in the MED section of this dossier as the 1.5 L/ha dose was already delivering between 80-90+ % control in many cases and was in many cases superior to the standard. In addition, the 2.0 L/ha dose is not supportable from a regulatory standpoint in some countries of the Central zone. Efficacy data presented within the tables in this section are from one key leaf layer, where differences were apparent at the time of assessment and which satisfy the minimum level of disease on the untreated leaves ($\geq 5\%$ infection). Where results on more than one leaf were available, the chosen leaf is the highest assessed leaf with $>5\%$ infection in the untreated, at assessment. In the majority of cases this is Leaf 1 or Leaf 2. It is considered that in all crops, Leaf 1 and Leaf 2 will have the most significant impact on yield of the crop, from disease control on that leaf and is therefore represents the best test of the effectiveness of GF-3307. Where lower leaves have been used, this due to higher levels of disease infection ($>10\%$) representing a more robust test of the product or in some trials, where assessments before a second is used, the highest available leaf or only available assessment.

Assessment timings chosen in the following summary tables are for effectiveness at approximately 4-7 weeks after application (28-49 DAA), to reflect the disease protection delivered by a single dose of GF-3307. The longer assessment timings have been used where disease levels were less than 5% at the earlier assessment timings. Early assessment timings (11-21 days) have been used when no appropriate later timings were available.

~~Note: Throughout this section, DAA = days after first/one application, DAB = days after second/two applications. 'DAA' is also used for trials where the single application treatment was applied as timing B and 'DAB' for the two application regime applied at timings A and C.~~

~~Where a trials report includes calculated percentage control values, those figures have been used. If the percentage control was not calculated in the trials report, (i.e. only percentage infection (severity) was recorded), the percentage control has been calculated using an Abbott's formula.~~

Note: Some of the supporting trials contained multiple application timings, but only the single application timing data have been used in this dossiers (apart from the 14 trials mentioned in the table below): Information on the application details from the efficacy trials is presented in Appendix 4 in the BAD.

For clarification, the results taken from the supporting trials were based on the following:

- Single dose regime (A timing in the reports). This was the case for the majority of trials.
- Single dose treatments at different timings (referred to as A or B timing in the reports). Depending on the disease levels at assessment, only one of these timings has been used.
- 2-dose regime (A + B timing in the reports): With the exception of the 14 trials listed in the table below, only assessments after application A and before a second application was applied (after A, but before B) have been used. These trials were not used for yield analysis due to the second application.
- Both single and 2-dose application regimes (B timing for a single dose and A + C timing for two-dose treatment). Some trials included both application regimes (referred to as the B timing for a single dose and A + C timing for two-dose treatment), the B timing treatments assessments have been used, as they matched the GAP (single dose applied between BBCH 30-69).

Throughout this section. DAA = days after first/one application, DAB = days after second/two applications. Results after two applications have been used from the following trials as disease did not develop in these trials until after the second application, 25-63 days after the first application, demonstrating how the disease can infect crops late in their development, and this is considered to be beyond the expected protection period for the first application of GF-3307. In addition, the assessed leaf (generally Leaf 1, or Leaf 2) had not emerged at the time of the first application in the majority of trials and would not have been protected by that spray. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. Full site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD. No two-dose trials have been used to support uses in the EPPO North-East zone.

Summary of two dose trials used in the dossier

Trial number	Country	Crop	Target Disease	1 st Application		2 nd Application		A-B interval (days)	Days after 2 nd Application disease found in trial (days after 1 st application)
				Timing (BBCH)	% infection	Timing (BBCH)	% infection		
HU14E7B014AB01C	HU	TRZAW	PUC CRT	32-33	0% all leaves	49-51	0% all leaves	22	41 days (63 days)
			PYR NTR	32-33	0% all leaves	49-51	0% all leaves		25 days (47 days)
HU15E7B012AB01C	HU	TRZAW	PUC CRT	32-33	0% all leaves	37-39	0% all leaves	11	15 days (26 days)
HU15E7B012AB02	HU	TRZAW	PUC CRT	32	0% all leaves	39-41	0% all leaves	21	14 days (35 days)
HU15E7B012AB02C	HU	TRZAW	PUC CRT	32-33	0% all leaves	39-41	0% all leaves	11	14 days (25 days)
HU15E7B040AB02C	HU	TRZAW	PUC CRT	33-34	0% all leaves	39-49	0% all leaves	15	13 days (28 days)
CZ15E7B010PV01C	CZ	TRZAW	ERYSGT	32	0% all leaves	43	0% all leaves	15	11 days (26 days)
CZ15E7B041PV01C	CZ	TRZAW	ERYSGT	31-32	3.0% L6	37-39	0% L4	27	-
CZ15E7B041PV03C	CZ	TRZAW	ERYSGT	31	0% all leaves	43-45	0% all leaves	23	25 days (48 days)
CZ18E7B007PV02C	CZ	HORVS	PUC-CHD	31-32	0% all leaves	47-49	0% all leaves	14	28 days (42 days)
DE18E7B007UB01C	DE	HORVW	PUC-CHD	37-39	0% all leaves	55-59	0% all leaves	13	20 days (33 days)
DE18E7B007UB4C	DE	HORVW	PUC-CHD	32	0% all leaves	49-51	0% all leaves	17	17 days (34 days)
GB17E7B046RH01	GB	HORVS	PUC-CHD	37	0% all leaves	49	0% all leaves	7	21 days (28 days)
GB17E7B049RH02	GB	HORVS	PUC-CHD	37	0% all leaves	45-49	0% all leaves	9	31 days (40 days)
SK18E7B008PV02C	SK	HORVS	PUC-CHD	31-32	0% all leaves	47-49	0% all leaves	16	26 days (42 days)

zRMS comments:

Despite the GAP claim of a single application per season, the total of 8 trials carried out in the Maritime zone and 6 – in the South-Eastern zone include double application of the test item, GF-3307. The zRMS was notified about the situation during the pre-submission meeting in 2021, as all of these trials were already complete at that time (they cover the years of 2015-2018). Their inclusion in the data set was accepted by the zRMS, as an exception, in view of the 39 additional efficacy trials that were to be and have been submitted now, in 2022, as an update.

The applicant argues that the infection levels before and following the first application made it impossible to carry out any reliable efficacy assessment, and the respective trial reports testify that this has indeed been the case. One may certainly dispute that the residue after the first application affects the control level seen later, even in organs still under development on the application day. That is why the zRMS has added the info on the A-B interval for each trial, in the table above (7-27 days). Taken that only in the two UK trials the interval was shorter than 10 days, considerations on the residue level affecting the target on the 0 DAAB would be splitting hair. The number of 14 trials with double application makes ca 5% of the 267 trials submitted overall, and to the opinion of zRMS this minor departure from the application pattern that is to be approved is acceptable.

Where a trials report includes calculated percentage control values, those figures have been used. If the percentage control was not calculated in the trials report *, (i.e. only percentage infection (severity) was recorded), the percentage control has been calculated using an Abbott's formula.

***zRMS comments:**

Across the dossier, considerable fraction of the efficacy data points submitted, including lower doses, is represented in the individual trial reports only by the raw values of PESSEV or, less frequently, also by the raw values of PESINC.

This often gives rise to inevitable discrepancy, between the efficacy calculated by zRMS: once for each treatment, as based on the mean treatment value of PESSEV, and the efficacy calculated from the raw data by the applicant (but not by the experimental units, and thus not included in the trial reports): using replicate (plot) values of PESSEV, followed by averaging 4 efficacy values into the mean efficacy of that treatment. As the result, in many cases the treatment efficacy means, calculated briefly by the evaluator as described above, cannot be linked unambiguously to the values in the BAD summaries, wherein they have been calculated otherwise, by the BAD authors. This sometimes makes summaries non-verifiable, or verifiable with lower accuracy. Regrettably, it is not possible for the zRMS to play with replicate data in order to verify any single mean value claimed in the dossier. Fortunately, where the experimental units did their job properly, the remaining mean efficacy values quoted in the BAD are in agreement with the respective trial reports, allowing for the proper evaluation of this part of data set, while assuming that the discrepancies observed in other parts are the result of no more but the incomplete data processing by the testing units.

Such situations should nonetheless be avoided, and closer attention should be paid to the issue in any future submissions. The zRMS kindly suggests that the efficacy calculation should be stipulated by the applicant from the experimental units, so that the mean values are submitted in the trial reports as the proper output of the ARM software, sparing the workload from both the applicant and the evaluator. To the knowledge of the zRMS presenting means calculated ready according to a declared formula is the standard, rather than a luxury, in producing contemporary trial reports.

Statistical analysis

The tabulated efficacy data presented in this section of the biological dossier include the treatment means of the percentage control, relative to the untreated. Across trials, the minimum and maximum means of percentage infection or control are also presented in the summary tables.

3.2.2.1 MED of GF-3307 for the control of SEPTTR in wheat

This section addresses the minimum effective dose (MED) of GF-3307, for the control of SEPTTR on wheat, when applied at the proposed label rate of 1.5 L/ha for the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone) and the proposed dose range of 1.0-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-564 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 19.3-25 m ² EPPO North-East: 15-36 m ² EPPO South-East: 12-27.5 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 8 TRZAW EPPO North-East: 12 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: 9 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Asano, Etana, Federer, Judita (2), Pionier, Socrates, Tobak EPPO North-East (TRZAW): Arkadia (2), Artis, Emil, Fidelius, Fredis, Sailor, Wydma. Zentos (3), Zyta EPPO North-East (TRZAS): Tybalt EPPO South-East: Antonius, Ariesan, Enova, GK Élet, Glosa, Iridium, Miranda, MV-Toldi, Sadovo 772
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-59 EPPO North-East: BBCH 31-51 EPPO South-East: BBCH 32-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of SEPTTR, applications were timed to cover both these situations, commencing when there was a risk of infection with SEPTTR or when the disease started to develop on the lower leaf levels, to applications against established infections.
	Number of applications	EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were conducted at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately aimed at the timing of application, 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field. Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent and challenging disease.

Introduction

In total, data from 24 30 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307 for the control of SEPTTR in winter wheat (TRZAW) and one on spring wheat (TRZAS). GF-3307 was tested at 1.5, 1.2 and 0.9/1.0 L/ha. **Note:** Results from 2020 and 2021 trials were based on a 1.0 L/ha lower dose. Results from these trials have been combined with those from earlier trials at the 0.9 L/ha dose, as these doses are within 10% of each other are therefore considered to be comparable dose rates. The trials were performed in accordance with the EPPO standard PP 1/225 '*Minimum effective dose*'. The reference standard products include Proline 275 applied at 0.72 L/ha, Aviator Xpro applied at 1.25 L/ha and Proline 250 applied at 0.6 L/ha. Proline 275 was applied in the majority of trial. Results for all standards have been combined in the following summary tables, however, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3307 in section 3.2.3.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Czech Republic (3) and Germany (3) in the EPPO Maritime climatic zone, Latvia (4) and Poland (7) in the EPPO North-East climatic zone, and Bulgaria (2), Hungary (4) and Romania (2) in the EPPO South-East climatic zone, between 2014 and 2020 2021.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates*', the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-13.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 3 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g /L fenpicoxamid + 100 g /L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6	150
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0-1.25	225-281

Experimental details

The 25 30 MED trials were conducted to GEP by officially recognized testing organisations and followed the appropriate EPPO standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12 m² and 36 m². The treatments in all trials, were applied

using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-300 L/ha.

GF-3307 was applied as a single application at BBCH 31-53 of wheat. The treatments were typically sprayed when SEPTTR had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were made at approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTTR or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were generally conducted on Leaf 1 and Leaf 2, with a few on Leaf 3 and Leaf 4 and one on the whole plant.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Six **Eight** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of SEPTTR in wheat, following a single application, applied at BBCH 31-~~53~~-**59** of the crop. The MED trials were conducted in the Czech Republic (~~3~~ **5**) and Germany (3) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4) so are considered to be a robust test of the product. One trial was based on assessment of the whole plant.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of ~~90.5%~~ **91.7%** (range 84.9-~~99.3%~~ **100%**) for SEPTTR, 17-42 days after application. Applied in the same trials, the 1.2 L/ha (80% rate/0.8N) dose of GF-3307 achieved a lower mean level of control of ~~84.6%~~ **87.2%**, with more variable results (range 74.7-~~97.7%~~ **100%**) and the 0.9 L/ha dose (~~60% rate/0.6N~~) **0.9/1.0 L/ha dose (60-67% rate/0.6-0.67N)** achieved ~~70.5%~~ **74.0%** control (range 57.9-87.9%). ~~In these trials GF 3307 achieved mean control of 91.3% using the proposed dose (range 80.6-100%).~~

Across all trials, control of SEPTTR demonstrated by the proposed dose rate of 1.5 L/ha was higher than the the reference standards at ~~78.9%~~ **82.4%** (~~four~~ **two** trials using the prothioconazole standard Proline and ~~two~~ **six** trials using the bixafen + prothioconazole standard, Aviator Xpro).

The results are summarised in Table 3.2-575 and individual trial results are detailed in the BAD.

Table 3.2-57 — Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60% dose rates against SEPTTR in winter wheat (TRZAW). Results from 6 trials conducted in the EPPO Maritime climatic zone between 2014-2020. Assessment at 17-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	6	51.8	11.3-87.5	70.5	57.9-87.9	84.6	74.7-97.7	90.5	84.9-99.3	78.9#	62.0-93.4

#Reference standards include prothioconazole applied at 180-198 g as/ha and two trials where Aviator Xpro at 1.25 L/ha used.

Table 3.2-58 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60-67% dose rates against SEPTTR in winter wheat (TRZAW). Results from 8 trials conducted in the EPPO Maritime climatic zone between 2014-2021. Assessment at 17-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3307 0.9-1.0 L/ha (60-67% rate)		GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	8	46.5	11.3-87.5	74.0	57.9-87.9	87.2	74.7-100	91.7	84.9-100	82.4	62.3-93.4

#Reference standards include prothioconazole applied at 198 g as/ha and Aviator Xpro at 1.0-1.25 L/ha used.

Summary and conclusions on the minimum effective dose (MED) for control of SEPTTR in winter wheat (EPPO Maritime climatic zone)

SEPTTR is a foliar disease which under favourable conditions builds up very rapidly and is important disease in wheat. Therefore, high levels of efficacy are required to successfully control this disease. SEPTTR is therefore an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of SEPTTR at the proposed dose rate of 1.5 L/ha. The proposed dose of 1.5 L/ha consistently achieved over 80% control, across all the trials. In all the trials, the proposed dose achieved levels of control higher than the 0.8N and 0.6-0.67N doses.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease, as both a protectant and curative fungicide, under the challenging environmental conditions most suitable for SEPTTR infections found within the EPPO Maritime climatic zone.

Proposed dose range of 1.0-1.5 L/ha for Poland (EPPO North-East climatic zone)

Thirteen GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the SEPTTR in winter wheat and spring wheat, following a single application applied at BBCH 31-51 of the crop. The MED trials were conducted in Latvia (4) and in Poland (9) in the EPPO North-East climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product. **Note:** In two trials, the latest assessment timing after a single application was 16-18 days. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP. **Note:** In the spring wheat trial, the latest assessment timing after a single application for SEPTTR control was 14 days. Later assessments were not undertaken for control of SEPTTR in this trial.

For winter wheat, a single application of GF-3307 applied at 1.5 L/ha achieved mean control of 92.4% (range 80.4-100%) for SEPTTR, 18-45 days after application across 11 trials. Applied in the same trials at 1.2 L/ha, GF-3307 achieved control of 86.2% (range 71.2-99.1%). Eight trials compared the 1.2 and 1.5 L/ha dose to the lower dose of 0.9/1.0 L/ha. In these trials the 1.5 L/ha achieved mean control of 92.9% compared to 86.0% for the 1.2 L/ha dose and 82.2% for the 0.9/1.0 L/ha dose. Across all trials, control of SEPTTR demonstrated by the proposed dose rate range of 0.9-1.5 L/ha was comparable to or higher than provided by the prothioconazole standard Proline (80.7-82.8%).

The results are summarised in Table 3.2-56 and individual trial results are detailed in the BAD.

Table 3.2-59 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and lower 0.9 L/ha dose against SEPTTR in winter wheat (TRZAW). Results from 10 trials conducted in the EPPO North-East climatic zone between 2014-2020. Assessment at 18-45 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	10	19.7	5.8-49.1	-	-	84.8	71.2-99.1	91.6	80.4-100	81.6#	58.5-97.1
North-East**	8	22.5	5.8-49.1	79.9	68.3-95.0	84.0	74.3-91.3	92.0	81.5-99.2	80.7#	58.5-94.3

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9 L/ha doses.

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha.

Table 3.2-60 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against SEPTTR in winter wheat (TRZAW). Results from 10-12 trials conducted in the EPPO North-East climatic zone between 2014-2020. Assessment at 18-45 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	11	18.6	5.8-49.1	-	-	86.2	71.2-99.1	92.4	80.4-100	82.8	58.5-97.1
North-East**	9	20.8	5.8-49.1	82.2	68.3-95.0	86.0	74.3-91.3	92.9	82.3 81.5-99.2	80.7	58.5-94.3

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9/1.0 L/ha doses.

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha.

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). This trial demonstrated a similar dose response to the winter wheat data with the 1.5 L/ha achieving 83.3% control, the 1.2 L/ha dose 74.9% control and the prothioconazole standard Proline 88.3% control. The results are summarised in Table 3.2-5757 and the results of the individual trials are detailed in the BAD.

Table 3.2-57 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.50 L/ha against SEPTTR in spring wheat (TRZAS). Results from one trial conducted in the EPPO North-East climatic zone in 2016. Assessment at 14 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3307 0.9 -1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	1	5.0	-	-	-	74.9	-	83.3	-	88.3	-

Summary and conclusions on the minimum effective dose (MED) for control of SEPTTR in winter wheat (EPPO North-East climatic zone)

SEPTTR is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of SEPTTR on winter wheat at the proposed dose rate range of 1.2-1.5 L/ha. Based

on the eight trials that compared all three doses directly, the proposed lower dose rate of 1.2 L/ha achieved overall control of 84.0%, compared to 79.9% for the 0.9 L/ha dose. The results for the higher dose rate of 1.5 L/ha (required for other diseases) demonstrate that high levels of control of SEPTTR (92.0%) will be achieved in mixed disease situations. The proposed dose rate range demonstrates control greater than, or equal to, the 0.9 L/ha dose across the majority of trials. In one trial on spring wheat a similar dose response was demonstrated.

It is considered that the proposed dose rate of 1.2 L/ha is the minimum effective dose of GF 3307 to deliver robust control of this disease on winter and spring wheat under a wide range of environmental conditions in Poland (EPPO North East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in wheat where FUSASP also occurs or is expected, the higher dose of 1.5 L/ha may be recommended for broad-spectrum disease control.

SEPTTR is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of SEPTTR on winter wheat at the proposed dose rate range of 1.0-1.5 L/ha. The proposed lower dose rate of 1.0 L/ha achieved overall control of 82.2% (across nine EPPO North-East trials). The results for the 1.2 L/ha dose rate required for other diseases, demonstrate that high levels of control of SEPTTR (86.2% across 11 EPPO North-East trials) where this dose is required in mixed disease situations. The results for the maximum dose rate of 1.5 L/ha (required for FUSASP) demonstrate that high levels of control of SEPTTR (92.4% across 11 EPPO North-East trials) where this dose is required in mixed disease situations. In one trial on spring wheat a comparable dose response was demonstrated.

It is considered that the proposed lower dose rate of 1.0 L/ha is the minimum effective dose of GF-3307 to deliver control of this disease on winter and spring wheat in a low disease situations. However, as cereal diseases may occur together, for higher disease pressure disease situations in wheat, or where FUSASP also occurs or is expected, the higher doses of 1.2 or 1.5 L/ha may be recommended for broad spectrum disease control.

A dose range of ~~1.2~~ 1.0-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose range of 1.0-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

~~Eight~~ **Nine** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the SEPTTR in winter wheat, following a single application applied at BBCH 37-~~47-49~~ of the crop. The MED trials were conducted in Bulgaria (2), Hungary (4) and Romania (2 ~~3~~) in the EPPO South-East climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product.

Across all ~~eight~~ **nine** trials, a single application of GF-3307 applied at 1.5 L/ha achieved mean control of ~~87.7~~ **87.9%** (range 77.7-100%) for SEPTTR, 22-43 days after application. Applied in the same trials at 1.2 L/ha, GF-3307 achieved control of ~~82.9~~ **83.4%** (range 74.5-97.5%). ~~Six~~ **Seven** trials compared the 1.2 and 1.5 L/ha dose with the lower dose of ~~1.0 L/ha~~ **0.9/1.0 L/ha**. In these trials the 1.5 L/ha achieved mean control of ~~90.6~~ **90.5%** compared to ~~85.6~~ **85.9%** for the 1.2 L/ha dose and ~~78.4~~ **79.3%** for the ~~0.9 L/ha~~ **0.9/1.0 L/ha** dose. Across all trials, control of SEPTTR demonstrated by the proposed dose rate range of ~~1.0-1.5~~ **0.9-1.5 L/ha** was comparable to or higher than the prothioconazole standard Proline (~~82.0~~ **82.8%** across ~~eight~~ **nine** trials and ~~84.2~~ **85.0%** across ~~six~~ **seven** trials).

The results are summarised in Table 3.2-6158 and individual trial results are detailed in the BAD.

Table 3.2-61 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.0-1.5 L/ha against SEPTTR in winter wheat (TRZAW). Results from 8 trials conducted in the EPPO South-East climatic zone between 2014-2020. Assessment at 22-43 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East*	8	22.6	6.0-51.3	-	-	82.9	74.5-97.5	87.7	77.7-100	82.0#	75.1
South-East**	6	22.0	6.0-51.3	78.4	64.2-97.5	85.6	82.0-97.5	90.6	83.3-100	84.2#	75.9-97.5

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha.

Table 3.2-62 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against SEPTTR in winter wheat (TRZAW). Results from 9 trials conducted in the EPPO South-East climatic zone between 2014-2021. Assessment at 22-43 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTTR		% control of SEPTTR							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East*	9	21.3	6.0-51.3	-	-	83.4	74.5-97.5	87.9	77.7-100	82.8#	75.1-97.5
South-East**	7	20.4	6.0-51.3	79.3	64.2-97.5	85.9	82.0-97.5	90.5	83.3-100	85.0#	75.9-97.5

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9/1.0 L/ha doses.

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha.

Summary and conclusions on the minimum effective dose (MED) range of 1.0-1.5 L/ha for control of SEPTTR in winter wheat (EPPO South-East climatic zone)

SEPTTR is an important target disease for GF-3307 and the data reported demonstrate that it provides effective control of SEPTTR at the proposed dose rate range (1.0-1.5 L/ha). Based on the ~~six~~ **seven** trials that compared all three doses directly, the maximum dose of 1.5 L/ha gave the highest level of control (~~90.6~~ **90.5**%) and will be recommended for all situations, including where varietal resistance to SEPTTR is low and fungicide resistance is a concern or in geographical locations which have a history of severe SEPTTR infections. In other situations, which may be more typical for SEPTTR in the South East EPPO zone, where disease pressure is lower and where FUSASP is not present or expected, a dose of 1.2 L/ha will give sufficient control of SEPTTR in the EPPO South-East climatic zone (~~85.6~~ **85.9**% demonstrated). For situations with low disease pressure such as earlier in the season, a dose of 1.0 L/ha will give sufficient control of SEPTTR in EPPO South-East conditions (~~78.4~~ **79.3**% control demonstrated).

It is considered that the proposed dose rate range of 1.0-1.5 L/ha is the minimum effective dose to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.2 MED of GF-3307 for the control of Puccinia in winter wheat

This section addresses the minimum effective dose (MED) of GF-3307, for the control of Puccinia in winter wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in and Poland (EPPO North-East climatic zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-63 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 19.3-30 m ² EPPO North-East: 15-36 m ² EPPO South-East: 20-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 11 TRZAW EPPO North-East: 8 TRZAW EPPO South-East: 8 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Artist, Bussard, Federer, Hermann, Judita, Muza, Patras, Pionier, Socrates, Tobak (2) EPPO North-East: Bogatka, Emil, Princeps, Sailor (2), Sukces, Turnia, Zyta EPPO South-East: Balaton (2), Dagmar, Enova, GK Élet, Iridium, MV Buzogany, Sadovo 772
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 37-61 EPPO North-East: BBCH 39-61 EPPO South-East: BBCH 37-51
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of Puccinia applications were timed to cover these situations from commencing when there was a risk of infection with Puccinia or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease.

Introduction

In total, data from 24 27 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of Puccinia in winter wheat (TRZAW). GF-3307 was tested at 1.5, 1.2 and 0.9/1.0 L/ha. **Note:** Results from 2020 and 2021 trials were based on a 1.0 L/ha lower dose. Results from these trials have been combined with those from earlier trials at the 0.9 L/ha dose, as these doses are within 10% of each other are therefore considered to be comparable dose rates. The trials were performed in accordance with the EPPO Standard PP 1/225 ‘Minimum effective dose’. The reference standard products include Proline 275 applied at 0.72 L/ha, Aviator Xpro applied at 1.0-1.25 L/ha and Proline 250 applied at 0.6 L/ha. Results for all standards have been combined in the following summary tables, however, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3307 in section 3.2.3.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO Standards and are officially recognized by the competent authorities to carry out registration field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (1), the Czech Republic (4) and Germany (4) in the EPPO Maritime climatic zone, Poland (6) in the EPPO North-East climatic zone, also Bulgaria (2) and Hungary (7 5) and Slovakia (1) in the EPPO South-East climatic zone, between 2014 and 2020 2021.

In line with EPPO Standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone includes countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-14.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 4 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6 0.72	150 180
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0-1.25	225-281

Experimental details

The 24 27 MED trials were conducted according to GEP, by officially recognized testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 19.3 m² and 36 m². The treatments in all trials, were

applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-300 L/ha.

~~In the EPPO Maritime and North East climatic zone trials,~~

In all trials, GF-3307 was applied as a single application at BBCH 37-61 of winter wheat. The treatments were typically sprayed when Puccinia striiformis (PuccRT) had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

~~The EPPO South East climatic zone trials were set up to support both a single and two dose regime and in many trials included both regimes. PuccRT is generally a late season disease, that spreads quickly during periods of hot weather. Some of the trials were targeted specifically at PuccRT and were based on a single application from BBCH 37-49, to provide mainly curative control of the disease. However, other trials were designed as general disease trials, with the first applications potentially applied too early for effective control of PuccRT, followed by a second application. Three Hungarian trials which were based on a two dose regime (HU14E7B014AB01C, HU15E7B012AB02 and HU15E7B040AB02C) and PuccRT did not develop until 13-41 days after the second application. In these trials, the first applications were made at BBCH 32-34 of the crop and the second applications were made at BBCH 39-51. PuccRT did not develop in these trials until 28-63 days after the first application, demonstrating how the disease can infect crops late in their development, and this is considered to be beyond the expected protection period for the first application of GF-3307 (see summary of disease levels at application for these trials below). In addition, the assessed leaf (Leaf 1) had not emerged at the time of the first application (BBCH 32-34) and would not have been protected by that spray. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. For full site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.~~

Summary of disease levels at application in two dose trials

Trial number	1 st Application timing (BBCH)	PuccRT % infection at 1 st application	2 nd Application timing (BBCH)	PuccRT % infection at 2 nd application	Days after 2 nd application PuccRT found in trial (days after 1 st application)
HU14E7B014AB01C	32-33	0% all leaves	49-51	0% all leaves	41 days (63 days)
HU15E7B012AB02	32	0% all leaves	39	0% all leaves	14 days (35 days)
HU15E7B040AB02C	33-34	0% all leaves	43-45	0% all leaves	13 days (28 days)

Assessments for efficacy (% infection) were made at approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PuccRT or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were generally conducted on Leaf 1.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

~~Nine~~ **Eleven** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of PuccRT in wheat, following a single application, applied at BBCH 37-61 of the crop. The MED trials were conducted in Austria (1), the Czech Republic (4) and Germany (4) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1) so are considered to be a robust test of the product. One trial did not specify which leaf.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of ~~85.5~~ **86.1**% (range 70.2-94.3%) for PuccRT, 29-47 days after application. Applied in the same trials, the 1.2 L/ha (80% rate/0.8N) of GF-3307 achieved a lower mean level of control of ~~83.3~~ **84.1**%, with more variable results (range 66.2-92.4%) and the ~~0.9 L/ha dose (60% rate/0.6N)~~ **0.9/1.0 L/ha dose (60-67% rate/0.6-0.67N)** demonstrated ~~77.9~~ **78.9**% overall control (range 55.6-94.0%).

Across all trials, control of Puccinia demonstrated by the proposed dose rate of 1.5 L/ha was **almost** comparable with the reference standard (83.6 92.2%).
The results are summarised in Table 3.2-64 and individual trial results are detailed in the BAD.

Table 3.2-64 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60% dose rates against Puccinia in winter wheat (TRZAW). Results from 9 trials conducted in the EPPO Maritime climatic zone between 2014 and 2020. Assessment at 29-47 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccinia		% control of Puccinia							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	9	22.6	5.6-74.8	77.9	55.6-94.0	83.3	66.2-92.4	85.5	70.2-94.3	83.6#	27.7-98.7

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha and four trials using Aviator Xpro applied at 1.25 L/ha.

Table 3.2-65 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60-67% dose rates against Puccinia in winter wheat (TRZAW). Results from 11 trials conducted in the EPPO Maritime climatic zone between 2014 and 2020. Assessment at 29-47 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccinia		% control of Puccinia							
				GF-3307 0.9-1.0 L/ha (60-67% rate)		GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	11	25.9	5.6-74.8	78.9	55.6-94.0	84.1	66.2-92.4	86.1	70.2-94.3	92.2	27.7-98.7 77.8-98.7

Summary and conclusions on the minimum effective dose (MED) for control of Puccinia in winter wheat (EPPO Maritime climatic zone)

Puccinia is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of Puccinia at the proposed dose rate of 1.5 L/ha. The proposed dose of 1.5 L/ha demonstrated the highest level of control (85.5 86.1%) and achieved levels of control higher than the 0.8N and 0.6/0.67N dose in all trials.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required for the control of Puccinia in winter wheat, in the EPPO Maritime climatic zone.

Proposed dose rate range 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

Six **Eight** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the Puccinia in winter wheat, following a single application applied at BBCH 39-61 of the crop. The MED trials were conducted in Poland (6 8) in the EPPO North-East climatic zone. Assessments across all trials were on Leaf 1, so was considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 91.7 92.2% (range 83.3-97.7%) for Puccinia, 23-49 days after application. Applied in the same trials, the 1.2 L/ha dose of GF-3307 achieved a good mean level of control of 89.5 89.6% (range 84.2-98.4%) and the 0.9 0.9/1.0 L/ha dose, lower but good control of 83.9 83.3%, with more variable results (range 65.2-98.6%). Across all trials, control of Puccinia demonstrated by the proposed dose rate range was comparable to, or higher than, the prothioconazole standard Proline the reference standards (85.9 82.2% overall

control).

The results are summarised in Table 3.2-661 and individual trial results are detailed in the BAD.

Table 3.2-66 — Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and lower 0.9 L/ha dose against Puccrt in winter wheat (TRZAW). Results from 6 trials conducted in the EPPO North-East climatic between 2014-2020. Assessment at 23-49 days after one application.

EPPO-Zone	Number of trials	Untreated control % infection Puccrt		% control of Puccrt							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	6	29.2	6.0-43.1	83.9	65.2-98.6	89.5	84.2-98.4	91.7	83.3-97.7	85.9#	62.0-95.0

#Reference standard results are based on 180-198 g as/ha and three trials using Aviator Xpro applied at 1.25 L/ha.

Table 3.2-67 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against Puccrt in winter wheat (TRZAW). Results from 8 trials conducted in the EPPO North-East climatic between 2014-2021. Assessment at 23-49 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccrt		% control of Puccrt							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	8	30.2	6.0-50.0	83.3	65.2-98.6	89.6	84.2-98.4	92.2	83.3-97.7	82.2	57.7-95.0

#Reference standard results are based on 180-198 g as/ha and Aviator Xpro applied at 1.25 L/ha.

Summary and conclusions on the minimum effective dose (MED) for the control of Puccrt in winter wheat (EPPO North-East climatic zone)

Puccrt is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control on wheat at the proposed dose rate range of 1.2-1.5 L/ha. The proposed lower dose rate of 1.2 L/ha achieved overall control of 89.5 89.6% on winter wheat, compared to 83.9 83.3% for the 0.9 0.9/1.0 L/ha dose (across all six trials). The results for the higher dose rate of 1.5 L/ha (required for other diseases) demonstrate that high levels of control of Puccrt (91.7 92.2%) will be achieved in mixed disease situations. The proposed dose rate range demonstrated control greater than the 0.9 0.9/1.0 L/ha dose across all trials.

It is considered that the proposed dose rate of 1.2 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease (Puccrt) on winter wheat under a wide range of environmental conditions in Poland (EPPO North-East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in wheat where FUSASP may occur or be expected, the higher dose of 1.5 L/ha may be recommended for broad spectrum disease control.

A dose range of 1.2-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Nine Eight GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the Puccrt in winter wheat, following application applied at BBCH 37-51 of the crop. The MED trials were conducted in Bulgaria (2) and Hungary (7 5) and Slovakia (1) in the EPPO South-East climatic zone. Assessments across all trials were on either Leaf 1 and was considered to be a robust test of the product.

Results for three trials are based on a two-dose regime. In these trials Puccrt did not develop until 13-41 days after the second application, 28-63 days after the first application, which is beyond the

protection period the first application of GF-3307 could be expected to deliver. It is also considered that as the first application was at BBCH 32-34 of the crop, the assessed leaf (Leaf 1) had not emerged at this timing and would not be protected by the first application. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. A comparison of control achieved by the single and two dose trials is presented in section 3.2.3 and confirm the comparability of the dose regimes in these trials.

Across all ~~six~~ **eight** trials, GF-3307 achieved mean control of ~~89.4~~ **90.2%** (range 69.4-100%) of Puccrt for the maximum 1.5 L/ha dose and ~~81.4~~ **84.0%** (range 62.5-95.2%) for the 1.2 L/ha dose, 28-42 days after application. ~~Five~~ **Four** trials also compared the proposed dose range, with a dose of ~~0.9~~ **0.9/1.0** L/ha, which demonstrated ~~72.1~~ **83.3%** overall control compared to ~~93.8~~ **96.6%** for the 1.5 L/ha dose and ~~85.6~~ **91.8 %** for the 1.2 L/ha dose rate. Across all trials, control of Puccrt demonstrated by the proposed dose rate range was comparable to, or higher than, the reference standards Proline (~~78.8% overall control~~ **84.2% across all eight trials and 93.9% in the four trials which included the 0.9/1.0 L/ha dose**).

The results are summarised in Table 3.2-68 and individual trial results are detailed in the BAD.

Table 3.2-68 — Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and lower 0.9 L/ha dose against Puccrt in winter wheat (TRZAW). Results from 9 trials conducted in the EPPO South-East climatic zone between 2014-2020. Assessment at 28-42 days after application.

EPPO Zone	Number of trials	Untreated control % infection Puccrt		% control of Puccrt							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East*	6	41.7	10.5-72.5	-	-	81.4	62.5-95.2	89.4	69.4-100	78.8#	59.1-92.9
South-East**	5	47.9	10.5-72.5	72.1	59.3-82.1	85.6	68.9-95.2	93.8	84.1-100	82.2#	59.1-92.9

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9 L/ha doses.

#Reference standards based on prothioconazole applied at 180-198 g as/ha

Table 3.2-69 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against Puccrt in winter wheat (TRZAW). Results from 8 trials conducted in the EPPO South-East climatic zone between 2016-2021. Assessment at 28-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccrt		% control of Puccrt							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East*	8	31.0	7.0-72.5	-	-	84.0	62.5-95.2	90.2	69.4-100	84.2	63.9-100
South-East**	4	28.0	7.0-72.5	83.3	72.1-93.1	91.8	85.6-95.2	96.6	92.9-100	93.9	82.8-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9/1.0 L/ha doses.

#Reference standards based on prothioconazole applied at 180-198 g as/ha

Summary and conclusions on the minimum effective dose (MED) range of 1.2-1.5 L/ha for control of Puccrt in winter wheat (EPPO South-East climatic zone)

Puccrt is an important target disease for GF-3307 and the data reported demonstrate that it provides effective control at the proposed dose rate range (1.2-1.5 L/ha). Based on the ~~five~~ **four** trials that compared all three doses directly, the maximum dose of 1.5 L/ha gave the highest level of control (~~93.8~~ **96.6%**) and will be recommended for all situations, ~~including~~, including where varietal

resistance to Puccinia blight (Puccinia) is low and fungicide resistance is a concern or in geographical locations which have a history of severe Puccinia infections. In other situations, where disease pressure is lower, a dose of 1.2 L/ha will give sufficient control of Puccinia in the EPPO South-East climatic zone (85.6-91.8% control demonstrated). It is considered that the 0.9-1.0 L/ha will not give sufficient control of this important disease in EPPO South-East conditions (72.1-83.3% control demonstrated). It is considered that the proposed dose rate range of 1.2-1.5 L/ha is the minimum effective dose to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.3 MED of GF-3307 for the control of PuccST in wheat

This section addresses the minimum effective dose (MED) of GF-3307, for the control of PuccST on winter wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-703 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 13.5-37.5 m ² EPPO North-East: 20-36 m ² EPPO South-East: 20-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 8 TRZAW EPPO North-East: 4 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: 5 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Akteur, Ambition, JB Asano (2), Santiago, Solstice, Substance (2) EPPO North-East (TRZAW): Arkadia, Fredis, Hondia, Tonacja , Zyta EPPO North-East (TRZAS): Tybalt EPPO South-East: Genius, GK Élet (2), Iridium, Miranda
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-45 EPPO North-East: BBCH 37-51 EPPO South-East: BBCH 39-47
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of PuccST applications were timed to cover these situations from commencing when there was a risk of infection with PuccST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PuccST is a prevalent disease.

Introduction

In total, data from 47 19 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of Puccinia in winter wheat (TRZAW) and one on spring wheat (TRZAS). GF-3307 was tested at 1.5, 1.2 and 0.9 L/ha. **Note:** Results from 2020 and 2021 trials were based on a 1.0 L/ha lower dose. Results from these trials have been combined with those from earlier trials at the 0.9 L/ha dose, as these doses are within 10% of each other are therefore considered to be comparable dose rates. The trials were performed in accordance with the EPPO Standard PP 1/225 ‘Minimum effective dose’. The reference standard products include Proline 275 applied at 0.72 L/ha and Proline 250 applied at 0.6 L/ha. **Proline 275 and Proline 250 applied at 0.72 L/ha and Aviator Xpro applied at 1.0 L/ha.** Proline 275 was applied in the majority of trials. Results for all standards have been combined in the following summary tables, however, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3307 in section 3.2.3.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (3), Germany (3) and the UK (2) in the EPPO Maritime climatic zone, Latvia (1) and Poland (4 5) in the EPPO North-East climatic zone, as well as Hungary (4) and Romania (1) in the EPPO South-East climatic zone, between 2014 and 2020 2021.

On the basis of the EPPO Standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-15.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 5 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6	150
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0	225

Experimental details

The 18 MED trials were conducted to GEP, by officially recognized testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 13.5 m² and 37.5 m². **Eighteen trials were on winter wheat and one trial on spring wheat.** The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-300 L/ha.

GF-3307 was applied as a single application at BBCH 31-51 of winter and spring wheat. The treatments were typically sprayed when Puccst had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with Puccst or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were generally conducted on Leaf 1, with some on Leaf 2.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Eight GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of Puccst in wheat, following a single application, applied at BBCH 31-45 of the crop. The MED trials were conducted in Denmark (3), Germany (3) and the UK (2) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 or Leaf 2) so are considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 94.4% (range 87.5-100%) for Puccst, 25-41 days after application. Applied in the same trials at 1.2 L/ha (80% rate/0.8N), GF-3307 achieved mean of control of 91.4% (range 81.5-100%) and a dose of 0.9 L/ha (60% rate/0.6N) achieved 90.1% control with more variable results (range 78.0-98.5%).

Across all trials, control of Puccst demonstrated by the proposed dose rate of 1.5 L/ha was comparable with the prothioconazole standard Proline (92.4% across all trials).

The results are summarised in Table 3.2-714 and individual trial results are detailed in the BAD.

Table 3.2-714 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60% dose rates against Puccst in winter wheat (TRZAW). Results from 8 trials conducted in the EPPO Maritime climatic zone between 2014-2016. Assessment at 25-41 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	8	30.0	7.4-65.0	90.1	78.0-98.5	91.4	81.5-100	94.4	87.5-100	92.4	81.9-100

Summary and conclusions on the minimum effective dose (MED) for control of Puccst in winter wheat (EPPO Maritime climatic zone)

Puccst is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of Puccst at the proposed dose rate of 1.5 L/ha. The proposed dose of 1.5 L/ha demonstrated the highest level of control and was the only dose to achieve control >85% in all trials.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required to deliver robust control of this disease, under a wide range of environmental conditions in the EPPO Maritime climatic zone.

Proposed dose range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

~~Five~~ **Six** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the Puccst in winter wheat and spring wheat, following a single application applied at BBCH 37-51 of the crop. The MED trials were conducted in Latvia (1) and Poland (4 **5**) in the EPPO North-East climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 or Leaf 2), so are considered to be a robust test of the product.

For winter wheat, a single application of GF-3307 achieved mean control of ~~95.7~~ **95.6**% (range 83.6-100%) of Puccst for the maximum 1.5 L/ha dose and 90.2% (range 69.6-100%) for the 1.2 L/ha dose, across ~~four~~ **five** trials, 28-37 days after application. ~~One trial~~ **Two trials** also compared the proposed dose range, with a dose of ~~0.9~~ **1.0**L/ha, which demonstrated ~~63.2~~ **70.4**% control compared to ~~83.6~~ **89.6**% for the 1.5 L/ha dose and ~~69.6~~ **80.0**% for the 1.2 L/ha dose rate. Across all trials, control of Puccst demonstrated by the proposed dose rate range was comparable to, ~~or higher than, the prothioconazole standard Proline~~ **the reference standards** (~~81.6~~ **91.7**% overall control) .

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These three trials were conducted in Germany and demonstrate a comparable dose response to the EPPO North-East data with the 1.5 L/ha achieving the highest level of control of 91.8% compared to 90.0% for the 1.2 L/ha dose and 88.5% for the ~~0.9~~ **0.9/1.0**L/ha dose. Combined with the ~~four~~ **five** EPPO North-East trials, these give overall control of Puccst across ~~seven~~ **eight** trials of ~~94.4~~ **94.2**% for the proposed maximum dose and ~~90.1~~ **90.2**% for the 1.2 L/ha dose. When compared directly with a lower ~~0.9~~ **0.9/1.0**L/ha dose (~~four~~ **five** trials), the proposed maximum dose achieved ~~89.8~~ **90.9**% control compared to ~~84.9~~ **86.0**% for the 1.2 L/ha dose and ~~82.2~~ **81.2**% for the ~~0.9~~ **0.9/1.0**L/ha dose range. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-725 and individual trial results are detailed in the BAD.

~~Table 3.2-72 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and lower 0.9 L/ha dose against Puccst in winter wheat (TRZAW). Results from 4 trials in the EPPO North-East climatic zone plus 3 DE trials, conducted between 2014-2020. Assessment at 28-37 days after one application.~~

EPPO-Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)-or other standards ^Δ	
		Mean n	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	4	20.8	6.4-40.6	-	-	90.2	69.6-100	95.7	83.6-100	81.6	32.8-100
North-East**	1	29.1	-	63.2	-	69.6	-	83.6	-	32.8	-
DE	3	28.6	20.0-37.5	88.5	81.9-98.5	90.0	84.0-100	91.8	87.5-100	87.6	81.9-98.0
North-East + DE*	7	24.2	6.4-40.6	-	-	90.1	69.6-100	94.0	83.6-100	84.2	32.8-100
North-East + DE**	4	28.7	20.0-37.5	82.2	63.2-98.5	84.9	69.6-100	89.8	83.6-100	73.9	32.8-98.0

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9 L/ha doses.

^ΔReference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-73 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against Puccst in winter wheat (TRZAW). Results from 5 trials in the EPPO North-East climatic zone plus 3 DE trials, conducted between 2014-2021. Assessment at 28-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	5	25.7	6.4-45.0	-	-	90.2	69.6-100	95.6	83.6-100	91.7	72.9-100
North-East**	2	32.0	29.1-45.0	70.4	63.2-77.6	80.0	69.6-90.3	89.6	83.6-95.5	82.6	72.9-92.2
DE	3	28.6	20.0-37.5	88.5	81.9-98.5	90.0	84.0-100	91.8	87.5-100	87.6	81.9-98.0
North-East + DE*	8	26.8	6.4-45.0	-	-	90.2	69.6-100	94.2	83.6-100	90.2	72.9-100
North-East + DE**	5	32.0	20.0-45.0	81.2	63.2-98.5	86.0	69.6-100	90.9	83.6-100	85.6	72.9-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses. **Direct comparison of 1.5 L/ha and 0.9/1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 198 g as/ha and Aviator Xpro applied at 1.0 L/ha

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). This trial demonstrated a similar dose response to the winter wheat data, with the proposed maximum 1.5 L/ha dose achieving the highest level of control (93.3%), compared to 90.8% for the 1.2 L/ha dose. The results are summarised in Table 3.2-66 and the results of the individual trials are detailed in the BAD.

Table 3.2-66 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against Puccst in spring wheat (TRZAS). Results from one trial conducted in the EPPO North-East climatic zone in 2016. Assessment at 32 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	1	8.7	-	-	-	90.8	-	93.3	-	95.8	-

Summary and conclusions on the minimum effective dose (MED) for control of Puccst in winter wheat (EPPO North-East climatic zone)

Puccst is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of Puccst on wheat at the proposed dose rate range of 1.2-1.5 L/ha. The proposed lower dose rate of 1.2 L/ha achieved overall control of 84.9 86.0% on winter wheat, compared to 82.2 81.2% for the 0.9 0.9/1.0 L/ha dose (across one two EPPO North-East trials and three DE trials). The results for the higher dose rate of 1.5 L/ha (required for other diseases) demonstrate that high levels of control of Puccst (89.8 94.2%) will be achieved in mixed disease situations. In one trial on spring wheat a similar dose response was demonstrated. The proposed dose rate range demonstrated control greater than the 0.9 0.9/1.0 L/ha dose across the majority of trials.

It is considered that the proposed dose rate of 1.2 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring wheat under a wide range of environmental conditions in Poland (EPPO North-East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in wheat where FUSASP also occurs or is expected to be a concern, the higher dose of 1.5 L/ha may be recommended for broad spectrum disease control.

A dose range of 1.2-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the Puccinia striiformis (PuccST) in winter wheat, following a single application applied at BBCH 39-47 of the crop. The MED trials were conducted in Hungary (4) and Romania (1) in the EPPO South-East climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1), so are considered to be a robust test of the product.

Across all five trials, a single application of GF-3307 achieved mean control of 93.5% (range 85.1-100%) of PuccST for the maximum 1.5 L/ha dose and 84.6% (range 72.6-99.0%) for the 1.2 L/ha dose, 28-49 days after application. Three trials also compared the proposed dose range, with a dose of 0.9 ~~0.9~~1.0 L/ha, which demonstrated 77.6% overall control compared to 89.2% for the 1.5 L/ha dose and 85.3% for the 1.2 L/ha dose rate. Across all trials, control of PuccST demonstrated by the proposed dose rate range was comparable to, or higher than, the prothioconazole standard Proline (91.5% overall control).

The results are summarised in Table 3.2-67 and individual trial results are detailed in the BAD.

Table 3.2-67 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and lower 0.9 L/ha dose against PuccST in winter wheat (TRZAW). Results from 5 trials conducted in the EPPO South-East climatic zone between 2014-2020. Assessment at 28-49 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PuccST		% control of PuccST							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East*	5	37.8	11.3-63.8	-	-	84.6	72.6-99.0	93.5	85.1-100	91.5^	73.7-100
South-East**	3	50.9	31.3-63.8	77.6	60.8-98.5	85.3	72.6-99.0	89.2	85.1-92.5	85.8^	73.7-99.5

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and ~~0.9~~ 0.9/1.0 L/ha doses.

^Reference standards used based on prothioconazole applied at 180-198 g as/ha

Summary and conclusions on the minimum effective dose (MED) range of 1.2-1.5 L/ha for control of PuccST in winter wheat (EPPO South-East climatic zone)

PuccST is an important target disease for GF-3307 and the data reported demonstrate that it provides effective control at the proposed dose rate range (1.2-1.5 L/ha). The maximum dose of 1.5 L/ha will give excellent control in all situations (93.5% across all five trials), including where varietal resistance to PuccST is low and fungicide resistance is a concern or in geographical locations which have a history of severe PuccST infections. In other situations, where disease pressure is lower, a dose of 1.2 L/ha will give sufficient control of PuccST in the EPPO South-East climatic zone (84.6% control across all five trials). It is considered that the 0.9 ~~0.9~~1.0 L/ha will not give sufficient control of this important disease in EPPO South-East conditions (77.6% control across three trials).

It is considered that the proposed dose rate range of 1.2-1.5 L/ha is the minimum effective dose to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.4 MED of GF-3307 for the control of Fusarium head blight (FUSASP)

This section addresses the minimum effective dose (MED) of GF-3307, for the control of fusarium head blight (FUSASP) on winter wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, 1.5 L/ha in in Poland (EPPO North-East climatic zone) and 1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-68 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-30 m² EPPO Maritime: 12.0-30 m ² EPPO North-East: 15.0 24.0m ² EPPO South-East: 22.5-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 10 TRZAW EPPO North-East: 5 5 TRZAW EPPO South-East: 3 TRZAW
	Varieties per crop	EPPO Maritime: JB Asano, Akteur, Altamira, Bernstein, Desamo, Grafton, Ilona, Muza, Naskov, Tobak. EPPO North-East: Artist, Euforia (2), Patras, Tobak EPPO South-East: Altigo, Genius, MV Nador,
Application	Crop stage (BBCH) at application	EPPO Maritime: BBCH 61-65 EPPO North-East: BBCH 61- 65 -69 EPPO South-East: BBCH 61-65
	Timing Pest stage at application (1)	Application was made to coincide with the most susceptible period of growth which was early to mid-flowering of the wheat
	Number of applications	1
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% incidence (frequency) of infected ears and the average % severity of ear infection of all ears assessed and the Disease severity Index (DSI). The deoxynivalenol (DON) content of the harvested grain was determined Assessments for efficacy (% infection with FHB) were aimed at BBCH 83-85 when symptoms of FHB were most obvious. % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, Hagberg falling number, Hectolitre weight, protein content and other quality parameters,
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% incidence) were aimed at the BBCH 83-85 in winter wheat
Other relevant information	Natural / artificial	Natural infection and artificial inoculation
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where FHB is an abundant disease.

Introduction

In total, data from ~~44~~ 18 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of fusarium head blight (FUSASP) on winter wheat (TRZAW). GF-

3307 was tested at 1.5, 1.2 and ~~0.9~~ 0.9/1.0 L/ha. **Note:** Results from 2021 trials were based on 1.0 L/ha and 1.25 L/ha lower doses. Results from these trials have been combined with those from earlier trials at the 0.9 L/ha dose and 1.2 L/ha dose respectively, as these doses are within 10% of each other are therefore considered to be comparable dose rates. The trials were performed in accordance with the EPPO Standard PP 1/225 ‘Minimum effective dose’. The reference product was Proline 275 applied at 0.72 L/ha or Prosaro applied at 1.0 L/ha.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials, in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (3), Germany (4), Denmark (1), France (1) and the UK (1) in the EPPO Maritime climatic zone and Poland (~~4~~ 5) in the EPPO North-East climatic zone ~~between 2014 and 2016~~ and Hungary (3) in the EPPO South-East climatic zone ~~between 2014 and 2021~~.

On the basis of EPPO Standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. ~~For FUSASP, this submission includes data from the Maritime and North East EPPO climatic zones, which are representative of the proposed GAP in each region. FUSASP is an important disease in the wetter regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South East climatic zone, the climatic conditions are less conducive to the development of FUSASP, as hot dry weather reduces the rate of disease development. As a result, this is a relatively minor disease in this climatic zone. As with data for other diseases in this dossier, the trial results from Poland in the EPPO North-East climatic zone and Austria in the EPPO Maritime climatic zone, as neighbouring countries, are comparable to those from the EPPO South East climatic zone and it is considered this will also be the case for FUSASP. It is therefore considered that data from Poland and Austria can be used to support this use in the EPPO South East climatic zone.~~ This submission includes data from each of these zones, so are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-16.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Fusarium head blight (FHB) is a prevalent disease. For trial site and application details, see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 6 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.2, 1.5	135, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.0, 1.2, 1.25, 1.5	135, 150, 180, 187.5, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Prosaro	EC	125 g /L tebuconazole + 125 g	1.0	250

		/L prothioconazole		
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Experimental details

The 18 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 12 m² and 30 m². To suppress foliar diseases during the growing season, cover sprays with fungicides were applied over the whole trial area. The trial treatments were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering a water volume between 200 and 300 L/ha.

GF-3307 at the rates tested and the reference product Proline were typically applied during the anthesis of the wheat crop as a single ‘ear wash’ spray applied between wheat growth stage BBCH 61 and BBCH 65 when the weather conditions for ear infections were favourable for FHB.

In some majority of trials *F.culmorum* and *F. graminearum* were artificially inoculated by spraying spore suspensions of the single species or both species in mixture close before or after the application of GF-3307 and the reference products (Table 3.2-74 in Efficacy chapter 3.2.3.4 FUSASP in winter wheat)

Table 3.2-74 Trials with natural infections or artificial inoculations

Trial-number	Country	Fusarium-species used for artificial inoculation
DE15E7B018UB02C	Austria	FUSACU
DE16E7B032UB02C	Austria	Natural infection
DE16E7B032UB03C	Austria	FUSACU+GIBBZE
DE14E7B023UB01C	Germany	Natural infection
DE15E7B018UB01C	Germany	Natural infection
DE16E7B032FS01	Germany	FUSACU+GIBBZE
DE16E7B032UB01C	Germany	FUSACU
DK16E7B032KF02C	Denmark	FUSACU+GIBBZE
FR16E7B035MC01C	France	FUSACU
GB15E7B018EB01C	UK	FUSACU+GIBBZE
PL16E7B032AS01C	Poland	FUSACU

FUSACU = *F. culmorum*

GIBBZE = *Gibberella zeae*, also known by the name of its anamorph *F. graminearum*

FHB was assessed on 50-100 randomly selected ears per plot as % incidence (frequency) of infected ears and the average % severity of ear infection of all ears assessed. In addition for the 2021 trials the FHB index or Disease Severity Index (DSI) was also calculated. For trials prior to 2021 where this is not included in the trials report, this has been calculated based on the % incidence and % severity reported in the trials. The deoxynivalenol (DON) content of the harvested grain was determined in all trials using liquid chromatography procedures or ELISA tests. Assessments for efficacy (% infection with FHB) were aimed at BBCH 83-85 when symptoms of FHB were most obvious. Percentage control was calculated based on the severity of ear infection and FHB index (DSI), relative to the infection level present in the untreated control. The percent reduction of the mycotoxin deoxynivalenol (DON) was calculated relative to the contents present in the grain of the control plots.

The prevailing *Fusarium* species present in the trials were *F. graminearum* and *F. culmorum* which belong to the most damaging diseases in cereal crops (see Table 3.2-74). Both species contaminate human food and animal feed through the production of mycotoxins such as DON, DON derivatives and zearalenone that belong to a group of structurally similar fungal metabolites called trichothecenes. However, it needs to be noted, that the FHB intensity shown in the trials and mycotoxin accumulation in the grain do not always closely correlate. Reasons might be that mycotoxins other than DON are produced by some *Fusarium* spp. that were not analysed or that head blight infections are present which are caused by pathogens such as *Microdochium nivale* that do not produce mycotoxins.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Ten GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of FUSASP in winter wheat, following a single application, applied at BBCH 61-65 of the crop. The MED trials were conducted in in Austria (3), Germany (4), Denmark (1), France (1) and the UK (1) in the EPPO Maritime climatic zone. All assessments were conducted on the ear.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 80.6% (range 71.0-92.0%) for FUSASP, 15-37 days after application, based on severity. Applied in the same trials, the 1.2 L/ha (80% rate/0.8N) dose of GF-3307 achieved lower mean control of 70.1%, with more variable results (range 51.2-83.7%). Nine trials included a 0.9 L/ha dose (60% rate/0.6N), which demonstrated control of 60.1% compared to 80.4% for the proposed 1.5 L/ha dose. Across all trials, control of FUSASP demonstrated by the proposed dose rate of 1.5 L/ha was higher than the prothioconazole standard Proline (74.8% overall).

Control based on the FHB Index (DSI) has also been calculated for these trials based on the % severity and % incidence (except for trial DK16E7B032KF02C, where % control based on the FHB index was included). GF-3307 applied at 1.5 L/ha achieved mean control of FUSAP based on the DSI of 88.6% compared to 83.6% for the 1.2 L/ha (80% rate/0.8N) dose. Nine trials included a 0.9 L/ha dose (60% rate/0.6N), which demonstrated DSI control of 74.9% compared to 87.9% for the proposed 1.5 L/ha dose. Across all trials, control of FUSASP, assessed as a DSI, demonstrated by the proposed dose rate of 1.5 L/ha was comparable to the prothioconazole standard Proline (87.2% overall).

The results are summarised in Table 3.2-7569 and individual trial results are detailed in the BAD.

Table 3.2-75 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, 80% and 60% dose rates against FUSASP in winter wheat (TRZAW). Results from 10 trials conducted in the EPPO Maritime climatic zone between 2014 and 2016. Assessment at 15-37 days after one application.

EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	10	31.2	5.7-93.8	-	-	70.1	51.2-83.7	80.6	71.0-92.0	74.8	47.1-83.0
Maritime**	9	33.7	5.7-93.8	60.1	34.3-76.8	69.4	51.2-83.7	80.4	71.0-92.0	77.9	68.6-83.0

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 0.9 L/ha doses.

Table 3.2-76 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, 80% and 60% dose rates against FUSASP in winter wheat (TRZAW). Results from 10 trials conducted in the EPPO Maritime climatic zone between 2014 and 2016. Assessment at 15-37 days after one application.

EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime* (severity)	10	31.2	5.7-93.8	-	-	70.1	51.2-83.7	80.6	71.0-92.0	74.8	47.1-83.0

EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime** (severity)	9	33.7	5.7-93.8	60.1	34.3-76.8	69.4	51.2-83.7	80.4	71.0-92.0	77.9	68.6-83.0
Maritime* (DSI)	10	27.3	2.7-93.8	-	-	83.6	59.3-95.2	88.6	61.6-98.4	87.2	68.6-98.2
Maritime** (DSI)	9	33.7	5.7-93.8	74.9	45.3-90.3	82.6	59.3-95.2	87.9	61.6-98.4	87.4	68.6-98.2

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 0.9 L/ha doses.

In addition to assessing the control of FUSASP, all trials included an assessment of the impact of the treatments on the deoxynivalenol (DON) content of the harvested grain. A single application of GF-3307 applied at 1.5 L/ha achieved a mean reduction of 67.9% for DON, 75-154 days after harvest. Applied in the same trials, the 1.2 L/ha dose achieved a lower mean reduction of 61.8%. In the nine trials that included a 0.9 L/ha dose, this dose demonstrated a 59.3% reduction in DON content compared to 69.0% for the proposed 1.5 L/ha dose. Across all trials, the reduction in DON content demonstrated by the proposed dose rate of 1.5 L/ha was comparable to that achieved by the prothioconazole standard Proline (70.8% overall).

Additional factors, other than just FUSASP control, can have an influence on the DON levels at harvest (e.g. weather around harvest, sooty moulds and variety), therefore the reduction in DON levels does not always equate to the level of control of FUSASP in the growing crop. However, the data demonstrate that the reduction in DON content from GF-3307 at the 1.5 L/ha dose was comparable to the reference product.

The results are summarised in Table 3.2-0 and individual trial results are detailed in the BAD.

Table 3.2-70 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, 80% and 60% dose rates on the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from 10 trials conducted in the EPPO Maritime climatic zone between 2014 and 2016. Assessment at 75-154 days after harvest.

EPPO Zone	Number of trials	Untreated control DON mg/kg content		% control reduction of DON							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	10	9.2	0.1-38.6	-	-	61.8	28.9-75.2	67.9	17.9-85.8	70.8	51.7-87.4
Maritime**	9	10.2	0.2-38.6	59.3	29.9-75.7	62.1	28.9-75.2	69.0	17.9-85.8	72.1	51.7-87.4

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 0.9 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for control of FUSASP in winter wheat (EPPO Maritime climatic zone)

FUSASP is an important target disease for GF-3307 on winter wheat and the data reported demonstrate that it provides excellent control of FUSASP and reduction in DON content, when applied at flowering at the proposed dose rate of 1.5 L/ha. The 1.5 L/ha dose of GF-3307 achieved the highest level of overall control of FUSASP (80.6% based on severity and 88.6% based on a DSI) and greatest reduction of DON (67.9%). The proposed dose consistently demonstrate control of FUSASP >70% and delivered control higher than the 0.8N and 0.6N doses in all trials.

It is considered that the proposed dose rate of 1.5 L/ha is the most effective dose of GF-3307, required to deliver robust control of this disease under a wide range of environmental conditions, in the EPPO Maritime climatic zone.

Proposed maximum dose of 1.5 L/ha for Poland (EPPO North-East climatic zone)

~~One~~ **Five** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the FUSASP in winter wheat, following a single application applied at BBCH 61-~~65~~**69** of the crop. The MED trial was conducted in Poland in the EPPO North-East climatic zone. Assessments were conducted on the ear.

A single application of GF-3307 applied at 1.5 L/ha achieved ~~83.6~~ **90.7%** control of FUSASP **based on severity**, 17-28 days after application. This compared to ~~68.3~~ **78.8%** for the ~~1.2~~ **1.2/1.25** L/ha, ~~68.1~~ **69.7%** for the ~~0.9~~ **0.9/1.0** L/ha dose and ~~79.1~~ **86.4%** for ~~prothioconazole/Proline standard the~~ **tebuconazole + prothioconazole standard Prosaro**.

In addition to this trial, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These ~~four~~ **three** trials were conducted in Germany and demonstrate a comparable dose response to the EPPO North-East climatic zone data, with the 1.5 L/ha achieving the highest level of control at ~~80.3~~ **79.5%** **based on severity**, compared to ~~69.9~~ **67.7%** for the ~~1.2~~ **1.2/1.25** L/ha dose and 61.4% for the ~~0.9~~ **0.9/1.0** L/ha dose. Combined with the one EPPO North-East climatic zone trial, these give overall control of FUSASP across the ~~five~~ **eight** trials of ~~80.9~~ **86.5%** for the proposed dose **based on severity**, and ~~69.6~~ **74.7%** for the ~~1.2~~ **1.2/1.25** L/ha dose and across ~~four~~ **eight** trials, ~~80.6~~ **86.6%** for the proposed dose and ~~63.1~~ **66.6%** for the ~~0.9~~ **0.9/1.0** L/ha dose. Details for these German trials are included in the EPPO Maritime climatic zone section, above.

Control based on the FHB Index (DSI) was included in the four 2021 Polish trials and has been calculated for all earlier trials based on the % severity and % incidence. GF-3307 applied at 1.5 L/ha achieved mean control of FUSAP based on the DSI of 97.2% for the five EPPO North-East trials compared to 89.5% for the 1.2/1.25 L/ha dose and 84.5% for the 0.9/1.0 L/ha dose. For the three DE trials, results were comparable at 94.6% for the 1.5 L/ha dose, 88.7% for the 1.2/1.25 L/ha dose and 84.1% for the 0.9/1.0 L/ha dose, giving overall results across all eight trials of 96.3%, 89.2% and 84.3% respectively for each dose. Only the proposed 1.5 L/ha dose achieved control comparable to the tebuconazole + prothioconazole standard Prosaro.

The results are summarised in Table 3.2-771 individual trial results are detailed in the BAD.

Table 3.2-77 — Minimum effective dose testing of GF-3307 at the proposed maximum label rate of 1.5 L/ha, 80% and 60% dose rates against FUSASP in winter wheat (TRZAW). Results from one trial in the EPPO North-East climatic zone and 4 DE trials, conducted between 2014 and 2016. Assessment at 17-37 days after one application.

EPPO-Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East**	1	13.7	-	68.1	-	68.3	-	83.6	-	79.1	-
DE*	4	47.8	8.5-93.8	-	-	69.9	57.0-83.7	80.3	71.0-92.0	71.6	47.1-80.6
DE**	3	60.9	30.3-93.8	61.4	50.0-75.2	67.7	57.0-83.7	79.5	71.0-92.0	79.7	78.1-80.6
North-East + DE*	5	41.0	8.5-93.8	-	-	69.6	57.0-83.7	80.9	71.0-92.0	73.1	47.1-80.6
North-East + DE**	4	49.1	13.7-93.8	63.1	50.0-75.2	67.9	57.0-83.7	80.6	71.0-92.0	79.6	78.1-80.6

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 0.9 L/ha doses.

Table 3.2-78 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against FUSASP in winter wheat (TRZAW). Results from five trials conducted in the EPPO North-East climatic zone and three DE trials between 2015 and 2021. Assessment at 17-37 days after one application.

EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East (severity)	5	47.2	13.7-91.3	69.7	52.3-93.4	78.8	66.1-97.6	90.7	83.6-100	86.4	82.5-96.7
DE (severity)	3	60.9	30.3-93.8	61.4	50.0-75.2	67.7	57.0-83.7	79.5	71.0-92.0	83.3	75.9-90.1
North-East + DE (severity)	8	52.4	13.7-93.8	66.6	50.0-93.4	74.7	57.0-97.6	86.5	71.0-100	85.2	75.9-100
North-East (DSI)	5	39.9	3.4-91.3	84.5	75.0-98.7	89.5	73.9-99.8	97.2	90.7-100	96.3	90.9-98.9
DE (DSI)	3	52.4	15.7-93.8	84.1	80.7-88.5	88.7	83.7-95.2	94.6	92.1-98.4	93.0	84.0-98.9
North-East + DE (DSI)	8	44.6	3.4-93.8	84.3	75.0-98.7	89.2	73.9-99.8	96.3	90.7-100	95.0	84.0-98.9

In addition to assessing the control of FUSASP, all trials included an assessment of the impact of the treatments on the deoxynivalenol (DON) content of the harvested grain. **Only four trials included DON assessment across all three dose rates.** A single application of GF-3307 applied at 1.5 L/ha achieved a reduction of 74.9% for DON, 101 days after harvest in the one EPPO North-East climatic zone trials, This compared to a 68.6% reduction for the 1.2 L/ha, a 56.3% reduction for the 0.9 L/ha dose and a 73.7% reduction for the tebuconazole + prothioconazole standard Prosaro. Combined with the three DE trials, an overall reduction of DON of 77.5% was achieved for the proposed dose, and 69.9% for the 1.2 L/ha dose (across five trials) and across four trials, a 77.5% reduction in DON for the proposed dose and 58.8% for the 0.9 L/ha dose, were achieved.

The results are summarised in Table 3.2-792 and individual trial results are detailed in the BAD.

Table 3.2-79 — Minimum effective dose testing of GF-3307 at the proposed maximum label rate of 1.5 L/ha, 80% and 60% dose rates on the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from one trial in the EPPO North-East climatic zone and 4 DE trials, conducted between 2014 and 2016. Assessment at 76-154 days after harvest.

EPPO Zone	Number of trials	Untreated control DON mg/kg		% control of DON							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East**	1	0.3	-	56.3	-	68.6	-	74.9	-	78.1	-
DE*	4	10.9	0.1-38.6	-	-	67.3	58.3-75.1	73.4	58.3-85.8	72.2	58.3-85.5
DE**	3	14.5	0.2-38.6	59.6	51.1-66.7	70.3	64.9-75.1	78.4	70.2-85.8	76.8	65.6-85.5
North-East + DE*	5	8.8	0.1-38.6	-	-	67.5	58.3-75.1	73.7	58.3-85.8	73.3	58.3-85.5

EPPO-Zone	Number of trials	Untreated control DON mg/kg		% control of DON							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East + DE**	4	10.9	0.2-38.6	58.8	51.1-66.7	69.9	64.9-75.1	77.5	70.2-85.8	77.1	65.6-85.5

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 0.9 L/ha doses.

Table 3.2-80 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha on the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from one trial in the EPPO North-East climatic zone and three DE trials, conducted between 2014 and 2016. Assessment at 76-153 days after application (after harvest).

EPPO Zone	Number of trials	Untreated control DON mg/kg content		% reduction of DON							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	1	0.3	-	56.3	-	68.6	-	74.9	-	73.7	-
DE	3	14.5	0.2-38.6	59.6	51.1-66.7	70.3	64.9-75.1	78.4	70.2-85.8	79.0	72.1-85.8
North-East + DE	4	10.9	0.2-38.6	58.8	51.1-66.7	69.9	64.9-75.1	77.5	70.2-85.8	77.7	72.1-85.8

Summary and conclusions on the minimum effective dose (MED) for control of FUSASP in winter wheat (EPPO North-East climatic zone)

FUSASP is an important target disease for GF-3307 on winter wheat and the data reported demonstrate that it provides excellent control of FUSASP and reduction in DON content, when applied at flowering at the proposed maximum dose rate of 1.5 L/ha. The 1.5 L/ha dose of GF-3307 achieved the highest level of overall control of FUSASP (86.5% based on severity and 96.3% based on a DSI across 5 EPPO North-East trials and three DE trials) and the greatest reduction of DON (77.5% across one EPPO North-East trial and three DE trials). The proposed dose delivered control higher than the 0.8N and 0.6N doses in all trials. The maximum dose of 1.5 L/ha was the only dose to achieve control comparable to the tebuconazole + prothioconazole standard Prosaro (85.2% control of FUSASP based on severity, 95.0% control of FUSASP based on a DSI and a 77.7% reduction of DON).

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease under a wide range of environmental conditions, in Poland (EPPO North-East climatic zone).

A dose range of 1.2-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed maximum dose of 1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

No data are presented from the EPPO South-East climatic zone using GF-3307 against this disease.

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the FUSASP in winter wheat, following a single application applied at BBCH 61-65 of the crop. The MED trials were conducted in Hungary in the EPPO South-East climatic zone. Assessments were conducted on the ear.

A single application of GF-3307 applied at 1.5 L/ha achieved 70.9% control of FUSASP based on severity, 17-25 days after application. This compared to 66.3% for the 1.2/1.25 L/ha and 81.8% for the tebuconazole + prothioconazole standard Prosaro.

FUSASP is an important disease in the wetter regions of the Central EU Authorization zone, where disease pressure is significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of FUSASP, as hot dry weather reduces the rate of disease development. As a result, FUSASP is a relatively minor disease in this region. The climate in Poland and Austria, as neighbouring countries, is similar to the EPPO South-East climatic zone (i.e., hot summers), but is slightly wetter than in the EPPO South-East climatic zone. It is therefore considered that trials from Poland and Austria represent a more robust test of the product against FUSASP, so these data can be used to support use in the EPPO South-East climatic zone.

Eight trials were conducted in Austria and Poland and demonstrate a comparable dose response to the EPPO South-East climatic zone data, with the 1.5 L/ha achieving the highest level of control at 87.1% based on severity, compared to 75.0% for the 1.2/1.25 L/ha dose and 67.3% for the 0.9/1.0 L/ha dose. Combined with the EPPO South-East climatic zone trials, these give overall control of FUSASP across the 11 trials of 82.6% for the proposed dose based on severity and 72.7% for the 1.2/1.25 L/ha dose. Details for these Austrian and Polish trials are included in the EPPO Maritime climatic zone section, above.

Control based on the FHB Index (DSI) was included in the three 2021 Hungarian trials and the four 2021 Polish trials and has been calculated for all earlier trials based on the % severity and % incidence. GF-3307 applied at 1.5 L/ha achieved mean control of FUSAP based on the DSI of 84.8% for the three EPPO North-East trials compared to 80.5% for the 1.2/1.25 L/ha dose. For the eight Austrian and Polish trials, results were comparable at 94.7% for the 1.5 L/ha dose, 87.0% for the 1.2/1.25 L/ha dose and 81.6% for the 0.9/1.0 L/ha dose, giving overall results across all 11 trials of 92.0% and 85.2% respectively for the 1.5 L/ha and 1.2/1.25 L/ha doses. Only the proposed 1.5 L/ha dose achieved control comparable to the tebuconazole + prothioconazole standard Prosaro.

The results for FUSASP control are summarised in Table 3.2-813 and individual trial results are detailed in the BAD.

Table 3.2-81 Minimum effective dose testing of GF-3307 at the proposed maximum label rate of 1.5 L/ha, 80% and 60% dose rates against FUSASP in winter wheat (TRZAW). Results from one PL trial and 3 AT trials conducted in 2015 and 2016. Assessment at 15-25 days after one application

EPPO-Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PL	1	13.7	-	68.1	-	68.3	-	83.6	-	79.1	-
AT	3	18.4	5.7-29.3	63.3	49.9-71.0	68.7	51.2-81.1	81.0	79.0-83.1	80.8	78.9-83.0
AT+PL	4	17.3	5.7-29.3	64.5	49.9-71.0	68.6	51.2-81.0	81.7	79.0-83.6	80.4	78.9-83.0

Table 3.2-82 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against FUSASP in winter wheat (TRZAW). Results from three (3) trials conducted in the EPPO South-East climatic zone, three (3) AT trials and five (5) PL trials between 2015 and 2021. Assessment at 15-28 days after one application

EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East (severity)	3	39.0	15.0-79.5	-	-	66.3	46.0-76.7	70.9	54.1-86.0	81.8	67.9-89.1
AT + PL (severity)	8	36.4	5.7-91.3	67.3	49.9-93.4	75.0	51.2-97.6	87.1	79.0-100	86.4	75.9-96.7
South-East + AT + PL (severity)	11	37.1	5.7-91.3	-	-	72.7	46.0-97.6	82.6	54.1-100	85.1	67.9-96.7
South-East (DSI)	3	35.8	11.5-74.8	-	-	80.5	63.0-92.3	84.8	70.1-94.1	92.4	84.5-96.7
AT + PL (DSI)	8	31.1	2.7-91.3	81.6	63.7-98.7	87.0	71.5-99.8	94.7	89.5-100	95.9	90.1-99.1
South-East + AT + PL (DSI)	11	32.4	2.7-91.3	-	-	85.2	63.0-99.8	92.0	70.1-100	95.0	84.5-99.1

In addition to assessing the control of FUSASP, all trials included an assessment of the impact of the treatments on the deoxynivalenol (DON) content of the harvested grain. Only seven trials included DON assessment across lower dose rates. A single application of GF-3307 applied at 1.5 L/ha achieved a reduction of 75.4% for DON, 37-73 days after harvest in the three EPPO South-East climatic zone trials. This compared to a 71.2% reduction for the 1.2/1.25 L/ha and an 88.8% reduction for the tebuconazole + prothioconazole standard Prosaro. Combined with the Austrian and Polish trials, an overall reduction of DON of 74.8% was achieved for the proposed dose, compared to 70.9% for the 1.2/1.25 L/ha dose. Additional factors, other than just FUSASP control, can have an influence on the DON levels at harvest (e.g. weather around harvest, sooty moulds and variety), therefore the reduction in DON levels does not always equate to the level of control of FUSASP in the growing crop. However, the data demonstrate that the reduction in DON content from GF-3307 at the maximum 1.5 L/ha dose was comparable to the reference product.

The results of DON reduction are summarised in

Table 3.2-834 and individual trial results are detailed in the BAD.

Table 3.2-83 Minimum effective dose testing of GF-3307 at the proposed maximum label rate of 1.5 L/ha, 80% and 60% dose rates on the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from one PL trial and 3 AT trials conducted in 2015 and 2016. Assessment at 75-101 days after harvest.

EPPO-Zone	Number of trials	Untreated control DON mg/kg		% control of DON							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PL	1	0.3	-	56.3	-	68.6	-	74.9	-	78.1	-
AT	3	12.0	9.3-16.4	67.9	64.5-70.5	71.4	66.5-75.2	74.0	66.4-84.4	79.3	73.9-87.4
AT+PL	4	9.1	9.3-16.4	65.0	56.3-70.5	70.7	66.5-	74.2	66.4-	79.0	73.9-87.4

EPPO-Zone	Number of trials	Untreated control DON mg/kg		% control of DON							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
							75.2		84.4		

Table 3.2-84 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha on the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from three (3) trials conducted in the EP-PO South-East climatic zone, three (3) AT trials and one (1) PL trial between 2015 and 2021. Assessment at 37-101 days after application (after harvest)

EPPO Zone	Number of trials	Untreated control DON mg/kg content		% reduction of DON							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East	3	16.4	6.8-28.0	-	-	71.2	56.4-87.5	75.4	52.7-89.7	88.8	75.0-95.8
AT + PL	4	9.1	0.3-16.4	65.0	56.3-70.5	70.7	66.5-75.2	74.3	66.4-84.4	79.8	72.3-88.9
South-East +AT + PL	7	12.2	0.3-28.0	-	-	70.9	56.4-87.5	74.8	52.7-89.7	83.7	72.3-95.8

These four Polish and Austrian trial results demonstrate that GF-3307 provides effective control of FUSASP at the proposed maximum dose rate of 1.5 L/ha. The maximum dose of 1.5 L/ha gave excellent control of FUSASP (81.7%) and a 74.2% reduction of DON. This was comparable to the prothioconazole reference standard Proline at 80.4% control of FUSASP and a 79.0% reduction of DON. For this disease the 1.2 L/ha and 1.0 L/ha doses demonstrated much lower control, which were also below the reference standard. As a result, only the maximum dose of 1.5 L/ha is recommended for control of this disease.

Summary and conclusions on the minimum effective dose (MED) for control of FUSASP in winter wheat (EPPO South-East climatic zone)

FUSASP is an important target disease for GF-3307 on winter wheat and the data reported demonstrate that it provides excellent control of FUSASP and reduction in DON content, when applied at flowering at the proposed maximum dose rate of 1.5 L/ha. The 1.5 L/ha dose of GF-3307 achieved the highest level of overall control of FUSASP (82.6% based on severity and 92.0% based on a DSI across three EPPO South-East trials and eight Austrian and Polish trials) and the greatest reduction of DON (74.5% across three EPPO South-East trials and four Austrian and Polish trials). The proposed dose delivered control higher than the 0.8N and 0.6N doses in all trials. The maximum dose of 1.5 L/ha was the only dose to achieve control comparable to the tebuconazole + prothioconazole standard Prosaro (85.1% control of FUSASP based on severity, 95.0% control of FUSASP based on a DSI and a 83.7% reduction of DON).

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease under a wide range of environmental conditions, in the EPPO South-East climatic zone.

3.2.2.5 MED of GF-3307 for the control of PYRNTR in wheat

This section addresses the minimum effective dose (MED) of GF-3307 for the control of PYRNTR on winter and spring wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-75 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: TRZAW (6 7) EPPO North-East: TRZAW (3 4), TRZAS (± 2) EPPO South-East: TRZAW (3)
	Varieties per crop	EPPO Maritime: Winter wheat: Akteur, Colonia, Element, Patras (2), Ritmo, Smaragd, Tobak. EPPO North-East: Winter wheat: Arkadia, Artis, Hondia, Zentos Spring wheat: Goplana, Zebra EPPO South-East: Winter wheat: Glosa, Iridium, Rubisko
Application	Crop stage (BBCH) at application	EPPO Maritime: BBCH 31-51 EPPO North-East: BBCH 35-51 EPPO South-East: 1 application (BBCH 39-41), 2 applications (One HU trial: BBCH 32-33 and BBCH 49-51)
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In all cases PYRNTR was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 (12 trials), 2 (one HU trial) EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop (2 trials), Two per crop (one trial)
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where the key target pathogen is an abundant disease. PYRNTR was assessed as a secondary pathogen present at reliable levels.

Introduction

In total, data from 43 16 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of PYRNTR in winter and spring wheat. GF-3307 was tested at 1.5,

1.2 and 0.9/1.0 L/ha. **Note:** Results from 2020 and 2021 trials were based on a 1.0 L/ha lower dose. Results from these trials have been combined with those from earlier trials at the 0.9 L/ha dose, as these doses are within 10% of each other are therefore considered to be comparable dose rates. The trials were performed in accordance with the EPPO standard PP 1/225 ‘*Minimum effective dose*’. ~~The reference products include Proline 275 applied at 0.72 L/ha, Aviator Xpro applied at 1.25 L/ha and Librax applied at 2.0 L/ha.~~ The reference products include Proline 275 and Proline 250 applied at 0.72 L/ha, Aviator Xpro applied at 1.0-1.25 L/ha and Librax applied at 2.0 L/ha. Proline 275 was applied in the majority of trial. Results for all standards have been combined in the following summary tables, however, individual results for each standard are presented in the individual trial tables and are compared orthogonally with GF-3307 in section 3.2.3.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (1), the Czech Republic (1 2) and Germany (4) in the EPPO Maritime climatic zone, Latvia (2 2) and Poland (2 4) in the EPPO North-East climatic zone and Hungary (1) and Romania (2) in the EPPO South-East climatic zone, between 2014 and 2020 2021.

On the basis of the EPPO standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these EPPO climatic zones, which is representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The MED efficacy trials were carried out by the testing facilities in the countries listed in **Table 3.2-17**.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PYRNTR is an abundant disease. PYRNTR is a disease which multiplies rapidly at short cycles under warm climatic conditions such as found in the EPPO Maritime, North-East and South-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 7 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g /L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6	150
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	1.25	281
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g /L fenpicoxamid + 100 g /L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0-1.25	225-281

Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
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Experimental details

The ~~13~~ **16** MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12 m² and 36 m². ~~Sixteen~~ **Fourteen** trials were carried out on winter wheat and ~~one~~ **two** on spring wheat. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after each application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PYRNTR or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments used were generally on Leaf 1 to Leaf 4 as the highest available assessed leaf with sufficient infection in the untreated.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

~~Six~~ **Seven** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of PYRNTR in wheat, following a single application, applied at BBCH 31-51 of the crop. The MED trials were conducted in Austria (1), the Czech Republic (~~1~~ **2**) and Germany (4) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product. **Note:** In one trial, the latest assessment timing after a single application was 22 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

A single application of GF-3307 ~~applied~~ at 1.5 L/ha achieved mean control of ~~82.8~~ **83.9%** (range 75.2-92.4%) for PYRNTR, 22-62 days after application. Applied in the same trials, at 1.2 L/ha (80% rate/0.8N), GF-3307 achieved lower mean control of ~~77.9~~ **79.7%**, with more variable results (range 64.0-86.2 **90.6%**). Five **Six** trials also compared the proposed dose (1.5 L/ha), with a dose of ~~0.9~~ **0.9/1.0** L/ha (60% rate/0.6N), which demonstrated ~~70.9~~ **73.6%** overall control (range 56.0-86.2 **87.1%**) compared to ~~81.9~~ **83.4%** for the 1.5 L/ha dose.

Across all trials, control of PYRNTR demonstrated by the proposed dose rate of 1.5 L/ha was comparable to or higher than, with the reference standards and the 1.2 L/ha dose was equivalent to the references.

The results are summarised in Table 3.2-8576 and individual trial results are detailed in the BAD.

~~Table 3.2-85 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60% dose rates against PYRNTR in winter wheat (TRZAW). Results from 6 trials conducted in the EPPO Maritime climatic zone between 2014–2020. Assessment at 22–62 days after one application.~~

EPPO Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9 L/ha (60% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	6	25.2	7.8-50.8	-	-	77.9	64.0-86.2	82.8	75.2-92.4	77.7^	48.0-94.5
Maritime**	5	28.7	10.3-50.8	70.9	56.0-86.2	76.7	64.0-86.2	81.9	75.2-92.4	76.5^^	78.0-94.5

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 0.9 L/ha doses.

~~△Reference standards used based on prothioconazole applied at 180-198 g as/ha and in one trial each Aviator Xpro at 1.25 L/ha and Librax at 2.0 L/ha were used.~~

~~△△Reference standards used based on prothioconazole applied at 180-198 g as/ha and in one trial Aviator Xpro at 1.25 L/ha.~~

Table 3.2-86 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60-67% dose rates against PYRNTR in winter wheat (TRZAW). Results from 7 trials conducted in the EPPO Maritime climatic zone between 2014 - 2021. Assessment at 22-62 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9-1.0 L/ha (60-67% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	7	24.0	7.8-50.8	-	-	79.7	64.0-90.6	83.9	75.2-92.4	84.5	73.6-94.5
Maritime**	6	26.7	10.3-50.8	73.6	56.0-87.1	79.0	64.0-90.6	83.4	75.2-92.4	84.6	73.6-94.5

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 0.9/1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 198 g as/ha, Aviator Xpro at 1.0-1.25 L/ha and Librax at 2.0 L/ha.

Summary and conclusions on the minimum effective dose (MED) for control of PYRNTR in winter wheat (EPPO Maritime climatic zone)

PYRNTR is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of PYRNTR at the proposed dose rate of 1.5 L/ha. The proposed dose of 1.5 L/ha was the only dose to achieve mean control >80%. The proposed dose achieved levels of control higher than the 0.8N and 0.6N dose, in all trials.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required to deliver robust control of this disease, under a wide range of environmental conditions in the EPPO Maritime climatic zone.

Proposed maximum dose of 1.5 L/ha and dose range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

~~Four~~ Six GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the PYRNTR in winter wheat and spring wheat, following a single application applied at BBCH 35-51 of the crop. The MED trials were conducted in Latvia (2) and Poland (2) in the EPPO North-East climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product. **Note:** ~~In two trials, the latest assessment timing after a single application was 16-20 days. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP. In one trial, the latest assessment timing after a single application was 16 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.~~

For winter wheat, a single application of GF-3307 applied at 1.5 L/ha achieved mean control of ~~84.6~~ 88.5% (range 79.0-~~92.3~~ 100%) for PYRNTR, 16-42 days after application compared to ~~78.4~~ 79.8 % for the 1.2 L/ha dose and ~~67.2~~ 67.7% for the ~~0.9~~ 0.9/1.0L/ha dose. ~~Across all trials, control of PYRNTR demonstrated by the proposed dose rate of 1.5 L/ha dose was higher than the prothioconazole standard Proline (65.7% overall control). Across all trials, control of PYRNTR demonstrated by the proposed doses was higher than, or equal to, the reference standards (78.9% overall control).~~

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These ~~four~~ five trials were conducted in the Czech Republic and Germany and demonstrate a comparable dose response to the

EPPO North-East data with the 1.5 L/ha achieving the highest level of control of ~~83.0~~ **84.6%**, compared to ~~77.2~~ **79.9%** for the 1.2 L/ha dose and ~~70.4~~ **73.7%** for the ~~0.9~~ **0.9/1.0** L/ha dose. Combined with the ~~three~~ **four** EPPO North-East trials, these give overall control of PYRNTR across ~~seven~~ **9** trials of ~~83.7~~ **86.3%** for the 1.5 L/ha dose compared to ~~77.9~~ **79.9%** for the 1.2 L/ha dose and ~~69.0~~ **71.1%** for the ~~0.9~~ **0.9/1.0** L/ha dose. Details for the Czech and German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-8777 and individual trial results are detailed in the BAD.

Table 3.2-87 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and 0.9 L/ha dose rate against PYRNTR in winter wheat (TRZAW). Results from 3 trials in the EPPO North-East climatic zone plus one CZ and 3 DE trials, conducted between 2014 and 2020 . Assessment at 16-62 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	3	20.6	13.8-26.3	67.2	56.8-74.6	78.4	68.1-84.1	84.6	79.0-92.3	65.7	31.5-82.9
CZ + DE	4	33.2	14.9-50.8	70.4	56.0-86.2	77.2	64.0-86.2	83.0	75.2-92.4	74.0	48.0-94.5
North-East + CZ + DE	7	27.8	13.8-50.8	69.0	56.0-86.2	77.9	64.0-86.2	83.7	75.2-92.4	70.4	31.5-94.5

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-88 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against PYRNTR in winter wheat (TRZAW). Results from four (4) trials in the EPPO North-East climatic zone plus two (2) CZ and 3 DE trials, conducted between 2014 and 2021 . Assessment at 16-62 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	4	18.3	11.3-26.3	67.7	56.8-74.6	79.8	68.1-84.2	88.5	79.0-100	78.9	59.4-90.8
CZ + DE	5	29.9	14.9-50.8	73.7	56.0-87.1	79.9	64.0-90.6	84.6	75.2-92.4	84.1	73.6-94.5
North-East + CZ + DE	9	24.7	11.3-50.8	71.1	56.0-87.1	79.9	64.0-90.6	86.3	75.2-100	81.8	59.4-94.5

#Reference standards used based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro at 1.0 L/ha

In addition to data on winter wheat, ~~one trial was~~ **two trials were** conducted on spring wheat (TRZAS). **These trials** demonstrated a similar dose response to the winter wheat data, with the proposed 1.5 L/ha dose achieving the highest level of control (~~78.6~~ **88.3%**) compared to ~~72.9~~ **80.5%** for the 1.2 L/ha dose and ~~76.2~~ **78.6%** for the ~~0.9~~ **0.9/1.0** L/ha dose.

The results are summarised in Table 3.2-89 and the results of the individual trials are detailed in the BAD.

Table 3.2-89 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and 0.9 L/ha dose rate against against PYRNTR in spring wheat (TRZAS). Results from one trial conducted in the EPPO North-East climatic zone in 2014. Assessment at 20 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	1	13.1	-	76.2	-	72.9	-	78.6	-	67.6	-

Table 3.2-90 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against PYRNTR in spring wheat (TRZAS). Results from two (2) trials conducted in the EPPO North-East climatic zone in 2014 and 2021. Assessment at 20-31 days after one application.

EPPO Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	2	16.7	13.1-20.3	78.6	76.2-81.0	80.5	72.9-88.0	88.3	78.6-98.0	75.3	67.6-83.0

Reference standards used based on prothioconazole applied at 180-198 g as/ha

Summary and conclusions on the minimum effective dose (MED) for control of PYRNTR in wheat (EPPO North-East climatic zone)

PYRNTR is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of PYRNTR on winter wheat at the proposed maximum dose rate of 1.5 L/ha. The 1.5 L/ha of GF-3307 achieved the highest level of overall control (84.6-88.5% control in three four EPPO North-East trials and 83.0-84.6 % in four five CZ and DE trials). In one trial two trials on spring wheat a similar dose response was demonstrated.

The 1.2 L/ha dose delivered good overall control of 77.9 79.9% (78.4 79.8% control in three four EPPO North-East trials and 77.2 79.9% in the four five CZ and DE trials). It is considered that the proposed maximum dose rate of 1.5 L/ha is the most effective dose of GF-3307 to deliver robust control of this PYRNTR on winter and spring wheat under a wide range of environmental conditions in Poland (EPPO North-East climatic zone), although the 1.2 L/ha dose rate also offers good control and would be appropriate in lower disease pressure situations and can be supported as levels of control were better than the reference. The 0.9/1.0 L/ha does not demonstrate sufficient control (71.1% across all 9 trials).

A dose range of 1.2-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions. Data in the efficacy section will present the 1.5 L/ha dose that will be advised in high risk situations for PYRNTR and also the 1.2 L/ha dose that can be used in the less severe disease situations where SEPTTR is the main target disease.

Proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the PYRNTR in winter wheat, following a single application applied at BBCH 39-51 of the crop. The MED trials were conducted in Hungary (1) and Romania (2) in the EPPO South-East climatic zone. Assessments across all trials were on Leaf 1 or Leaf 2 and are considered to be a robust test of the product. One trial was based on a two-dose regime (HU14E7B014AB01C), however, PYRNTR did not develop in the trial until 25 days after the second application. In this trial the first application was applied at BBCH 32-33 of the crop and the second application was applied at BBCH 49-51. PYRNTR did not develop until 47 days after the first application, demonstrating how the disease can infect crops late in their development and this is

considered to be beyond the protection period, the first application of GF-3307 could be expected to deliver, particularly as the assessed leaf (Leaf 2) would not have been emerged at the time of the first application. For this trial, the results after two applications have been used, as it is considered that the second application is comparable to a single dose regime.

All three trials compared the proposed dose range of 1.2-1.5 L/ha with a lower dose of ~~0.9~~ 0.9/1.0 L/ha. GF-3307 at 1.5 L/ha achieved mean control of 92.0% (range 88.6-97.3%), 25-45 days after application. Applied in the same trials, the 1.2 L/ha dose of GF-3307 achieved mean control of 81.7% (range 74.2-90.0%) and the ~~0.9~~ 0.9/1.0 L/ha dose, lower mean control of 71.2% with more variable results (range 64.0-80.0%).

Across all trials, control of PYRNTR demonstrated by the proposed dose rate range of 1.2-1.5 L/ha was comparable to the prothioconazole standard Proline at 86.4%.

In addition to these trials from the EPPO South-East climatic zone, data are available from Austria (1 trial), the Czech Republic (1 trial ~~2 trials~~) and Poland (2 ~~3~~ trials), which are neighbouring countries, bordering the EPPO South-East climatic zone. These countries have conditions that favour the development of PYRNTR (warmer/wetter conditions) more than the EPPO South-East climatic zone, which is reflected in the increased levels of disease in the trials (10.3-26.3%) compared to EPPO South-East climatic zone (5.2-10.0%). It is therefore considered that results from these trials can be considered a more challenging situation for PYRNTR control and can be used to support the claims for control of this disease in this zone. Data from these ~~four~~ six trials demonstrate a similar dose response and when combined with the three EPPO South-East trials give ~~87.3~~ 89.1% control of PYRNTR for the 1.5 L/ha dose, compared to ~~79.6~~ 81.3% for the 1.2 L/ha dose and ~~70.3~~ 72.0% for the ~~0.9~~ 0.9/1.0 L/ha dose, ~~across 9 trials~~. Results for the 1.2 and 1.5 L/ha doses were comparable to or higher than the reference standard at ~~75.6~~ 83.3%.

The results are summarised in Table 3.2-9179 and individual trial results are detailed in the BAD.

~~Table 3.2-91 Minimum effective dose testing of GF-3307 at the proposed label rates of 1.2 and 1.5 L/ha and lower 0.9 L/ha rate against PYRNTR in winter wheat (TRZAW). Results from 3 trials from the EPPO South-East climatic zone, two trials from Poland, one trial from Austria and one trial from the Czech Republic, conducted between 2014 and 2020. Assessment at 16-45 days after application.~~

EPPO-Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East	3	7.2	5.2-10.0	71.2	64.0-80.0	81.7	74.2-90.0	92.0	88.6-97.3	86.4#	80.0-94.3
AT+ CZ+ PL	4	18.3	10.3-26.3	69.6	56.8-78.1	77.9	68.1-86.1	83.7	77.5-82.3	67.5 ^Δ	31.5-86.6
South-East+ AT+ CZ+ PL	7	13.5	5.2-26.3	70.3	56.8-80.0	79.6	68.1-90.0	87.3	77.5-97.3	75.6 ^Δ	31.5-94.3

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

^ΔReference standards used based on prothioconazole applied at 180-198 g as/ha and one trial using Aviator Xpro at 1.25 L/ha

Table 3.2-92 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against PYRNTR in winter wheat (TRZAW). Results from three (3) trials from the EPPO South-East climatic zone, three (3) trials from Poland, one (1) trial from Austria and two (2) trials from the Czech Republic, conducted between 2014 and 2021. Assessment at 16-45 days after application.

EPPO Zone	Number of trials	Untreated control % infection PYRNTR		% control of PYRNTR							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East	3	7.2	5.2-10.0	71.2	64.0-80.0	81.7	74.2-90.0	92.0	88.6-97.3	86.4	80.0-94.3
AT + CZ + PL	6	16.9	10.3-26.3	72.4	56.8-87.1	81.1	68.1-90.6	87.6	77.5-100	81.3	59.4-90.8
South-East + AT + CZ + PL	9	13.6	5.2-26.3	72.0	56.8-87.1	81.3	68.1-90.6	89.1	77.5-100	83.0	59.4-94.3

#Reference standards used based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro at 1.0-1.25 L/ha

Summary and conclusions on the minimum effective dose (MED) range of 1.2-1.5 L/ha for control of PYRNTR in winter wheat (EPPO South-East climatic zone)

PYRNTR is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of PYRNTR at the proposed maximum dose rate of 1.5 L/ha. The maximum dose of 1.5 L/ha will give excellent control in all situations. Where disease pressure is lower, a dose of 1.2 L/ha will still provide sufficient control of PYRNTR. Control by the ~~0.9~~ 0.9/1.0 L/ha dose was not considered sufficient.

It is considered that the proposed dose rate range of 1.2-1.5 L/ha is the minimum effective dose to deliver effective control of this disease across a wide range of environmental conditions, in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.6 MED of GF-3307 for the control of ERYSGT in wheat

This section addresses the minimum effective dose (MED) of GF-3307 for the control of ERYSGT on winter and spring wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of ~~1.2~~ 1.0-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-80 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-30 m² EPPO Maritime: 16-30 m ² EPPO North-East: 15-25 m ² EPPO South-East: 20-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: TRZAW (6) EPPO North-East: TRZAW (2 6), TRZAS (1) EPPO South-East: TRZAW (4 5)
	Varieties per crop	EPPO Maritime: Winter wheat: Akteur, Dagmar, Princeps, Tobak (3). EPPO North-East: Winter wheat: Arkadia, Artist, Bilanz, Julius, Zyta (2), Balaton, Basilio, Cellule, Miranda Spring wheat: Harenda EPPO South-East: Winter wheat: Balaton, Basilio, Cellule, Miranda, Rubisko
Application	Crop stage (BBCH) at application	EPPO Maritime: 1 application (BBCH 32-49), 2 applications (3 CZ trials: BBCH 31-32 and BBCH 37-49) EPPO North-East: BBCH 39-49 37-55 EPPO South-East: BBCH 32-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In all cases ERYSGT was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 (10 trials), 2 (three CZ trials) EPPO Maritime: One per crop (4 trials), Two per crop (3 trials) EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where the key target pathogen is an abundant disease. ERYSGT was assessed as a secondary pathogen present at reliable levels.

Introduction

In total, data from 13 18 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of ERYSGT in winter and spring wheat. GF-3307 was tested at 1.5, 1.2 and 0.9/1.0 L/ha. **Note:** Results from 2020 and 2021 trials were based on a 1.0 L/ha lower dose. Results from these trials in the EPPO Maritime and North-East climatic zones have been combined with those from earlier trials at the 0.9 L/ha dose, as these doses are within 10% of each other are therefore considered to be comparable dose rates. The trials were performed in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’. The reference product was Proline 275 applied at 0.72 L/ha across all trials. The reference products were Proline 275 or Proline 250 applied at 0.72 L/ha or Aviator Xpro applied at 1.0 L/ha.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Czech Republic (6) in the EPPO Maritime climatic zone, Poland (3 7) in the EPPO North-East climatic zone and Hungary (3) and Romania (1 2) in the EPPO South-East climatic zone, between 2014 and 2020 2021.

On the basis of the EPPO standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these EPPO climatic zones, which is representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The MED efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-18

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGT is an abundant disease. ERYSGT is a disease which multiplies rapidly at short cycles under warm climatic conditions such as found in the EPPO Maritime, North-East and South-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 8 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test-product	Formulation type	Active-substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6	150

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0	225

Experimental details

The 13 18 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12 m² and 30 m². Fourteen Seventeen trials were carried out on winter wheat and one on spring wheat. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

In the EPPO South-East and North-East climatic zone trials, GF-3307 was applied as a single application at BBCH 32-4955 of winter wheat. The treatments were typically sprayed when ERYSGT had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

The EPPO Maritime climatic zone trials were set up to support both a single and two-dose regime and in many trials included both regimes. ERYSGT is generally a late season disease, that spreads quickly during periods of hot weather. Some of the trials were targeted specifically at ERYSGT and were based on a single application from BBCH 37-49, to provide mainly curative control of the disease. However, other trials were designed as general disease trials, with the first applications potentially applied too early for effective control of ERYSGT, followed by a second application. Three Czech trials which were based on a two-dose regime (CZ15E7B010PV01C, CZ15E7B041PV01C and CZ15E7B041PV04C) and ERYSGT did not develop until 11-25 days after the second application. In these trials, the first applications were made at BBCH 31-32 of the crop and the second applications were made at BBCH 37-45. ERYSGT did not develop in these trials until 26-48 days after the first application, demonstrating how the disease can infect crops late in their development, and this is considered to be beyond the expected protection period for the first application of GF-3307 (see summary of disease levels at application for these trials below). In addition, the assessed leaf (Leaf 2 and 3) had not emerged at the time of the first application (BBCH 31-32) and would not have been protected by that spray. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. For full site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

zRMS comments:

The situation is accepted and explained by the zRMS in first of the two commenting boxes following the introduction to the MED chapter (3.2.2), in the page 149.

Summary of disease levels at application in two-dose trials

Trial number	1 st Application timing (BBCH)	ERYSGT % infection at 1 st application	2 nd Application timing (BBCH)	ERYSGT % infection at 2 nd application	Days after 2 nd application ERYSGT found in trial (days after 1 st application)
CZ15E7B010PV01C	32	0% all leaves	43	0% all leaves	11 days (26 days)
CZ15E7B041PV01C	31-32	3.0% L6	37-39	0% L4	18 days (44 days)
CZ15E7B041PV03C	31	0% all leaves	43-45	0% all leaves	25 days (48 days)

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after each application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with ERYSGT or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments used were generally on Leaf 1 to Leaf 3 as the highest available assessed leaf with sufficient infection in the untreated.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Six GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of ERYSGT in wheat, following a single application, applied at BBCH 32-49 of the crop. The MED trials were conducted in the Czech Republic (6) in the EPPO

Maritime climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (mostly Leaf 3), so are considered to be a robust test of the product. Results for three trials are based on a two-dose regime. In these trials ERYSGT did not develop until 11-25 days after the second application, 16-48 days after the first application, which is beyond the protection period the first application of GF-3307 could be expected to deliver. It is also considered that as the first application was at BBCH 31-32 of the crop, the assessed leaf (Leaf 2/Leaf 3) had not emerged at this timing. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. A comparison of control achieved by the single and two-dose trials is presented in section 3.2.3 and confirm the comparability of the dose regimes in these trials.

Note: In one trial, the latest assessment timing after a single application was 11 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

An application of GF-3307 applied at 1.5 L/ha achieved mean control of 92.8% (range 90.4-94.6%) for ERYSGT, 17-34 days after application across four trials. Applied in the same trials, at 1.2 L/ha (80% rate/0.8N), GF-3307 achieved very good control of 87.9%, but with more variable results (range 73.0-99.4%). All six trials compared the proposed dose (1.5 L/ha), with a dose of ~~0.9~~ **0.9/1.0** L/ha (60% rate/0.6N), which demonstrated 83.3% overall control (range 71.6-99.2%) compared to 92.9% for the 1.5 L/ha dose, at 11-34 days after application.

Across all trials, control of ERYSGT demonstrated by the proposed dose rate of 1.5 L/ha was comparable with ~~the the prothioconazole standard Proline at 86.4%~~ **the reference standards (Proline and Aviator Xpro) at 93.4%.**

The results are summarised in Table 3.2-81, and individual trial results are detailed in the BAD.

Table 3.2-81 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 60-~~67~~% dose rates against ERYSGT in winter wheat (TRZAW). Results from 6 trials conducted in the EPPO Maritime climatic zone between 2015 - 2020. Assessment at 11-34 days after application.

EPPO Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 0.9-1.0 L/ha (60-67% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	4	11.0	8.1-14.9	78.9	71.6-99.2	87.9	73.0-99.4	92.8	90.4-94.6	93.4	80.2-100
Maritime**	6	10.6	7.9-14.9	83.3	71.6-99.2	-	-	92.9	86.3-100	95.6	80.2-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

Direct comparison of 1.5 L/ha and **0.9/1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 198 g as/ha **and Aviator Xpro at 1.0 L/ha.**

Summary and conclusions on the minimum effective dose (MED) for control of ERYSGT in winter wheat (EPPO Maritime climatic zone)

ERYSGT is an important secondary target disease for GF-3307 and the data reported demonstrate that it provides excellent control of ERYSGT at the proposed dose rate of 1.5 L/ha. The proposed dose of 1.5 L/ha was the only dose to achieve mean control >90%. The proposed dose achieved levels of control higher than the 0.8N and 0.6N dose, in the majority of trials.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required to deliver robust control of this disease, under a wide range of environmental conditions in the EPPO Maritime climatic zone.

Proposed dose range of ~~1.2~~ **1.0-1.5** L/ha for Poland (EPPO North-East climatic zone)

~~Three~~ **Seven** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the ERYSGT in winter wheat and spring wheat, following a single application applied at ~~BBCH 39-49~~ **BBCH 37-55** of the crop. The MED trials were conducted

in Poland (3 7) in the EPPO North-East climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1, Leaf 2 or Leaf 3), so are considered to be a robust test of the product.

For winter wheat (two six trials), a single application of GF-3307 applied at 1.5 L/ha achieved mean control of 88.2 94.0% (range 88.0-88.3 87.5-100%) for ERYSGT, 21-42 days after application compared to 88.4 89.4% for the 1.2 L/ha dose and 83.7 82.6% for the 0.9 0.9/1.0 L/ha dose. Across all trials, control of ERYSGT demonstrated by the proposed dose rate range of 1.2 0.9-1.5 L/ha was comparable to the prothioconazole standard Proline (90.8 90.4% overall control).

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These three trials were conducted in the Czech Republic based on a single application. The 1.5 L/ha achieved 92.5% control compared to 80.9% for the 1.2 L/ha dose and 90.4% compared to 77.6% for the 0.9 0.9/1.0 L/ha dose. Combined with the six two EPPO North-East trials, these give overall control of ERYSGT across four eight winter wheat trials of 90.3 93.6% for the proposed dose compared to 84.6 87.3% for the 1.2 L/ha dose and across five trials, 89.5% for the proposed dose compared to 80.0% for the 0.9 L/ha dose and 80.9% for the 0.9/1.0 L/ha dose, across nine trials. Details for the Czech trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-932 and individual trial results are detailed in the BAD.

Table 3.2-93 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and 0.9 L/ha dose rate against ERYSGT in winter wheat (TRZAW). Results from two trials in the EPPO North-East climatic zone plus three CZ trials, conducted between 2014 and 2020 . Assessment at 11-42 days after one application.

EPPO-Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 0.9 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	2	7.5	7.0-8.0	83.7	78.5-88.9	88.4	87.1-89.7	88.2	88.0-88.3	90.8	89.6-91.9
CZ*	2	13.4	11.9-14.9	72.0	71.6-72.4	80.9	73.0-88.7	92.5	90.4-94.6	60.4	46.9-73.8
CZ**	3	12.9	11.9-14.9	77.6	71.6-88.8	-	-	90.4	86.3-94.6	73.6	46.9-100
North-East + CZ*	4	10.4	7.0-14.9	77.9	71.6-88.9	84.6	73.0-89.7	90.3	88.0-94.6	75.6	46.9-91.9
North-East + CZ**	5	10.7	7.0-14.9	80.0	71.6-88.9	-	-	89.5	86.3-94.6	80.4	46.9-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9 L/ha doses.

#Reference standards used based on prothioconazole applied at 180-198 g a.s/ha.

Table 3.2-94 Minimum effective dose testing of GF-3307 at 0.9-1.5 L/ha against ERYSGT in winter wheat (TRZAW). Results from six (6) trials in the EPPO North-East climatic zone plus three (3) CZ trials, conducted between 2014 and 2021 . Assessment at 11-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	6	10.8	6.0-17.5	82.6	57.5-100	89.4	72.5-100	94.0	87.5-100	90.4	73.8-100
CZ*	2	13.4	11.9-14.9	72.0	71.6-72.4	80.9	73.0-88.7	92.5	90.4-94.6	87.8	80.2-95.3
CZ**	3	12.9	11.9-14.9	77.6	71.6-88.8	-	-	90.4	86.3-94.6	91.8	80.2-100
North-East +	8	11.4	6.0-17.5	79.9	57.5-100	87.3	72.5-100	93.6	87.5-100	89.7	73.8-100

EPPO Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
CZ*											
North-East + CZ**	9	11.5	6.0-17.5	80.9	57.5-100	-	-	92.8	86.3-100	90.9	73.8-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.9/1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro at 1.0 L/ha

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). In this trial the proposed 1.5 L/ha dose achieved the highest level of control (85.5%) compared to 69.7% for the 1.2 L/ha dose and 58.0% for the 0.9 L/ha dose.

The results are summarised Table 3.2-953 and the results of the individual trials are detailed in the BAD.

Table 3.2-95 83 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and 0.9 L/ha dose rate against ERYSGT in spring wheat (TRZAS). Results from one trial conducted in the EPPO North-East climatic zone in 2020. Assessment at 28 days after one application.

EPPO Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 0.9 L/ha 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	1	11.5	-	58.0	-	69.7	-	85.5	-	79.4	-

Summary and conclusions on the minimum effective dose (MED) for control of ERYSGT in wheat (EPPO North-East climatic zone)

ERYSGT is an important secondary target disease for GF-3307 and the data reported demonstrate that it provides excellent control of ERYSGT on winter wheat at the proposed dose rate range of 1.2–1.5 L/ha. The proposed lower dose rate of 1.2 L/ha achieved overall control of 84.6%, compared to 77.9% for the 0.9 L/ha dose (across two EPPO North East trials and two CZ DE trials). The results for the maximum dose rate of 1.5 L/ha (required for other diseases) demonstrate that high levels of control of ERYSGT (89.5% across five trials) where this dose is required in mixed disease situations. The proposed dose rate range demonstrated control greater than the 0.9 L/ha dose across the majority of trials. In one trial on spring wheat a comparable dose response was demonstrated.

It is considered that the proposed lower dose rate of 1.2 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring wheat under a wide range of environmental conditions in Poland (EPPO North East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in wheat or where FUSASP also occurs or is expected, the higher dose of 1.5 L/ha may be recommended for broad spectrum disease control.

ERYSGT is an important secondary target disease for GF-3307 and the data reported demonstrate that it provides excellent control of ERYSGT on winter wheat at the proposed dose rate range of 1.0-1.5 L/ha. The proposed lower dose rate of 1.0 L/ha (supported by data at 0.9/1.0 L/ha) achieved overall control of 80.9% (across six EPPO North-East trials and three CZ DE trials). The results for the 1.2 L/ha dose rate, required for other diseases, demonstrate that high levels of control of ERYSGT (87.3% across eight trials) where this dose is required in mixed disease situations. The results for the

maximum dose rate of 1.5 L/ha (required for FUSASP) demonstrate that high levels of control of ERYSGT (92.8% across nine trials) where this dose is required in mixed disease situations. In one trial on spring wheat a comparable dose response was demonstrated.

It is considered that the proposed lower dose rate of 1.0 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring wheat in a low disease situations. However, as cereal diseases may occur together, for higher disease pressure disease situations in wheat or where FUSASP also occurs or is expected, the higher doses of 1.2 or 1.5 L/ha may be recommended for broad spectrum disease control.

A dose range of 1.0-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

~~Four~~ **Five** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the ERYSGT in winter wheat, following a single application applied at BBCH 39-49 of the crop. The MED trials were conducted in Hungary (3) and Romania (~~4~~ **2**) in the EPPO South-East climatic zone. Assessments across all trials were on Leaf 1 to Leaf 3 and are considered to be a robust test of the product.

All ~~four~~ **five** trials compared the ~~proposed dose range~~ **doses** of 1.2-1.5 L/ha with a lower dose of 1.0 L/ha. GF-3307 at 1.5 L/ha achieved mean control of ~~91.4~~ **87.8%** (range ~~89.4~~ **73.1**-92.7%), 33-~~39~~**49** days after application. Applied in the same trials, the 1.2 L/ha dose of GF-3307 achieved mean control of ~~85.2~~ **82.0%** (range ~~78.6~~ **69.3**-91.5%) and the 1.0 L/ha dose, lower mean control of ~~74.6~~ **69.9%** with more variable results (range 50.3-90.0%).

Across all trials, control of ERYSGT demonstrated by ~~the proposed dose rate range~~ **dose rates** of 1.2-1.5 L/ha was comparable to the prothioconazole standard Proline at ~~91.7~~ **86.0%**.

The results are summarised in Table 3.2-964 and individual trial results are detailed in the BAD.

~~Table 3.2-96 Minimum effective dose testing of GF-3307 at the proposed label rates of 1.2 and 1.5 L/ha and lower 1.0 L/ha rate against ERYSGT in winter wheat (TRZAW). Results from 4 trials from the EPPO South-East climatic zone conducted in 2020. Assessment at 33-39 days after one application.~~

EPPO-Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 250 at 0.6 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East	4	17.1	12.0-25.0	74.6	50.3-90.0	85.2	78.6-91.5	91.4	89.4-92.7	91.7	87.7-95.6

Table 3.2-97 Minimum effective dose testing of GF-3307 at 1.0-1.5 L/ha against ERYSGT in winter wheat (TRZAW). Results from 5 trials from the EPPO South-East climatic zone, conducted in 2020 and 2021. Assessment at 33-49 days after one application.

EPPO Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 250 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East	5	15.8	10.5-25.0	69.9	50.3-90.0	82.0	69.3-91.5	87.8	73.1-92.7	86.0	63.3-95.6

Summary and conclusions on the minimum effective dose (MED) range of 1.2-1.5 L/ha for control of ERYSGT in winter wheat (EPPO South-East climatic zone)

ERYSGT is an important secondary target disease for GF-3307 and the data reported demonstrate that it provides excellent control of ERYSGT at the proposed maximum dose rate of 1.5 L/ha. The

maximum dose of 1.5 L/ha will give excellent control in all situations. Where disease pressure is lower, a dose of 1.2 L/ha will still provide sufficient control of ERYSGT. Control by the 1.0 L/ha dose was not considered sufficient.

It is considered that the proposed dose rate range of 1.2-1.5 L/ha is the minimum effective dose to deliver effective control of this disease across a wide range of environmental conditions, in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.7 MED of GF-3307 for the control of Puccinia in winter rye

This section addresses the minimum effective dose (MED) of GF-3307, for the control of Puccinia on winter rye, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and in Poland (EPPO North-East climatic zone).

Table 3.2-85 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-25 m ² EPPO North-East: 24-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 10 SECCW EPPO North-East: 3-5 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Palazzo (7), Recrut, Visello (2) EPPO North-East: Bono, Brasetto, Dankowskie Diamant, Kier, SU Performer
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 32-51 EPPO North-East: BBCH 37-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of Puccinia applications were timed to cover these situations from commencing when there was a risk of infection with Puccinia or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop
	Spray volumes	200-230-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease.

Introduction

In total, data from 13-15 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of Puccinia in winter rye (SECCW). GF-3307 was tested at 1.5, 1.2 and 1.0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 'Minimum effective dose'. The reference product was Proline 275 applied at 0.72 L/ha. The reference products were Proline 275 or Proline 250 applied at 0.72 L/ha. The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials, in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (10) in the EPPO Maritime climatic zone and Poland (3-5) in the EPPO North-East climatic zone in 2015, 2016 and 2021.

On the basis of EPPO Standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-19.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease. For trial site and application details, see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 9 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.5	150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180

Experimental details

The 13 15 MED trials were conducted by officially recognized testing organisations to GEP and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 20m² and 30m². In all trials, the treatments were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 300 L/ha.

GF-3307 was applied as a single application at BBCH 32-52 of winter rye. The treatments were typically sprayed when Puccinia had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with Puccinia or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were conducted on Leaf 1 or Leaf 2 as the highest leaf or the leaf with the highest level of infection.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Ten GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of Puccinia striiformis (Puccre) in winter rye, following a single application, applied at BBCH 32-51 of the crop. The MED trials were conducted in Germany (10) in the EPPO Maritime climatic zone. Assessments were conducted on Leaf 1 or Leaf 2, as the highest leaf or the leaf with highest levels of Puccre infection, so are considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 89.6% (range 82.5-100%) for Puccre, 33-56 days after application. Applied in the same trials, the 1.2 L/ha (80% rate/0.8N) dose of GF-3307 achieved lower mean control of 83.3%, with more variable results (range 71.4-95.0%). Across all trials, control of Puccre demonstrated by the proposed dose rate of 1.5 L/ha was comparable with the prothioconazole standard Proline (88.1%).

The results are summarised in Table 3.2-8686 and individual trial results are detailed in the BAD.

Table 3.2-86 Minimum effective dose testing of GF-3307 at the proposed maximum label rate of 1.5 L/ha and 80% dose rate against Puccre in winter rye (SECCW). Results from 10 trials conducted in the EPPO Maritime climatic zone in 2015 and 2016. Assessment at 33-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccre		% control of Puccre					
				GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	10	15.5	5.0-41.2	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100

Summary and conclusions on the minimum effective dose (MED) for control of Puccre in winter rye (EPPO Maritime climatic zone)

Puccre is an important target disease for GF-3307 on winter rye and the data reported demonstrate that it provides excellent control of Puccre at the proposed dose rate of 1.5 L/ha. The proposed dose of GF-3307 achieved the highest level of overall control (89.6%) and was the only dose to consistently demonstrate control >80% across all trials. It delivered control higher than the 0.8N dose in all trials.

It is considered that the proposed dose rate of 1.5 L/ha is the most effective dose of GF-3307, required to deliver robust control of this disease under a wide range of environmental conditions, in the EPPO Maritime climatic zone.

Proposed maximum dose of 1.5 L/ha for Poland (EPPO North-East climatic zone)

Three Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the Puccre in winter rye, following a single application applied at BBCH 37-52 of the crop. The MED trials were conducted in Poland (3 5) in the EPPO North-East climatic zone. Assessments were conducted on Leaf 1 or Leaf 2, as the highest leaf or the leaf with the highest levels of Puccre infection, so are considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 77.1 84.7% (range 69.0-84.7 100%) against Puccre, 41-49 days after application. Applied in the same trials at 1.2 L/ha, GF-3307 achieved mean control of 67.4 77.4% (range 54.7-77.8 100%). Across all three trials, control of Puccre demonstrated by the proposed maximum dose rate of 1.5 L/ha was higher than comparable to the prothioconazole/Proline standard, at 73.8 83.3% overall control. Two trials included a 1.0 L/ha dose (67% of the proposed maximum dose) and GF-3307 demonstrated lower control of 84.4% at this dose rate, compared to 96.2% for the proposed 1.5 L/ha dose and 92.3% for the lower 1.2 L/ha dose.

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose range of 1.2-1.5 L/ha. These 10 trials were conducted in Germany and demonstrate a comparable dose response to the EPPO North-East climatic zone data, with the 1.5 L/ha achieving the highest level of control at 89.6%, compared to

83.3% for the 1.2 L/ha dose. Combined with the three EPPO North-East climatic zone trials, these give overall control of Puccre across the 13 trials of 86.7% for the proposed dose and 79.6% for the 1.2 L/ha dose. Details for these German trials are included in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-98/87 individual trial results are detailed in the BAD.

Table 3.2-98 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against Puccre in winter rye (SECCW). Results from 3 trials conducted in the EPPO North-East climatic zone and 10 trials conducted in DE in 2015 and 2016. Assessment at 33-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccre		% control of Puccre					
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	3	32.8	18.1-49.1	67.4	54.7-77.8	77.1	69.0-84.7	73.8	66.2-86.3
DE	10	15.5	5.0-41.2	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100
North-East + DE	13	19.5	5.0-49.1	79.6	54.7-95.0	86.7	69.0-100	84.8	66.2-100

Table 3.2-99 Minimum effective dose testing of GF-3307 at 1.0-1.5 L/ha against Puccre in winter rye (SECCW). Results from 5 trials conducted in the EPPO North-East climatic zone and 10 trials conducted in DE between 2015 and 2021. Assessment at 33-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccre		% control of Puccre							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	5	26.2	8.8-49.1	-	-	77.4	54.7-100	84.7	69.0-100	83.3	66.2-100
North-East**	2	16.3	8.8-23.8	84.4	78.8-90.0	92.3	84.5-100	96.2	92.3-100	97.7	95.3-100
DE*	10	15.5	5.0-41.2	-	-	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100
North-East + DE*	15	21.1	5.0-49.1	-	-	79.6	54.7-95.0	86.6	69.0-100	86.5	66.2-100

*Direct comparison with 1.2 L/ha dose. **Direct comparison with 1.0 L/ha dose.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Summary and conclusions on the minimum effective dose (MED) for control of Puccre in winter rye (EPPO North-East climatic zone)

Puccre is an important target disease for GF-3307 on winter rye and the data reported demonstrate that it provides effective control of Puccre, at the proposed maximum dose rate of 1.5 L/ha. The proposed maximum dose of GF-3307 achieved the highest level of overall control (77.1 84.7% in three across five EPPO North-East climatic zone trials and 89.6% in the 10 German trials). Across all 15 trials, the maximum proposed dose of 1.5 L/ha GF-3307 achieved levels of control higher than the 1.2 L/ha dose, with only two results below 80% while using the 1.5 L/ha dose, compared to six results below 80% for the 1.2 L/ha dose. Where other diseases are the main target and when Puccre pressure is lower, then the 1.2 L/ha dose would be acceptable (79.6% overall control), though 1.5 L/ha is the most effective dose when rust pressure is higher.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease under a wide range of environmental conditions, in Poland (EPPO North-East climatic zone).

A dose range of 1.2-1.5 L/ha will be proposed for diseases of rye to offer growers flexibility so they can adjust dose according to the conditions. Data in the efficacy section will be presented for the 1.5

L/ha dose that will be advised in high risk situations for PUCCRE and also the 1.2 L/ha dose that can be used in the less severe disease situations.

3.2.2.8 MED of GF-3307 for the control of RHYNSE in winter rye

This section addresses the minimum effective dose (MED) of GF-3307, for the control of RHYNSE on winter rye, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone).

Table 3.2-88 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-25 m ² EPPO North-East: 19.6-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 8 SECCW EPPO North-East: 5 6 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Palazzo (5), Recrut, Visello (2) EPPO North-East: Bono, Brasetto , Dankowskie Diament (2), Kier, Palazzo
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 32-51 EPPO North-East: BBCH 37-59
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of RHYNSE applications were timed to cover these situations from commencing when there was a risk of infection with RHYNSE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop
	Spray volumes	200- 230 300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease.

Introduction

In total, data from ~~13~~ 14 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of RHYNSE in winter rye (SECCW). GF-3307 was tested at 1.5, 1.2 and 1.0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 ‘Minimum effective dose’. ~~The reference product was Proline 275 applied at 0.72 L/ha.~~ **The reference products were Proline 275 or Proline 250 applied at 0.72 L/ha.** The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (8) in the EPPO Maritime climatic zone and Poland (~~5~~ 6) in the EPPO North-East climatic zone, in 2015 and 2016 and 2021.

On the basis of the EPPO Standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-20.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 10 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.5	150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180

Experimental details

The 13 14 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 19.6m² and 30m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 300 L/ha.

GF-3307 was applied as a single application at BBCH 32-59 of winter rye. The treatments were typically sprayed when RHYNSE had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately, 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were already senesced to a high degree in both the treated and untreated plots, were excluded from summarization. Assessments were conducted on Leaf 1, Leaf 2 or Leaf 3 as the highest leaf or the leaf with the highest level of infection.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Eight GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of RHYNSE in winter rye, following a single application, applied at BBCH 32-51 of the crop. The MED trials were conducted in Germany (8) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf (Leaf 1, Leaf 2 or Leaf 3), as this leaf had high levels of RHYNSE infection, so was considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 89.9% (range 75.0-100%) for RHYNSE, 33-56 days after application. Applied in the same trials at 1.2 L/ha (80% rate/0.8N), GF-3307 achieved lower mean control of 84.5%, with more variable results (range 68.2-100%).

Across all trials, control of RHYNSE demonstrated by the proposed dose rate of 1.5 L/ha was higher than the prothioconazole standard Proline at 83.2% overall control.

The results are summarised in Table 3.2-89 and individual trial results are detailed in the BAD.

Table 3.2-89 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha and 80% dose rate against RHYNSE in winter rye (SECCW). Results from 8 trials conducted in the EPPO Maritime climatic zone in 2015 and 2016. Assessment at 33-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE					
				GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	8	15.3	6.8-27.0	84.5	68.2-100	89.9	75.0-100	83.2	59.3-100

Summary and conclusions on the minimum effective dose (MED) for control of RHYNSE in winter rye (EPPO Maritime climatic zone)

RHYNSE is an important target disease for GF-3307 on winter rye, and the data reported demonstrate that it provides excellent control of RHYNSE at the proposed dose rate of 1.5 L/ha. The proposed dose of GF-3307 achieved the highest level of overall control at 89.9% compared to lower control of 84.5% for the 0.8N dose. In all trials, the proposed dose achieved levels of control higher than or equal to the 0.8N dose.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required for the control of RHYNSE in winter rye, in the EPPO Maritime climatic zone.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

~~Five~~ **Six** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the RHYNSE in winter rye, following a single application applied at BBCH 37-59 of the crop. The MED trials were conducted in Poland (~~5~~ **6**) in the EPPO North-East climatic zone. Assessments were conducted on Leaf 1 or Leaf 2, as the highest leaf or the leaf with the highest levels of RHYNSE infection, so are considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of ~~81.5~~ **81.1%** (range 68.1-97.6%) against RHYNSE, 35-~~42~~**43** days after application. Applied in the same trials at 1.2 L/ha, GF-3307 achieved good control of ~~76.0~~ **75.7%** (range 63.5-93.8%). Control of RHYNSE demonstrated by GF-3307 at both doses was higher than the prothioconazole/Proline standard, at ~~68.6~~ **70.7%** overall control. **One trial included a 1.0 L/ha dose (67% of the proposed maximum dose) and GF-3307 demonstrated significantly lower control of 69.1% at this dose rate, compared to 79.2% for the proposed 1.5 L/ha dose and 74.2% for the lower 1.2 L/ha dose. This trial also had the highest level of RHYNSE across the data set (40.0% severity in the untreated at assessment) and confirms the importance of the higher dose to achieve good levels of control in high disease pressure situations.**

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose rate range. These eight trials were conducted in Germany and demonstrate a comparable dose response to the EPPO North-East climatic zone data, with the 1.5 L/ha achieving the highest level of control at 89.9%, compared to 84.5% for the 1.2 L/ha dose which also delivered high levels of control. Combined with the ~~five~~ **six** EPPO North-East climatic zone trials, these give overall control of RHYNSE across the ~~13~~ **14** trials of ~~86.3~~ **86.1** % for the proposed maximum dose of 1.5 L/ha and ~~81.2~~ **80.7**% for the 1.2 L/ha dose. Details for these German trials are included in the EPPO Maritime climatic zone section, above. The results are summarised in Table 3.2-1000 and individual trial results are detailed in the BAD.

~~Table 3.2-100 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against RHYNSE in winter rye (SECCW). Results from 5 trials conducted in the EPPO North-East climatic zone in 2016 and 8 trials conducted in DE in 2015 and 2016. Assessment at 33-56 days after one application.~~

EPPO Zone	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE					
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	5	13.1	5.0-28.4	76.0	63.5-93.8	81.5	68.1-97.6	68.6	56.0-77.3
DE	8	15.3	6.8-27.0	84.5	68.2-100	89.9	75.0-100	83.2	59.3-100
North-East + DE	13	14.5	5.0-28.5	81.2	63.5-100	86.7	68.1-100	77.6	56.0-100

Table 3.2-101 Minimum effective dose testing of GF-3307 at 1.0-1.5 L/ha against RHYNSE in winter rye (SECCW). Results from 6 trials conducted in the EPPO North-East climatic zone in 2016 and 2021, plus 8 trials conducted in DE in 2015 and 2016. Assessment at 33-56 days after one application.

EPPO Zone	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	6	17.6	5.0-40.0			75.7	63.5-93.8	81.1	68.1-97.6	70.7	56.0-77.3
North-East**	1	40.0	-	61.9		74.2	-	79.2	-	81.3	-
DE*	8	15.3	6.8-27.0			84.5	68.2-100	89.9	75.0-100	83.2	59.3-100
North-East + DE*	14	16.3	5.0-40.0			80.7	63.5-100	86.1	68.1-100	77.9	56.0-100

*Direct comparison with 1.2 L/ha dose. ** direct comparison with 1.0 L/ha dose.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro at 1.0 L/ha

Summary and conclusions on the minimum effective dose (MED) for control of RHYNSE in winter rye (EPPO North-East climatic zone)

RHYNSE is an important target disease for GF-3307 on winter rye and the data reported demonstrate the proposed maximum dose rate of 1.5 L/ha provides excellent control of RHYNSE (~~86.3% across 13~~ **86.1% across 14** trials). Where disease pressure is lower, then the 1.2 L/ha dose would provide good control (~~81.2~~ **80.7**% control across ~~13~~ **14** trials), though the maximum 1.5 L/ha is the most effective dose when disease pressure is higher or when a longer period of protection is required or other diseases, including rusts, are dominant in the crop.

It is considered that the proposed maximum dose rate of 1.5 L/ha is the most effective dose of GF-3307 to provide robust control of this disease under a wide range of environmental conditions in Poland (EPPO North-East climatic zone), though the 1.2 L/ha dose achieved very good levels of control that would be acceptable for a grower.

A dose range of 1.2-1.5 L/ha will be proposed for diseases of rye to offer growers flexibility so they can adjust dose according to the conditions.

3.2.2.9 MED of GF-3307 for the control of SEPTSP in winter triticales

This section addresses the minimum effective dose (MED) of GF-3307, for the control of SEPTSP on winter triticales, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and in Poland (EPPO North-East climatic zone).

Table 3.2-1021 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 21-25 m ² EPPO North-East: 30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 4 TTLWI EPPO North-East: 3 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: Adverda, Agostino (2), Talendro EPPO North-East: Grenado, Magnat, Tulus
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 33-51 EPPO North-East: BBCH 33-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of SEPTSP applications were timed to cover these situations from commencing when there was a risk of infection with SEPTSP or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease.

Introduction

In total, data from seven field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of SEPTSP in winter triticales (TTLWI). GF-3307 was tested at 1.5 and 1.2 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference product was Proline 275 applied at 0.72 L/ha. The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (4) in the EPPO Maritime climatic zone and Poland (3) in the EPPO North-East climatic zone, in 2015 and 2016.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates*', the trials included in the dossier have been grouped and summarised by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the EPPO Maritime and North-East climatic zones, as

described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-21.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 11 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198

Experimental details

The seven MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 21m² and 30m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 L/ha.

GF-3307 was applied as a single application at BBCH 33-52 of winter triticale. The treatments were typically sprayed when SEPTSP had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTSP or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were on Leaf 1, Leaf 2 or Leaf 3.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Four GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of SEPTSP in winter triticale, following a single application, applied at BBCH 33-51 of the crop. The MED trials were conducted in Germany (4) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf (Leaf 1 or Leaf 2), as this leaf had high levels of SEPTSP infection, so was considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 88.2% (range 82.3-100%) for SEPTSP, 41-50 days after application. Applied in the same trials, at 1.2 L/ha (80% rate/0.8N), GF-3307 achieved lower mean control of 75.1%, with more variable results (range 69.2-90.3%). Across all trials, control of SEPTSP demonstrated by the proposed dose rate of 1.5 L/ha was higher than the prothioconazole standard Proline (72.5% overall).

In addition to these trials, data from three trials in neighbouring countries of the EPPO North-East climatic zone are available and can also be considered supportive of the proposed dose. These three

trials were conducted in Poland and demonstrate a comparable dose response to the EPPO Maritime climatic zone trials, with the 1.5 L/ha achieving the highest level of control of 78.4% compared to 72.3% for the 1.2 L/ha dose. Combined with the four EPPO Maritime trials, these give mean control of SEPTSP across seven trials of 84.0% for the proposed dose and 73.9% for the 1.2 L/ha dose. Details for these Polish trials are included in the EPPO North-East climatic zone section, below. The results are summarised in Table 3.2-1032 and individual trial results are detailed in the BAD.

Table 3.2-1032 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha and 80% dose rate against SEPTSP in winter triticale (TTLWI). Results from 4 trials conducted in the EPPO Maritime climatic zone and 3 trials conducted in PL in 2015 and 2016. Assessment at 21-50 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTSP		% control of SEPTSP					
				GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime	4	25.0	7.8-47.5	75.1	69.2-90.3	88.2	82.3-100	72.5	63.4-87.1
PL	3	17.9	8.9-33.8	72.3	68.6-74.5	78.4	76.0-81.6	74.3	58.3-86.5
Maritime + PL	7	22.0	7.8-47.5	73.9	68.6-90.3	84.0	76.0-100	73.3	58.3-87.1

Summary and conclusions on the minimum effective dose (MED) for control of SEPTSP in winter triticale (EPPO Maritime climatic zone)

SEPTSP is an important target disease for GF-3307 on winter triticale and the data reported demonstrate that it provides effective control of SEPTSP at the proposed dose rate of 1.5 L/ha. The proposed dose of GF-3307 achieved the highest level of overall control (mean control of 84.0% across all 7 trials). In all trials, the proposed dose achieved levels of control higher than the 0.8N dose. It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required to deliver robust control of this disease under a wide range of environmental conditions, in the EPPO Maritime climatic zone.

Proposed maximum dose of 1.5 L/ha for Poland (EPPO North-East climatic zone)

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the SEPTSP in winter triticale, following a single application applied at BBCH 33-52 of the crop. The MED trials were conducted in Poland (3) in the EPPO North-East climatic zone. Assessments across all trials were on Leaf 1 or Leaf 3, as this leaf had high levels of SEPTSP infection, so was considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 78.4% (range 76.0-81.6%) for SEPTSP, 21-43 days after application. Applied in the same trials at 1.2 L/ha, GF-3307 achieved good control of 72.3% (range 68.6-74.5%). Across all trials, control of SEPTSP demonstrated by the proposed maximum dose rate 1.5 L/ha was better than the prothioconazole/Proline standard at 74.3% overall control and the 1.2 L/ha dose of GF-3307 was similar to the standard.

In addition to these trials, data from neighbouring Germany, in the EPPO Maritime climatic zone, are available and can also be considered supportive of the proposed dose. Four trials were conducted in Germany and demonstrates a comparable dose response to the EPPO North-East data with the 1.5 L/ha dose achieving excellent control of 88.2% and the 1.2 L/ha dose delivered good control at 75.1%. Combined with the three Polish trials, these give overall control of SEPTSP across seven trials of 84.0% for the proposed maximum dose of 1.5 L/ha and 73.9% for the lower 1.2 L/ha dose. Details for these German trials are provided in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-1043 and individual trial results are detailed in the BAD.

Table 3.2-1043 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against SEPTSP in winter triticale (TTLWI). Results from 3 trials conducted in the EPPO North-East climatic zone and 4 trials conducted in DE in 2015 and 2016. Assessment at 21-50 days after one application.

EPPO Zone	Number of trials	Untreated control % infection SEPTSP		% control of SEPTSP					
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East	3	17.9	8.9-33.8	72.3	68.6-74.5	78.4	76.0-81.6	74.3	58.3-86.5
DE	4	25.0	7.8-47.5	75.1	69.2-90.3	88.2	82.3-100	72.5	63.4-87.1
North-East + DE	7	22.0	7.8-47.5	73.9	68.6-90.3	84.0	76.0-100	73.3	58.3-87.1

Summary and conclusions on the minimum effective dose (MED) for control of SEPTSP in winter triticale (EPPO North-East climatic zone)

SEPTSP is an important target disease for GF-3307 on winter triticale and the data reported demonstrate that it provides effective control of SEPTSP, at the proposed maximum dose rate of 1.5 L/ha. The proposed dose of GF-3307 achieved the highest level of overall control (78.4% in three EPPO North-East climatic zone trials and 88.2% in the four DE trials). Across seven trials, the proposed 1.5 L/ha maximum dose of GF-3307 achieved levels of control higher than the 1.2 L/ha dose in every trial, with only two results below 80% for the 1.5 L/ha dose, compared to six results below 80% for the 1.2 L/ha dose though mean disease control was still good at 73.9%. In three trials where control was around 69% from GF-3307 at 1.2 L/ha, there was 33-47% infection on the untreated leaf and the reference Proline delivered 58%, 63.4% and 70% control, which was below that delivered by GF-3307 at 1.2 L/ha. This data goes some way to support a dose range as control from the lower dose of 1.2 L/ha was better than that achieved by Proline in high pressure situations and similar under low to moderate disease pressure. Where other diseases are the main target and when SEPTSP pressure is lower, then the 1.2 L/ha dose would be acceptable, though 1.5 L/ha is the most effective dose when rust pressure is higher, which is similar to the proposal in wheat.

It is considered that the proposed maximum dose rate of 1.5 L/ha is the effective dose of GF-3307 to deliver the most robust control of this disease under a wide range of environmental conditions, in Poland (EPPO North-East climatic zone).

A dose range of 1.2-1.5 L/ha will be proposed for diseases of triticale to offer growers flexibility so they can adjust dose according to the conditions. Data in the efficacy section will be presented for the 1.5 L/ha dose that will be advised in high risk situations for SEPTSP and also the 1.2 L/ha dose that can be used in the less severe disease situations.

3.2.2.10 MED of GF-3307 for the control of ERYSGT in winter triticale

This section addresses the minimum effective dose (MED) of GF-3307, for the control of ERYSGT on winter triticale, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone).

Table 3.2-1054 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 25 m ² EPPO North-East: 15-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 1 TTLWI EPPO North-East: 5 6 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: Agostino EPPO North-East: Grenado (2), Magnat, Remiko (2)
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 33-37 EPPO North-East: BBCH 33-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of ERYSGT applications were timed to cover these situations from commencing when there was a risk of infection with ERYSGT or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 EPPO Maritime: one per crop EPPO North-East: one per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGT is a prevalent disease.

Introduction

In total, data from ~~six~~ **seven** field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of ERYSGT in winter triticale (TTLWI). GF-3307 was tested at 1.5, 1.2 and 1.0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 ‘Minimum effective dose’. ~~The reference products were Proline 275 applied at 0.72 L/ha in five trials and in one trial, Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha. The reference products were Proline 275 applied at 0.72 L/ha in four trials, or Proline 250 applied at 0.75-0.8 L/ha in two trials and in one trial the reference was applied as a sequence at timing A and C, Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha but GF-3307 was only applied once at timing B.~~ The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (1) in the EPPO Maritime climatic zone and Poland (~~5~~ **6**) in the EPPO North-East climatic zone, between 2015 and 2020.

On the basis of the EPPO Standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the EPPO Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-22.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGT is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 12 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.5	150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Wirtuoz 520 EC in sequence with Artea	EC	320 g/L prochloraz + 160 g/L tebuconazole + 40 g/L proquinazid	1.0	520
	EC	80 g/L cyproconazole + 250 G/L propiconazole	0.5	165

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.5	150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72-0.8	180-200
Wirtuoz 520 EC in sequence with Artea	EC	320 g/L prochloraz + 160 g/L tebuconazole + 40 g/L proquinazid	1.0	520
	EC	80 g/L cyproconazole + 250 G/L propiconazole	0.5	165

Experimental details

The ~~six~~ **seven** MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15m² and 30m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-300 L/ha.

GF-3307 was applied as a single application at BBCH 33-49 of winter triticale. The treatments were typically sprayed when ERYSGT had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with ERYSGT or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were on Leaf 1 or Leaf 2 and one on the whole plant.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

One GEP small plot field trial was conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of ERYSGT in winter triticale, following a single application, applied at BBCH 33-37 of the crop. The MED trial was conducted in Germany (1) in the EPPO Maritime climatic zone. Assessment was on the whole plant.

A single application of GF-3307 applied at 1.5 L/ha achieved control of 85.3% for ERYSGT, 35 days after application. Applied in the same trial, at 1.2 L/ha (80% rate/0.8N), GF-3307 achieved 86.2% and the prothioconazole standard Proline 90.9%. As this is based on a single trial, the results are inconclusive.

In addition to this trial, data from ~~five~~ **six** trials in neighbouring countries of the EPPO North-East climatic zone are available and can also be considered supportive of the proposed dose. These ~~five~~ **six** trials were conducted in Poland and demonstrate a comparable dose response to the EPPO Maritime climatic zone trials, with the 1.5 L/ha achieving the highest level of control of ~~91.4~~ **91.8%** compared to ~~83.7~~ **84.2%** for the 1.2 L/ha dose and ~~70.3~~ **70.9%** for the 1.0 L/ha (~~one trial~~ **two trials** only). Combined with the EPPO Maritime trial, these give mean control of ERYSGT across ~~six~~ **seven** trials of ~~90.4~~ **90.9%** for the proposed dose, ~~84.2~~ **84.5%** for the 0.8N dose and ~~91.6%~~ **90.7%** for the reference standards (**Proline, and Wirtuoz 520 EC in sequence with Artea**). Details for these Polish trials are included in the EPPO North-East climatic zone section, below.

The results are summarised in Table 3.2-10695 and individual trial results are detailed in the BAD.

~~Table 3.2-106 — Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, 80% and 67% dose rates against ERYSGT in winter triticale (TTLWI). Results from one trial conducted in the EPPO Maritime climatic zone and five trials conducted in PL between 2015 and 2020. Assessment at 27-42 days after one application.~~

EPPO-Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	1	34.1	-	-	-	86.2	-	85.3	-	90.9	-
PL**	1	10.1	-	70.3	-	87.0	-	94.7	-	97.0	-

EPPO-Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PL*	5	14.9	7.8-29.4	-	-	83.7	59.1-96.1	91.4	65.5-99.3	91.7	70.3-100
Maritime + PL	6	18.1	7.8-34.1	-	-	84.2	59.1-96.1	90.4	65.5-99.3	91.6	70.3-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses.

Table 3.2-107 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, 80% and 67% dose rates against ERYSGT in winter triticale (TTLWI). Results from one (1) trial conducted in the EPPO Maritime climatic zone and six (6) trials conducted in PL between 2015 and 2021. Assessment at 27-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	1	34.1	-	-	-	86.2	-	85.3	-	90.9	-
PL**	2	21.0	10.1-31.9	70.9	70.3-71.5	86.8	86.6-87.0	94.2	93.7-94.7	91.1	85.1-97.0
PL*	6	17.8	7.8-31.9	-	-	84.2	59.1-96.1	91.8	65.5-99.3	90.6	70.3-100
Maritime + PL	7	20.1	7.8-34.1	-	-	84.5	59.1-96.1	90.9	65.5-99.3	90.7	70.3-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha and Wirtuoz 520 EC in sequence with Artea.

Summary and conclusions on the minimum effective dose (MED) for control of ERYSGT in winter triticale (EPPO Maritime climatic zone)

ERYSGT is an important target disease for GF-3307 on winter triticale and the data reported demonstrate that it provides effective control of ERYSGT at the proposed dose rate of 1.5 L/ha. The proposed dose of GF-3307 achieved the highest level of overall control (mean control of 90.4% across all six trials) (mean control of 90.9% across all seven trials). In the majority of trials, the proposed dose achieved levels of control higher than the 0.8N dose.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required to deliver robust control of this disease under a wide range of environmental conditions, in the EPPO Maritime climatic zone.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

Five Six GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the ERYSGT in winter triticale, following a single application applied at BBCH 33-49 of the crop. The MED trials were conducted in Poland (§ 6) in the EPPO North-East climatic zone. Assessments across all trials were on Leaf 1 or Leaf 2, so are considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 91.4 91.8% (range 65.5-99.3%) for ERYSGT, 27-42 days after application. Applied in the same trials at 1.2 L/ha, GF-3307 achieved very good control of 83.7 84.2% (range 59.1-96.1%). A dose of 1.0 L/ha achieved lower control of 70.9% (two trials only) 70.3% (one trial only). Across all trials, control of ERYSGT

demonstrated by the proposed maximum dose rate of 1.5 L/ha was comparable to the prothioconazole/Proline standard at 91.4% reference standards (Proline and Wirtuoz 520 EC in sequence with Artea) at 90.7% (overall control).

In addition to these trials, data from neighbouring Germany, in the EPPO Maritime climatic zone, are available and can also be considered supportive of the proposed dose. One trial was conducted in Germany and demonstrates a comparable dose response to the EPPO North-East data with the 1.5 L/ha dose achieving control of 85.3%, the 1.2 L/ha dose 86.2% control and the prothioconazole/Proline standard 90.9%. Combined with the five six Polish trials, these give overall control of ERYSGT across six seven trials of 90.4 90.9% for the proposed maximum dose of 1.5 L/ha and 84.2 84.5% for the 1.2 L/ha dose. Details for this German trial are provided in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-10896 and individual trial results are detailed in the BAD.

~~Table 3.2-108 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha and lower 1.0 L/ha dose rate against ERYSGT in winter triticales (TTLWI). Results from five trials conducted in the EPPO North-East climatic zone and one DE trial conducted between 2015 and 2020. Assessment at 27-42 days after one application.~~

EPPO-Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha) or other standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	5	14.9	7.8-29.4	-	-	83.7	59.1-96.1	91.4	65.5-99.3	91.7	70.3-100
North-East**	1	10.1	-	70.3	-	87.0	-	94.7	-	97.0	-
DE	1	34.1	-	-	-	86.2	-	85.3	-	90.9	-
North-East + DE*	6	18.1	7.8-34.1	-	-	84.2	59.1-96.1	90.4	65.5-99.3	91.6	70.3-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses.

Table 3.2-109 Minimum effective dose testing of GF-3307 at 1.0-1.5 L/ha against ERYSGT in winter triticales (TTLWI). Results from six trials conducted in the EPPO North-East climatic zone and one DE trial conducted between 2015 and 2021. Assessment at 27-42 days after one application.

EPPO Zone	Number of trials	Untreated control % infection ERYSGT		% control of ERYSGT							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	6	17.8	7.8-31.9	-	-	84.2	59.1-96.1	91.8	65.5-99.3	90.6	70.3-100
North-East**	2	21.0	10.1-31.9	70.9	70.3-71.5	86.8	86.6-87.0	94.2	93.7-94.7	91.1	85.1-97.0
DE	1	34.1	-	-	-	86.2	-	85.3	-	90.9	-
North-East + DE*	7	20.1	7.8-34.1	-	-	84.5	59.1-96.1	90.9	65.5-99.3	90.7	70.3-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha and Wirtuoz 520 EC in sequence with Artea.

Summary and conclusions on the minimum effective dose (MED) for control of ERYSGT in winter triticale (EPPO North-East climatic zone)

ERYSGT is an important target disease for GF-3307 on winter triticale and the data reported demonstrate that it provides excellent control of ERYSGT at the proposed dose rate range of 1.2-1.5 L/ha. The proposed lower dose rate of 1.2 L/ha achieved very good control of 84.2% (across five EPPO North-East trials and one German trial). In one trial, a lower dose of 1.0 L/ha was not effective at 70.3% control. This dose rate can also be considered to be supported by the data on winter wheat, which demonstrated 88.4% control of ERYSGT for the 1.2 L/ha dose and 83.7% for the 0.9 L/ha dose across two EPPO North-East winter wheat trials. The results for the higher dose rate of 1.5 L/ha (required for other diseases where pressure is high) demonstrate that high levels of control of ERYSGT will be achieved in mixed disease situations.

ERYSGT is an important target disease for GF-3307 on winter triticale and the data reported demonstrate that it provides excellent control of ERYSGT at 1.2-1.5 L/ha. The proposed lower dose rate 1.2 L/ha dose achieved very good control of ~~84.2~~ 84.5% (across ~~five~~ six EPPO North-East trials and one German trial). In ~~one trial~~ two trials, a lower dose of 1.0 L/ha was not effective at ~~70.3~~ 70.9% control. ~~This~~ The 1.2 L/ha dose rate can also be considered to be supported by the data on winter wheat, which demonstrated 88.4% control of ERYSGT for the 1.2 L/ha dose and lower 83.7% for the ~~0.9~~ 0.9/1.0 L/ha dose across two EPPO North-East winter wheat trials. The results for the higher dose rate of 1.5 L/ha (required for other diseases where pressure is high) demonstrate that high levels of control of ERYSGT will be achieved in mixed disease situations.

It is considered that the proposed lower dose rate of 1.2 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease under a wide range of environmental conditions, in Poland (EPPO North-East climatic zone). As cereal diseases may occur together, for disease situations in triticale where ERYSGT and other diseases such as SEPTSP occur, the higher dose of 1.5 L/ha would be recommended maximum dose for broad spectrum disease control where pressure is high, especially where SEPTSP is the main target disease.

A dose range of 1.2-1.5 L/ha will be proposed for diseases of triticale to offer growers flexibility so they can adjust dose according to the conditions. Data in the efficacy section will be presented at 1.2 and 1.5 L/ha doses to enable a larger data set to be viewed at both dose rates.

3.2.2.11 MED of GF-3307 for the control of PuccST in winter triticale

This section addresses the minimum effective dose (MED) of GF-3307, for the control of PuccST on winter triticale, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone).

Table 3.2-97 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 18-25m ² EPPO North-East: 25-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 8 TTLWI EPPO North-East: 3 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: KWS Avea, SU Agendus, Talento (2), Talendro, Tender (3) EPPO North-East: Magnat, Trismart, Twingo
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 37-51 EPPO North-East: BBCH 35-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of PuccST applications were timed to cover these situations from commencing when there was a risk of infection with PuccST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PuccST is a prevalent disease.

Introduction

In total, data from 11 trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of PuccST in winter triticale (TTLWI). GF-3307 was tested at 1.5, 1.2 and 1.0 L/ha. The trials were performed in accordance with the EPPO Standard PP 1/225 '*Minimum effective dose*'. The reference product was Proline 275, applied at 0.72 L/ha ~~in all trials~~ or **Proline 250, applied at 0.8 L/ha**.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials, in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (8) in the EPPO Maritime climatic zone and Poland (3) in the EPPO North-East climatic zone between 2015 and 2020.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates*', the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have

been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-23.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccst is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 13 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.5	150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.8	200

Experimental details

The 11 MED trials were conducted to GEP by officially recognized testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 18m² and 30m². The treatments in all trials, were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes of 200-230 L/ha.

GF-3307 was applied as a single application at BBCH 35-52 of winter triticale. The treatments were typically sprayed when Puccst had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with Puccst or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were either on Leaf 1 or Leaf 2.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Eight GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of Puccst in winter triticale, following a single application, applied at BBCH 37-51 of the crop. The MED trials were conducted in Germany (8) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf (Leaf 1 or Leaf 2), as this leaf had high levels of Puccst infection, so was considered to be a robust test of the product.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 88.5% (range 81.8-100%) for Puccst, 28-53 days after application. Applied in the same trials, at 1.2 L/ha (80% rate/0.8N), GF-3307 achieved a slightly lower mean level of control of 85.0%, but more variable results (range 75.0-100%). A dose of 1.0 L/ha (67% rate/0.67N) was included in four trials and demonstrated 85.8% mean control compared to 90.8% for the proposed dose.

Across all trials, control of Puccst demonstrated by the proposed dose rate of 1.5 L/ha was comparable with the prothioconazole standard Proline (88.5%).

The results are summarised in Table 3.2-98 and individual trial results are detailed in the BAD.

Table 3.2-98 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80% and 67% dose rates against Puccst in winter triticale (TTLWI). Results from 8 trials conducted in the EPPO Maritime climatic zone in 2015 and 2020. Assessment at 28-53 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80 % rate)		GF-3307 1.5 L/ha (100 % rate)		Proline 0.72 L/ha Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime*	8	38.1	6.0-96.5	-	-	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100
Maritime**	4	63.8	13.8-96.5	85.8	74.5-100	89.7	78.2-100	90.8	81.8-100	91.3	83.6-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha.

Summary and conclusions on the minimum effective dose (MED) for control of Puccst in winter triticale (EPPO Maritime climatic zone)

Puccst is an important target disease for GF-3307 on winter triticale and the data reported demonstrate that it provides excellent control of Puccst at the proposed dose rate of 1.5 L/ha. The proposed dose of GF-3307 achieved the highest level of overall control (88.5%), compared to 85.0% for the 0.8N dose. In the majority trials, the 1.5 L/ha dose achieved only slightly higher control than the 1.2 L/ha dose (2 trials demonstrated identical levels of control).

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required for the control of Puccst in winter triticale, in the EPPO Maritime climatic zone and would be the dose rate used in mixed disease situations that are typical in triticale.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

Three GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the Puccst in winter triticale, following a single application applied at BBCH 35-52 of the crop. The MED trials were conducted in Poland (3) in the EPPO North-East climatic zone. Assessments across the trials were on Leaf 1 or Leaf 2, so are considered to be a robust test of the product.

A single application of GF-3307 applied at the maximum dose of 1.5 L/ha achieved mean control of 85.0% (range 82.4-89.4%) for Puccst, 38-43 days after application. Applied in the same trials at 1.2 L/ha, GF-3307 achieved good mean control of 76.4% (range 73.5-93.6%). In two trials the proposed

doses were compared to a lower dose of 1.0 L/ha and achieved 86.3% and 76.5% control respectively, compared to 56.7% (range 44.7-68.7%) for the 1.0 L/ha dose. Across all trials, control of Puccst demonstrated by the proposed dose rate range of 1.2-1.5 L/ha by the 1.2-1.5 L/ha doses of GF-3307 was higher than that achieved by the prothioconazole/Proline standard, at 55.9% overall control and this goes some way to support a dose range on the label from 1.2-1.5 L/ha of GF-3307.

In addition to these trials, data from neighbouring Germany in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These eight trials conducted in Germany demonstrate a comparable dose response to the Polish trials data, with the 1.5 L/ha achieving the highest level of control of 88.5% compared to 85.0% for the 1.2 L/ha dose. Combined with the three Polish trials, these give overall control of Puccst across 11 trials of 87.5% for the proposed maximum dose and 82.5% for the 1.2 L/ha dose. In six trials the proposed doses were compared to a lower dose of 1.0 L/ha and achieved 89.3% and 85.3% control respectively, compared to 76.1% for the 1.0 L/ha dose. Across all trials, control of Puccst demonstrated by the proposed dose rate range of 1.2-1.5 L/ha of GF-3307 was higher than that achieved by the prothioconazole/Proline standard, at 79.2% overall control. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2- and individual trial results are detailed in the BAD.

Table 3.2-104 Minimum effective dose testing of GF- at the proposed label rate range of 1.2-1.5 L/ha and lower 1.0 L/ha dose rate against Puccst in winter triticale (TTLWI). Results from 3 trials conducted in the EPPO North-East climatic zone and 8 trials conducted in DE between 2015 and 2020. Assessment at 28-53 days after one application.

EPPO-Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.72 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	3	31.4	7.1-50.0	-	-	76.4	73.9-79.0	85.0	82.4-89.4	55.9	36.6-73.7
North-East**	2	22.2	7.1-37.2	56.7	44.7-68.7	76.5	73.9-79.0	86.3	83.2-89.4	55.2	36.6-73.7
DE*	8	38.1	6.0-96.5	-	-	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100
DE**	4	63.8	13.8-96.5	85.8	74.5-100	89.7	78.2-100	90.8	81.8-100	91.3	83.6-100
North-East + DE*	11	36.2	6.0-96.5	-	-	82.6	73.9-100	87.5	81.8-100	79.8	36.6-100
North-East + DE**	6	49.9	7.1-96.5	76.1	44.7-100	85.3	73.9-100	89.3	81.8-100	79.2	36.6-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses.

Table 3.2-110 Minimum effective dose testing of GF-3307 at 1.0-1.5 L/ha against Puccst in winter triticale (TTLWI). Results from 3 trials conducted in the EPPO North-East climatic zone and 8 trials conducted in DE between 2015 and 2020. Assessment at 28-53 days after one application.

EPPO Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East*	3	31.4	7.1-50.0	-	-	76.4	73.9-79.0	85.0	82.4-89.4	55.9	36.6-73.7
North-East**	2	22.2	7.1-37.2	56.7	44.7-68.7	76.5	73.9-79.0	86.3	83.2-89.4	55.2	36.6-73.7

EPPO Zone	Number of trials	Untreated control % infection Puccst		% control of Puccst							
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
DE*	8	38.1	6.0-96.5	-	-	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100
DE**	4	63.8	13.8-96.5	85.8	74.5-100	89.7	78.2-100	90.8	81.8-100	91.3	83.6-100
North-East + DE*	11	36.2	6.0-96.5	-	-	82.6	73.9-100	87.5	81.8-100	79.8	36.6-100
North-East + DE**	6	49.9	7.1-96.5	76.1	44.7-100	85.3	73.9-100	89.3	81.8-100	79.2	36.6-100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha.

Summary and conclusions on the effective dose (MED) for control of Puccst in winter triticale (EPPO North-East climatic zone)

Puccst is an important target disease for GF-3307 on winter triticale and the data reported demonstrate that it provides excellent control of Puccst at the proposed dose rate range of 1.2-1.5 L/ha. The proposed lower dose rate of 1.2 L/ha achieved control of 82.6% (across three EPPO North-East trials and 8 German trials). In six trials, a lower dose of 1.0 L/ha was not as effective at 76.3% control. The results for the higher dose rate of 1.5 L/ha (required for other diseases that are dominant at high pressure) demonstrate that high levels of control of Puccst will be achieved in mixed disease situations.

It is considered that the proposed lower dose rate of 1.2 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease under a wide range of environmental conditions, in Poland (EPPO North-East climatic zone). As cereal diseases may occur together, for disease situations in triticale where Puccst and other diseases such as SEPTSP occur, the higher dose of 1.5 L/ha would be recommended for broad spectrum disease control and especially where SEPTSP is the main target disease.

A dose range of 1.2-1.5 L/ha will be proposed for diseases of triticale to offer growers flexibility so they can adjust dose according to the conditions. Data in the efficacy section will be presented at 1.2 and 1.5 L/ha dose to enable a larger data set to be viewed at oth dose rates.

3.2.2.12 MED of GF-3307 for the control of RAMUCC in barley

This section addresses the minimum effective dose (MED) of GF-3307 for the control of RAMMUC on winter and spring barley, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose of 1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-1110 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	22.2-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (2), Spring barley (5)
	Varieties per crop	EPPO Maritime: Winter barley: Lomerit, SU Vireni Spring barley: Grace (3), Laurikka, Milford
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-51
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of <i>Ramularia collo-cygni</i> (RAMUCC) application was timed to cover this situation from commencing when there was a risk of infection with RAMUCC or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 EPPO Maritime: one per crop
	Spray volumes	200 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3 weeks, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RAMUCC is an abundant disease.

Introduction

In total, data from seven field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of RAMUCC in winter and spring barley. GF-3307 was tested at 1.5, 1.2 and 1.0 L/ha. **Note:** ~~Results from all trials were based on application at 1.25 L/ha, instead of the proposed lower dose of 1.2 L/ha. As these doses are within 10% of each other (4% difference), it is considered that the 1.25 L/ha data is fully supportive of the proposed 1.2 L/ha dose rate.~~ **Results from all trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been used to support the 1.2 L/ha dose rate in the EPPO South-East.** The trials were performed in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. The reference product was Proline, applied at 0.8 L/ha in

all trials.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (2) and Germany (5) in the EPPO Maritime climatic zone, between 2017 and 2019.

On the basis of the EPPO standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data for the control of RAMUCC, from Germany which is within both the EPPO Maritime climatic zone and the Central EU Authorization zone. RAMUCC is an important disease in the EPPO Maritime climatic zone of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. It is considered that data from Germany are a robust test of the product. In the EPPO North-East and South-East climatic zones, the climatic conditions are less conducive to the development of RAMUCC and is considered more of a secondary disease in these regions. This is reflected in the trials programme for GF-3307, where RAMUCC was either not found or the disease levels were low (<5%). It is therefore considered that these data from Germany (EPPO Maritime climatic zone) fully support the claims for control of RAMUCC across the whole Central EU Authorization zone.

zRMS comments:

*Please see the zRMS comments on RAMUCC data, placed later, in the RAMUCC section within the *Efficacy tests* chapter.

Materials and Methods

Testing facilities or organisations

The Minimum Effective Dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-24.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RAMUCC is an abundant disease. RAMUCC is a disease which multiplies rapidly at short cycles under warm climatic conditions such as found in the EPPO Maritime climatic zone. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 14 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.25, 1.5	150, 180, 187.5, 225
Proline	EC	250 g/L prothioconazole	0.8	200

Experimental details

The seven MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 22.2 m² and 30 m². Two trials were carried out on winter barley and five on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering a water volume of 200 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RAMUCC or leaves which were senesced to a high degree in treated and untreated plots were excluded from the summary tables. Assessments were generally conducted on Leaf 1 or Leaf 2, with one on Leaf 3 and one on 'Mid-Leaf'.

Results

Proposed dose of 1.5 L/ha for the Central EU Authorisation zone

Seven GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the RAMUCC in barley, following a single application, applied between BBCH 31-51 of the crop. The MED trials were conducted in Denmark (2) and Germany (5) in the EPPO Maritime climatic zone, on winter and spring barley. In the majority of trials RAMUCC did not develop until after application and these trials can therefore be considered to be a robust test of the protectant properties of GF-3307. Assessment were on the highest leaf or the leaf with the highest level of infection and were generally on Leaf 1 and Leaf 2. This is considered to be a robust test of the product. **Note:** In one trial, the latest assessment timing after a single application was 18 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

From these seven trials conducted in the EPPO Maritime climatic zone, GF-3307 applied at 1.5 L/ha between BBCH 31-51 achieved mean control of 85.0% (range 72.0-96.3%) for RAMUCC on barley at 18-40 days after application. Applied in the same trials at ~~1.2~~ 1.25 L/ha, GF-3307 achieved a lower mean level of control at 81.8% (range 74.9-90.0%). Two trials compared the proposed 1.5 L/ha dose with a dose of 0.75 L/ha. In these trials, GF-3307 achieved control of 82.7% using the proposed dose compared to a lower level of control at 57.5% using the 0.75 L/ha dose. One trial compared the proposed 1.5 L/ha dose with a dose of 1.0 L/ha. In this trials GF-3307 achieved control of 76.3% using the proposed dose compared to 50.0% using the 1.0 L/ha dose.

A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops.

Although no data are available from the EPPO North-East and South-East climatic zones, data from neighbouring countries (DE) in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose in these zones. In five German trials, GF-3307 applied at 1.5 L/ha achieved mean control of 83.9% (range 72.0-96.3%), compared to 81.4% (range 74.9-90.0%) for the ~~1.2~~ 1.25 L/ha dose. A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops.

The results are summarised in Table 3.2-1121 and individual trial results are detailed in the BAD. Results in in Table 3.2-1121 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley and for comparison of different doses.

Table 3.2-1121 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 100%, 80%, 67% and 50% dose rates against RAMUCC in barley. Results from 7 trials conducted in the EPPO Maritime climatic zone between 2017-2019. Assessment at 18-40 days after application.

EPPO Zone/Crop	Number of trials	Untreated control % infection RAMUCC		% control of RAMUCC									
				GF-3307 0.75 L/ha (50% rate)		GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80% rate) 1.25 L/ha (83% rate)		GF-3307 1.5 L/ha (100 % rate)		Proline 0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Maritime* (All crops)	7	40.6	5.0- 88.8	-	-	-	-	81.8	74.9- 90.0	85.0	72.0- 96.3	70.7	45.0- 92.7
Maritime* (HORVW)	2	48.0	7.1- 88.8	-	-	-	-	83.5	77.0- 89.9	84.2	72.0- 96.3	77.9	63.0- 92.7
Maritime* (HORVS)	5	37.7	5.0- 74.5	-	-	-	-	81.2	74.9- 90.0	85.4	76.3- 93.7	67.8	45.0- 86.3
Maritime/DE** (HORVS)	1	47.5	-	50.0	-	68.4	-	75.3	-	76.3	-	71.1	-
Maritime/DE*** (HORVS)	2	26.3	5.0- 47.5	57.5	50.0- 65.0	-	-	82.7	75.3- 90.0	83.2	76.3- 90.0	58.1	45.0- 71.1
DE only* (All crops)	5	40.0	5.0- 88.8	-	-	-	-	81.4	74.9- 90.0	83.9	72.0- 96.3	68.2	45.0- 92.7
DE only* (HORVW)	2	48.0	7.1- 88.8	-	-	-	-	83.5	77.0- 89.9	84.2	72.0- 96.3	77.9	63.0- 92.7
DE only* (HORVS)	3	34.8	5.0- 51.8	-	-	-	-	80.1	74.9- 90.0	83.7	76.3- 90.0	61.7	45.0- 71.1

*Direct comparison of 1.5 L/ha and ~~1.2~~ **1.25** L/ha doses.

**Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

***Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for RAMUCC on barley in the EPPO Maritime climatic zone

RAMUCC is an important target disease for GF-3307 in this zone and the data reported demonstrate that it provides excellent control of RAMUCC, at the proposed dose rate of 1.5 L/ha. The proposed dose achieved the highest level of control at 85.0% compared to 81.8% for the ~~1.2~~ **1.25** L/ha dose and achieved control >80% in 5 of the 7 trials compared to the ~~1.2~~ **1.25** L/ha dose, which only demonstrated control >80% in three trials. A similar dose response was seen in both the winter barley and spring barley trials and results have been combined to determine the minimum effective dose across both crops.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease, as both a protectant and curative fungicide, under the challenging environmental conditions most suitable for RAMUCC infections found within the EPPO Maritime climatic zone.

Summary and conclusions on the minimum effective dose (MED) for RAMUCC on barley in the EPPO North-East climatic zone

This submission includes data from the EPPO Maritime climatic zone only. RAMUCC is an important disease in the Maritime regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. It is considered that data from this region are a robust (and worst case) test of the product.

Data from neighbouring countries (DE) in the EPPO Maritime climatic zone are available and can be considered supportive of the proposed use for control of this disease in Poland/EPPO North-East

climatic zone. RAMUCC is a disease that develops in similar conditions to PYRNTE and has the same risk factors which include infected seed, infected barley trash, volunteers, susceptible varieties, high humidity/rainfall and mild temperatures in spring and summer. As control of PYRNTE requires the maximum dose rate of 1.5 L/ha for effective control (see section PYRNTE section) and both diseases are likely to occur in a crop at the same time and represent a high disease pressure situations, the maximum dose of 1.5 L/ha is also recommended for control of RAMUCC.

Across the five DE trials, the proposed maximum dose of 1.5 L/ha achieved the highest level of control at 83.9% compared to 81.4% for the ~~1.2~~ 1.25 L/ha dose. A similar dose response was seen in both the winter barley and spring barley trials and results have been combined to determine the minimum effective dose across both crops. It is therefore considered that the proposed maximum dose rate of 1.5 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring barley under a wide range of environmental conditions in Poland (EPPO North-East climatic zone).

A dose range of 1.2-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions. However, if RAMUCC and/or PYRNTE is found in the crop or expected, the maximum dose rate of 1.5 L/ha is recommended.

Summary and conclusions on the minimum effective dose (MED) for RAMUCC on barley in the EPPO South-East climatic zone

No data are available from the EPPO South-East climatic zone for this disease. However, this submission includes data from Germany in the EPPO Maritime climatic zone. RAMUCC is an important disease in the maritime regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. It is considered that data from Germany are a robust (and worst case) test of the product. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of RAMUCC and this is a relatively minor disease in this region. This is reflected in the trials programme for GF-3307, where RAMUCC was either not found or disease levels were low (<5%) in trials from this region. Data for other diseases in this dossier have shown a high degree of comparability in control achieved by GF-3307 across all three EPPO climatic zones of the Central EU Authorization zone. It is therefore considered that these data from Germany (EPPO Maritime climatic zone) fully support the claims for control of RAMUCC across the whole Central EU Authorization zone, including the EPPO South-East climatic zone.

The EPPO Maritime climatic zone data reported from Germany (5 trials) demonstrates that GF-3307 provides effective control of RAMUCC at the proposed dose rate range (1.2-1.5 L/ha). The maximum dose of 1.5 L/ha will give excellent control in all situations (83.9% control in 5 German trials), including where varietal resistance to RAMUCC is low and fungicide resistance is a concern or in geographical locations which have a history of RAMUCC infections. In other situations, which may be more typical for RAMUCC in the South East EPPO zone, where disease pressure is lower than in Maritime conditions and if PYRNTE is not present in the crop (or expected to be a concern, see section PYRNTE section), a dose of 1.2 L/ha will give sufficient control of RAMUCC in the EPPO South-East climatic zone (81.4% control in 5 German trials at 1.25 L/ha). Results for both the ~~1.2~~ 1.25 L/ha and 1.5 L/ha doses were higher than the prothioconazole reference standard at 68.2%.

It is considered that the proposed dose rate range of 1.2-1.5 L/ha is the minimum effective dose to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.13 MED of GF-3307 for the control of RHYNSE in barley

This section addresses the minimum effective dose (MED) of GF-3307 for the control of RHYNSE on winter and spring barley, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of ~~1.2~~ 1.0-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of ~~1.2~~ 1.0-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-1132 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	15-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (7), Spring barley (3) EPPO North-East: Winter barley (6), Spring barley (4)
	Varieties per crop	EPPO Maritime: Winter barley: Casino, Etincel (2), Lomerit, Maltesse, Maris Otter, KWS Meridian Spring barley: Concerto, Propino, Sebastian EPPO North-East: Winter barley: Bartosz, Bazant , Carola, Kobuz, Kosmos, Padura, Zenek. Spring barley: Blask, Iron, KWS Vermont, Nokia
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-51 EPPO North-East: BBCH 31-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of <i>Rhynchosporium secalis</i> (RHYNSE) application was timed to cover this situation from commencing when there was a risk of infection with RHYNSE or when the disease started to develop on the lower Leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: one per crop EPPO North-East: one per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is an abundant disease.

Introduction

In total, data from 20 21 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of RHYNSE in winter and spring barley. GF-3307 was tested at 1.5, 1.25, 1.2, 1.0 and 0.75 L/ha. **Note:** Results from the majority of trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to give a single result for the 1.2 L/ha dose. Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East. The trials were performed in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’. The reference product was Proline, applied at 0.6-0.8 L/ha, in all trials.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Belgium (1), France (4), Germany (2) and UK (3) in the EPPO Maritime climatic zone, Latvia (1) and Poland (9 10) in the EPPO North-East climatic zone between 2017 and 2020 2021.

On the basis of the EPPO standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. This submission includes data from the Maritime and North-East EPPO climatic zones, which are representative of the proposed GAP in each region. RHYNSE is an important disease in the wetter regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of RHYNSE, as hot dry weather reduces the rate of disease development. As a result, this is a relatively minor disease in this climatic zone. As with data for other diseases in this dossier, the trial results from Poland in the EPPO North-East climatic zone, as a neighbouring country, are comparable to those from the EPPO South-East climatic zone and it is considered this will also be the case for RHYNSE. It is therefore considered that data from Poland can be used to support this use in the EPPO South-East climatic zone.

Materials and Methods

Testing facilities or organisations

The Minimum Effective Dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-25.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is an abundant disease. RHYNSE is a disease which multiplies rapidly at short cycles under wet climatic conditions such as found in the EPPO Maritime and North-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 15 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.75, 1.0, 1.2, 1.25, 1.5	112.5, 150, 180, 187.5, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8	150-200
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	0.8-1.0	180-225

Experimental details

The ~~20~~ 21 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15 m² and 36 m². ~~Thirteen~~ Fourteen trials were carried out on winter barley and seven on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200-300 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were senesced to a high degree in treated and untreated plots were excluded from the summary tables. Assessments used were Leaf 1, Leaf 2 or Leaf 3, as the highest assessed leaf in the trial or the leaf with high levels of disease.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Ten GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the RHYNSE in barley following a single application applied at BBCH 31-51 of the crop. The MED trials were conducted in Belgium (1), France (4), Germany (2) and UK (3) in the EPPO Maritime climatic zone, on winter and spring barley. The data includes trials where RHYNSE was established before application (including on the leaves assessed for control in some trials) and trials where RHYNSE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on Leaf 2 or Leaf 3 and this is considered to be a robust test of the product. **Note:** In six trials, the latest assessment timing after a single application was 17-28 days. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

From these 10 trials conducted in the EPPO Maritime climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 31-51, achieved mean control of 86.5% (range 75.1-100%) for RHYNSE on barley, 17-35 days after application (87.1% for HORVW and 85.0% for HORVS). Applied in the same trials at ~~1.2~~ 1.25 L/ha, GF-3307 achieved a lower mean level of control of 81.1% (82.9% for HORVW and 77.1% for HORVS), with more variable results (range 66.5-100%).

Five trials compared the proposed 1.5 L/ha dose with lower doses of 1.0 L/ha and 0.75 L/ha. Overall results were 88.5% for the proposed dose (90.5% for HORVW and 85.5% for HORVS), 80.0% for the 1.0 L/ha dose rate (90.3% for HORVW and 64.4% for HORVS) and 73.1% for the 0.75 L/ha dose rate (87.4% for HORVW and 51.6% for HORVS).

As a similar dose response was seen in both winter and spring barley, it is considered that the data can be combined to determine the minimum effective dose across both crops.

The results are summarised in Table 3.2-1143 and individual trial results are detailed in the BAD. Results in Table 3.2-114 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley and for comparison of different doses.

Table 3.2-1143 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80%, 67% and 50% dose rates against RHYNSE in barley. Results from 10 trials conducted in the EPPO Maritime climatic zone between 2017-2019. Assessment at 17-35 days after application.

EPPO Zone/Crop	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE									
				GF-3307 0.75 L/ha (50% rate)		GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80% rate) 1.25 L/ha (83% rate)		GF-3307 1.5 L/ha (100% rate)		Proline 0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Maritime* (all crops)	10	15.6	5.0- 39.8	-	-	-	-	81.1	66.5- 100	86.5	75.1- 100	80.7	43.1- 100
Maritime* (HORVW)	7	14.9	7.6- 39.8	-	-	-	-	82.9	66.5- 100	87.1	76.7- 100	79.1	43.1- 100
Maritime* (HORVS)	3	17.3	5.0- 32.5	-	-	-	-	77.1	68.5- 82.5	85.0	75.1- 95.8	84.3	80.0- 88.2
Maritime** (all crops)	5	14.7	7.6- 32.5	73.1	44.6- 100	80.0	47.5- 100	83.7	68.5- 100	88.5	75.1- 100	89.3	75.0- 100
Maritime** (HORVW)	3	8.8	7.6- 100	87.4	68.8- 100	90.3	76.3- 100	89.1	72.5- 100	90.5	78.1- 100	91.2	75.0- 100
Maritime** (HORVS)	2	23.5	14.4- 32.5	51.6	44.6- 58.5	64.4	47.5- 81.3	75.7	68.5- 82.8	85.5	75.1- 95.8	86.4	84.6- 88.2

*Direct comparison of 1.5 L/ha and ~~1.2~~ 1.25 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.0 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for control of RHYNSE in barley (EPPO Maritime climatic zone)

RHYNSE is an important target disease for GF-3307 and the EPPO Maritime data reported (demonstrate that it provides excellent control of RHYNSE, at the proposed dose rate of 1.5 L/ha. The proposed dose of 1.5 L/ha achieved the highest level of control and was the only dose to achieve overall control >80% in the majority of trials. A similar dose response was seen in both the winter barley and spring barley trials and results have been combined to determine the minimum effective dose across both crops.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307, required for the control of RHYNSE in barley, in the EPPO Maritime climatic zone.

Proposed dose range of ~~1.2~~ 1.0-1.5 L/ha for Poland (EPPO North-East climatic zone)

~~Ten~~ **Eleven** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of RHYNSE in barley, following a single application applied at BBCH 31-52 of the crop. The MED trials were conducted in Latvia (1) and Poland (~~9~~ **10**) in the EPPO North-East climatic zone, on both winter and spring barley. The data include trials where RHYNSE was established before application (including on the leaves assessed for control in some trials) and trials where RHYNSE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments used across all trials used the highest leaf, ranging from Leaf 1 to Leaf 3. **Note:** In two trials, the latest assessment timing after a single application was 14-18 days. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

From these ~~10~~ **11** trials conducted in the EPPO North-East climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 31-52, achieved mean control of ~~95.6~~ **96%** (range 88.7-100%) for RHYNSE on barley, 14-43 days after application (~~94.1~~ **94.9%** for HORVW and 97.9% for HORVS). Applied in the same trials at ~~1.2~~ **1.2/1.25** L/ha, GF-3307 achieved a slightly lower mean level of control of ~~92.1~~ **92.9%** (~~89.4~~ **90.9%** for HORVW and 96.3% for HORVS).

Nine Ten trials compared the proposed 1.2-1.2/1.25 L/ha and 1.5 L/ha doses of GF-3307, with a dose of 1.0 L/ha. In these trials GF-3307 achieved mean control of 95.5 96.0% using the proposed maximum 1.5 L/ha dose (93.6 94.7% for HORVW and 97.9% for HORVS) and 91.6 92.5% using the lower 1.2-1.2/1.25 L/ha dose (87.9 90.0% for HORVW and 96.3% for HORVS) compared to mean control of 82.8 84.4% using the 1.0 L/ha dose (84.7 87.0% for HORVW and 80.4% for HORVS). Three trials on HORVW compared the proposed doses with a dose of 0.75 L/ha; the 0.75 L/ha dose achieved a much lower level of control of 83.3%, compared to 92.8% using the proposed maximum 1.5 L/ha dose and 88.6% using the lower 1.2 L/ha dose and 87.0% using the lower 1.0 L/ha dose.

A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops. The results are summarised in Table 3.2-1154 and individual trial results are detailed in the BAD. Results in Table 3.2-1154 are shown across all trials first (shaded grey), before being shown orthogonally for spring and winter barley and for comparison of different doses.

Table 3.2-115 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2–1.5 L/ha against RHYNSE in barley. Results from 10 trials conducted in the EPPO North-East climatic zone between 2017–2020. Assessment at 14–43 days after one application

EPPO Zone/Crop	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
North-East (All crops)*	10	13.9	5.6- 35.0	-	-	-	-	92.1	80.0- 100	95.6	88.7- 100	83.7	48.5- 100
North-East (HORVW)*	6	16.4	5.6- 35.0	-	-	-	-	89.4	80.0- 99.1	94.1	88.7- 100	79.2	48.5- 100
North-East (All crops)**	9	11.5	5.6- 22.5	-	-	82.8	59.2- 99.2	91.6	80.0- 100	95.5	88.7- 100	81.9	48.5- 100
North-East (HORVW)**	5	12.7	5.6- 22.5	-	-	84.7	78.0- 99.1	87.9	80.0- 99.1	93.6	88.7- 100	75.0	48.5- 100
North-East (HORVS)***	4	10.1	5.6- 17.8	-	-	80.4	59.2- 99.2	96.3	87.5- 100	97.9	92.1- 100	90.4	80.2- 100
North-East (HORVW)#	3	11.8	6.9- 15.9	83.3	76.0- 97.3	87.0	78.0- 99.1	88.6	80.0- 99.1	92.8	88.7- 100	76.8	52.8- 100

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

***Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses. #Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Table 3.2-116 Minimum effective dose testing of GF-3307 at 0.75-1.5 L/ha against RHYNSE in barley. Results from 11 trials conducted in the EPPO North-East climatic zone between 2017-2021. Assessment at 14-43 days after one application

EPPO Zone/Crop	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
North-East (All crops)*	11	14.5	5.6- 35.0	-	-	-	-	92.9	80.0- 100	96.0	88.7- 100	92.6	78.7- 100
North-East (HORVW)*	7	17.0	5.6- 35.0	-	-	-	-	90.9	80.0- 100	94.9	88.7- 100	91.7	80.0- 100
North-East (All crops)**	10	12.5	5.6- 22.5	-	-	84.4	59.2- 99.2	92.5	80.0- 100	96.0	88.7- 100	91.8	78.7- 100
North-East	6	14.0	5.6-	-	-	87.0	78.0-	90.0	80.0-	94.7	88.7-	90.3	80.0-

EPPO Zone/Crop	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
(HORVW)**			22.5				99.1		100		100		100
North-East (HORVS)***	4	10.1	5.6- 17.8	-	-	80.4	59.2- 99.2	96.3	87.5- 100	97.9	92.1- 100	94.1	78.7- 100
North-East (HORVW)#	3	11.8	6.9- 15.9	83.3	76.0- 97.3	87.0	78.0- 99.1	88.6	80.0- 99.1	92.8	88.7- 100	87.3	80.0- 100

*Direct comparison of 1.5 L/ha and 1.2/1.25 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

***Direct comparison of 1.5 L/ha, 1.2/1.25 L/ha and 1.0 L/ha doses. #Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for control of RHYNSE in barley (EPPO North-East climatic zone)

RHYNSE is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of RHYNSE on both winter and spring barley at the proposed dose rate range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha**. The ~~proposed lower dose rate of 1.2 L/ha achieved overall control of 91.6%, compared to 82.8% for the 1.0 L/ha dose (across 9 trials) and 88.6%, compared to 83.3% for the 0.75 L/ha dose (across 3 trials). The proposed maximum dose rate of 1.5 L/ha achieved overall control of 95.5% compared to the 1.0 L/ha dose and 92.8% compared to the 0.75 L/ha dose, across the same trials.~~ The proposed lower dose rate of 1.0 L/ha achieved overall control of 87.0%, compared to 83.3% for the 0.75 L/ha dose (across 3 trials). The proposed maximum dose rate of 1.5 L/ha achieved overall control of 92.8% and the 1.2/1.25 L/ha dose 88.6% control, across the same trials. Across 10 trials the proposed lower dose rate of 1.0 L/ha achieved overall control of 84.4%, compared to 92.5% for the 1.2/1.25 L/ha dose and 96.0% control for the proposed maximum dose rate of 1.5 L/ha.

~~It is considered that the proposed dose rate of 1.2 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring barley under a wide range of environmental conditions in Poland (EPPO North East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in barley e.g. where PYRNTE is also present or expected, the higher dose of 1.5 L/ha may be recommended for broad spectrum disease control.~~ It is considered that the proposed lower dose rate of 1.0 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring barley under low disease pressure situations where RHYNSE is the only concern. However, as cereal diseases may occur together, for higher disease pressure disease situations in barley e.g. where PYRNTE is also present or expected, the higher doses of 1.2 or 1.5 L/ha may be recommended for broad spectrum disease control.

Doses below the proposed dose range give lower and more variable control and confirm the proposed dose range as being the minimum for effective control of RHYNSE.

A dose range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose of ~~1.2~~ **1.0-1.5 L/ha** for EPPO South-East climatic zone countries of the Central EU Authorisation zone

No data are presented from the EPPO South-East climatic zone using GF-3307 against this disease. RHYNSE is an important disease in the wetter regions of the Central EU Authorization zone, where disease pressure is significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of RHYNSE, as hot dry weather reduces the rate of disease development. As a result, RHYNSE is a relatively minor disease in this region. The climate in Poland, as a neighbouring country, is similar to the EPPO South-East climatic zone (i.e., hot summers), but is slightly wetter than in the EPPO South-East climatic zone. It is therefore considered

that trials from Poland (Table 3.2-105) represent a more robust test of the product against RHYNSE, so these data can be used to support use in the EPPO South-East climatic zone.

zRMS comments:

The trials from Poland may indeed “represent a more robust test of the product against RHYNSE”, but the decision on acceptance of the NE zone data by the cMSs of Romania and Slovakia should be kindly left for their individual consideration.

Table 3.2-117 — Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2–1.5 L/ha against RHYNSE in barley. Results from 9 trials conducted in Poland between 2017–2020. Assessment at 14-43 days after one application

Country/ Crop	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Poland (All crops)*	9	14.7	5.6- 35.0	-	-	-	-	91.4	80.0- 100	95.1	88.7- 100	81.9	48.5- 100
Poland (HORVW)*	5	18.3	5.6- 35.0	-	-	-	-	87.4	80.0- 96.6	92.9	88.7- 100	75.0	48.5- 100
Poland (All crops)**	8	12.1	5.6- 22.5	-	-	80.8	59.2- 99.2	90.7	80.0- 100	94.9	88.7- 100	79.6	48.5- 100
Poland (HORVW)**	4	14.1	5.6- 22.5	-	-	81.1	78.0- 84.0	85.2	80.0- 90.1	92.0	88.7- 97.2	68.8	48.5- 96.2
Poland (HORVS)***	4	10.1	5.6- 17.8	-	-	80.4	59.2- 99.2	96.3	87.5- 100	97.9	92.1- 100	90.4	80.2- 100
Poland (HORVW)#	2	14.2	12.5- 15.9	76.4	76.0- 76.7	81.0	78.0- 84.0	93.4	80.0- 86.8	89.2	88.7- 89.6	65.2	52.8- 77.6

Individual trial results are detailed in the BAD

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

***Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses. #Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Table 3.2-118 Minimum effective dose testing of GF-3307 at 0.75- 1.5 L/ha against RHYNSE in barley. Results from 10 trials conducted in Poland between 2017-2021. Assessment at 14-43 days after one application

Country/ Crop	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha	
		Mean	min- max	Mean	min-max	Mean	min-max	Mean	min- max	Mean	min- max	Mean	min-max
Poland (All crops)*	10	15.3	5.6-35.0	-	-	-	-	92.2	80.0-100	95.6	88.7-100	91.8	78.7-100
Poland (HORVW)*	6	18.7	5.6-35.0	-	-	-	-	89.5	80.0-100	94.1	88.7-100	90.3	80.0-100
Poland (All crops)**	9	13.1	5.6-22.5	-	-	82.7	59.2-99.2	91.7	80.0-100	95.5	88.7-100	90.9	78.7-100
Poland (HORVW)**	5	15.5	5.6-22.5	-	-	84.6	78.0-98.5	88.1	80.0-100	93.6	88.7-100	88.4	80.0-93.7
Poland (HORVS)***	4	10.1	5.6-17.8	-	-	80.4	59.2-99.2	96.3	87.5-100	97.9	92.1-100	94.1	78.7-100
Poland	2	14.2	12.5-	76.4	76.0-76.7	81.0	78.0-84.0	93.4	80.0-	89.2	88.7-	80.9	80.0-81.8

Country/ Crop	Number of trials	Untreated control % infection RHYNSE		% control of RHYNSE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha	
		Mean	min- max	Mean	min-max	Mean	min-max	Mean	min- max	Mean	min- max	Mean	min-max
(HORVW)#			15.9						86.8		89.6		

Individual trial results are detailed in in the BAD.

*Direct comparison of 1.5 L/ha and 1.2/1.25 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

***Direct comparison of 1.5 L/ha, 1.2/1.25 L/ha and 1.0 L/ha doses. #Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

These ~~nine~~ 10 Polish trial results demonstrate that GF-3307 provides effective control of RHYNSE at the proposed dose rate range ~~(1.2-1.5 L/ha)~~ (1.0-1.5 L/ha). A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops. The maximum dose of 1.5 L/ha will give excellent control (95.1 95.6%) in all situations and across both winter and spring barley, particularly in geographical locations which have a history of RHYNSE infections. In other situations, which may be more typical for RHYNSE in the South East EPPO zone, where disease pressure is lower, ~~and if PYRNTE is not present in the crop (or expected to be a concern, see PYRNTE section)~~, a dose of 1.2 L/ha will give sufficient control of RHYNSE in the EPPO South-East climatic zone ~~(91.4%)~~ (92.2% based on data at 1.2 and 1.25 L/ha). Results for both the 1.2/1.25 L/ha and 1.5 L/ha doses were comparable with the bixafen + the prothioconazole reference standard Aviator Xpro (90.9%). If PYRNTE is not present in the crop (or expected to be a concern, see PYRNTE section), a dose of 1.0 L/ha will give sufficient control of RHYNSE in the EPPO South-East climatic zone (82.7%). ~~Results for both the 1.2 L/ha and 1.5 L/ha doses were higher than the prothioconazole reference standard at 81.9%.~~

Doses below the proposed dose range give lower and more variable control and confirm the proposed dose range as being the minimum for effective control of RHYNSE.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.2.14 MED of GF-3307 for the control of PYRNTE in barley

This section addresses the minimum effective dose (MED) of GF-3307, for the control of PYRNTE on winter and spring barley, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-106 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	15-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (7) EPPO North-East: Winter barley (5 7), Spring barley (7) EPPO South-East: Winter barley (5 11), Spring barley (2 3)
	Varieties per crop	EPPO Maritime: Winter barley: Arcanda, Etincel (3), KWS Meridian, Tonic, Yatzy EPPO North-East: Winter barley: Bartosz, Bazant, Kosmos, SU Jule, KWS Meridian, Padura, Zenek EPPO North-East: Spring barley: Iron (2), Nokia, Ringo, Tocada (2), KWS Vermont, EPPO South-East: Winter barley: Calypso, Cardinal, Casanova (2), SU Ellen, KWS Meridian (2), Obzor (2), Planet, Vanessa. EPPO South-East: Spring barley: Bojos, Conchita, Xanadu
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH)* at application	BBCH 32-52 EPPO Maritime: BBCH 32-49 EPPO North-East: BBCH 32-52 EPPO South-East: BBCH 37-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of <i>Pyrenophora teres</i> (PYRNTE) application was timed to cover this situation from commencing when there was a risk of infection with PYRNTE or when the disease started to develop on the lower Leaf levels to applications against established infection.
	Number of applications	1
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PYRNTE is an abundant disease.

Introduction

In total, data from ~~26~~ 35 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of PYRNTE in winter and spring barley. GF-3307 was tested at 1.5, 1.25, 1.2, 1.0 and 0.75 L/ha. **Note:** ~~Results from the majority of trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other, the data has been combined to give a single result for the proposed lower dose of 1.2 L/ha.~~ Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East. The trials were performed in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’. ~~The reference product was Proline, applied at 0.6 or 0.8 L/ha, in all trials.~~ The reference products were Proline, applied at 0.6 to 0.8 L/ha or Aviator Xpro at 0.8-1.0 L/ha.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (2), Belgium (1), France (3) and Germany (1) in the EPPO Maritime climatic zone, Latvia (2) and Poland (~~10~~ 12) in the EPPO North-East climatic zone and Bulgaria (2), ~~and Hungary (5)~~ Hungary (7) and Romania (5) in the EPPO South-East climatic zone, between 2017 and ~~2020~~ 2021.

On the basis of the EPPO standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The minimum effective dose (MED) efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-26.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PYRNTE is an abundant disease. PYRNTE is a disease which multiplies rapidly at short cycles under warm climatic conditions such as found in the EPPO Maritime, North-East and South-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 16 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.75, 1.0, 1.2, 1.25, 1.5	112.5, 150, 180, 187.5, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8	150-200
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	0.8-1.0	180-225

Experimental details

The ~~26~~ 35 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15 m² and 36 m². ~~Seventeen~~ Twenty-five trials were carried out on winter barley and nine on spring barley. The treatments in all trials, were applied using

self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 300 L/ha.

Depending on the time of appearance of the disease within the season and the speed of progression of PYRNTE infections, the treatments were typically applied when disease had established on the lower leaves, to stop further development of the disease. The disease develops over a wide temperature range but development is favoured by warmer temperatures, along with or followed by long periods of rain, dew, or irrigation. The disease requires between 6 and 24+ hours of moisture, to successfully infect leaves. This means that rain, significant dew, or high canopy humidity are factors that can lead to infection and rapid development of the disease.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PYRNTE or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments were generally ~~on Leaf 1 or Leaf 2, with one on Leaf 3,~~ on Leaf 1, Leaf 2, or Leaf 3, as the highest assessed leaf in the trial or the leaf with high levels of disease.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Seven GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of PYRNTE in barley, following a single application, applied at BBCH 32-49 of the crop. The MED trials were conducted in Austria (2), Belgium (1), Germany (1) and France (3) in the EPPO Maritime climatic zone, on winter barley. ~~The data include trials where PYRNTE was established before application (including on the leaves assessed for control in some trials) and trials where PYRNTE did not develop until after application.~~ The data include trials where PYRNTE was established at low levels on lower leaves before application and trials where PYRNTE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across the trials were mainly on Leaf 2, as this leaf had high infection levels of PYRNTE and is considered to be a robust test of the product.

From these seven trials conducted in the EPPO Maritime climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 32-49 achieved mean control of 82.4% (range 72.0-88.3%) for PYRNTE on barley, 30-48 days after application. Applied in the same trials, at ~~1.2~~ 1.2/1.25 L/ha, GF-3307 achieved a lower mean level of control of 79.2% (range 72.0-85.3%). Two trials compared the proposed dose (1.5 L/ha), with doses of 0.75 L/ha and 1.0 L/ha. In these trials GF-3307 achieved mean control of 86.0% using the proposed dose (range 83.7-88.3%) compared to lower levels of control of 65.3% and 72.1% for the 0.75 L/ha and 1.0 L/ha doses, respectively.

All the data were generated from use on winter barley (HORVW). PYRNTE is a more significant disease of winter barley than spring barley, as infection can become well established in the over-wintering crop. As data from other EPPO climatic zones against PYRNTE demonstrated comparable levels of control of PYRNTE in winter and spring crops and data on other diseases in the EPPO Maritime climatic zone have shown comparable levels of control using GF-3307 in both winter and spring crops, it is considered that these data are fully supportive of the claim for control of PYRNTE in spring barley (HORVS).

The results are summarised in Table 3.2-11907 and individual trial results are detailed in the BAD. Results in Table 3.2-11907 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for comparison of different doses.

Table 3.2-11907 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80%, 67% and 50% dose rates against PYRNTE in barley. Results from 7 trials conducted in the EPPO Maritime climatic zone between 2017-2019. Assessment at 30-48 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection PYRNTE		% control of PYRNTE									
				GF-3307 0.75 L/ha (50% rate)		GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80% rate) 1.2 -1.25 L/ha (80-83% rate)		GF-3307 1.5 L/ha (100% rate)		Proline 0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Maritime* (HORVW)	7	33.2	5.4- 73.3	-	-	-	-	79.2	72.0- 85.3	82.4	72.0- 88.3	79.4	71.0- 86.0
Maritime** (HORVW)	2	43.6	17.1- 70.0	65.3	65.2- 65.4	72.1	69.9- 74.2	80.0	74.7- 85.3	86.0	83.7- 88.3	77.5	71.0- 83.9

*Direct comparison of 1.5 L/ha and ~~1.2~~ **1.2/1.25** L/ha doses.

**Direct comparison of 1.5 L/ha, 1.0 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for PYRNTE on barley (EPPO Maritime climatic zone)

PYRNTE is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of PYRNTE, at the proposed dose rate of 1.5 L/ha. The proposed dose of 1.5 L/ha demonstrated the highest levels of control and was the only dose to achieve overall control > 80%.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose of GF-3307 required for the control of PYRNTE in barley, in the EPPO Maritime climatic zone.

Proposed dose range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

~~Twelve~~ **Fourteen** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the PYRNTE in barley, following a single application applied at BBCH 32-52 of the crop. The MED trials were conducted in Latvia (2) and Poland (~~10~~ **12**) in the EPPO North-East climatic zone, on both winter and spring barley. The data include trials where PYRNTE was established before application (including on the leaves assessed for control in some trials) and trials where PYRNTE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessment across all trials used the highest leaf assessed (generally Leaf 1 or Leaf 2). **Note:** In one trial, the latest assessment timing after a single application was 16 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

From these ~~12~~ **14** trials conducted in the EPPO North-East climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 32-52, achieved mean control of ~~87.2~~ **85.8%** (range ~~79.6~~ **67.6**-100%) for PYRNTE on barley, 16-43 days after application (~~85.2~~ **82.5** % for HORVW and 89.2% for HORVS). Applied in the same trials at ~~1.2~~ **1.2/1.25** L/ha, GF-3307 achieved slightly lower mean level of control of ~~82.0~~ **80.6** % (~~80.7~~ **78.2** % for HORVW and 83.0% for HORVS).

~~Nine~~ **Eleven** trials compared the proposed ~~1.2~~ **1.2/1.25** L/ha and 1.5 L/ha doses of GF-3307, with a dose of 1.0 L/ha. In these trials GF-3307 achieved mean control of ~~86.3~~ **84.3%** using the proposed maximum 1.5 L/ha dose (~~86.5~~ **82.9** % for HORVW and 86.0% for HORVS) and ~~79.8~~ **78.4%** using the lower ~~1.2~~ **1.2/1.25** L/ha dose (~~81.2~~ **78.1**% for HORVW and 78.5% for HORVS) compared to lower mean control of ~~71.1~~ **69.1** % using the 1.0 L/ha dose (~~73.7~~ **69.2**% for HORVW and 69.1% for HORVS). Three trials compared the proposed doses, with a dose of 0.75 L/ha; the 0.75 L/ha dose achieved a much lower level of control of 68.4% (76.2% for HORVW and 52.9% for HORVS), compared to 84.2% using the proposed 1.5 L/ha dose (84.2% for HORVW and HORVS) and 79.0% using the lower ~~1.2~~ **1.2/1.25** L/ha dose (82.6% for HORVW and 71.9% for HORVS).

A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops.

The results are summarised in Table 3.2-12008 and individual trial results are detailed in the BAD. Results in Table 3.2-12008 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley and for comparison of different doses.

~~Table 3.2-120 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2–1.5 L/ha against PYRNTE in barley. Results from 12 trials conducted in the EPPO North-East climatic zone between 2017–2020. Assessment at 16–43 days after one application.~~

EPPO Zone/Crop	Number of trials	Untreated control % infection PYRNTE		% control of PYRNTE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6–0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
North-East (All crops)*	12	17.4	5.0– 30.6	-	-	-	-	82.0	67.9– 95.7	87.5	79.6– 100	72.2	42.4– 95.7
North-East (HORVW)*	5	16.4	5.0– 29.4	-	-	-	-	80.7	72.1– 87.3	85.2	80.0– 91.4	66.0	48.4– 85.4
North-East (HORVS)*	7	18.1	5.5– 30.6	-	-	-	-	83.0	67.9– 95.7	89.2	79.6– 100	76.6	42.4– 95.7
North-East (All crops)**	9	17.8	5.5– 29.4	-	-	71.1	57.9– 83.2	79.8	67.9– 89.0	86.3	79.6– 93.6	67.2	42.4– 85.4
North-East (HORVW)**	4	19.3	6.5– 29.4	-	-	73.7	60.0– 83.2	81.2	72.1– 87.3	86.5	80.3– 91.4	64.0	48.4– 85.4
North-East (HORVS)**	5	16.6	5.5– 22.8	-	-	69.1	57.9– 80.0	78.5	67.9– 89.0	86.0	79.6– 93.6	69.8	42.4– 81.3
North-East (All crops)#	3	20.2	16.1– 25.0	68.4	52.9–80	74.8	65.2– 83.2	79.0	71.9– 86.8	84.2	80.3– 88.0	63.1	48.8– 73.5
North-East (HORVW)#	2	20.6	16.1– 25.0	76.2	72.3– 80.0	79.6	76.0– 83.2	82.6	78.4– 86.8	84.2	80.3– 88.0	61.2	48.8– 73.5
North-East (HORVS)#	1	19.4	-	52.9	-	65.2	-	71.9	-	84.2	-	67.1	-

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

#Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Table 3.2-121 Minimum effective dose testing of GF-3307 at 0.75-1.5 L/ha against PYRNTE in barley. Results from 14 trials conducted in the EPPO North-East climatic zone between 2017-2021. Assessment at 16-43 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection PYRNTE		% control of PYRNTE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East (All crops)*	14	19.5	5.0-36.4	-	-	-	-	80.6	61.8-95.7	85.8	67.6-100	85.5	66.7-100
North-East (HORVW)*	7	20.9	5.0-36.4	-	-	-	-	78.2	61.8-87.3	82.5	67.6-91.4	85.5	66.7-97.5
North-East (HORVS)*	7	18.1	5.5-30.6	-	-	-	-	83.0	67.9-95.7	89.2	79.6-100	85.2	69.6-100
North-East (All crops)**	11	20.4	5.5-36.4	-	-	69.1	52.3-83.2	78.4	61.8-89.0	84.3	67.6-93.6	82.9	66.7-100
North-East (HORVW)**	6	23.5	6.5-36.4	-	-	69.2	61.8-83.2	78.1	61.8-87.3	82.9	67.6-91.4	83.8	66.7-90.1
North-East (HORVS)**	5	16.6	5.5-22.8	-	-	69.1	57.9-80.0	78.5	67.9-89.0	86.0	79.6-93.6	84.3	69.9-100
North-East	3	20.2	16.1-25.0	68.4	52.9-80	74.8	65.2-83.2	79.0	71.9-86.8	84.2	80.3-88.0	80.4	73.9-100

EPPO Zone/Crop	Number of trials	Untreated control % infection PYRNTE		% control of PYRNTE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
(All crops)#													
North-East (HORVW)#	2	20.6	16.1-25.0	76.2	72.3-80.0	79.6	76.0-83.2	82.6	78.4-86.8	84.2	80.3-88.0	83.7	79.1-88.3
North-East (HORVS)#	1	19.4	-	52.9	-	65.2	-	71.9	-	84.2	-	73.9	-

*Direct comparison of 1.5 L/ha and 1.2/1.25 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses.

#Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for PYRNTE on barley (EPPO North-East climatic zone)

PYRNTE is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of PYRNTE on both winter barley (5 trials) and spring barley (7 trials) at the proposed dose rate range of 1.2-1.5 L/ha. The proposed lower dose rate of 1.2 L/ha achieved overall control of 79.8%, compared to 71.1% for the 1.0 L/ha dose (across 9 trials) and 68.4% for the 0.75 L/ha dose (across 3 trials). The proposed maximum dose rate of 1.5 L/ha achieved overall control of 86.3% compared to the 1.0 L/ha dose which delivered 71.1% across 9 trials and 84.2% control compared to the 0.75 L/ha dose which delivered 68.4% control across 3 trials where they were directly compared.

PYRNTE is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of PYRNTE on both winter barley (7 trials) and spring barley (7 trials) at 1.2/1.25-1.5 L/ha. The proposed lower dose rate of 1.2/1.25 L/ha achieved overall control of 78.4%, compared to 69.1% for the 1.0 L/ha dose (across 11 trials) and 68.4% for the 0.75 L/ha dose (across 3 trials). The proposed maximum dose rate of 1.5 L/ha achieved overall control of 84.3% compared to the 1.0 L/ha dose which delivered 69.1% across these eleven trials and 84.2% control compared to the 0.75 L/ha dose which delivered 68.4% control across 3 trials where they were directly compared.

It is considered that the proposed dose rate of 1.2 L/ha (supported by data at 1.2 and 1.25 L/ha) is the minimum effective dose of GF-3307 to deliver control of this disease on winter and spring barley under low disease pressure situations in Poland (EPPO North-East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in barley, the higher dose of 1.5 L/ha may be recommended for broad spectrum disease control.

Doses below the proposed dose range give lower and more variable control and confirm the proposed dose range as being the minimum for effective control of PYRNTE.

A dose range of 1.2-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Seven ~~Fourteen~~ GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the PYRNTE in barley, following a single application applied at BBCH 37-49 of the crop. The MED trials were conducted in Bulgaria (2), Hungary (5) ~~Hungary (7) and Romania (5)~~ in the EPPO South-East climatic zone, on winter and spring barley. ~~The data include trials where PYRNTE was established before application (including on the leaves assessed for control in some trials) and trials where PYRNTE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials used the highest leaf assessed (Leaf 1).~~ The data include trials where PYRNTE was established at low levels on lower leaves before application and trials where PYRNTE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials used the highest leaf assessed (Leaf 1, Leaf 2 or Leaf 3).

From these seven trials conducted in the EPPO South-East climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 37-49, achieved mean control of 87.2% (range 81.1-96.9%) for PYRNTE on barley, 30-46 days after application (87.2% for HORVW over 5 trials and 87.3% for HORVS over 2 trials). Applied in the same trials at 1.2 L/ha, GF-3307 achieved mean level of control of 77.3% (75.5% for HORVW and 81.6% for HORVS). Also applied in the same trials at 1.0 L/ha, GF-3307 achieved a lower mean level of control of 67.9% (62.5% for HORVW and 81.4% for HORVS), with more variable results (range 35.2-87.0%). From these 14 trials conducted in the EPPO South-East climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 37-49, achieved mean control of 86.4% (range 80.1-96.9%) for PYRNTE on barley, 28-46 days after application (86.1% for HORVW over 11 trials and 87.8% for HORVS over 3 trials). Applied in the same trials at 1.2/1.25 L/ha, GF-3307 achieved mean level of control of 77.5% (75.9% for HORVW and 83.7% for HORVS). Also applied in the same trials at 1.0 L/ha, GF-3307 achieved a lower mean level of control of 68.1% (65.2% for HORVW and 78.8% for HORVS), with more variable results (range 35.2-87.0%).

Two HORVW trials compared the proposed maximum dose of 1.5 L/ha with a dose of 0.75 L/ha. Overall results were 83.1% for the proposed maximum dose and 65.9% for the 0.75 L/ha dose rate. A similar dose response was seen in both the winter barley (5 11) and spring barley trials (2 3); therefore it is considered that the data can be combined to determine the minimum effective dose across both crops.

The results are summarised in Table 3.2-12209 and individual trial results are detailed in the BAD. Results in Table 3.2-12209 shown across all trials first (shaded grey), before being shown orthogonally for spring and winter barley and for comparison of different doses.

Table 3.2-122 Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against PYRNTE in barley. Results from 7 trials conducted in the EPPO South-East climatic zone between 2017-2020. Assessment at 30-46 days after one application

EPPO Zone/Crop	Number of trials	Untreated control % infection PYRNTE		% control of PYRNTE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East (All crops)*	7	26.6	10.0-40	-	-	67.9	35.2-87.0	77.3	70.0-87.8	87.2	81.1-96.9	81.9	71.3-92.9
South-East (HORVW)*	5	25.8	10.0-40.0	-	-	62.5	35.2-78.1	75.5	70.0-87.8	87.2	81.1-96.9	83.4	74.1-92.9
South-East (HORVS)*	2	28.8	21.3-36.3	-	-	81.4	75.8-87.0	81.6	79.9-83.2	87.3	87.0-87.6	78.1	71.3-84.8
South-East (HORVW)**	2	35.0	30.0-40.0	65.9	62.8-68.9	71.2	67.1-75.2	72.5	70.0-74.9	83.1	81.1-85.1	76.7	74.1-79.2

*Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Table 3.2-123 Minimum effective dose testing of GF-3307 at 0.75-1.5 L/ha against PYRNTE in barley. Results from 14 trials conducted in the EPPO South-East climatic zone between 2017-2021. Assessment at 28-46 days after one application

EPPO Zone/Crop	Number of trials	Untreated control % infection PYRNTE		% control of PYRNTE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East (All crops)*	14	21.5	5.0-42.5	-	-	68.1	35.2-87.0	77.5	69.5-88.1	86.4	80.1-96.9	79.6	69.1-92.9

EPPO Zone/Crop	Number of trials	Untreated control % infection PYRNTE		% control of PYRNTE									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East (HORVW)*	11	21.3	5.0-42.5	-	-	65.2	35.2-78.1	75.9	69.5-87.8	86.1	80.1-96.9	79.9	69.1-92.9
South-East (HORVS)*	3	22.4	9.5-36.3	-	-	78.8	73.7-87.0	83.7	79.9-88.1	87.8	87.0-88.9	78.6	71.3-84.8
South-East (HORVW)**	2	35.0	30.0-40.0	65.9	62.8-68.9	71.2	67.1-75.2	72.5	70.0-74.9	83.1	81.1-85.1	76.7	74.1-79.2

*Direct comparison of 1.5 L/ha, 1.2/1.25 L/ha and 1.0 L/ha doses.

**Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for PYRNTE on barley (EPPO South-East climatic zone)

PYRNTE is an important target disease for GF-3307 and the data reported demonstrate that it provides excellent control of PYRNTE at the proposed maximum dose rate date of 1.5 L/ha (87.2 86.4% control across 7 11 trials). The maximum dose of 1.5 L/ha will give excellent control in all situations, as this dose rate demonstrated >80% control in the trials . Where disease pressure is low-moderate, a dose of 1.2 L/ha (supported by data at 1.2 and 1.25 L/ha) will provide effective control of PYRNTE. Results for the 1.5 L/ha dose were higher than the prothioconazole reference standard at 81.9 79.6%, the 1.2/1.25 L/ha dose demonstrated control in line with the prothioconazole reference.

It is considered that the proposed dose rate range of 1.2-1.5 L/ha is the minimum effective dose to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.15 MED of GF-3307 for the control of PUCCHD in barley

This section addresses the minimum effective dose (MED) of GF-3307, for the control of PUCCHD on winter and spring barley, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.0-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-1240 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	15-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (5) EPPO North-East: Winter barley (4 2), Spring barley (5) EPPO South-East: Winter barley (3) , Spring barley (2)
	Varieties per crop	EPPO Maritime: Winter barley: Frigg, KWS Meridian, KWS Tonic (2), Wootan EPPO North-East: Winter barley: Bazant , Kosmos Spring barley: Blask, Iron, Nokia, Propino, Ringo, Tocada EPPO South-East: Winter barley: Astaire, Cardinal, SU Ellen Spring barley: Tango, Kangoo
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH) at application	BBCH 31-52: one application (12 trials) EPPO Maritime: BBCH 31-49 EPPO North-East: BBCH 32-52 EPPO South-East: BBCH 31-49 (one application); BBCH 31-32 and BBCH 47-49 two applications (1 SK trial)
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In many trials PUCCHD was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 (12 trials) – 2 (1 SK trial) EPPO Maritime: BBCH 31-49 EPPO North-East: BBCH 32-52 EPPO South-East: BBCH 31-49 (one application);
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCHD is an abundant disease.

Introduction

In total, data from 13 field trials are presented in this section, to demonstrate the minimum effective dose (MED) of GF-3307, for the control of PUCCHD in winter and spring barley. GF-3307 was tested at 1.5, 1.2, 1.0 and 0.75 L/ha. **Note:** Results from the majority of trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD.). As these doses are within 10% of each other, the data has been combined to give a single result for the 1.2 L/ha dose. The trials were performed in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. The reference product was Proline, applied at 0.6 or 0.8 L/ha, in all trials.

In total, data from 17 field trials are presented in this section, to demonstrate the minimum effective dose (MED) of GF-3307, for the control of PUCCHD in winter and spring barley. GF-3307 was tested at 1.5, 1.25, 1.2, 1.0 and 0.75 L/ha. **Note:** Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East. The trials were performed in accordance with the EPPO standard PP 1/225 'Minimum effective dose'. The reference products were Proline 250 applied at 0.8 or Prosaro applied at 0.75 L/ha.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field trials for registration, in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Belgium (1), Denmark (2), France (1) and Germany (1) in the EPPO Maritime climatic zone, Latvia (1) and Poland (5 6) in the EPPO North-East climatic zone, Hungary (2), Romania (1) and Slovakia (2) in the EPPO South-East climatic zone, between 2017 and 2020 2021.

On the basis of the EPPO standard PP 1/241 'Guidance on comparable climates', the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of the climatic zones which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The MED efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-27.

Sites

Trial sites were selected on the basis of known pest pressure, as well as favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCHD is an abundant disease. PUCCHD is a disease which multiplies rapidly at short cycles under warm climatic conditions, such as are encountered in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 17 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.75, 0.8, 1.0, 1.2, 1.25, 1.5	112.5, 120, 150, 180, 187.5, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8 0.72-0.80	150-200 180-200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	0.75	188

Experimental details

The ~~13~~ 17 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15 m² and 36 m². ~~Six~~ Ten trials were carried out on winter barley and seven trials on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 300 L/ha.

Depending on the time of appearance of the disease within the season and the speed of progression of PUCCHD infections, the treatments were applied typically when the disease had established on the lower leaves, to stop further development of the disease. The disease develops over a wide temperature range, but development is favoured by warmer temperatures.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCHD or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments were generally on Leaf 1 or Leaf 2, with one on Leaf 3.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Five GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of PUCCHD in barley, following a single application applied at BBCH 32-49 of the crop. The MED trials were conducted in Belgium (1), Denmark (2), France (1) and Germany (1) in the EPPO Maritime climatic zone on winter and spring barley. ~~The data include trials where PUCCHD was established before application (including on the leaves assessed for control in some trials) and trials where PUCCHD did not develop until after application.~~ The data include trials where PUCCHD was established at low levels on lower leaves before application and trials where PUCCHD did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments were generally on Leaf 1 or Leaf 2, with one on Leaf 3, as the highest assessed leaf in the trial or the leaf with high levels of disease.

From these five trials conducted in the EPPO Maritime climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 32-49, achieved mean control of 94.0% (range 78.9-100%) for PUCCHD on winter barley, 25-36 days after application. Applied in the same trials at ~~1.2~~ 1.25 L/ha, GF-3307 achieved a lower mean level of control of 93.2%.

Two trials compared the proposed 1.5 L/ha dose with lower doses of 1.0 L/ha and 0.75 L/ha. Overall results were 95.4% for the proposed dose and 95.0% for the 1.0 L/ha dose rate (one trial) and 97.7% for the proposed dose and 83.8% for the 0.75 L/ha dose rate (two trials)

All the data were generated from use on winter barley (HORVW). As data from other EPPO climatic zones against PUCCHD demonstrate comparable levels of control of PUCCHD in winter and spring crops and data on other diseases in the EPPO Maritime climatic zone have shown comparable levels of control using GF-3307 in both winter and spring crops, it is considered that these data are fully supportive of the claim for control of PUCCHD in spring barley (HORVS).

The results are summarised in Table 3.2-1251 and individual trial results are detailed in the BAD. Results in Table 3.2-1251 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for comparison of different doses.

Table 3.2-125 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80%, 67% and 50% dose rates against PUCCHD in barley. Results from 5 trials conducted in the EPPO Maritime climatic zone between 2017-2019. Assessment at 25-36 days after application

EPPO Zone/Crop	Number of trials	Untreated control % infection PUCCHD		% control of PUCCHD									
				GF-3307 0.75 L/ha (50% rate)		GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (100% rate)		Proline 0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Maritime* (HORVW)	5	14.7	7.7- 23.8	-	-	-	-	93.2	75.5- 99.5	94.0	78.9- 100	93.5	83.4- 97.9
Maritime** (HORVW)	1	7.7	-	92.9	-	95.0	-	94.4	-	95.4	-*	97.5	-
Maritime*** (HORVW)	2	8.0	7.7-8.2	83.8	74.7- 92.9	-	-	96.5	94.4- 98.6	97.7	95.4- 100	90.5	83.4- 97.5

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.0 L/ha and 0.75 L/ha doses.

***Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Table 3.2-126 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 83%, 67% and 50% dose rates against PUCCHD in barley. Results from 5 trials conducted in the EPPO Maritime climatic zone between 2017-2019. Assessment at 25-36 days after application

EPPO Zone/Crop	Number of trials	Untreated control % infection PUCCHD		% control of PUCCHD									
				GF-3307 0.75 L/ha (50% rate)		GF-3307 1.0 L/ha (67% rate)		GF-3307 1.25 L/ha (83% rate)		GF-3307 1.5 L/ha (100% rate)		Proline 0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Maritime* (HORVW)	5	14.7	7.7- 23.8	-	-	-	-	93.2	75.5- 99.5	94.0	78.9- 100	93.5	83.4- 97.9
Maritime** (HORVW)	1	7.7	-	92.9	-	95.0	-	94.4	-	95.4	-*	97.5	-
Maritime*** (HORVW)	2	8.0	7.7-8.2	83.8	74.7- 92.9	-	-	96.5	94.4- 98.6	97.7	95.4- 100	90.5	83.4- 97.5

*Direct comparison of 1.5 L/ha and 1.25 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.0 L/ha and 0.75 L/ha doses.

***Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for PUCCHD on barley (EPPO Maritime climatic zone)

PUCCHD is a secondary target disease for GF-3307 and the data demonstrate that it will provide excellent control of PUCCHD at a range of dose rates from 0.75 L/ha to 1.5 L/ha. The proposed dose of 1.5 L/ha for the EPPO Maritime climatic zone, is based on being the minimum required for other more critical diseases (e.g. PYRNTE). However, these data demonstrate that a dose of 1.5 L/ha provides consistently high levels of control of PUCCHD.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose for GF-3307 to control PUCCHD in barley, in the EPPO Maritime climatic zone.

Proposed dose rate range of 1.2-1.5 1.0-1.5 L/ha for Poland (EPPO North-East climatic zone)

~~Six~~ **Seven** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the PUCCHD in barley, following a single application applied at BBCH 37-52 of the crop. The MED trials were conducted in Latvia (2 1) and Poland (4 6) in the EPPO North-East climatic zone, on both winter and spring barley. ~~The data include trials where PUCCHD was established before application (including on the leaves assessed for control in some~~

trials) and trials where PUCCHD did not develop until after application. The data include trials where PUCCHD was established at low levels on lower leaves before application and trials where PUCCHD did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Data from assessments on Leaf 1 or Leaf 2 data were available and the leaf with the highest level of disease was used.

From these ~~6~~ **seven** trials conducted in the EPPO North-East climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 37-52, achieved mean control of ~~96.4~~ **96.9%** (range 89.9-100%) for PUCCHD on barley, 21-~~34~~ **38** days after application (~~98.1~~ **99.1%** for HORVW and 96.1% for HORVS). Applied in the same trials at ~~1.2~~ **1.2/1.25** L/ha, GF-3307 achieved slightly lower mean control of ~~91.4~~ **92.6%** (~~96.0~~ **98.0%** for HORVW and 90.4% for HORVS).

All ~~six~~ **seven** trials also compared the proposed ~~1.2~~ **1.2/1.25** and 1.5 L/ha doses of GF-3307, with a dose of 1.0 L/ha. In these trials GF-3307 achieved ~~lower~~ mean control of ~~86.8~~ **86.2%** using the 1.0 L/ha dose (~~94.1~~ **88.3%** for HORVW and 85.3% for HORVS). Two trials compared the proposed dose range, with a dose of 0.75 L/ha; the 0.75 L/ha dose achieved a much lower level of control of 82.0%, compared to 98.5% using the proposed maximum dose of 1.5 L/ha and 87.8% using the lower dose of ~~1.2~~ **1.2/1.25** L/ha.

A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops. The results are summarised in Table 3.2-1272 and individual trial results are detailed in the BAD. Results in Table 3.2-1272 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley and for comparison of different doses.

Table 3.2-127 — Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against PUCCHD in barley. Results from 6 trials conducted in the EPPO North-East climatic zone between 2018-2020. Assessment at 21-34 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection PUCCHD		% control of PUCCHD									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East (All crops)*	6	19.3	5.5-47.5	-	-	86.8	77.6-97.1	91.4	79.6-98.4	96.4	89.9-100	86.9	71.4-92.9
North-East (HORVW)	1	47.5	-	92.0	-	94.1	-	96.0	-	98.1	-	84.8	-
North-East (HORVS)*	5	13.7	5.5-31.9	-	-	85.3	77.6-97.1	90.4	79.6-98.4	96.1	89.9-100	87.3	71.4-92.9
North-East (All crops)**	2	26.7	5.8-47.5	82.0	72.0-92.0	90.1	86.0-94.1	87.8	79.6-96.0	98.5	98.1-98.9	88.1	84.8-91.4
North-East (HORVS)**	1	5.8	-	72.0	-	86.0	-	79.6	-	98.9	-	91.4	-

*Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses. **Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Table 3.2-128 Minimum effective dose testing of GF-3307 at 0.75-1.5 L/ha against PUCCHD in barley. Results from 7 trials conducted in the EPPO North-East climatic zone between 2018-2021. Assessment at 21-38 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection PUCCHD		% control of PUCCHD									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East (All crops)*	7	19.5	5.5-47.5	-	-	86.2	77.6-97.1	92.6	79.6-100	96.9	89.9-100	90.8^	80.3-100

EPPO Zone/Crop	Number of trials	Untreated control % infection PUCCHD		% control of PUCCHD									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference standards	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
North-East (HORVW)*	2	34.2	20.8- 47.5	-	-	88.3	82.5- 94.1	98.0	96.0- 100	99.1	98.1- 100	92.4^	84.8- 100
North-East (HORVW)**	1	47.5	-	92.0	-	94.1	-	96.0	-	98.1	-	84.8^^	-
North-East (HORVS)*	5	13.7	5.5- 31.9	-	-	85.3	77.6- 97.1	90.4	79.6- 98.4	96.1	89.9- 100	90.2^	80.3- 98.4
North-East (All crops)**	2	26.7	5.8- 47.5	82.0	72.0- 92.0	90.1	86.0- 94.1	87.8	79.6- 96.0	98.5	98.1- 98.9	88.1^^	84.8- 91.4
North-East (HORVS)**	1	5.8	-	72.0	-	86.0	-	79.6	-	98.9	-	91.4^^	-

*Direct comparison of 1.5 L/ha, 1.2/1.25 L/ha and 1.0 L/ha doses. **Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

^Reference standards used based on Proline 250 (P) applied at 0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

#Reference standards used based on Proline 250 (P) applied at 0.8 L/ha.

Summary and conclusions on the minimum effective dose (MED) for PUCCHD on barley (EPPO North-East climatic zone)

PUCCHD is a secondary target disease for GF-3307, but the data reported demonstrate that it provides excellent control of PUCCHD on both winter and spring barley at the proposed dose rate range of ~~1.2-1.5~~ **1.0-1.5 L/ha**. The proposed lower dose rate of 1.2 L/ha achieved overall control of 91.4%, compared to 86.8% for the 1.0 L/ha dose (across 6 trials) and 87.8%, compared to 82.8% for the 0.75 L/ha dose (across two trials). The proposed maximum dose rate of 1.5 L/ha achieved overall control of 96.4% compared to the 1.0 L/ha dose and 98.5% compared to the 0.75 L/ha dose, across the same trials. The proposed lower dose rate of 1.0 L/ha achieved overall control of 90.1%, compared to 82.0% for the 0.75 L/ha dose (across 2 trials). The proposed maximum dose rate of 1.5 L/ha achieved overall control of 98.5% and the 1.2/1.25 L/ha dose 87.8% control, across the same trials. Across 7 trials the proposed lower dose rate of 1.0 L/ha achieved overall control of 86.2%, compared to 92.6% for the 1.2/1.25 L/ha dose and 96.9% control for the proposed maximum dose rate of 1.5 L/ha.

It is considered that the proposed dose rate of 1.2 L/ha is the minimum effective dose of GF 3307 to deliver robust control of this disease on winter and spring barley under a wide range of environmental conditions in Poland (EPPO North East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in barley e.g. where PUCCHD and PYRNTE occur together, the higher dose of 1.5 L/ha may be recommended for broad spectrum disease control in higher pressure mixed disease situations.

It is considered that the proposed lower dose rate of 1.0 L/ha is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring barley under low disease pressure situations where PUCCHD is the only concern. However, as cereal diseases may occur together, for higher disease pressure disease situations in barley e.g. where PYRNTE is also present or expected, the higher doses of 1.2 L/ha (supported by data at 1.2 and 1.25 L/ha) or 1.5 L/ha may be recommended for broad spectrum disease control.

A dose range of ~~1.2-1.5~~ **1.0-1.5 L/ha** will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose rate range of 1.0-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

~~Two~~ **Five** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of the PUCCHD in barley, following a single application applied at BBCH 31-49 of the crop. The MED trials were conducted in **Hungary (2), Romania (1) and**

Slovakia (2) in the EPPO South-East climatic zone, on winter and spring barley. Assessment across all trials was on Leaf 1, Leaf 2 or Leaf 3, as this leaf had high infection levels of PUCCHD and is therefore considered to be a robust test of the product. One trial was based on a two-dose regime (SK18E7B008PV02C), however, PUCCHD did not develop in the trial until 26 days after the second application. In this trial the first application was applied at BBCH 31-32 of the crop (in May) and the second application was applied at BBCH 47-59 (in June). PUCCHD did not develop until 46 days after the first application, demonstrating how the disease can infect crops late in their development and this is considered to be beyond the protection period; the first application of GF-3307 could be expected to deliver. For this trial, the results after two applications have been used, as it is considered that the second application is comparable to a single dose regime.

From these five trials conducted in the EPPO South-East climatic zone, a single application of GF-3307 at 1.5 L/ha applied between BBCH 31-49 achieved mean control of 92.4 91.9% (range 89.5-95.3 89.0-95.9%) for PUCCHD on barley, 21-26 42 days after application. Applied in the same trials, the 1.2 1.2/1.25 L/ha (80% rate/0.8N) dose of GF-3307 achieved a slightly lower mean control of 90.9 90.3% (range 88.2 88.0-93.5%) and the 1.0 L/ha dose demonstrated 84.9 85.3% control (range 76.3-93.5%). The 0.75 L/ha dose of GF-3307 was only included in two trials and achieved lower mean control of 70.3%, with more variable results (ranges of 51.3-89.3%). Results for all three proposed doses were comparable to the prothioconazole reference standard at 91.5 91.3%.

In addition to these data from the EPPO South East Climatic zone, data are available from Poland, which is a neighbouring country. Poland has similar climatic conditions in the later stages of the crop that encourage the development of PUCCHD (hot and dry weather). Data from five trials are available that demonstrate a similar flat dose response: 95.9% for the 1.5 L/ha dose, 93.7% for the 1.2 L/ha dose and 86.9% for the 1.0 L/ha dose. Results for all doses were comparable to or higher than the prothioconazole reference standard at 86.0%.

The majority of the data were generated from use on spring barley (HORVS). As data from other EPPO climatic zones against PUCCHD demonstrate comparable levels of control of PUCCHD in winter and spring crops and data on other diseases in the EPPO South East climatic zone have shown comparable levels of control using GF-3307 in both winter and spring crops, it is considered that these data are fully supportive of the claim for control of PUCCHD in winter barley (HORVW).

The results are summarised in Table 3.2-129 and individual trial results are detailed in the BAD.

The data were generated from use on both winter and spring barley and demonstrated a comparable dose response.

The results are summarised in Table 3.2-129 and individual trial results are detailed in the BAD.

Table 3.2-129 — Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.0-1.5 L/ha against PUCCHD in barley. Results from 2 trials conducted in the EPPO South-East climatic zone plus 5 Polish trials, between 2018-2020. Assessment at 21-26 days after application

EPPO Zone/Crop	Number of trials	Untreated control % infection PUCCHD		% control of PUCCHD									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East (HORVS)	2	12.3	7.6-16.9	70.3	51.3-89.3	84.9	76.3-93.5	90.9	88.2-93.5	92.4	89.5-95.3	91.5	84.2-98.8
Poland (all crops)	5	22.0	5.5-47.5	-	-	86.9	77.6-97.1	93.7	87.2-98.4	95.9	89.9-100	86.0	71.4-92.9

Individual results for PL trials are detailed in the BAD.

Table 3.2-130 Minimum effective dose testing of GF-3307 at 0.75-1.5 L/ha against PUCCHD in barley. Results from five trials conducted in the EPPO South-East climatic zone between 2018-2021. Assessment at 21-42 days after application

EPPO Zone/Crop	Number of trials	Untreated control % infection PUCCHD		% control of PUCCHD									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Proline 0.72-0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
South-East (all crops)	5	10.1	5.3- 16.9	-	-	85.3	76.3- 93.5	90.3	88.0- 93.5	91.9	89.0- 95.9	91.3	84.2- 98.8
South-East (HORVW)	3	8.7	5.3- 11.4	-	-	85.5	79.6- 91.9	90.0	88.0- 93.0	91.6	89.0- 95.9	91.2	89.0- 95.5
South-East (HORVS)	2	12.3	7.6- 16.9	70.3	51.3- 89.3	84.9	76.3- 93.5	90.9	88.2- 93.5	92.4	89.5- 95.3	91.5	84.2- 98.8

Summary and conclusions on the minimum effective dose (MED) for PUCCHD on barley (EPPO South-East climatic zone)

PUCCHD is a secondary target disease for GF-3307 and the data reported demonstrate that it provides effective control of PUCCHD at the proposed dose rate range (1.0-1.5 L/ha). The maximum dose of 1.5 L/ha will give excellent control (92.4 91.9%) in all situations, including in geographical locations which have a history of severe PUCCHD infections. In other situations, where disease pressure is lower and if PYRNTE is not present in the crop (or expected to be a concern, see PYRNTE section), a dose of 1.2 L/ha (supported by data at 1.2 and 1.25 L/ha) will give sufficient control of PUCCHD in the EPPO South-East climatic zone (90.9 90.3% control). For situations with low disease pressure such as earlier in the season, a dose of 1.0 L/ha will give sufficient control of PUCCHD in EPPO South-East conditions (84.9 85.3%). A dose of 0.75 L/ha does not generally give sufficient control of PUCCHD (mean control of 70.3%).

The data were generated from use on both winter and spring barley and demonstrated a comparable dose response.

Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the later stages of the crop/summer that encourage the development of PUCCHD (hot and dry weather). Data from these trials demonstrate a similar flat dose response: 95.9% for the 1.5 L/ha dose, 93.7% for the 1.2 L/ha dose and 86.9% for the 1.0 L/ha dose and results for all doses were comparable to or higher than the prothioconazole reference standard at 86.0%.

It is considered that the proposed dose rate range of 1.0-1.5 L/ha is the minimum effective dose range to deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

3.2.2.16 MED of GF-3307 for the control of ERYSGH in barley

This section addresses the minimum effective dose (MED) of GF-3307 for the control of ERYSGH on winter and spring barley, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-1314 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (4), Spring barley (3) EPPO North-East: Winter barley (5), Spring barley (5) EPPO South-East: Winter barley (2) , Spring barley (2)
	Varieties per crop	EPPO Maritime: Winter barley: Cassia, Cervoise, Frigg, Lomerit, Spring barley: Avalon, Grace (2) EPPO North-East: Winter barley: Carola (3), Meridian, Zenek Spring barley: Blask, Iron, Propino, Stratus, Tocada EPPO South-East: Winter barley: SE Ellen, Astaire Spring barley: Xanadu, Kangoo
	Sowing period	Winter barley: September-October. Spring barley: March-May
Application	Crop stage (BBCH) at application	BBCH 31-52 EPPO Maritime: BBCH 31-41 EPPO North-East: BBCH 31-52 EPPO South-East: BBCH 31-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In all cases ERYSGH was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: one application EPPO North-East: one application EPPO South-East: one application
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where the key target pathogen is an abundant disease. ERYSGH was assessed as a secondary pathogen present at reliable levels.

Introduction

~~In total, data from 19 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of ERYSGH in winter and spring barley. GF-3307 was tested at 1.5, 1.2, 1.0 and 0.75 L/ha. **Note:** Results from the majority of trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other, the data has been combined to give a single result for the 1.2 L/ha dose. The trials were performed in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’. The reference product was Proline, applied at 0.6 or 0.8 L/ha, in all trials.~~

In total, data from 21 field trials are presented in this section to demonstrate the minimum effective dose of GF-3307, for the control of ERYSGH in winter and spring barley. GF-3307 was tested at 1.5, 1.25, 1.2, 1.0 and 0.75 L/ha. **Note:** Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East. The trials were performed in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’. The reference products were Proline 250 applied at 0.8 or Prosaro applied at 0.75 L/ha.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (1), France (1), Germany (4), United Kingdom (1) in the EPPO Maritime climatic zone, Latvia (5) and Poland (5) in the EPPO North-East climatic zone and Hungary (1) and Slovakia (1) in the EPPO South-East climatic zone, between 2017 and 2021.

On the basis of the EPPO standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these EPPO climatic zones, which is representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The MED efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-28.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGH is an abundant disease. ERYSGH is a disease which multiplies rapidly at short cycles under warm climatic conditions such as found in the EPPO Maritime, North-East and South-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 18 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.75, 1.0, 1.2, 1.5	112.5, 150, 180, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8	150-200

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.75, 1.0, 1.2, 1.25, 1.5	112.5, 150, 180, 187.5, 225

Proline 250	EC	250 g/L prothioconazole	0.8	200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	0.75	188

Experimental details

The ~~19~~ 21 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12 m² and 36 m². Eleven trials were carried out on winter barley and ~~eight~~ 10 on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4.6 weeks after each application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with ERYSGH or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments used were generally on Leaf 1, Leaf 2, Leaf 3, or Leaf 4 as the highest available assessed leaf with sufficient infection in the untreated. In four trials, (LV17E7B039KF01C, LV18E7B011KF01C, PL18E7B009AS02C, PL18E7B009AS04C) the latest assessment timing after a single application was used at 16-20 days after application. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP, but the earlier assessments after the first application and before the second application are valid to support the GAP.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Seven GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of ERYSGH in barley, following a single application ~~applied~~ at BBCH 31-55 of the crop. The MED trials were conducted in Denmark (1), Germany (4), France (1) and the United Kingdom (1) in the EPPO Maritime climatic zone, on both winter and spring barley. ~~The data include trials where ERYSGH was established before application (including on the leaves assessed for control in some trials) and trials where ERYSGH did not develop until after application.~~ The data include trials where ERYSGH was established at low levels on lower leaves before application and trials where ERYSGH did not develop until after application. These trials can therefore be considered to represent a robust test of both the curative and protectant properties of GF-3307. ERYSGH is a disease that establishes early in the crop on the lower leaves, therefore the majority of results for this disease are from the lower leaves (Leaf 2 to Leaf 4). **Note:** In one trial, the latest assessment timing after a single application was 18 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

From these seven trials conducted in the EPPO Maritime climatic zone, a single application of GF-3307 ~~applied~~ at 1.5 L/ha between BBCH 31-55, achieved mean control of 96.1% (range 80.0-100%) for ERYSGH on barley, 18-40 days after application (94.3% for HORVW and 98.6% for HORVS). Applied in the same trials at ~~1.2~~ 1.25 L/ha, GF-3307 achieved a slightly lower mean level of control of 90.6% (86.4% for HORVW and 96.4% for HORVS), with more variable results (range 56.1-100%).

Three trials compared the proposed 1.5 L/ha dose with lower doses of 1.0 L/ha and 0.75 L/ha. Overall results were 100% for the proposed dose and 100% for the 1.0 L/ha dose rate (one trial) and 100% for the proposed dose and 90.3% for the 0.75 L/ha dose rate (three trials)

A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops. The results are summarised in Table 3.2-13215 and individual trial results are detailed in the BAD. Results in Table 3.2-13215 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley and for comparison of different doses.

Table 3.2-13215 Minimum effective dose testing of GF-3307 at the proposed label rate of 1.5 L/ha, at 80, 83%, 67% and 50% dose rates against ERYSGH in barley. Results from 7 trials conducted in the EPPO Maritime climatic zone between 2017-2019. Assessment at 18-40 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection ERYSGH		% control of ERYSGH									
				GF-3307 0.75 L/ha (50% rate)		GF-3307 1.0 L/ha (67% rate)		GF-3307 1.2 L/ha (80% rate) 1.25 L/ha (83 % rate)		GF-3307 1.5 L/ha (100% rate)		Proline 0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
Maritime* (all crops)	7	19.1	5.8-60.0	-	-	-	-	90.6	56.1-100	96.1	80.0-100	94.9	69.1-100
Maritime* (HORVW)	4	22.9	5.8-60.0	-	-	-	-	86.4	56.1-100	94.3	80.0-100	92.2	69.1-100
Maritime* (HORVS)	3	14.0	5.8-30.0	-	-	-	-	96.4	89.1-100	98.6	95.7-100	98.6	95.7-100
Maritime** (HORVW)	1	30.0	-	87.5	-	100	-	100	-	100	-	100	-
Maritime*** (all crops)	3	32.1	6.3-60	90.3	83.3-100	-	-	100	100-100	100	100-100	100	100-100

*Direct comparison of 1.5 L/ha and 1.25 L/ha doses.

**Direct comparison of 1.5 L/ha, 1.0 L/ha and 0.75 L/ha doses.

***Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Summary and conclusions on the minimum effective dose (MED) for ERYSGH on barley (EPPO Maritime climatic zone)

ERYSGH is not a primary target disease for GF-3307. However, the data reported demonstrate that it will provide excellent control of ERYSGH at a range of dose rates. The proposed dose of 1.5 L/ha on barley in the EPPO Maritime climatic zone, is based on being the minimum required for other critical disease (e.g. PYRNT). However, these data demonstrate that a dose of 1.5 L/ha also provides the most consistent control of ERYSGH (all results above 80% control).

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose for the control of ERYSGH in barley, in the EPPO Maritime climatic zone.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

Ten GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) of GF-3307, for the control of ERYSGH in barley, following a single application applied at BBCH 31-52 of the crop. The MED trials were conducted in Latvia (5) and Poland (5) in the EPPO North-East climatic zone, on both winter and spring barley. The data include trials where ERYSGH was established before application (including on the leaves assessed for control in some trials) and trials where ERYSGH did not develop until after application. The data include trials where ERYSGH was established at low levels on lower leaves before application and trials where ERYSGH did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. The results for this disease are from a range of leaves (Leaf 1 to Leaf 4) as the highest available assessed leaf with sufficient infection in the untreated. **Note:** In four trials, (LV17E7B039KF01C, LV18E7B011KF01C, PL18E7B009AS02C, PL18E7B009AS04C) the latest assessment timing after a single application was used at 16-20 days after application. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP. In another trial (EA19E7B007F-DHW09) only a 14 day assessment is available for ERYSGH, as the disease was not found in the crop at later assessments.

From these 10 trials conducted in the EPPO North-East climatic zone, a single application of GF-3307 applied at 1.5 L/ha between BBCH 31-52, achieved mean control of 89.8% (range 75.8-100%) for ERYSGH on barley, 14-37 days after application (92.7% for HORVW and 87.9% for HORVS).

Applied in the same trials at ~~1.2~~ 1.2/1.25 L/ha, GF-3307 achieved a slightly lower mean level of control of 86.3% (85.8% for HORVW and 86.6% for HORVS).

Seven trials compared the ~~proposed 1.2~~ 1.2/1.25 L/ha and 1.5 L/ha doses of GF-3307, with a dose of 1.0 L/ha. In these trials GF-3307 achieved mean control of 88.4% using the proposed maximum 1.5 L/ha dose (92.1% for HORVW and 85.7% for HORVS) and 83.9% using the lower ~~1.2~~ 1.2/1.25 L/ha dose (88.7% for HORVW and 80.2% for HORVS), compared to mean control of 78.5% using the 1.0 L/ha dose (85.0% for HORVW and 73.6% for HORVS). Five trials compared the proposed doses, with a dose of 0.75 L/ha; the 0.75 L/ha dose achieved a much lower level of control of 79.3% (79.9% for HORVW and 79.0% for HORVS), compared to 86.5% (91.2% for HORVW and 83.3% for HORVS) using the proposed maximum 1.5 L/ha dose and 83.3% (87.7% for HORVW and 80.4% for HORVS) using the lower ~~1.2~~ 1.2/1.25 L/ha dose.

A similar dose response was seen in both the winter barley and spring barley trials; therefore it is considered that the data can be combined to determine the minimum effective dose across both crops. The results are summarised in ~~Table 3.2-133~~ 16 and individual trial results are detailed in the BAD. Results in ~~Table 3.2-133~~ 16 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley and for comparison of different doses.

~~Table 3.2-133~~ Minimum effective dose testing of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against ERYSGH in barley. Results from 10 trials conducted in the EPPO North-East climatic zone between 2017-2020. Assessment at 14-37 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection ERYSGH		% control of ERYSGH									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
North-East (All crops)*	10	11.5	5.6- 23.3	-	-	-	-	86.3	63.6- 100	89.8	75.8- 100	84.2	48.8- 100
North-East (HORVW)	4	10.6	5.6- 21.3	-	-	-	-	85.8	76.8- 90.8	92.7	85.7- 96.7	85.8	68.2- 100
North-East (HORVS)*	6	12.0	5.9- 23.3	-	-	-	-	86.6	63.6- 100	87.9	75.8- 100	83.1	48.8- 100
North-East (All crops)**	7	13.3	5.8- 23.3	-	-	78.5	64.5- 92.4	83.9	63.6- 93.5	88.4	75.8- 96.7	78.2	48.8- 96.7
North-East (HORVW)**	3	12.3	5.8- 21.6	-	-	85.0	79.4- 92.4	88.7	85.2- 90.8	92.1	85.7- 96.7	81.1	68.2- 96.7
North-East (HORVS)**	4	14.4	8.3- 23.3	-	-	73.6	64.5- 80.6	80.2	63.6- 93.5	85.7	75.8- 90.3	76.1	48.8- 93.1
North-East (All crops)***	5	8.9	5.8- 10.9	79.3	69.7- 92.0	-	-	83.3	63.6- 98.8	86.5	75.8- 96.7	87.2	73.5- 96.7
North-East (HORVW)***	2	7.7	5.8-9.5	79.9	78.2- 81.5	85.9	79.4- 92.4	87.7	85.2- 90.2	91.2	85.7- 96.7	87.5	78.3- 96.7
North-East (HORVS)***	3	9.8	8.3- 10.9	79.0	69.7- 92.0	-	-	80.4	63.6- 98.8	83.3	75.8- 89.7	87.0	73.5- 94.4

*Direct comparison of 1.5 L/ha and 1.2 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses. ***Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

Table 3.2-134 Minimum effective dose testing of GF-3307 at 0.75-1.5 L/ha against ERYSGH in barley. Results from 10 trials conducted in the EPPO North-East climatic zone between 2017-2020. Assessment at 14-37 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection ERYSGH		% control of ERYSGH									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference standards	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
North-East (All crops)*	10	11.5	5.6-23.3	-	-	-	-	86.3	63.6-100	89.8	75.8-100	89.9^	73.5-100
North-East (HORVW)	4	10.6	5.6-21.3	-	-	-	-	85.8	76.8-90.8	92.7	85.7-96.7	91.2^	78.3-100
North-East (HORVS)*	6	12.0	5.9-23.3	-	-	-	-	86.6	63.6-100	87.9	75.8-100	89.0^	73.5-100
North-East (All crops)**	7	13.3	5.8-23.3	-	-	78.5	64.5-92.4	83.9	63.6-93.5	88.4	75.8-96.7	86.3^	73.5-96.7
North-East (HORVW)**	3	12.3	5.8-21.6	-	-	85.0	79.4-92.4	88.7	85.2-90.8	92.1	85.7-96.7	88.2^	78.3-96.7
North-East (HORVS)**	4	14.4	8.3-23.3	-	-	73.6	64.5-80.6	80.2	63.6-93.5	85.7	75.8-90.3	84.9^	73.5-93.1
North-East (All crops)***	5	8.9	5.8-10.9	79.3	69.7-92.0	-	-	83.3	63.6-98.8	86.5	75.8-96.7	87.2#	73.5-96.7
North-East (HORVW)***	2	7.7	5.8-9.5	79.9	78.2-81.5	85.9	79.4-92.4	87.7	85.2-90.2	91.2	85.7-96.7	87.5#	78.3-96.7
North-East (HORVS)***	3	9.8	8.3-10.9	79.0	69.7-92.0	-	-	80.4	63.6-98.8	83.3	75.8-89.7	87.0#	73.5-94.4

*Direct comparison of 1.5 L/ha and 1.2/1.25 L/ha doses. **Direct comparison of 1.5 L/ha and 1.0 L/ha doses. ***Direct comparison of 1.5 L/ha and 0.75 L/ha doses.

^Reference standards used based on Proline 250 (P) applied at 0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

#Reference standards used based on Proline 250 (P) applied at 0.8 L/ha.

Summary and conclusions on the minimum effective dose (MED) for ERYSGH on barley (EPPO North-East climatic zone)

ERYSGH is a secondary target disease for GF-3307, but the data reported demonstrate that it provides excellent control of PUCCHD on both winter and spring barley at the proposed dose rate range of 1.2-1.5 L/ha. The proposed lower dose rate of 1.2 L/ha achieved overall control of 83.9%, compared to 78.5% for the 1.0 L/ha dose (across 7 trials) and 83.3%, compared to 79.3% for the 0.75 L/ha dose (across five trials). The proposed maximum dose rate of 1.5 L/ha achieved overall control of 88.4% compared to the 1.0 L/ha dose and 86.5% compared to the 0.75 L/ha dose, across the same trials.

It is considered that the proposed dose rate of 1.2 L/ha (supported by data at 1.2 and 1.25 L/ha) is the minimum effective dose of GF-3307 to deliver robust control of this disease on winter and spring barley under a wide range of environmental conditions in Poland (EPPO North-East climatic zone). However, as cereal diseases may occur together, for higher disease pressure disease situations in barley e.g. where ERYSGH and PYRNT occur together, the higher dose of 1.5 L/ha may be recommended for broad spectrum disease control.

A dose range of 1.2-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose of 1.2-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

~~Two~~ **Four** GEP small plot field trials were conducted in order to determine the minimum effective dose (MED) for the control of the ERYSGH in barley following a single application applied at BBCH 31-~~33~~**49** of the crop. The MED trials were conducted in Hungary (~~1~~ **3**) and Slovakia (1) in the EPPO South-East climatic zone, on ~~winter and~~ **winter and** spring barley. ~~The data include trials where ERYSGH was established before application (including on the leaves assessed for control in some trials) and trials where ERYSGH did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF 3307. The results for this disease are from Leaf 2 and Leaf 3, as the highest available assessed leaf with sufficient infection in the untreated.~~ The data include trials where ERYSGH was established at low levels on lower leaves before application and trials where ERYSGH did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. The results for this disease are from **Leaf 1**, Leaf 2 ~~and~~ **or** Leaf 3, as the highest available assessed leaf with sufficient infection in the untreated.

~~Data from the 2 trials conducted in the EPPO South-East climatic zone, using a single application of GF 3307 at 1.5 L/ha applied between BBCH 31-33, achieved mean control of 87.3% (range 81.9-92.8%) for ERYSGH on barley, 21-46 days after application. Applied in the same trials at 1.2 L/ha, GF 3307 achieved a slightly lower mean level of control of 86.2% (range 81.0-91.5%) and a significantly lower mean level of control of 66.9% (range 55.5-78.3%) using the 1.0 L/ha dose. One trial included a 0.75 L/ha dose and this demonstrated significantly lower control of 53.4% compared to 91.5% and 92.8% for the 1.2 L/ha and 1.5 L/ha doses, respectively. Results for both the 1.2 L/ha and 1.5 L/ha doses were comparable to the prothioconazole reference standard at 87.3%.~~

~~In addition to these data from the EPPO South-East Climatic zone, data are available from Poland, which is a neighbouring country. Poland has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of ERYSGH (warm and humid weather). Data from five trials are available that demonstrate a comparable dose response of 86.5% for the 1.5 L/ha dose and 83.6% for the 1.2 L/ha dose, compared to 75.3% for the 1.0 L/ha dose and 74.0% for the 0.75 L/ha dose (two trials only). Results for both the 1.2 L/ha and 1.5 L/ha doses were higher than the prothioconazole reference standard at 71.5%.~~

~~The majority of data were generated from use on spring barley (HORVS). As data from other EPPO climatic zones against ERYSGH demonstrate comparable levels of control of ERYSGH in winter and spring crops and data on other diseases in the EPPO South-East climatic zone have shown comparable levels of control using GF 3307 in both winter and spring crops, it is considered that these data are fully supportive of the claim for control of ERYSGH in winter barley (HORVW).~~

From these four trials conducted in the EPPO South-East climatic zone, a single application of GF-3307 at 1.5 L/ha applied between BBCH 31-49 achieved mean control of 85.9% (range 81.9-92.8%) for ERYSGH on barley, 21-46 days after application. Applied in the same trials, the 1.2/1.25 L/ha dose of GF-3307 achieved a slightly lower mean control of 81.8% (range 69.0-91.5%). Results for both proposed doses were comparable to the prothioconazole reference standard at 81.6%. The 1.0 L/ha dose of GF-3307 achieved lower mean control of 73.3%, with more variable results (ranges of 55.5-86.0%) and overall control below the reference standard (81.6% for Proline).

The data were generated from use on both winter and spring barley and demonstrated a comparable dose response.

The results are summarised in Table 3.2-13517 and individual trial results are detailed in the BAD. Results in Table 3.2-13517 are shown across all trials first (shaded grey), before being shown orthogonally for spring and winter barley and for comparison of different doses.

Table 3.2-135 — Minimum effective dose testing of GF-3307 at the proposed label dose rates of 1.2-1.5 L/ha against ERYSGH in barley. Results from two trials conducted in the EPPO South-East climatic zone plus 5 Polish trials, between 2017-2019. Assessment at 21-46 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control %infection ERYSGH		% control of ERYSGH									
				GF-3307 0.75 L/ha		GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East (HORVS)*	2	32.1	20.8-43.3	-	-	66.9	55.5-78.3	86.2	81.0-91.5	87.3	81.9-92.8	87.3	86.3-88.3
South-East (HORVS)**	1	20.8	-	53.4	-	78.3	-	91.5	-	92.8	-	86.3	-
Poland (all crops)*	5	15.3	8.3-23.3	-	-	75.3	64.5-83.3	83.6	63.6-93.5	86.5	75.8-93.9	71.5	48.8-88.8
Poland (HORVW)*	2	15.9	9.5-21.6	-	-	81.4	79.4-83.3	88.0	85.2-90.8	89.8	85.7-93.9	73.3	68.2-78.3
Poland (HORVS)*	3	15.1	8.3-23.3	-	-	71.2	64.5-75.8	80.6	63.6-93.5	84.3	75.8-90.3	70.4	48.8-88.8
Poland (all crops)**	2	8.9	8.3-9.5	74.0	69.7-78.2	77.6	75.8-79.4	74.4	63.6-85.2	80.8	75.8-85.7	75.9	73.5-78.3

*Direct comparison of 1.5 L/ha, 1.2 L/ha and 1.0 L/ha doses. **Direct comparison of 1.5 L/ha and 0.75 L/ha doses. Individual trial results for PL trials are detailed in the BAD.

Table 3.2-136 Minimum effective dose testing of GF-3307 at 1.0-1.5 L/ha against ERYSGH in barley. Results from four trials conducted in the EPPO South-East climatic zone between 2018-2021. Assessment at 21-46 days after one application.

EPPO Zone/Crop	Number of trials	Untreated control % infection ERYSGH		% control of ERYSGH							
				GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
South-East (all crops)	4	20.8	8.0-43.3	73.3	55.5-86.0	81.8	69.0-91.5	85.9	81.9-92.8	81.6	69.0-88.3
South-East (HORVW)	2	9.6	8.0-11.1	79.8	73.6-86.0	77.3	69.0-85.5	84.4	84.0-84.8	75.9	69.0-82.8
South-East (HORVS)	2	32.1	20.8-43.3	66.9	55.5-78.3	86.2	81.0-91.5	87.3	81.9-92.8	87.3	86.3-88.3

Summary and conclusions on the minimum effective dose (MED) for barley of 1.2-1.5 L/ha (EPPO South-East climatic zone)

ERYSGH is not a primary target disease for GF 3307, but the data reported demonstrate that it will provide excellent control of ERYSGH at a range of dose rates. These data demonstrate that a dose range of 1.2-1.5 L/ha GF 3307, in the EPPO South East climatic zone is the minimum required to provide consistent control of ERYSGH of 86.2-86.7% (dependent upon whether disease pressure is higher or lower) and control comparable to the reference standards (83.7%).

Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of PUCCHD (warm and humid weather). Data from five trials are available that demonstrate a comparable dose response of 86.5% for the 1.5 L/ha dose and 83.6% for the 1.2 L/ha dose, compared to 75.3% for the 1.0 L/ha dose and 74.0% for the 0.75 L/ha dose (two

~~trials only). Results for both the 1.2 L/ha and 1.5 L/ha doses were higher than the prothioconazole reference standard at 71.5%.~~

ERYSGH is not a primary target disease for GF-3307, but the data reported demonstrate that it will provide excellent control of ERYSGH at a range of dose rates. The maximum dose of 1.5 L/ha will give excellent control (85.9%) in all situations, including in geographical locations which have a history of severe ERYSGH infections. In other situations, where disease pressure is lower and if PYRNTE is not present in the crop (or expected to be a concern, see PYRNTE section), a dose of 1.2 L/ha (supported by data at 1.2 and 1.25 L/ha) will give sufficient control of ERYSGH in the EPPO South-East climatic zone (81.8% control). A dose of 1.0 L/ha does not give sufficient control of ERYSGH (mean control of 73.3%).

The data were generated from use on both winter and spring barley and demonstrated a comparable dose response.

It is considered that the proposed dose rate range of 1.2-1.5 L/ha is the minimum effective dose range to control ERYSGH in barley, in the EPPO South-East climatic zone.

~~**Note:** Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.~~

Summary and conclusions on the minimum effective dose (all crops and disease claims)

The summary tables below are split by EPPO climatic zone and the following colour coding has been used to illustrate the differences in effectiveness between the dose rates.

Level of Effectiveness
>80% control
70-79.9% control
<69.9% control

zRMS comments:

The present chapter: “**Summary and conclusions on the minimum effective dose (all crops and disease claims)**” has been amended profoundly by the applicant in the course of the dRR updating. The updated tables represented originally a patchwork of fragments marked by two different font colours. Considering the importance of the summary, in order to make the chapter more reader-friendly the zRMS decided to mark the tables with the black font uniformly, i.e. including also the updated values. For completeness, the old tables are struck through and left in place, each one preceding its respective updated version.

3.2.2.17 **Summary and conclusions on the minimum effective dose** **EPPO** **Maritime zone**

Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)

The proposed uses are for a single application at 1.5 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, PUCCRT, PUC CST, FUSASP, PYRNTR and ERYSGT.

The results from the EPPO Maritime climatic zone trials in the summary table below, demonstrate that the proposed dose of 1.5 L/ha of GF-3307 is the minimum effective dose required to achieve a claim of ‘very good control’ across all the proposed diseases on winter wheat. The 0.8N dose (1.2 L/ha) was effective in delivering good control in the 70-80% range, but did not always provide consistent control of FUSASP when compared to the 1.5 L/ha dose. The proposed 1.5 L/ha dose delivered the highest control across all diseases and exceeded the reference standards used. All supporting data where on winter wheat and it is considered these data fully support the 1.5 L/ha on spring wheat and other minor wheat crops (spelt and durum wheat).

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose rate to support all proposed disease claims on the label in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone.

Winter and spring rye (SECCW and SECCS) and winter and spring triticale (TTLWI and TTLSO)

The proposed uses are for a single application at 1.5 L/ha applied at BBCH 30-69 to winter and spring rye (SECCW and SECCS) for the control of PUCCRE and RHYNSE and to winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP, ERYSGT and PUC CST.

The results from the EPPO Maritime climatic zone trials (supported by data from Poland), in the summary table below, demonstrate that the proposed dose of 1.5 L/ha of GF-3307 is the minimum effective dose required to achieve a claim of ‘very good control’ across all the proposed diseases on rye and triticale. The 0.8N dose (1.2 L/ha) was effective in delivering good control in the 70-80% range, but did not always provide consistent control when compared to the 1.5 L/ha dose. The proposed 1.5 L/ha dose delivered the highest control across all diseases and exceeded the reference standards used in the majority of diseases. All supporting data where on winter crops and it is considered these data fully support the 1.5 L/ha on spring rye and spring triticale.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose rate to support all proposed disease claims on the label in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone.

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at 1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH.

Across all diseases, results from both winter and spring crops demonstrated comparable dose responses on these target diseases and have been combined to give an overall result to support the proposed dose across both crops in the summary table below. For PYRNTE and PUCCHD only data from winter barley are available, however it is considered that the data also support use on spring barley.

The results from the EPPO Maritime climatic zone trials demonstrate that the proposed dose of 1.5 L/ha of GF-3307 is the minimum effective dose required to achieve a claim of ‘very good control’ across all the proposed diseases. The lower 1.2 L/ha dose was effective in delivering good control in the 70-80% range, but did not always provide consistent control of PYRNTE and RHYNSE, when compared to the 1.5 l/ha dose. The proposed 1.5 L/ha dose delivered the highest control across all diseases and exceeded the reference standards used.

It is considered that the proposed dose rate of 1.5 L/ha is the minimum effective dose rate to support all proposed disease claims on the label in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone.

Summary of minimum effective dose testing of GF-3307 for EPPO Maritime zone (wheat data)

Target (EPPO-code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 0.9 L/ha (60% rate)*		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (Full rate)		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	MAR	6	31-53	51.8	11.3-87.5	70.5	57.9-87.9	84.6	74.7-97.7	90.5	84.9-99.3	78.0*	62.0-93.4
PUCCRT	TRZAW	MAR	9	37-61	22.6	5.6-74.8	77.0	55.6-94.0	83.3	66.2-92.4	85.5	70.2-94.3	83.6 ⁺	27.7-98.7
PUCST	TRZAW	MAR	8	32-45	30.0	7.4-65.0	90.1	78.5-98.5	91.4	81.5-100	94.4	87.5-100	92.4	81.9-100
FUSASP	TRZAW	MAR	10	61-65	31.2	5.7-93.8	60.1*	34.3-76.8	70.1	51.2-83.2	80.6	71.0-92.0	74.8	47.1-82.0
PYRNTR	TRZAW	MAR	6	31-51	25.2	7.8-50.8	70.0*	56.0-86.2	77.0	64.0-86.2	82.8	75.2-92.4	77.7*	48.0-94.5
ERYSGT	TRZAW	MAR	6	32-49	10.6	7.9-14.9	83.3	71.6-99.2	87.9**	73.0-99.4	92.9	86.3-100	86.4	46.9-100

*Results for the 0.9 L/ha dose on FUSASP are based on 9 trials and for PYRNTR based on 5 trials

**Results for the 1.2 L/ha dose for ERYSGT are based on 4 trials only.

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

ΔReference standard results are based on prothioconazole applied at 180-198 g as/ha and two trials using Aviator Xpro at 1.25 L/ha.

*Reference standard results are based on prothioconazole applied at 180-198 g as/ha and four trials using Aviator Xpro at 1.25 L/ha.

\$Reference standard results are based on prothioconazole applied at 180-198 g as/ha and one trial each using Aviator Xpro at 1.25 L/ha and Librax at 2.0 L/ha.

Summary of minimum effective dose testing of GF-3307 for EPPO Maritime zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 0.9-1.0 L/ha (60-67% rate)*		GF-3307 1.2-1.25 L/ha (80-87.5% rate)		GF-3307 1.5 L/ha (Full rate)		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	MAR	8	31-59	46.5	11.3-87.5	74.0	57.9-87.9	87.2	74.7-100	91.7	84.9-100	82.4^	62.3-93.4
PUCCRT	TRZAW	MAR	11	37-61	25.9	5.6-74.8	78.9	55.6-94.0	84.1	66.2-92.4	86.1	70.2-94.3	92.2^	27.7-98.7
PUC CST	TRZAW	MAR	8	32-45	30.0	7.4-65.0	90.1	78.5-98.5	91.4	81.5-100	94.4	87.5-100	92.4	81.9-100
FUSASP	TRZAW	MAR	10	61-65	31.2	5.7-93.8	60.1*	34.3-76.8	70.1	51.2-83.7	80.6	71.0-92.0	74.8	47.1-83.0
PYRNTR	TRZAW	MAR	7	31-51	24.0	7.8-50.8	73.6*	56.0-87.1	79.7	64.0-90.6	83.9	75.2-92.4	84.5\$	73.6-94.5
ERYSGT	TRZAW	MAR	6	32-49	10.6	7.9-14.9	83.3	71.6-99.2	87.9**	73.0-99.4	92.9	86.3-100	95.6^	80.2-100

*Results for the 0.9 L/ha dose on FUSASP are based on 9 trials and for PYRNTR based on 6 trials

**Results for the 1.2 L/ha dose for ERYSGT are based on 4 trials only.

#Reference standard results are based on prothioconazole applied at 198 g as/ha, unless specified

^Reference standard results are based on prothioconazole applied at 198 g as/ha and Aviator Xpro at 1.0-1.25 L/ha.

\$Reference standard results are based on prothioconazole applied at 198 g as/ha, Aviator Xpro at 1.0-1.25 L/ha and Librax at 2.0 L/ha.

Summary of minimum effective dose testing of GF-3307 for EPPO Maritime zone (rye and triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha (67% rate)*		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (Full rate)		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PUCCRE	SECCW	MAR	10	32-51	15.5	5.0-41.2	-	-	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100
RHYNSE	SECCW	MAR	8	32-51	15.3	6.8-27.0	-	-	84.5	68.2-100	89.9	75.0-100	83.2	59.3-100
SEPTSP	TTLWI	MAR	4	33-51	25.0	7.8-47.5	-	-	75.1	60.2-90.4	88.2	82.3-100	71.5	63.4-87.4
		PL	3	33-52	17.9	8.9-33.8	-	-	72.3	68.6-74.5	78.4	76.0-81.6	74.3	68.2-86.3
		ALL	7	33-52	22.0	7.8-47.5	-	-	73.9	68.6-90.3	84.0	76.0-100	73.3	68.3-87.4
ERYSGT	TTLWI	MAR	1	33-37	34.1	-	-	-	86.2	-	85.3	-	90.9	-
		PL	5	33-49	14.9	7.8-29.4	70.3*	-	83.7	59.1-96.1	91.4	65.5-99.3	91.7 ^Δ	70.3-100
		ALL	6	33-49	18.1	7.8-34.1			84.2	59.1-96.1	90.4	65.5-99.3	91.6 ^Δ	70.3-100
PUCST	TTLWI	MAR	8	37-51	38.1	6.0-96.5	85.8*	74.5-100	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100

*Results for the 1.0 L/ha dose are from a lower number of trials.

#Proline applied at 0.72 L/ha used as the reference standard, unless specified.

^ΔProline applied at 0.72 L/ha used as the reference standard in all trials, except one trial using Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Summary of minimum effective dose testing of GF-3307 for EPPO Maritime zone (rye and triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha (60% rate)*		GF-3307 1.2 L/ha (80% rate)		GF-3307 1.5 L/ha (Full rate)		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PUCCRE	SECCW	MAR	10	32-51	15.5	5.0-41.2	-	-	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100
RHYNSE	SECCW	MAR	8	32-51	15.3	6.8-27.0	-	-	84.5	68.2-100	89.9	75.0-100	83.2	59.3-100
SEPTSP	TTLWI	MAR	4	33-51	25.0	7.8-47.5	-	-	75.1	69.2-90.3	88.2	82.3-100	72.5	63.4-87.1
		PL	3	33-52	17.9	8.9-33.8	-	-	72.3	68.6-74.5	78.4	76.0-81.6	74.3	58.3-86.5
		All	7	33-52	22.0	7.8-47.5	-	-	73.9	68.6-90.3	84.0	76.0-100	73.3	58.3-87.1
ERYSGT	TTLWI	MAR	1	33-37	34.1	-	-	-	86.2	-	85.3	-	90.9	-
		PL	6	33-49	17.8	7.8-31.9	70.9*	-	84.2	59.1-96.1	91.8	65.5-99.3	90.6^	70.3-100
		All	7	33-49	20.1	7.8-34.1	70.9*	-	84.5	59.1-96.1	90.9	65.5-99.3	90.7^	70.3-100
PUCCST	TTLWI	MAR	8	37-51	38.1	6.0-96.5	85.8*	74.5-100	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100

*Results for the 1.0 L/ha dose are from a lower number of trials.

#Proline applied at 0.72 L/ha used as the reference standard, unless specified.

^Proline applied at 0.72 L/ha used as the reference standard in all trials, except one trial using Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Summary of minimum effective dose testing of GF-3307 for EPPO Maritime zone (barley data)

Target (EPPO-code)	Crop (EPPO)	EPPO Zone	Number-of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha (67%-rate)*		GF-3307 1.2 L/ha (80%-rate)		GF-3307 1.5 L/ha (Full-rate)		Reference-standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	MAR	2	35-39	48.0	7.1-88.8	-	-	83.5	77.0-89.9	84.2	72.0-96.3	77.9	63.0-92.7
	HORVS	MAR	5	31-51	37.7	5.0-74.5	68.4*	-	81.2	74.9-90.0	85.4	76.3-93.7	67.8	63.0-92.7
	Both	MAR	7	31-51	40.6	5.0-88.8	68.4*	-	81.8	74.9-90.0	85.0	72.0-96.3	70.7	45.0-92.7
RHYNSE	HORVW	MAR	7	31-39	14.9	7.6-39.8	87.4	68.8-100	82.9	66.5-100	87.1	76.7-100	79.1	43.1-100
	HORVS	MAR	3	37-51	17.3	5.0-32.5	51.6	44.6-58.8	77.1	68.5-82.5	85.0	75.1-95.8	84.3	80.0-88.2
	Both	MAR	10	31-51	15.6	50.0-39.8	73.1*	44.6-100	81.1	66.5-100	86.5	75.1-100	80.7	43.1-100
PYRNTE	HORVW	MAR	7	32-49	33.2	5.4-73.3	72.1*	60.0-74.3	70.3	72.0-85.3	82.4	72.0-88.3	77.5	71.0-86.0
PUCCHD	HORVW	MAR	5	32-49	14.7	7.7-23.8	95.0*	-	93.2	75.5-99.5	94.0	78.9-100	93.5	83.4-97.9
ERYSGH	HORVW	MAR	4	31-41	22.9	5.8-60.0	100*	-	86.4	56.1-100	94.3	80.0-100	92.2	69.1-100
	HORVS	MAR	3	37-55	14.0	5.8-30.0	-	-	96.4	89.1-100	98.6	95.7-100	98.6	95.7-100
	Both	MAR	7	31-55	19.1	5.8-60.0	100*	-	90.6	56.1-100	96.1	80.0-100	94.9	69.1-100

*Results for the 1.0 L/ha dose are from a lower number of trials for most diseases

#Proline 250 applied at 0.8 L/ha (200 g prothioconazole/h) used as the reference standard.

Summary of minimum effective dose testing of GF-3307 for EPPO Maritime zone (barley data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha (67% rate)*		GF-3307 1.2-1.25 L/ha (80-83% rate)		GF-3307 1.5 L/ha (Full rate)		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	MAR	2	35-39	48.0	7.1-88.8	-	-	83.5	77.0-89.9	84.2	72.0-96.3	77.9	63.0-92.7
	HORVS	MAR	5	31-51	37.7	5.0-74.5	68.4*	-	81.2	74.9-90.0	85.4	76.3-93.7	67.8	63.0-92.7
	Both	MAR	7	31-51	40.6	5.0-88.8	68.4*	-	81.8	74.9-90.0	85.0	72.0-96.3	70.7	45.0-92.7
RHYNSE	HORVW	MAR	7	31-39	14.9	7.6-39.8	87.4	68.8-100	82.9	66.5-100	87.1	76.7-100	79.1	43.1-100
	HORVS	MAR	3	37-51	17.3	5.0-32.5	51.6	44.6-58.8	77.1	68.5-82.5	85.0	75.1-95.8	84.3	80.0-88.2
	Both	MAR	10	31-51	15.6	50.0-39.8	73.1*	44.6-100	81.1	66.5-100	86.5	75.1-100	80.7	43.1-100
PYRNTE	HORVW	MAR	7	32-49	33.2	5.4-73.3	72.1*	69.9-74.2	79.2	72.0-85.3	82.4	72.0-88.3	77.5	71.0-86.0
PUCCHD	HORVW	MAR	5	32-49	14.7	7.7-23.8	95.0*	-	93.2	75.5-99.5	94.0	78.9-100	93.5	83.4-97.9
ERYSGH	HORVW	MAR	4	31-41	22.9	5.8-60.0	100*	-	86.4	56.1-100	94.3	80.0-100	92.2	69.1-100
	HORVS	MAR	3	37-55	14.0	5.8-30.0	-	-	96.4	89.1-100	98.6	95.7-100	98.6	95.7-100
	Both	MAR	7	31-55	19.1	5.8-60.0	100*	-	90.6	56.1-100	96.1	80.0-100	94.9	69.1-100

*Results for the 1.0 L/ha dose are from a lower number of trials for most diseases

#Proline 250 applied at 0.8 L/ha (200 g prothioconazole/h) used as the reference standard.

3.2.2.18 **Summary and conclusions on the minimum effective dose EPPO** **North-East zone**

Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)

The proposed use is for a single application at a dose range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, Puccrt, Puccst, FUSASP, PYRNTR and ERYSGT.

~~The lower dose of 1.2 L/ha is recommended for application where SEPTTR, Puccrt, Puccst or ERYSGT are the major diseases requiring control and where there is lower pressure from PYRNTR. Where disease pressure is higher or mixed disease situation and/or FUSASP is also present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.~~ **The lower dose of 1.0 L/ha (supported by data at 0.9 L/ha and 1.0 L/ha) is recommended for application where disease levels are low and SEPTTR or ERYSGT are the only diseases requiring control.** The 1.2 L/ha dose is recommended for application where SEPTTR, Puccrt, Puccst or ERYSGT are the major diseases requiring control and where there is lower pressure from PYRNTR. Where disease pressure is higher or mixed disease situation and/or FUSASP is also present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.

The maximum 1.5 L/ha dose achieved the highest levels of control across all diseases. The proposed dose range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** exceeded the control achieved by the reference standards in the majority of situations (see summary table below).

~~For SEPTTR, Puccrt, Puccst and ERYSGT the results demonstrate that the proposed minimum dose of 1.2 L/ha of GF 3307 is sufficient to achieve a claim of 'good control' of these target diseases. The 0.9 L/ha dose provided insufficient control on many diseases and was more variable.~~ **For SEPTTR and ERYSGT the results demonstrate that the proposed minimum dose of 1.0 L/ha of GF-3307 (supported by data at 0.9 L/ha and 1.0 L/ha) is sufficient to achieve a claim of 'good control' of these target diseases. For Puccrt and Puccst the results demonstrate that the proposed dose of 1.2 L/ha dose of GF-3307 is sufficient to achieve a claim of 'good control' of these target diseases.**

For PYRNTR, the results demonstrate that the proposed maximum dose is the most effective dose required to achieve a claim of 'very good control' of PYRNTR, with minimum control levels of 80+%. The 1.2 L/ha dose offered good control of 70-80% of this disease, but did not always provide consistently high levels of control, as control was more variable in some trials. It is considered that the 1.2 L/ha dose will be sufficient in situations where PYRNTR is a secondary disease and not the main target. **The 0.9/1.0 L/ha dose provided insufficient control on this disease and was more variable.**

For FUSASP, the maximum dose of 1.5 L/ha is required, as the ~~1.2 L/ha dose~~ **0.9/1.0 and 1.2/1.25 L/ha doses** did not give sufficient control of this disease (>70%).

~~**Note:** Additional EPPO North East trials are being generated on FUSASP and ERYSGT in 2021 and can be submitted to support these claims if the current data is not considered sufficient to support the dose range from 1.2-1.5 L/ha against ERYSGT and 1.5 L/ha against FUSASP.~~

Results for spring wheat are more limited, but demonstrate a similar dose response to winter wheat, with the 1.5 L/ha dose achieving the highest levels of control and dose range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** can be supported as it is in winter wheat, with the exception of *Fusarium* Spp. It is considered these data fully support these dose rates on other minor wheat crops (spelt and durum wheat).

Winter and spring rye (SECCW and SECCS) and winter and spring triticale (TTLWI and TTLSO)

The proposed uses are for a single application at 1.2-1.5 L/ha applied at BBCH 30-69 to winter and spring rye (SECCW and SECCS) for the control of Puccre and RHYNSE and to winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP, ERYSGT and Puccst.

On rye, the lower dose of 1.2 L/ha is recommended for application where RHYNSE is the major disease requiring control and where there is lower pressure from Puccre. Where Puccre is also

present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility (see summary table below). On triticale, the lower dose of 1.2 L/ha is recommended for application where ERYSGT or PUCST are the major disease requiring control and where there is lower pressure from SEPTSP. Where SEPTSP is also present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility (see summary table below).

The results from the EPPO North-East climatic zone trials (supported by data from DE) demonstrate that the proposed minimum dose of 1.2 L/ha of GF-3307 is sufficient to achieve a claim of ‘very good control’ of RHYNSE on rye and ERYSGT and PUCST on triticale. The 1.0 L/ha dose provided insufficient control and was more variable.

For the maximum 1.5 L/ha dose, results from the EPPO North-East climatic zone trials (supported by data from DE) demonstrate that the proposed maximum dose is the most effective dose required to achieve a claim of ‘very good control’ of PUCRE on rye and SEPTSP on triticale, with minimum control levels of 80+%. The 1.2 L/ha dose offered good control of 70-80%, but did not always consistently provide highest levels of control, as control was more variable in some trials with highest disease pressure, but generally performance across diseases and crops was similar to the reference Proline 275 and hence a dose range of 1.2-1.5 L/ha can be supported in rye and triticale for GF-3307.

All supporting data where on winter crops and it is considered these data fully support the same dose range (1.2-1.5 L/ha) on spring rye and spring triticale.

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH. ~~The lower dose of 1.2 L/ha is recommended for application where RHYNSE, PUCCHD or ERYSGH are the major disease requiring control and where there is lower pressure from PYRNTE and RAMUCC. The lower dose of 1.0 L/ha is recommended for application where disease levels are low and RHYNSE or PUCCHD are the only diseases requiring control. The 1.2 L/ha dose (supported by data at 1.2/1.25 L/ha) is recommended for application where ERYSGH is the major diseases requiring control and where there is lower pressure from PYRNTE and/or RAMUCC.~~ Where PYRNTE and/or RAMUCC are also present and expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** is proposed, to offer growers the greatest flexibility.

Across all diseases, results from both winter and spring crops demonstrated comparable dose responses on these target diseases and have been combined to give an overall result to support the proposed dose across both crops in the summary table below.

~~The results from the EPPO North East climatic zone trials demonstrate that the proposed minimum dose of 1.2 L/ha of GF 3307 is sufficient to achieve a claim of ‘very good control’ of RHYNSE, PUCCHD and ERYSGH. The 1.0 L/ha dose provided insufficient control for some diseases and was more variable. For RHYNSE and PUCCHD the results demonstrate that the proposed minimum dose of 1.0 L/ha of GF-3307 is sufficient to achieve a claim of ‘good control’ of these target diseases. For ERYSGH the results demonstrate that the proposed dose of 1.2 L/ha dose (supported by data at 1.2/1.25 L/ha) of GF-3307 is sufficient to achieve a claim of ‘good control’ of these target diseases. The 1.0 L/ha dose provided insufficient control on this disease and was more variable.~~

For the maximum 1.5 L/ha dose, results from the EPPO North-East climatic zone trials (supported by data from DE for RAMUCC) demonstrate that the proposed maximum dose is the most effective dose required to achieve a claim of ‘very good control’ of PYRNTE and RAMUCC, with minimum control levels of 80+%. The 1.2 L/ha dose (**supported by data at 1.2/1.25 L/ha**) offered good control of around 80%, but did not always provide consistently high levels of control, as control was more variable in some trials. ~~Hence a label dose range of 1.2-1.5 L/ha is proposed in barley, to offer growers the~~

~~greatest flexibility.~~ The 1.0 L/ha dose provided insufficient control on these diseases and was more variable.

Summary of minimum effective dose testing of GF-3307 for EPPO North-East zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 0.9 L/ha*		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	N-E	8	31-51	22.5	5.8-49.1	79.9	68.3-85.0	84.0	74.3-91.3	92.0	81.5-99.2	80.7	58.5-94.3
	TRZAS	N-E	1	39-41	5.0	-	-	-	74.9	-	83.3	-	88.3	-
PUCCRT	TRZAW	N-E	6	39-61	29.2	6.0-43.1	83.9	65.2-98.6	89.5	84.2-98.4	91.7	83.3-97.7	85.9 ^Δ	62.0-95.0
PUCCST	TRZAW	N-E	4	37-51	20.8	6.4-40.6	63.2*	-	90.2	69.6-100	95.7	83.6-100	81.6	32.8-100
		DE	3	31-45	28.6	20.0-37.5	88.5	81.9-98.5	90.0	84.0-100	91.8	87.5-100	87.6	81.9-98.0
		All	7	31-51	28.7	20.0-37.5	82.2*	63.2-98.5	84.9	69.6-100	89.8	83.6-100	73.9	32.8-98.0
	TRZAS	N-E	1	39-41	8.7	-	-	-	90.8	-	93.3	-	95.8	-
FUSASP	TRZAW	N-E	1	61-65	13.7	-	68.1	-	68.3	-	83.6	-	70.1	-
		DE	4	61-65	47.8	8.5-93.8	61.4*	50.0-75.2	69.9	57.0-83.7	80.3	71.0-92.0	71.6	47.1-80.6
		All	5	61-65	41.0	8.5-93.8	63.1*	50.0-75.2	67.9	57.0-83.7	80.6	71.0-92.0	79.6	78.1-80.6
PYRNTTR	TRZAW	N-E	3	35-51	20.6	13.8-26.3	67.2	56.8-74.6	78.4	68.1-84.1	84.6	79.0-92.3	65.7	31.5-82.9
		CZ+DE	4	31-49	33.2	14.9-50.8	78.4	56.0-86.3	77.2	64.0-86.3	83.0	75.2-92.4	74.0	48.0-94.5
		All	7	31-51	27.8	13.8-50.8	69.0	56.0-86.2	77.9	64.0-86.3	83.7	75.2-92.4	70.4	31.5-94.5
	TRZAS	NE	1	39-49	13.1	-	76.3	-	73.0	-	78.6	-	67.6	-
ERYSGT	TRZAW	N-E	2	39-49	7.5	7.0-8.0	83.7	78.5-88.9	88.4	87.1-89.7	88.2	88.0-88.3	90.8	89.6-91.9
		CZ+DE	3	32-49	12.9	11.9-14.9	77.6	71.6-88.8	80.9	73.0-88.7	90.4	86.3-94.6	73.6	46.9-100
		All	5	32-49	10.7	7.0-14.9	80.0	71.6-88.9	84.6**	73.0-89.7	89.5	86.3-94.6	80.4	46.9-100
	TRZAS	NE	1	47-49	11.5	-	58.0	-	69.7	-	85.5	-	50.4	-

*Results for the 0.9 L/ha dose are from a lower number of trials for some target diseases. **Results for the 1.2 L/ha dose for ERYSGT are based on 4 trials only.

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

^ΔReference standard results are based on 180-198 g as/ha and three trials using Aviator Xpro applied at 1.25 L/ha.

Summary of minimum effective dose testing of GF-3307 for EPPO North-East zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 0.9-1.0 L/ha*		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	N-E	11	31-51	18.6	5.8-49.1	82.2	68.3-95.0	86.2	71.2-99.1	92.4	80.4-100	82.8	58.5-97.1
	TRZAS	N-E	1	39-41	5.0	-	-	-	74.9	-	83.3	-	88.3	-
PUCCRT	TRZAW	N-E	8	39-61	30.2	6.0-50.0	83.3	65.2-98.6	89.6	84.2-98.4	92.2	83.3-97.7	82.2^	57.7-95.0
PUCST	TRZAW	N-E	5	37-51	25.7	6.4-45.0	70.4*	63.2-77.6	90.2	69.6-100	95.6	83.6-100	91.7	72.9-100
		DE	3	31-45	28.6	20.0-37.5	88.5	81.9-98.5	90.0	84.0-100	91.8	87.5-100	87.6	81.9-98.0
		All	8	31-51	26.8	6.4-45.0	81.2*	63.2-98.5	90.2	69.6-100	94.2	83.6-100	90.2	72.9-100
	TRZAS	N-E	1	39-41	8.7	-	-	-	90.8	-	93.3	-	95.8	-
FUSASP	TRZAW	N-E	5	61-69	47.2	13.7-91.3	69.7	52.3-93.4	78.8	66.1-97.6	90.7	83.6-100	86.4+	82.5-96.7
		DE	3	61-65	60.9	30.3-93.8	61.4*	50.0-75.2	67.7	57.0-83.7	79.5	71.0-92.0	83.3+	75.9-90.1
		All	8	61-69	52.4	13.7-93.8	66.6	50.0-93.4	74.7	57.0-97.6	86.5	71.0-100	85.2+	75.9-100
PYRNTR	TRZAW	N-E	4	35-51	18.3	11.3-26.3	67.7	56.8-74.6	79.8	68.1-84.2	88.5	79.0-100	78.9^	59.4-90.8
		CZ + DE	5	31-49	29.9	14.9-50.8	73.7	56.0-87.1	79.9	64.0-90.6	84.6	75.2-92.4	84.1^	73.6-94.5
		All	9	31-51	24.7	11.3-50.8	71.1	56.0-87.1	79.9	64.0-90.6	86.3	75.2-100	81.8^	59.4-94.5
	TRZAS	NE	2	39-49	16.7	13.1-20.3	78.6	76.2-81.0	80.5	72.9-88.0	88.3	78.6-98.0	75.3	67.6-83.0
ERYSGT	TRZAW	N-E	6	37-55	10.8	6.0-17.5	82.6	57.5-100	89.4	72.5-100	94.0	87.5-100	90.4^	73.8-100
		CZ + DE	3	32-49	12.9	11.9-14.9	77.6	71.6-88.8	80.9	73.0-88.7	90.4	86.3-94.6	91.8^	80.2-100
		All	9	32-55	11.5	6.0-17.5	80.9	57.5-100	87.3**	72.5-100	92.8	86.3-100	90.9^	73.8-100
	TRZAS	NE	1	47-49	11.5	-	58.0	-	69.7	-	85.5	-	79.4	-

*Results for the 1.0 L/ha dose are from a lower number of trials for some target diseases. **Results for the 1.2 L/ha dose for ERYSGT are based on 8 trials only.

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

^Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro applied at 1.25 L/ha.

*Reference standard Prosaro at 1.0 L/ha

Summary of minimum effective dose testing of GF-3307 for EPPO North-East zone (rye and triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha*		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PUCCRE	SECCW	N-E	3	37-52	32.8	18.1-49.1	-	-	67.4	54.7-77.8	77.1	69.0-84.7	73.8	66.2-86.3
		DE	10	32-51	15.5	5.0-41.2	-	-	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100
		All	13	32-52	19.5	5.0-49.1	-	-	79.6	54.7-95.0	86.7	69.0-100	84.8	66.2-100
RHYNSE	SECCW	N-E	5	37-52	13.1	5.0-28.4	-	-	76.0	64.5-91.8	81.5	68.1-97.6	68.6	56.0-77.3
		DE	8	32-51	15.3	6.8-27.0	-	-	84.5	68.2-100	89.9	75.0-100	83.2	59.3-100
		All	13	32-52	14.5	5.0-28.4	-	-	81.2	63.5-100	86.7	68.1-100	77.6	56.0-100
SEPTSP	TTLWI	N-E	3	33-52	17.9	8.9-33.8	-	-	72.3	68.6-74.5	78.4	76.0-81.6	74.3	58.3-86.5
		DE	4	33-51	25.0	7.8-47.5	-	-	78.4	69.3-90.3	88.2	82.3-100	72.8	63.4-87.4
		All	7	33-52	22.0	7.8-47.5	-	-	73.0	68.6-90.3	84.0	76.0-100	71.3	58.3-87.4
ERYSGT	TTLWI	N-E	5	33-49	14.9	7.8-29.4	70.3*	-	83.7	59.1-96.1	91.4	65.5-99.3	91.7 ^Δ	70.3-100
		DE	1	33-37	34.1	-	-	-	86.2	-	85.3	-	90.9	-
		All	6	33-49	18.1	7.8-34.1	70.3*	-	84.2	59.1-96.1	90.4	65.5-99.3	91.6 ^Δ	70.3-100
PUCCST	TTLWI	N-E	3	35-52	31.4	7.1-50.0	56.7*	44.7-68.7	76.4	54.0-90.0	85.0	82.4-89.4	55.9	36.6-73.7
		DE	8	37-51	38.1	6.0-96.5	85.8*	74.5-100	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100
		All	11	35-52	36.2	6.0-96.5	76.1*	44.7-100	82.6	73.9-100	87.5	81.8-100	79.8	36.6-100

*Results for the 1.0 L/ha dose are from a lower number of trials.

#Proline applied at 0.72 L/ha used as the reference standard, unless specified

^ΔProline applied at 0.72 L/ha used as the reference standard in all trials, except one trial using Wirtuoz 520 EC at 1.0 L/ha in sequence with Arteo at 0.5 L/ha

Summary of minimum effective dose testing of GF-3307 for EPPO North-East zone (rye and triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha*		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
PUCCRE	SECCW	N-E	5	37-52	26.2	8.8-49.1	84.4*	78.8-90.0	77.4	54.7-100	84.7	69.0-100	83.3##	66.2-100
		DE	10	32-51	15.5	5.0-41.2	-	-	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100
		All	15	32-52	21.1	5.0-49.1	84.4*	78.8-90.0	79.6	54.7-95.0	86.6	69.0-100	86.5##	66.2-100
RHYNSE	SECCW	N-E	6	37-52	17.6	5.0-40.0	61.9*		75.7	63.5-93.8	81.1	68.1-97.6	70.7##	56.0-77.3
		DE	8	32-51	15.3	6.8-27.0	-	-	84.5	68.2-100	89.9	75.0-100	83.2	59.3-100
		All	14	32-52	16.3	5.0-40.0	61.9*		80.7	63.5-100	86.1	68.1-100	77.9##	56.0-100
SEPTSP	TTLWI	N-E	3	33-52	17.9	8.9-33.8	-	-	72.3	68.6-74.5	78.4	76.0-81.6	74.3	58.3-86.5
		DE	4	33-51	25.0	7.8-47.5	-	-	75.1	69.2-90.3	88.2	82.3-100	72.5	63.4-87.1
		All	7	33-52	22.0	7.8-47.5	-	-	73.9	68.6-90.3	84.0	76.0-100	73.3	58.3-87.1
ERYSGT	TTLWI	N-E	6	33-49	17.8	7.8-31.9	70.9*	70.3-71.5	84.2	59.1-96.1	91.8	65.5-99.3	90.6^	70.3-100
		DE	1	33-37	34.1	-	-	-	86.2	-	85.3	-	90.9	-
		All	7	33-49	20.1	7.8-34.1	70.9*	70.3-71.5	84.5	59.1-96.1	90.9	65.5-99.3	90.7^	70.3-100
PUCCST	TTLWI	N-E	3	35-52	31.4	7.1-50.0	56.7*	44.7-68.7	76.4	73.9-79.0	85.0	82.4-89.4	55.9	36.6-73.7
		DE	8	37-51	38.1	6.0-96.5	85.8*	74.5-100	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100
		All	11	35-52	36.2	6.0-96.5	76.1*	44.7-100	82.6	73.9-100	87.5	81.8-100	79.8	36.6-100

*Results for the 1.0 L/ha dose are from a lower number of trials.

#Proline 275 applied at 0.72 L/ha used as the reference standard, unless specified

##Proline 275 or Proline 250 applied at 0.72 L/ha (108-198 g as/ha) used as the reference standard

^Proline 275 or Proline 250 applied at 0.72 L/ha (108-198 g as/ha) used as the reference standard, plus one trial using Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Summary of minimum effective dose testing of GF-3307 for EPPO North-East zone (barley data)

Target (EPPO-code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha*		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	DE	2	35-39	48.0	7.1-88.8	-	-	83.5	77.0-89.9	84.2	72.0-96.3	77.9	63.0-92.7
	HORVS	DE	3	31-39	34.8	5.0-51.8	68.4*	-	80.1	74.9-90.0	83.7	76.3-90.0	61.7	45.0-71.1
	Both	DE	5	31-39	40.0	5.0-88.8	68.4*	-	81.4	74.9-90.0	83.9	72.0-96.3	68.2	45.0-92.7
RHYNSE	HORVW	N-E	6	31-52	16.4	5.6-35.0	84.7*	78.0-99.1	89.4	80.0-99.1	94.1	88.7-100	79.1	48.5-100
	HORVS	N-E	4	37-49	10.1	5.6-22.5	80.4	59.2-99.2	96.3	87.5-100	97.9	92.1-100	90.4	80.2-100
	Both	N-E	10	31-52	13.9	5.6-35.0	82.8*	59.2-99.2	92.1	80.0-100	95.6	88.7-100	83.7	48.5-100
PYRNTE	HORVW	N-E	5	32-52	16.4	5.0-29.4	73.7*	60.0-83.2	80.7	72.1-87.3	85.2	80.0-91.4	66.0	48.4-85.4
	HORVS	N-E	7	32-52	18.1	5.5-30.6	69.1	57.9-83.2	83.0	67.9-95.7	89.2	79.6-100	76.6	42.4-95.7
	Both	N-E	12	32-52	17.4	5.0-30.6	71.1*	57.9-83.2	82.0	67.9-95.7	87.5	79.6-100	71.3	42.4-95.7
PUCCHD	HORVW	N-E	1	47-51	47.5	-	94.1	-	96.0	-	98.1	-	84.8	-
	HORVS	N-E	5	37-52	13.7	5.5-31.9	85.3	77.6-97.1	90.4	79.6-98.4	96.1	89.9-100	87.3	71.4-92.9
	Both	N-E	6	37-52	19.3	5.5-47.5	86.8	77.6-97.1	91.4	79.6-98.4	96.4	89.9-100	86.9	71.4-92.9
ERYSGH	HORVW	N-E	4		10.6	5.6-21.3	85.0*	79.4-92.4	85.8	76.8-90.8	92.7	85.7-96.7	85.8	68.2-100
	HORVS	N-E	6		12.0	5.9-23.3	73.6*	64.5-80.6	86.6	63.6-100	87.9	75.8-100	83.1	48.8-100
	Both	N-E	10		11.5	5.6-23.3	78.5*	64.5-92.4	86.3	63.6-100	89.8	75.8-100	84.2	48.8-100

*Results for the 1.0 L/ha dose are from a lower number of trials for most diseases.

#Proline 250 applied at 0.6-0.8 L/ha (150-200 g prothioconazole/h) used as the reference standard.

Summary of minimum effective dose testing of GF-3307 for EPPO North-East zone (barley data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control									
							GF-3307 0.75 L/ha*		GF-3307 1.0 L/ha*		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	DE	2	35-39	48.0	7.1-88.8	-	-	-	-	83.5	77.0-89.9	84.2	72.0-96.3	77.9	63.0-92.7
	HORVS	DE	3	31-39	34.8	5.0-51.8	57.5*	50.0-65.0	68.4*	-	80.1	74.9-90.0	83.7	76.3-90.0	61.7	45.0-71.1
	Both	DE	5	31-39	40.0	5.0-88.8	57.5*	50.0-65.0	68.4*	-	81.4	74.9-90.0	83.9	72.0-96.3	68.2	45.0-92.7
RHYNSE	HORVW	N-E	7	31-52	17.0	5.6-35.0	83.3*	76.0-97.3	87.0*	78.0-99.1	90.9	80.0-100	94.9	88.7-100	91.7^	80.0-100
	HORVS	N-E	4	37-49	10.1	5.6-22.5	-	-	80.4	59.2-99.2	96.3	87.5-100	97.9	92.1-100	94.1^	78.7-100
	Both	N-E	11	31-52	14.5	5.6-35.0	83.3*	76.0-97.3	84.4*	59.2-99.2	92.9	80.0-100	96.0	88.7-100	92.6^	78.7-100
PYRNTE	HORVW	N-E	7	32-52	20.9	5.0-36.4	76.2*	72.3-80.0	69.2*	61.8-83.2	78.2	61.8-87.3	82.5	67.6-91.4	85.5^	66.7-97.5
	HORVS	N-E	7	32-52	18.1	5.5-30.6	52.9*	-	69.1*	57.9-83.2	83.0	67.9-95.7	89.2	79.6-100	85.2^	69.6-100
	Both	N-E	14	32-52	19.5	5.0-36.4	68.4*	52.9-80	69.1*	52.3-83.2	80.6	61.8-95.7	85.8	67.6-100	85.5^	66.7-100
PUCCHD	HORVW	N-E	2	47-51	34.2	20.8-47.5	92.0*	-	88.3	82.5-94.1	98.0	96.0-100	99.1	98.1-100	92.4+	84.8-100
	HORVS	N-E	5	37-52	13.7	5.5-31.9	72.0*	-	85.3	77.6-97.1	90.4	79.6-98.4	96.1	89.9-100	90.2+	80.3-98.4
	Both	N-E	7	37-52	19.5	5.5-47.5	82.0*	72.0-92.0	86.2	77.6-97.1	92.6	79.6-100	96.9	89.9-100	90.8+	80.3-100
ERYSGH	HORVW	N-E	4	31-52	10.6	5.6-21.3	79.9*	78.2-81.5	85.0*	79.4-92.4	85.8	76.8-90.8	92.7	85.7-96.7	91.2+	78.3-100
	HORVS	N-E	6	31-52	12.0	5.9-23.3	79.0*	69.7-92.0	73.6*	64.5-80.6	86.6	63.6-100	87.9	75.8-100	89.0+	73.5-100
	Both	N-E	10	31-52	11.5	5.6-23.3	79.3*	69.7-92.0	78.5*	64.5-92.4	86.3	63.6-100	89.8	75.8-100	89.9+	73.5-100

*Results for the 0.75 L/ha and 1.0 L/ha doses are from a lower number of trials for most diseases.

#Proline 250 applied at 0.6-0.8 L/ha (150-200 g prothioconazole/h) used as the reference standard.

^Aviator Xpro applied at 0.8-1.0 L/ha used as reference standard

*Proline 250 applied at 0.8 L/ha (200 g prothioconazole/h) and Prosaro applied at 0.75 L/ha used as the reference standards

3.2.2.19 **Summary and conclusions on the minimum effective dose EPPO** **South-East zone**

Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)

The proposed use is for a single application at a dose range of 1.0-1.5 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, PUCCRT, PUCST, FUSASP, PYRNTR and ERYSGT.

The lower dose of 1.0 L/ha of GF-3307 (**supported by data at 0.9 L/ha and 1.0 L/ha**) is recommended for application where disease pressure is low and only SEPTTR is present or forecast to be a concern. In moderate disease situations a dose of 1.2 L/ha GF-3307 is recommended. Where disease pressure is very high, particularly for FUSASP and PYRNTR, the highest dose rate of 1.5 L/ha is recommended. The maximum 1.5 L/ha dose achieved the highest levels of control across all diseases. The proposed dose range of 1.0-1.5 L/ha (SEPTTR) and 1.2-1.5 L/ha (all other diseases, except *Fusarium*) exceeded the control achieved by the reference standards in the majority of situations (see summary table below).

For SEPTTR, PUCCRT, PUCST and ERYSGT the results demonstrate that the proposed minimum dose of 1.2 L/ha of GF-3307 is sufficient to achieve a claim of 'good control' of these target diseases. The ~~0.9 L/ha~~ **1.0 L/ha** dose provided insufficient control on many diseases and was more variable.

For PYRNTR, the results demonstrate that the proposed maximum dose is the most effective dose required to achieve a claim of 'very good control' of PYRNTR, with minimum control levels of 80+%. The 1.2 L/ha dose offered good control of 70-80% of this disease, but did not always provide consistently high levels of control, as control was more variable in some trials. It is considered that the 1.2 L/ha dose will be sufficient in situations where PYRNTR is a secondary disease and not the main target.

For FUSASP, the maximum dose of 1.5 L/ha is required, as the ~~1.2 L/ha~~ **1.2/1.25 L/ha** dose did not give sufficient control of this disease (>70%).

All supporting data were on winter wheat and it is considered these data fully support ~~the 1.5 L/ha~~ **the proposed dose range of 1.0-1.5 L/ha** on spring wheat and other minor wheat crops (spelt and durum wheat).

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at 1.0-1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH. The lower dose of 1.0 L/ha is recommended for application where disease pressure is low and only **RHYNSE or PUCCHD** is present or forecast to be a concern. In moderate disease situations a dose of 1.2 L/ha is recommended. Where disease pressure is high, particularly for PYRNTE, a higher dose rate of 1.5 L/ha is recommended.

Across all diseases, results from both winter and spring crops demonstrated comparable dose responses on these target diseases and have been combined to give an overall result to support the proposed dose across both crops in the following table.

The results from the EPPO South-East climatic zone trials (supported by data from Germany and Poland) demonstrate that the proposed dose range of 1.0-1.5 L/ha GF-3307, is the minimum effective dose range, depending on the target disease. The 1.2 L/ha (**supported by data at 1.2 L/ha and 1.25 L/ha**) and 1.5 L/ha doses of GF-3307 will give effective control in most situations. However, depending on the disease pressure, the 1.5 L/ha dose of GF-3307 would be the minimum effective dose, where broad spectrum control across a range of target disease is required or where disease pressure from PYRNTE is high. The lower dose of 1.0 L/ha can be expected to provide effective control of **RHYNSE or PUCCHD** in low disease pressure situations. The 0.75 L/ha dose did not provide sufficient control of the target diseases.

Summary of minimum effective dose testing of GF-3307 for EPPO South-East zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO-Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 0.9/1.0 L/ha*		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	S-E	6	32-47	22.0	6.0-51.3	78.4	64.2-97.5	85.6	82.0-97.5	90.6	83.3-100	84.2	75.9-97.5
PUCCRT	TRZAW	S-E	5	37-51	47.9	10.5-72.5	72.4	59.3-83.4	85.6	68.9-95.2	93.8	84.1-100	82.2	59.4-92.9
PUCST	TRZAW	S-E	5	39-47	37.8	11.3-63.8	77.6*	60.8-98.5	84.6	72.6-99.0	93.5	85.1-100	91.5	73.7-100
FUSASP	TRZAW	PL+AT	4	61-65	17.3	5.7-29.3	64.5	49.0-74.0	68.6	54.2-84.0	81.7	79.0-83.6	81.4	78.9-83.0
PYRNTR	TRZAW	S-E	3	39-51	7.2	5.2-10.0	71.3	64.0-80.4	81.7	74.2-90.0	92.0	88.6-97.3	86.4	80.0-94.3
		AT+CZ+PL	4	35-51	18.3	10.3-26.3	69.6	56.8-78.4	77.0	68.1-86.4	83.7	77.5-82.3	67.5^	34.5-86.6
		All	7	35-51	13.5	5.2-26.3	70.3	56.8-80.0	79.6	68.1-90.0	87.3	77.5-97.3	75.6^	34.5-94.3
ERYSGT	TRZAW	SE	4	39-49	17.1	12.0-25.0	74.6	60.3-90.0	85.2	78.6-91.5	91.4	89.4-92.7	91.7	87.7-95.6

*Results for the 0.9/1.0 L/ha dose for PUCST are from 3 trials

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

^Reference standards used based on prothioconazole applied at 180-198 g as/ha and one trial using Aviator Xpro at 1.25 L/ha.

Summary of minimum effective dose testing of GF-3307 for EPPO South-East zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	S-E	9	32-49	21.3	6.0-51.3	79.3*	64.2-97.5	83.4	74.5-97.5	87.9	77.7-100	82.8	75.1-
PUCCRT	TRZAW	S-E	8	37-51	31.0	7.0-72.5	83.3**	72.1-93.1	84.0	62.5-95.2	90.2	69.4-100	84.2	63.9-100
PUCCST	TRZAW	S-E	5	39-47	37.8	11.3-63.8	77.6***	60.8-98.5	84.6	72.6-99.0	93.5	85.1-100	91.5	73.7-100
FUSASP	TRZAW	S-E	3	61-65	39.0	15.0-79.5	-	-	66.3	46.0-76.7	70.9	54.1-86.0	81.8 ⁺	67.9-89.1
		AT + PL	8	61-69	36.4	5.7-91.3	67.3	49.9-93.4	75.0	51.2-97.6	87.1	79.0-100	86.4 ⁺	75.9-96.7
		All	11	61-69	37.1	5.7-91.3	-	-	72.7	46.0-97.6	82.6	54.1-100	85.1 ⁺	67.9-96.7
PYRNTR	TRZAW	S-E	3	39-51	7.2	5.2-10.0	71.2	64.0-80.0	81.7	74.2-90.0	92.0	88.6-97.3	86.4	80.0-94.3
		AT + CZ + PL	6	35-51	16.9	10.3-26.3	72.4	56.8-87.1	81.1	68.1-90.6	87.6	77.5-100	81.3 [^]	59.4-90.8
		All	9	35-51	13.6	5.2-26.3	72.0	56.8-87.1	81.3	68.1-90.6	89.1	77.5-100	83.0 [^]	59.4-94.3
ERYSGT	TRZAW	SE	5	39-49	15.8	10.5-25.0	69.9	50.3-90.0	82.0	69.3-91.5	87.8	73.1-92.7	86.0	63.3-95.6

*Results for the 1.0 L/ha dose for SEPTTR are from 7 trials

**Results for the 1.0 L/ha dose for PUCCRT are from 4 trials

***Results for the 1.0 L/ha dose for PUCCST are from 3 trials

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

[^]Reference standards used based on prothioconazole applied at 180-198 g as/ha and one trial using Aviator Xpro at 1.25 L/ha.

*Reference standard Prosaro at 1.0 L/ha

Summary of minimum effective dose testing of GF-3307 for EPPO South-East zone (barley data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control									
							GF-3307 0.75 L/ha*		GF-3307 1.0 L/ha*		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	DE	2	35-39	48.0	7.1-88.8	-	-	-	-	83.5	77.0-89.9	84.2	72.0-96.3	77.9	63.0-92.7
	HORVS	DE	3	31-39	34.8	5.0-51.8	57.5*	50.0-65.0	68.4*	-	80.1	74.9-90.0	83.7	76.3-90.0	61.7	45.0-74.1
	Both	DE	5	31-39	40.0	5.0-88.8	57.5*	50.0-65.0	68.4*	-	81.4	74.9-90.0	83.9	72.0-96.3	68.2	45.0-74.1
RHYNSE	HORVW	PL	5	32-52	18.3	5.6-35.0	76.4*	76.0-76.7	81.1*	78.0-84.0	87.4	80.0-96.6	92.9	88.7-100	75.9	48.5-100
	HORVS	PL	4	37-49	10.1	5.6-17.8	-	-	80.4*	59.2-99.2	96.3	87.5-100	97.9	92.1-100	90.4	80.2-100
	Both	PL	9	32-52	14.7	5.6-35.0	76.4*	76.0-76.7	80.8*	59.2-99.2	91.4	80.0-100	95.1	88.7-100	81.9	48.5-100
PYRNTE	HORVW	S-E	5	37-49	25.8	10.0-40.0	65.9*	62.8-68.9	62.5	35.2-78.1	78.5	70.0-87.8	87.2	81.1-96.9	83.4	74.1-92.9
	HORVS	S-E	2	39-49	28.8	21.3-36.3	-	-	81.4	75.8-87.0	81.6	79.9-83.2	87.3	87.0-87.6	76.1	71.3-84.8
	Both	S-E	7	37-49	26.6	10.0-40	65.9*	62.8-68.9	67.9	35.2-87.0	77.3	70.0-87.8	87.2	81.1-96.9	81.9	71.3-92.9
PUCCHD	HORVS	S-E	2	31-49	12.3	7.6-16.9	70.3	31.3-85.3	84.9	76.3-93.5	90.9	88.2-93.5	92.4	89.5-95.3	91.5	84.2-98.8
	Both	PL	5	37-52	22.0	5.5-47.5	-	-	86.9	77.6-97.1	93.7	87.2-98.4	95.9	89.9-100	86.0	71.4-92.9
ERYSGH	HORVS	S-E	2	31-33	32.1	20.8-43.3	53.4*	-	66.9	55.5-78.3	86.2	81.0-91.5	87.3	81.9-92.8	87.3	86.3-88.3
	Both	PL	5	32-52	15.3	8.3-23.3	74.0*	69.7-78.7	75.3	64.5-83.3	83.6	63.6-93.5	86.5	75.8-93.9	71.5	48.5-98.8

*Results for most 0.75 L/ha and some 1.0 L/ha doses are from less trials

#Proline 250 applied at 0.6-0.8 L/ha (150-200 g prothioconazole/h) used as the reference standard.

Summary of minimum effective dose testing of GF-3307 for EPPO South-East zone (barley data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control									
							GF-3307 0.75 L/ha*		GF-3307 1.0 L/ha*		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	DE	2	35-39	48.0	7.1-88.8	-	-	-	-	83.5	77.0-89.9	84.2	72.0-96.3	77.9	63.0-92.7
	HORVS	DE	3	31-39	34.8	5.0-51.8	57.5*	50.0-65.0	68.4*	-	80.1	74.9-90.0	83.7	76.3-90.0	61.7	45.0-71.1
	Both	DE	5	31-39	40.0	5.0-88.8	57.5*	50.0-65.0	68.4*	-	81.4	74.9-90.0	83.9	72.0-96.3	68.2	45.0-71.1
RHYNSE	HORVW	PL	6	32-52	18.7	5.6-35.0	76.4*	76.0-76.7	84.6*	78.0-98.5	92.2	80.0-100	95.6	88.7-100	91.8^	78.7-100
	HORVS	PL	4	37-49	10.1	5.6-17.8	-	-	80.4*	59.2-99.2	96.3	87.5-100	97.9	92.1-100	94.1^	78.7-100
	Both	PL	10	32-52	15.3	5.6-35.0	76.4*	76.0-76.7	82.7*	59.2-99.2	92.2	80.0-100	95.6	88.7-100	91.8^	78.7-100
PYRNTE	HORVW	S-E	11	37-49	21.3	5.0-42.5	65.9*	62.8-68.9	65.2	35.2-78.1	75.9	69.5-87.8	86.1	80.1-96.9	79.9	69.1-92.9
	HORVS	S-E	3	39-49	22.4	9.5-36.3	-	-	78.8	73.7-87.0	83.7	79.9-88.1	87.8	87.0-88.9	78.6	71.3-84.8
	Both	S-E	14	37-49	21.5	5.0-42.5	65.9*	62.8-68.9	68.1	35.2-87.0	77.5	69.5-88.1	86.4	80.1-96.9	79.6	69.1-92.9
PUCCHD	HORVW	S-E	3	43-49	8.7	5.3-11.4	-	-	85.5	79.6-91.9	90.0	88.0-93.0	91.6	89.0-95.9	91.2	89.0-95.5
	HORVS	S-E	2	31-49	12.3	7.6-16.9	70.3	51.3-89.3	84.9	76.3-93.5	90.9	88.2-93.5	92.4	89.5-95.3	91.5	84.2-98.8
	Both	S-E	5	31-49	10.1	5.3-16.9	70.3*	51.3-89.3	85.3	76.3-93.5	90.3	88.0-93.5	91.9	89.0-95.9	91.3	84.2-98.8
ERYSGH	HORVW	S-E	2	45-49	9.6	8.0-11.1	-	-	79.8	73.6-86.0	77.3	69.0-85.5	84.4	84.0-84.8	75.9	69.0-82.8
	HORVS	S-E	2	31-33	32.1	20.8-43.3	-	-	66.9	55.5-78.3	86.2	81.0-91.5	87.3	81.9-92.8	87.3	86.3-88.3
	Both	S-E	4	31-49	20.8	8.0-43.3	-	-	73.3	55.5-86.0	81.8	69.0-91.5	85.9	81.9-92.8	81.6	69.0-88.3

*Results for most 0.75 L/ha and some 1.0 L/ha doses are from less trials

#Proline 250 applied at 0.6-0.8 L/ha (150-200 g prothioconazole/h) used as the reference standard.

^Aviator Xpro applied at 0.8-1.0 L/ha used as reference standard

zRMS summary of the Minimum Effective Dose:

EPPO Maritime zone

Wheat

1.5L/ha is the MED for SEPTTR (Table 3.2-55), PUCCRT (Table 3.2-60), PUCGST (Table 3.2-64), FUSASP (Table 3.2-69-70), PYRNTR (Table 3.2-76) and ERYSGT (Table 3.2-81),

Rye

1.5L/ha is the MED for PUCCRE (Table 3.2-85) and RHYNSE (Table 3.2-89).

Triticale

1.5L/ha is the MED for SEPTSP (Table 3.2-92), ERYSGT (Table 3.2-95) and PUCGST (Table 3.2-98),

Barley

1.5L/ha is the MED for RAMUCC (Table 3.2-101), RHYNSE (Table 3.2-103), PYRNTE (Table 3.2-107), PUCCHD (Table 3.2-111) and ERYSGH (Table 3.2-115).

EPPO North-Eastern zone

Wheat

1.0-1.5L/ha dose range is proposed for SEPTTR and for ERYSGT, with **1.0L/ha** considered as **MED** and 1.2 and 1.5 L/ha dose rates intended for higher disease pressure situations or when other pathogens are present (Table 3.2-56-57 – SEPTTR, Table 3.2-82-83 - ERYSGT),

1.2-1.5L/ha dose range is proposed for PUCCRT, PUCGST and PYRNTR, with **1.2L/ha** considered as **MED** and 1.5 intended for higher disease pressure or pathogen complex situations (Table 3.2-61 – PUCCRT, Table 3.2-65-66 – PUCGST, Table 3.2-77-78 - PYRNTR),

1.5L/ha dose is considered as the MED for FUSASP (Table 3.2-71-72),

Rye

1.2-1.5L/ha dose range is proposed for PUCCRE and RHYNSE (Table 3.2-87 – PUCCRE, Table 3.2-90 - RHYNSE), with **1.2L/ha** considered as **MED** and 1.5 intended for higher disease pressure or pathogen complex situations.

Triticale

1.2-1.5 L/ha dose range is proposed for SEPTSP, ERYSGT and PUCGST, with the **1.2L/ha** considered as the **MED**, intended for situations with lower pathogen pressure (Table 3.2-93 – SEPTSP, Table 3.2-96 – ERYSGT, Table 3.2-99 - PUCGST).

Barley

1.2-1.5L/ha dose range is proposed by the applicant for RAMUCC (Table 3.2-101)*,

1.2-1.5L/ha dose range is proposed for PYRNTE and ERYSGH (Table 3.2-108 – PYRNTE, Table 3.2-116 - ERYSGH), with **1.2L/ha** considered as the **MED**, intended for situations with lower pathogen pressure,

1.0-1.5L/ha dose range is proposed for RHYNSE and PUCCHD (Table 3.2-105 – RHYNSE, Table 3.2-112 - PUCCHD), with **1.0L/ha** considered as the **MED**, intended for situations with lower pathogen pressure,

EPPO South-Eastern zone

Wheat

1.0-1.5L/ha dose range is proposed for SEPTTR, with **1.0L/ha** considered as the **MED**, intended for situations with lower pathogen pressure (Table 3.2-58),

1.2-1.5L/ha dose range is proposed for PUCCRT, PUCGST, PYRNTR and ERYSGT, with **1.0L/ha** considered as the **MED**, intended for situations with lower pathogen pressure (Table 3.2-62 – PUCCRT, Table 3.2-67 – PUCGST, Table 3.2-79 – PYRNTR, Table 3.2-84 - ERYSGT),

1.5L/ha dose is considered as MED for FUSASP in TRZAW (Table 3.2-73-74),

Barley

1.2-1.5L/ha dose range is proposed by the applicant for RAMUCC (Table 3.2-101)*,

1.2-1.5L/ha dose range is proposed for PYRNTE and ERYSGH, (Table 3.2-109 – PYRNTE, Table 3.2-117 - ERYSGH), with **1.2L/ha** considered as the **MED**, intended for situations with lower pathogen pressure.

1.0-1.5L/ha dose range is proposed by the applicant for PUCCHD (Table 3.2-113), with **1.0L/ha** considered as the **MED**, intended for situations with lower pathogen pressure,

1.0-1.5L/ha dose range is also proposed for RHYNSE, based on the NE zone data alone (Table 3.2-105), with **1.0L/ha** considered as the **MED**, intended for situations with lower pathogen pressure. No MED data are submitted for the SE EPPO zone.

* The dose range proposed is built on data from the Maritime zone (Table 3.2-101), in which **1.2L/ha** should be considered as **MED** for the control of RAMUCC, but neither the MED nor the efficacy data are submitted for RAMUCC from the NE or the SE EPPO zone.

3.2.3 Efficacy tests (KCP 6.2)

This chapter covers the effectiveness tests of GF-3307 for the control of foliar diseases in wheat, rye, triticale and barley. Data are presented across a range of diseases in wheat, rye, triticale and barley based on a single application of GF-3307 applied between BBCH 30-65.

The data in this section relate to the proposed claims for use of GF-3307:

- a dose of 1.5 L/ha in the EPPO Maritime countries of the Central EU Authorisation zone across all crops and targets,
- ~~• a dose rate range of 1.2-1.5 L/ha in the EPPO North-East countries of the Central EU Authorisation zone across all crops (rate target specific);~~
- ~~• a dose rate range of 1.0-1.5 L/ha in the EPPO South-East countries of the Central EU Authorisation zone on wheat and barley.~~
- a dose rate range of 1.2-1.5 L/ha in the EPPO North-East countries of the Central EU Authorisation zone across all crops (lower dose of 1.0 L/ha on specific target diseases/crop),
- a dose rate range of 1.2-1.5 L/ha in the EPPO South-East countries of the Central EU Authorisation zone on wheat and barley (lower dose of 1.0 L/ha on specific target diseases/crop)

For the proposed dose rates in the EPPO North-East and South-East, some barley trials in this dossier (and 2021 FUSASP trials on wheat) are based on a dose rate of 1.25 L/ha, instead of the proposed 1.2 L/ha. As these doses are within 10% of each other (4% difference), it is considered that the results at 1.25 L/ha are fully supportive of the proposed 1.2 L/ha dose rate. For wheat/SEPTTR/ERYSGT, much of the lower dose data is based on application at 0.9 L/ha, instead of the proposed 1.0 L/ha. As these doses are within 10% of each other (10% difference), it is considered that the results at 0.9 L/ha are fully supportive of the proposed 1.0 L/ha dose rate, which is a more practical dose rate for growers and avoids any potential pesticide wastage, as a 5 Litre pack size will treat multiples of 5 ha, at the 1.0 L/ha dose rate.

For constancy across the dossier, the dose rates used in the supporting trials (0.9, 0.9-1.0 or 1.0 L/ha, 1.2, 1.2-1.25 or 1.25 L/ha) are specified in the summary tables and individual trials summaries.

Efficacy data presented within the tables in this section are from one key leaf layer, where differences were apparent at the time of assessment and which satisfy the minimum level of disease on the untreated leaves ($\geq 5\%$ infection). Where results on more than one leaf were available, the chosen leaf is the highest assessed leaf with $>5\%$ infection in the untreated, at assessment. In the majority of cases this is Leaf 1 or Leaf 2. It is considered that in all crops, Leaf 1 and Leaf 2 will have the most significant impact on yield of the crop, from disease control on that leaf and is it therefore represents the best test of the effectiveness of GF-3307. Where lower leaves have been used, this was due to higher levels of disease infection ($>10\%$) representing a more robust test of the product or in some trials, where assessments before a second treatment is used, the highest available leaf or only available assessment.

~~Assessment timings chosen in the following summary tables are for effectiveness at approximately 4-7 weeks after application (28-49 DAA), to reflect the disease protection delivered by a single dose of GF-3307. The longer assessment timings have been used where disease levels were less than 5% at the earlier assessment timings. Early assessment timings (11-21 days) have been used when no appropriate later timings were available.~~

~~**Note:** Throughout this section, DAA = days after first/one application, DAB = days after second/two applications. 'DAA' is also used for trials where the single application treatment was applied as timing B and 'DAB' for the two application regime applied at timings A and C.~~

~~Where a trials report includes calculated percentage control values, those figures have been used. If the percentage control was not calculated in the trials report, (i.e. only percentage infection (severity) was recorded), the percentage control has been calculated using an Abbott's formula.~~

Note: Some of the supporting trials contained multiple application timings, but only the single application timing data have been used in this dossiers (apart from the 14 trials mentioned in the table

below): Information on the application details from the efficacy trials is presented in Appendix 4 in the BAD.

For clarification, the results taken from the supporting trials were based on the following:

- Single dose regime (A timing in the reports). This was the case for the majority of trials.
- Single dose treatments at different timings (referred to as A or B timing in the reports). Depending on the disease levels at assessment, only one of these timings has been used.
- 2-dose regime (A + B timing in the reports): With the exception of the 14 trials listed in the table below, only assessments after application A and before a second application was applied (after A, but before B) have been used. These trials were not used for yield analysis due to the second application.
- Both single and 2-dose application regimes (B timing for a single dose and A + C timing for two-dose treatment). Some trials included both application regimes (referred to as the B timing for a single dose and A + C timing for two-dose treatment), the B timing treatments assessments have been used, as they matched the GAP (single dose applied between BBCH 30-69).

Throughout this section. DAA = days after first/one application, DAB = days after second/two applications.

Results after two applications have been used from the following trials as disease did not develop in these trials until after the second application, 25-63 days after the first application, demonstrating how the disease can infect crops late in their development, and this is considered to be beyond the expected protection period for the first application of GF-3307. In addition, the assessed leaf (generally Leaf 1, or Leaf 2) had not emerged at the time of the first application in the majority of trials and would not have been protected by that spray. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. Full site and application details of individual trials see Appendix 3 and Appendix 4 in the BAD. No two-dose trials have been used to support uses in the EPPO North-East zone.

Summary of two dose trials used in the dossier

Trial number	Country	Crop	Target Disease	1 st Application		1 st Application		Days after 2 nd Application disease found in trial (days after 1 st application)
				Timing (BBCH)	% infection	Timing (BBCH)	% infection	
HU14E7B014AB01C	HU	TRZAW	PUCCRT	32-33	0% all leaves	49-51	0% all leaves	41 days (63 days)
			PYRNTR	32-33	0% all leaves	49-51	0% all leaves	25 days (47 days)
HU15E7B012AB01C	HU	TRZAW	PUCCRT	32-33	0% all leaves	37-39	0% all leaves	15 days (26 days)
HU15E7B012AB02	HU	TRZAW	PUCCRT	32	0% all leaves	39-41	0% all leaves	14 days (35 days)
HU15E7B012AB02C	HU	TRZAW	PUCCRT	32-33	0% all leaves	39-41	0% all leaves	14 days (25 days)
HU15E7B040AB02C	HU	TRZAW	PUCCRT	33-34	0% all leaves	39-49	0% all leaves	13 days (28 days)
CZ15E7B010PV01C	CZ	TRZAW	ERYSGT	32	0% all leaves	43	0% all leaves	11 days (26 days)
CZ15E7B041PV01C	CZ	TRZAW	ERYSGT	31-32	3.0% L6	37-39	0% L4	-
CZ15E7B041PV03C	CZ	TRZAW	ERYSGT	31	0% all leaves	43-45	0% all leaves	25 days (48 days)
CZ18E7B007PV02C	CZ	HORVS	PUCCHD	31-32	0% all leaves	47-49	0% all leaves	28 days (42 days)
DE18E7B007UB01C	DE	HORVW	PUCCHD	37-39	0% all leaves	55-59	0% all leaves	20 days (33 days)
DE18E7B007UB4C	DE	HORVW	PUCCHD	32	0% all leaves	49-51	0% all leaves	17 days (34 days)
GB17E7B046RH01	GB	HORVS	PUCCHD	37	0% all leaves	49	0% all leaves	21 days (28 days)
GB17E7B049RH02	GB	HORVS	PUCCHD	37	0% all leaves	45-49	0% all leaves	31 days (40 days)
SK18E7B008PV02C	SK	HORVS	PUCCHD	31-32	0% all leaves	47-49	0% all leaves	26 days (42 days)

zRMS comments:

For the zRMS standpoint concerning double application data see the first one of the two commenting boxes following the introduction to the MED chapter (3.2.2), in the page 148.

Where a trials report includes calculated percentage control values, those figures have been used. If the percentage control was not calculated in the trials report, (i.e. only percentage infection (severity) was recorded), the percentage control has been calculated using an Abbott's formula.

Statistical analysis

The tabulated efficacy data presented in this section of the biological dossier include the treatment means of the percentage control, relative to the untreated. Across trials, the minimum and maximum means of percentage infection or control are also presented in the summary tables.

3.2.3.1 Effectiveness of GF-3307 for the control of SEPTTR in wheat

This section addresses the efficacy of GF-3307, for the control of SEPTTR on wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone) and the proposed dose range of 1.0-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-13718 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 19.3-30 m ² EPPO North-East: 15-36 m ² EPPO South-East: 12-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: ± 13 TRZAW EPPO North-East: 12 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: ± 15 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: JB Asano (3), Akteur, Bohemia, Etana, Judita, Federer, Judita (2), Pionier, Socrates, Tobak, Toras EPPO North-East (TRZAW): Arkadia (2), Artis, Emil, Fidelius, Fredis, Sailor, Wydma. Zentos (3), Zyta EPPO North-East (TRZAS): Tybalt EPPO South-East: Antonius, Ariesan (2), Enova, GK Élet, Genius, Glosa, Glossa (2 3), Iridium, Miranda (2), MV Suba, MV-Toldi, Sadovo 772
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31- 53 59 EPPO North-East: BBCH 31-51 EPPO South-East: BBCH 30- 47 49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of SEPTTR, applications were timed to cover both these situations, commencing when there was a risk of infection with SEPTTR or when the disease started to develop on the lower leaf levels, to applications against established infections.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were conducted at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately aimed at the timing of application, 2-3 weeks after application, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field. Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent and challenging disease.

Introduction

~~In total 37 field trials were conducted to demonstrate the efficacy of GF 3307 for the control of SEPTTR in winter wheat (TRZAW) and one trial on spring wheat (TRZAS). To support the label claims, GF 3307 was tested at the proposed label rate of 1.5 L/ha (EPPO Maritime zone), 1.2-1.5 L/ha (EPPO North East) and a range from 1.0 to 1.5 L/ha in EPPO South East trials, in accordance with the EPPO Standard PP 1/26, 'Foliar and ear diseases on cereals'.~~

In total ~~40~~ **41** field trials were conducted to demonstrate the efficacy of GF-3307 for the control of SEPTTR in winter wheat (TRZAW) and one trial on spring wheat (TRZAS). To support the label claims, GF-3307 was tested at the proposed label rate of 1.5 L/ha (EPPO Maritime zone), 0.9-1.5 L/ha (EPPO North-East) and a range from 1.0 to 1.5 L/ha in EPPO South-East trials, in accordance with the EPPO Standard PP 1/26, 'Foliar and ear diseases on cereals'.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Czech Republic (~~4~~ **6**) and Germany (7) in the EPPO Maritime climatic zone, Latvia (4) and Poland (9) in the EPPO North-East climatic zone and Bulgaria (2), Hungary (6) and Romania (~~6~~ **7**) in the EPPO South-East climatic zone, between 2014 and ~~2020~~ **2021**.

On the basis of the EPPO Standard PP 1/241 'Guidance on comparable climates', the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, so are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-13.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTTR is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 3 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.5	150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6	150
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0-1.25	225-281
Input	EC	160 g/L prothioconazole + 300 g/L spiroxamine	1.0	460

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9 , 1.0, 1.2, 1.5	135 , 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L	1.0-1.25	225-281

		prothioconazole		
Input	EC	160 g/L prothioconazole + 300 g/L spiroxamine	1.0	460

Experimental details

The 38 41 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12m² and 36m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 300 L/ha. GF-3307 was applied as a single application at BBCH 30-5359 of winter and spring wheat. The treatments were typically sprayed when SEPTTR had established on the lower leaves, to stop further disease development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTTR or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were generally conducted on Leaf 1 and Leaf 2, with a few on Leaf 3 and Leaf 4 and one on the whole plant.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total 11 13 small plot GEP efficacy field trials were conducted to demonstrate the effectiveness of GF-3307 for the control of SEPTTR in winter wheat, at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 31-5359 of the crop. The trials were conducted in the Czech Republic (4 6) and Germany (7) in the EPPO Maritime climatic zone, between 2014-2020 2021. The data includes trials where SEPTTR was established before application (including on the leaves assessed for control in some trials) and trials where SEPTTR did not develop until after application. The data includes trials where SEPTTR was established at low levels on lower leaves before application and trials where SEPTTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4) so are considered to be a robust test of the product. One trial was based on assessment of the whole plant.

Across these 11 13 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of SEPTTR of 92.2 92.7% (range 84.8-100%), 17-43 days after a single application, compared to 86.9 87.9% for the reference standards. In seven five trials, GF-3307 was compared directly to the prothioconazole standard, Proline, and achieved mean control of 92.9 95.0% compared to mean control of 86.9 87.9% using Proline (198 g prothioconazole/ha). In four eight trials, GF-3307 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3307 achieved mean control of 91.0 91.3% compared to mean control of 87.7 84.0% using Aviator Xpro. Across all trials, control of SEPTTR achieved by GF-3307 was either statistically higher or not statistically different from the standards.

The results are summarised in Table 3.2-13819, with the results of the individual trials detailed the BAD. Results in Table 3.2-13819 are shown across all trials first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-138: Effectiveness of GF-3307 at proposed label rate of 1.5 L/ha against SEPTTR in winter wheat (TRZAW). Results from 11 trials conducted in the EPPO Maritime climatic zone between 2014-2020. Assessment at 17-43 days after one application

EPPO Zone	Number of trials	Untreated: SEPTTR % infection	% control of SEPTTR		Significantly >=< Standards
			GF-3307 1.5 L/ha	Reference standard	

		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	11	36.7	5.0-87.5	92.2	84.8-100	86.9	62.0-100	All	3 >, 4 = P, 4 = A
Maritime*	7	42.1	5.0-87.5	92.9	84.9-100	86.5	62.0-100	Proline#	3 > P, 4 = P
Maritime**	4	27.3	6.1-47.5	91.0	89.6-94.9	87.7	71.4-96.7	Aviator Xpro/1.25 L/ha	4 = A

*Direct comparison to Proline (P)

**Direct comparison to Aviator Xpro (A)

#Reference standards used based on prothioconazole applied at 180-198 g as/ha.

Table 3.2-139: Effectiveness of GF-3307 at proposed label rate of 1.5 L/ha against SEPTTR in winter wheat (TRZAW). Results from 13 trials conducted in the EPPO Maritime climatic zone between 2014-2021. Assessment at 17-43 days after one application

2021: Assessment at 1-4 days after one application									
EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
Maritime	13	35.8	5.0-87.5	92.7	84.8-100	87.9	62.3-100	All	1 >, 4 = P, 2 >, 6 = A
Maritime*	5	29.5	5.0-61.0	95.0	88.5-100	94.0	82.3-100	Proline	1 >, 4 = P
Maritime**	8	39.8	6.1-87.5	91.3	84.9-100	84.0	62.3-96.7	Aviator Xpro	2 >, 6 = A

*Direct comparison to Proline (P) applied at 198 g prothioconazole/ha

**Direct comparison to Aviator Xpro (A) applied at 1.0-1.25 L/ha

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on results from the 11 13 EPPO Maritime climatic zone trials, demonstrating mean overall control of SEPTTR in winter wheat of 92.2 92.7% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed label claim for control of SEPTTR is fully supported.

Proposed dose range of 1.2-1.5 L/ha 1.0-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, 13 small plot GEP efficacy field trials were conducted to demonstrate the effectiveness of GF-3307 for the control of SEPTTR in winter and spring wheat at the proposed label rates of 1.2 and 1.5 L/ha at dose rates of 0.9-1.5 L/ha, following a single application applied at BBCH 31-51 of the crop. The trials were conducted in Latvia (4) and Poland (9) in the EPPO North-East climatic zone. The data included trials where SEPTTR was established before application (including on the leaves assessed for control in some trials) and trials where SEPTTR did not develop until after application. The data included trials where SEPTTR was established at low levels on lower leaves before application and trials where SEPTTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product. **Note:** In two trials, the latest assessment timing after a single application was 16-18 days. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP. In the spring wheat trial, the latest assessment timing after a single application for SEPTTR control was 14 days. Later assessments were not undertaken for control of SEPTTR in this trial.

Across the 12 EPPO North-East climatic zone trials on winter wheat, GF-3307 at 1.5 L/ha achieved mean control of SEPTTR of 92.6% (range 80.4-100%), 16-45 days after one application. This is higher than the level of control achieved by the prothioconazole standard Proline, at 83.8% (range 58.5-97.1%). Across all trials, control of SEPTTR achieved by GF-3307 was statistically higher than or not statistically different to the standard, Proline.

Across 11 EPPO North-East climatic zone trials on winter wheat, GF-3307 at 1.2 L/ha achieved mean control of SEPTTR of 86.2% (range 71.2-100%), 16-45 days after one application, which is comparable to control achieved by the prothioconazole standard Proline, at 82.8% (range 58.5-97.1%).

Across 9 EPPO North-East climatic zone trials on winter wheat, GF-3307 at 0.9/1.0 L/ha achieved mean control of SEPTTR of 82.2% (range 68.3-100%), 16-45 days after one application, which is comparable to control achieved by the prothioconazole standard Proline, at 82.3% (range 58.5-97.1%). Across all trials, control of SEPTTR achieved by GF-3307 was higher than or not statistically different to the standard, Proline.

The results are summarised in Table 3.2-1400 and the results of the individual trials are detailed in the BAD.

Table 3.2-140: Effectiveness of GF-3307 at the proposed label rate range of 1.2-1.5 L/ha against SEPTTR in winter wheat (TRZAW). Results from 12 trials conducted in the EPPO North-East climatic zone between 2014-2020. Assessment at 16-45 days after one application

EPPO Zone/ Country	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR							Significantly >=, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North-East (1.5 L/ha)	12	18.5	5.8-49.1	-	-	92.6	80.4-100	83.8	58.5-97.1	Proline#	3>, 9=P
North-East (1.2 L/ha)	11	18.6	5.8-49.1	86.2	71.2-100	92.4	80.4-100	82.8	58.5-97.1	Proline#	2>, 9=P

#Reference standards used based on prothioconazole applied at 180-198 g a.s/ha

Table 3.2-141: Effectiveness of GF-3307 at 0.9-1.5 L/ha against SEPTTR in winter wheat (TRZAW). Results from 12 trials conducted in the EPPO North-East climatic zone between 2014-2020. Assessment at 16-45 days after one application

10-15 days after one application												
EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR								Significantly >, =, < Standards
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard#		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North- East (1.5 L/ha dose)	12	18.5	5.8- 49.1	-	-	-	-	92.6	80.4- 100	83.8	58.5- 97.1	3 >, 9 = P
North- East (1.2 L/ha dose)	11	18.6	5.8- 49.1	-	-	86.2	71.2- 100	92.4	80.4- 100	82.8	58.5- 97.1	2 >, 9 = P
North- East (1.0 L/ha dose)	9	20.8	5.8- 49.1	82.2	68.3- 100	-	-	92.9	81.5- 100	82.3	58.5- 94.7	1 >, 8 = P

#Reference standards used based on prothioconazole applied at 180-198 g prothioconazole/ha

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). This trial demonstrated broadly comparable levels of control of SEPTTR to those seen on winter wheat (74.9% using the 1.2 L/ha dose rate, 83.3% using the 1.5 L/ha dose rate, and 88.3% using Proline) at 14 days after application - the latest timing for assessment of control of SEPTTR in this trial.

The results are summarised in Table 3.2-1421 and the results of the individual trials are detailed in the BAD.

Table 3.2-142: Efficacy of GF-3307 applied at the dose rate range of 1.2-1.5 L/ha for the control of SEPTTR in spring wheat (TRZAS) in 2016. Assessment at 14 days after a single application

SEPTTR in spring wheat (PR22A5) in 2010: Assessment at 14 days after a single application											
EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	1	5.0	-	74.9	-	83.3	-	88.3	-	Proline/0.72 L/ha Proline#	1.2 < P, 1.5 = P

P = Proline Proline# = Proline applied at 198 g prothioconazole/ha

Summary and conclusions for the proposed dose rate range of ~~1.2-1.5 L/ha~~ 1.0-1.5 L/ha in the EPPO North-East climatic zone

~~Where disease pressure is low and only SEPTTR requires control, the lower dose of 1.2 L/ha is recommended. Based on data from 11 EPPO North East climatic zone trials on winter wheat using the 1.2 L/ha dose rate of GF-3307, demonstrating mean overall control of SEPTTR of 86.2%, plus one EPPO North East climatic zone trial on spring wheat demonstrating 74.9% control of SEPTTR, it is considered that the proposed claim for control of SEPTTR using GF-3307 at a dose rate of 1.2 L/ha on winter wheat is fully supported.~~

Where disease pressure is low and only SEPTTR requires control, the lower dose of 1.0 L/ha is recommended. Based on data from nine EPPO North-East climatic zone trials on winter wheat using the 0.9/1.0 L/ha dose rate of GF-3307, demonstrating mean overall control of SEPTTR of 82.2%, it is considered that the proposed claim for control of SEPTTR using GF-3307 at a dose rate of 1.0 L/ha on winter wheat is fully supported under these circumstances.

In mixed disease situations, the 1.2 L/ha dose is recommended. Based on data from 11 EPPO North-East climatic zone trials on winter wheat using the 1.2 L/ha dose rate of GF-3307, demonstrating mean overall control of SEPTTR of 86.2%, plus one EPPO North-East climatic zone trial on spring wheat demonstrating 74.9% control of SEPTTR, it is considered that the proposed claim for control of SEPTTR using GF-3307 at a dose rate of 1.2 L/ha on winter wheat is fully supported.

In high pressure mixed disease situations (or FUSASP also present or expected) the higher dose of 1.5 L/ha may be recommended. Based on data from 12 EPPO North-East climatic zone trials on winter wheat using the 1.5 L/ha dose rate, demonstrating mean overall control of SEPTTR of 92.6%, plus one EPPO North-East climatic zone trial on spring wheat demonstrating 83.3% control of SEPTTR, it is considered that the proposed claim for control of SEPTTR using GF-3307 at a maximum dose rate of 1.5 L/ha on winter wheat is fully supported.

A dose range of ~~1.2-1.5 L/ha~~ 1.0-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose of 1.0-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

In total, ~~14~~ 15 GEP small plot efficacy field trials were conducted to demonstrate the effectiveness of GF-3307 for the control of SEPTTR in winter wheat, across the range of proposed label rates, following a single application at BBCH 30-47/49 of the crop. The trials were conducted in Bulgaria (2), Hungary (6) and Romania (~~6~~ 7) in the EPPO South-East climatic zone. ~~The data included trials where SEPTTR was established before application (including on the leaves assessed for control in some trials) and trials where SEPTTR did not develop until after application.~~ The data included trials where SEPTTR was established at low levels on lower leaves before application and trials where SEPTTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product.

A single application of GF-3307 at 1.5 L/ha achieved mean control of 90.1% (range 77.7-100%) against SEPTTR across the ~~10~~ 11 trials where this dose was applied, compared to ~~85.6~~ 86.0% using the reference standard Proline. The 1.2 L/ha dose rate achieved mean control of SEPTTR of ~~86.4~~

86.5% (range 71.2-100%) across all ~~14~~ 15 trials, compared to ~~85.4~~ 85.7% using the reference standards. When compared directly to the various standards used, GF-3307 at 1.2 L/ha achieved mean control of ~~86.3~~ 86.4%, compared to ~~85.6~~ 86.0% using the prothioconazole standard Proline (~~10~~ 11 trials), 71.2% control compared to 70.3% using the bixafen + prothioconazole standard Aviator Xpro (one trial), 94.2% control compared to 89.4% using the prothioconazole + spiroxamine standard Input (three trials).

The ~~1.0 L/ha~~ 0.9/1.0 L/ha dose rate achieved mean control of SEPTTR of ~~81.5~~ 81.9% (range 64.2-100%) across the ~~seven~~ eight trials where this dose was applied, which was comparable to the reference standard Proline at 86.5%.

~~Results for the 1.0 L/ha dose rate are mostly based on a dose rate of 0.9 L/ha (5 trials). The proposed 1.0 L/ha dose rate is a a more practical dose rate for growers to use and matches the lower dose proposed for use on barley. Therefore, as this dose is 10% of the results have been combined to support the proposed 1.0 L/ha dose.~~

The results are summarised in Table 3.2-1432 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1432 are shown across all trials for each dose first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-143: Efficacy of GF-3307 applied at 1.0, 1.2 and 1.5 L/ha for the control of SEPTTR in winter wheat (TRZAW)). Results from 14 trials conducted in the EPPO South-East climatic zone between 2014 and 2020. Assessment at 22-45 days after a single application.

EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR								Significantly ≥, =, ≤ Standards
				GF 3307 1.0 L/ha		GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Reference standard		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
South- East# (1.5 L/ha dose)	10	22.8	6.0- 51.3	-	-	-	-	90.1	77.7- 100	85.6	75.1- 100	10 = P
South- East (1.2 L/ha dose)	14	21.4	6.0- 51.3	-	-	86.4	71.2- 100	-	-	85.4	70.3- 100	10 = P, 1 = A, 3 = I
South- East#	10	22.8	6.0- 51.3	-	-	86.3	74.5- 100	90.1	77.7- 100	85.6	75.1- 100	10 = P
South- East+	1	6.8	-	-	-	71.2	-	-	-	70.3	-	1 = A
South- East△	3	21.5	8.7- 31.3	-	-	91.9	86.4- 98.6	-	-	89.6	75.3- 98.6	3 = I
South- East# (1.0 L/ha dose)	7	20.0	6.0- 51.3	81.5	64.2- 100	-	-	-	-	86.5	75.9- 100	7 = P

#Direct comparison with prothioconazole applied at 180-198 g as/ha, +Direct comparison with Aviator Xpro (A) applied at 1.25 L/ha, ^Direct comparison with Input (I) applied at 1.0 L/ha

Table 3.2-144: Efficacy of GF-3307 applied at 0.9- 1.5 L/ha for the control of SEPTTR in winter wheat (TRZAW)). Results from 15 trials conducted in the EPPO South-East climatic zone between 2014 and 2021. Assessment at 22-45 days after a single application.

2021 Assessment at 22-45 days after a single application												
EPPO Zone	Number of trials	Untreated: SEPTTR % infection		% control of SEPTTR								Significantly >, =, < Standards
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard		
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
South-East# (1.5 L/ha dose)	11	21.7	6.0-51.3	-	-	-	-	90.1	77.7-100	86.0	75.1-100	11 = P
South-East (1.2 L/ha dose)	15	20.6	6.0-51.3	-	-	86.5	71.2-100	-	-	85.7	70.3-100	11 = P, 1 = A, 3 = I
South-East#	11	21.7	6.0-51.3	-	-	86.4	74.5-100	90.1	77.7-100	86.0	75.1-100	11 = P
South-East+	1	6.8	-	-	-	71.2	-	-	-	70.3	-	1 = A
South-East^	3	21.5	8.7-31.3	-	-	91.9	86.4-98.6	-	-	89.6	75.3-98.6	3 = I
South-East# (1.0 L/ha dose)	8	18.9	6.0-51.3	81.9	64.2-100	-	-	-	-	86.5	75.9-100	8 = P

#Direct comparison with prothioconazole applied at 180-198 g as/ha, +Direct comparison with Aviator Xpro (A) applied at 1.0 L/ha, ^Direct comparison with Input (I) applied at 1.0 L/ha

Summary and conclusions for the proposed dose range of 1.0-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on ~~10~~ 11 EPPO South-East climatic zone trials results, demonstrating mean overall control of SEPTTR in winter wheat of 90.1% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed maximum dose rate for control of SEPTTR is fully supported. The 1.5 L/ha dose is

considered to be appropriate for situations where the wheat variety has low resistance to SEPTTR or where fungicide resistance to SEPTTR may be a concern and season long control is required or high disease pressure with mixed disease situations. In situations where fungicide resistance is not a concern and lower disease pressure, a lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated ~~86.4~~ 86.5% control across a total of ~~14~~ 15 trials.

For situations where SEPTTR concerns are low (e.g. earlier in the season), the wheat variety has inherent resistance to SEPTTR and fungicide resistance is not a concern, the lowest dose in the proposed range of 1.0 L/ha is considered appropriate, as this demonstrated ~~81.5~~ 81.9% control across a total of ~~seven~~ eight trials.

Across all trials, the level of control of SEPTTR achieved by GF-3307, at all three dose rates tested, was not statistically different from the standards.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.2 Effectiveness of GF-3307 for the control of Puccinia on winter wheat

This section addresses the efficacy of GF-3307, for the control of Puccinia on winter wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone), and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-145 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 19.3-30 m ² EPPO North-East: 15-30 m ² EPPO South-East: 12-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 15 TRZAW EPPO North-East: 8-10 TRZAW EPPO South-East: 15 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Akeur, Artist, Bohemia, Bussard, Federer, Hermann, Judita, Muza, Patras, Pionier, Socrates, Tobak (3), Toras EPPO North-East: Bogatka (3), Emil, Princeps, Sailor (2), Sukces, Turnia, Zyta EPPO South-East: Antonius, Balaton (2-3), Dagmar, Enova, GK Élet (2), Iridium (3), Lupus, Marshall, MV Buzogány, Sadovo 772
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 37-61 EPPO North-East: BBCH 39-61 EPPO South-East: One application (BBCH 37-41-55), two applications (BBCH 32-34 and BBCH 37-51)
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of Puccinia applications were timed to cover these situations from commencing when there was a risk of infection with Puccinia or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	EPPO Maritime: 1 application EPPO North-East: 1 application EPPO South-East: 1 application (8 trials), 2 applications (5 trials)
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 5-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease.

Introduction

In total, 34 field trials were conducted to demonstrate the efficacy of GF 3307 for the control of Puccinia on winter wheat (TRZAW). To support the label claims, GF 3307 was tested at the proposed

label rates of 1.2 and 1.5 L/ha, in accordance with the EPPO Standard PP 1/26, ‘*Foliar and ear diseases on cereals*’.

In total, 40 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccinia in winter wheat (TRZAW). To support the label claims, GF-3307 was tested at the proposed label rates of 1.5 L/ha in the EPPO Maritime zone trials and a range from 1.2 L/ha to 1.5 L/ha in the EPPO North-East and South-East climatic zone trials, in accordance with the EPPO Standard PP 1/26, ‘*Foliar and ear diseases on cereals*’.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (1), the Czech Republic (6 2 8*) and Germany (6) in the EPPO Maritime climatic zone, in Poland (8 10) in the EPPO North-East climatic zone and in Bulgaria (2), Hungary (11 12) and Slovakia (1) in the EPPO South-East climatic zone, between 2014 and 2020 2021.

zRMS comments: *see Table 3.2-14.

On the basis of the EPPO Standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, so are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-14.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease. Puccinia is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details, see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 4 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline-275	EC	275 g/L prothioconazole	0.72	198
Proline-250	EC	250 g/L prothioconazole	0.6	150
Aviator Xpro-225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.25	281
Vertisan-200-EC	EC	200 g/L penthiopyrad	1.0	200
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
Zantara	EC	50 g/L bixafen + 166 g/L tebuconazole	1.0	216

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0-1.25	225-281
Vertisan 200 EC	EC	200 g /L penthiopyrad	1.0	200
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
Zantara	EC	50 g/L bixafen + 166 g/L tebuconazole	1.0	216

Experimental details

The 34 40 efficacy trials were conducted to GEP and followed the appropriate EPPO standards, by officially recognized efficacy testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 19.3 m² and 36 m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

In the EPPO Maritime and North-East climatic zone trials, GF-3307 was applied as a single application at BBCH 37-61 of winter wheat. The treatments were typically sprayed when Puccrt had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

The EPPO South-East climatic zone trials were set up to support both a single and two-dose regime and in many trials included both regimes. Puccrt is generally a late season disease, that spreads quickly onto the upper leaves of crops from BBCH 37-49, during periods of hot weather. Some of the trials were targeted specifically at Puccrt and were based on a single application from BBCH 37-39 onwards, to provide mainly protective control of the disease. However, other trials were designed as general disease trials, with the first applications applied from BBCH 32, which is potentially too early for effective control of Puccrt, followed by a second application at BBCH 37-49. In five EPPO South-East climatic zone trials which were based on a two-dose regime (HU14E7B014AB01, HU15E7B012AB01C, HU15E7B012AB02, HU15E7B012AB02C and HU15E7B040AB02C), Puccrt did not develop until 13-41 days after the second application. In these trials, the first applications were made at BBCH 32-34 of the crop and the second applications were made at BBCH 37-51. Puccrt did not develop in these trials until 25-63 days after the first application, demonstrating how the disease can infect crops late in their development, and this is considered to be beyond the expected protection period for the first application of GF-3307 (see summary of disease levels at application for these trials below). In addition, the assessed leaf (Leaf 1) had not emerged at the time of the first application (BBCH 32-34) and would not have been protected by that spray. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. For full site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Summary of disease levels at application in two-dose trials

Trial number	1 st Application timing (BBCH)	Puccrt % infection at 1 st application	2 nd Application timing (BBCH)	Puccrt % infection at 2 nd application	Days after 2 nd application Puccrt found in trial (days after 1 st application)
HU14E7B014AB01C	32-33	0% all leaves	49-51	0% all leaves	41 days (63 days)
HU15E7B012AB01C	32-33	0% all leaves	37-39	0% all leaves	15 days (26 days)
HU15E7B012AB02	32	0% all leaves	39-41	0% all leaves	14 days (35 days)
HU15E7B012AB02C	32-33	0% all leaves	39-41	0% all leaves	14 days (25 days)
HU15E7B040AB02C	33-34	0% all leaves	39-49	0% all leaves	13 days (28 days)

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the

infection level present in the untreated control. Leaves showing less than 5% infection with Puccinia or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were generally on Leaf 1, with three trials on Leaf 2 and one trial on Leaf 3.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, 13 15 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccinia in winter wheat at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 37-61 of the crop. The trials were conducted in Austria (1), the Czech Republic (6 8), Germany (6) in the EPPO Maritime climatic zone, between 2014 and 2020 2021. The data included trials where Puccinia was established before application (including on the leaves assessed for control in some trials) and trials where Puccinia did not develop until after application.

The data included trials where Puccinia was established at low levels on lower leaves before application and trials where Puccinia did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 or Leaf 2) so are considered to be a robust test of the product. One trial did not specify which leaf.

Across these 13 15 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of Puccinia of 87.8 88.0% (range 70.2-100%), 28-47 days after application, compared to 85.3 91.4% for the reference standards. In seven four trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of 88.2 91.3% compared to mean control of 76.3 86.1% using Proline. In five 10 trials, GF-3307 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3307 achieved mean control of 87.9 87.0% compared to mean control of 97.0 93.6% using Aviator Xpro. One trial used the fluxapyroxad + metconazole product Librax as the reference standard and GF-3307 achieved 85.0% control compared to 90.0% for Librax.

Across the majority of trials, control of Puccinia achieved by GF-3307 was statistically higher or not statistically different, compared to the standards.

The results are summarised in Table 3.2-1464 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1464 are shown across all trials first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-146: Effectiveness of GF-3307 at proposed label rate of 1.5 L/ha against Puccrt in winter wheat (TRZAW). Results from 13 trials conducted in the EPPO Maritime climatic zone in 2014-2020. Assessment at 28-47 days after one application.

EPPO-Zone	Number of trials	Untreated: PuccRT % infection		% control of PuccRT					Significantly >, =, < Standards
				GF 3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	13	19.0	5.0-74.8	87.8	70.2-100	85.3	27.7-100	All	2>, 5=P 1<, 4=A, 1=L
Maritime*	7	19.2	10.0-39.1	88.2	70.2-100	76.3	27.7-100	Proline#	2>, 5=P
Maritime**	5	21.7	5.6-74.8	87.9	82.7-94.3	97.0	95.0-98.7	Aviator Xpro/1.25 L/ha	1<, 4=A
Maritime***	1	5.0	-	85.0	-	90.0	-	Librax/2.0 L/ha	1=L

*Direct comparison to Proline (P). **Direct comparison to Aviator Xpro (A). ***Direct comparison to Librax (L)

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-147: Effectiveness of GF-3307 at proposed label rate of 1.5 L/ha against Puccrt in winter wheat (TRZAW). Results from 15 trials conducted in the EPPO Maritime climatic zone in 2014-2021. Assessment at 28-47 days after one application.

EPPO Zone	Number of trials	Untreated: Puccrt % infection		% control of Puccrt					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	15	22.0	5.0-74.8	88.0	70.2-100	91.4	67.2-100	All	1 >, 3 = P 2 <, 8 = A, 1 = L
Maritime*	4	15.5	10.0-22.5	91.3	77.8-100	86.1	67.2-100	Proline	1 >, 3 = P
Maritime^	10	26.3	5.6-74.8	87.0	70.2-94.3	93.6	82.5-98.7	Aviator Xpro	2 <, 8 = A
Maritime#	1	5.0	-	85.0	-	90.0	-	Librax	1 = L

*Direct comparison to Proline (P) applied at 198 g prothioconazole/ha. ^Direct comparison to Aviator Xpro (A) applied at 1.0-1.25 L/ha. #Direct comparison to Librax (L) applied at 2.0 L/ha

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on ~~13~~ 15 EPPO Maritime climatic zone trials demonstrating mean overall control of Puccrt in winter wheat of ~~87.8~~ 88.0% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed label claims for control of Puccrt is fully supported.

Proposed dose range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, ~~eight~~ 10 small plot GEP efficacy field trials were conducted to demonstrate the effectiveness of GF-3307 against Puccrt in winter wheat, ~~at the proposed label rate range of 1.2-1.5 L/ha, at dose rates of 1.2-1.5 L/ha,~~ following a single application applied at BBCH 39-61 of the crop. ~~The trials were conducted in Poland (8 10) in the EPPO North-East climatic zone. The data include trials where Puccrt was established before application (including on the leaves assessed for control in some trials) and trials where Puccrt did not develop until after application. The data include trials where Puccrt was established at low levels on lower leaves before application and trials where Puccrt did not develop until after application.~~ These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on Leaf 1, as this leaf had high levels of Puccrt infection, so was considered to be a robust test of the product.

Across all ~~eight~~ 10 EPPO North-East climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of Puccrt of ~~90.1~~ 90.8% (range 81.1-97.7%), 23-49 days after one application, compared to ~~83.3~~

80.8% using the reference standards. In ~~four~~ **six** trials, GF-3307 at 1.5 L/ha was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~90.5~~ **91.5%** compared to mean control of ~~75.6~~ **74.1%** using Proline. In three trials GF-3307 at 1.5 L/ha was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3307 achieved mean control of 92.5% compared to mean control of 93.8% using Aviator Xpro. In one trial, GF-3307 at 1.5 L/ha was compared directly to the penthiopyrad standard, Vertisan, and GF-3307 achieved 81.1% control, compared to 82.7% using Vertisan. Across all trials, control of PUCCRT achieved by GF-3307 at 1.5 L/ha was statistically higher or not statistically different, compared to the standards.

Across ~~six~~ **eight** EPPO North-East climatic zone trials, GF-3307 at 1.2 L/ha achieved mean control of PUCCRT of ~~89.5~~ **89.6%** (range 84.2-98.4%), compared to ~~91.7~~ **92.2%** for the 1.5 L/ha dose and ~~85.9~~ **82.2%** for the reference standards. In ~~three~~ **five** trials, GF-3307 at 1.2 L/ha was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~89.8~~ **89.9%** compared to mean control of ~~77.9~~ **75.2%** using Proline. In three trials GF-3307 at 1.2 L/ha was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3307 achieved mean control of 89.2% compared to mean control of 93.8% using Aviator Xpro. Across ~~the majority of trials~~ **all trials**, control of PUCCRT achieved by GF-3307 at 1.2 L/ha was statistically higher or not statistically different, compared to the standards.

~~In addition to these trials, data from five trials conducted in neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. Five other trials from the Czech Republic and one German trial used in the Maritime data set are not included to support the EPPO North-East uses because the 1.2 L/ha dose of GF-3307 was not included in these trials. The performance of the 1.5 L/ha dose in these trials can be observed in the Maritime summary. The five trials included as data from neighbouring countries were all conducted in the Germany and demonstrated comparable control to that seen in the EPPO North East climatic zone trials, at 86.8% for the 1.5 L/ha dose (range 77.8-94.3%) and 84.9% for the 1.2 L/ha dose (range 77.8-91.4%). Combined with the eight EPPO North East trials, these 13 trials gave mean control of PUCCRT of 88.8% for the 1.5 L/ha dose, compared to 86.8% using the reference standards. In 11 trials, GF-3307 at 1.2 L/ha achieved 87.4% control compared to 89.4% for the 1.5 L/ha dose and 88.9% for the reference standards. Details for the German trials are in the EPPO Maritime climatic zone section, above.~~

The results are summarised in Table 3.2-14825 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-14825 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

~~Table 3.2-148: Effectiveness of GF-3307 at the proposed label rates of 1.2 and 1.5 L/ha against PUCCRT in winter wheat (TRZAW). Results from 8 trials in the EPPO North-East climatic zone plus 5 DE trials conducted between 2014-2020. Assessment at 23-49 days after one application~~

EPPO Zone	Number of trials	Untreated: PUCCRT % infection		% control of PUCCRT							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North- East (1.5 L/ha)	8	27.0	6.0- 43.1	-	-	90.1	81.1- 97.7	83.3	62.0- 95.0	All	2>, 2=P 1>, 2=A, 1=V
North- East* (1.5 L/ha)	4	33.8	18.8- 43.1	-	-	90.5	83.3- 97.7	75.6	62.0- 95.0	Proline#	2>, 2=P
North- East** (1.2 and 1.5 L/ha)	3	19.7	6.0- 27.8	89.2	84.2- 91.9	92.5	89.7- 94.3	93.8	92.8- 94.6	Aviator Xpro/1.25 L/ha	1>, 2=A
North- East ^Δ (1.5 L/ha)	1	22.0	-	-	-	81.1	-	82.7	-	Vertisan/1.0 L/ha	1=V
DE (1.2 and 1.5 L/ha)	5	24.3	5.0- 74.8	84.9	77.8- 91.4	86.8	77.8- 94.3	92.4	77.8- 98.7	All	1=P, 1<, 2 =A, 1=L (Both doses)

North-East + DE (1.5 L/ha)	13	26.0	5.0- 74.8	-	-	88.8	77.8- 97.7	86.8	62.0- 98.7	All	1 >, 3 = P 1 <, 1 >, 4 = A, 1 = L, 1 = V
North-East (1.2 L/ha)	6	29.2	6.0- 43.1	89.5	84.2- 98.4	91.7	83.3- 97.7	85.9	62.0- 95.0	All	1 >, 2 = P 1 >, 2 = A
North-East (1.2 L/ha)	3	38.7	32.2- 43.1	89.8	85.4- 98.4	90.8	83.3- 97.7	77.9	62.0- 95.0	Proline#	1 >, 2 = P
North-East + DE (1.2 L/ha)	11	27.0	5.0- 74.8	87.4	77.8- 98.4	89.4	77.8- 97.7	88.9	62.0- 98.7	All	1 >, 3 = P 1 <, 1 >, 4 = A 1 = L

*Direct comparison to Proline (P). **Direct comparison to Aviator Xpro (A). ^Direct comparison to Vertisan (V)

L = Librax applied at 2.0 L/ha

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-149: Effectiveness of GF-3307 at 1.2 and 1.5 L/ha against Puccrt in winter wheat (TRZAW). Results from 10 trials in the EPPO North-East climatic zone conducted between 2014-2021. Assessment at 23-49 days after one application

EPPO Zone	Number of trials	Untreated: Puccrt % infection		% control of Puccrt							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North- East (1.5 L/ha)	10	28.2	6.0- 50.0	-	-	90.8	81.1- 97.7	80.8	57.7- 95.0	All^	3 >, 3 = P, 1 >, 2 = A, 1 = V
North- East* (1.5 L/ha)	6	33.6	16.3- 50.0	-	-	91.5	83.3- 97.7	74.1	57.7- 95.0	Proline	3 >, 3 = P
North- East** (1.2 and 1.5 L/ha)	3	19.7	6.0- 27.8	89.2	84.2- 91.9	92.5	89.7- 94.3	93.8	92.8- 94.6	Aviator Xpro	1 >, 2 = A
North- East# (1.5 L/ha)	1	22.0	-	-	-	81.1	-	82.7	-	Vertisan	1 = V
North- East (1.2 L/ha)	8	30.2	6.0- 50.0	89.6	84.2- 98.4	92.2	83.3- 97.7	82.2	57.7- 95.0	All^	2 >, 3 = P 1 >, 2 = A
North- East* (1.2 L/ha)	5	36.5	16.3- 50.0	89.9	85.4- 98.4	91.9	83.3- 97.7	75.2	57.7- 95.0	Proline	2 >, 3 = P

*Direct comparison to Proline (P) applied at 180-198 g prothioconazole/ha. **Direct comparison to Aviator Xpro (A) applied at 1.25 L/ha.

#Direct comparison to Vertisan (V) applied at 1.0 L/ha

^Reference standard results are based on prothioconazole applied at 198 g as/ha, Aviator Xpro applied at 1.25 L/ha and Vertisan at 1.0 L/ha

Summary and conclusions for the proposed range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and only Puccrt requires control, the lower dose of 1.2 L/ha is recommended. Based on data from **11** **eight** trials on winter wheat using the 1.2 L/ha dose rate of GF-3307 (~~Six EPPO North-East climatic zone trials and five DE trials~~), demonstrating mean overall control of SEPTTR of **87.4-89.6%**, it is considered that the proposed claim for control of Puccrt using GF-3307 at a dose rate of 1.2 L/ha on winter wheat is fully supported.

In high pressure mixed disease situations (or FUSASP also present or expected) the higher dose of 1.5 L/ha may be recommended. Based on data from **13** **10** trials on winter wheat using the 1.5 L/ha dose rate of GF-3307 (~~eight EPPO North-East climatic zone trials and five DE trials~~), demonstrating mean overall control of Puccrt of **88.8-90.8%**, it is considered that the proposed claim for control of Puccrt using GF-3307 at a maximum dose rate of 1.5 L/ha on winter wheat is fully supported.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in wheat to offer grower flexibility to adjust to the disease conditions. The lower dose may be used earlier in the season or where pressure from Puccinia striiformis (PuccRT) is the main target disease and pressure from other disease such as Puccinia recondita (PuccNR) is lower. Where disease pressure is high the 1.5 L/ha dose will give excellent control of PuccRT.

Proposed dose of 1.2-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

~~Thirteen~~ **Fifteen** GEP small plot field trials were conducted to demonstrate the efficacy of GF-3307 for the control of PuccRT in winter wheat at the proposed label rate range following application at BBCH 37-55 of the crop. Results ~~for~~ **of** five trials are based on a two-dose regime. In these trials PuccRT did not develop until 13-41 days after the second application, 25-63 days after the first application, which is beyond the protection period the first application of GF-3307 could be expected to deliver. It is also considered that as the first application was at BBCH 32-34 of the crop, the assessed leaf (Leaf 1) had not emerged at this timing. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. In Table 3.2-15026 the results from single dose and two-dose trials are shown separately and demonstrate comparable levels of control. GF-3307 at 1.5 L/ha delivered ~~90.3~~ **91.6%** control of PuccRT from one application across ~~8~~ **10** trials and 94.4% control from a two-dose regime across six trials. For the 1.2 L/ha dose rate, ~~six~~ **eight** single dose trials delivered ~~82.2~~ **84.0%** control and three two-dose trials delivered 79.9% control. These results confirm the conclusion that in the absence of disease in the crop before the second application, results from these trials are comparable to a single dose regime.

The trials were conducted in Bulgaria (2), Hungary (~~4~~ **12**) and Slovakia (1) in the EPPO South-East climatic zone. ~~The data include trials where PuccRT was established before application (including on the leaves assessed for control in some trials) and trials where PuccRT did not develop until after application.~~ **The data include trials where PuccRT was established at low levels on lower leaves before application and trials where PuccRT did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were generally on Leaf 1 (plus one trial on Leaf 3), so was considered to be a robust test of the product.

GF-3307 at 1.5 L/ha achieved mean control of ~~91.9~~ **92.4%** (range 69.4-100%) against PuccRT across ~~13~~ **15** trials, compared to ~~83.5~~ **85.7%** for the reference standards. Compared directly to the various standards used, GF-3307 at 1.5 L/ha achieved ~~90.9~~ **91.8%** compared to ~~80.5~~ **83.5%** control for the prothioconazole standard Proline, 100% control for both products, in one trial using the penthiopyrad standard Vertisan and 94.4% compared to 99.5% for the bixafen + tebuconazole reference Zantara. The 1.2 L/ha dose rate achieved mean control of PuccRT of ~~81.4~~ **82.9%** (range 62.5-95.2%) across ~~nine~~ **11** trials, compared to ~~78.8~~ **82.6%** control for the prothioconazole standard Proline.

The results are summarised in Table 3.2-15026 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-15026 are shown across all trials for each dose first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-150: Effectiveness of GF 3307 at proposed label rate of 1.2 and 1.5 L/ha against Puccrt in winter wheat (TRZAW). Results from 13 trials conducted in the EPPO South East climatic zone between 2014-2020. Assessment at 27-42 days after application.

EPPO Zone	Number of trials	Untreated: Puccrt % infection		% control of Puccrt						Significantl y >=, < Standards	
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mea n	min- max	Mea n	min- max	Mea n	min- max	Mea n	min- max	Product/dos e	
South East (1.5 L/ha)	13	40.3	8.4 72.5	-	-	91.9	69.4 100	83.5	59.1 100	All	3 >, 8 = P, 1 = V, 1 = Z
South East* (1.5 L/ha)	11	42.3	10.5 72.5	-	-	90.9	69.4 100	80.5	59.1 92.9	Proline#	3 >, 8 = P
South East ^Δ (1.5 L/ha)	1	8.4	-	-	-	100	-	100	-	Vertisan/1.0 L/ha	1 = V
South East+ (1.5 L/ha)	1	50.0	-	-	-	94.4	-	99.5	-	Zantara/1.0 L/ha	1 = Z
South East* (1.2 L/ha)	9	41.7	10.5 72.5	81.4	62.5 95.2	89.4	69.4 100	78.8	59.1 92.9	Proline#	1 >, 8 = P
South East (One application)	8	34.7	8.4 72.5	82.2 (6 trials)	62.5 95.2	90.3	69.4 100	84.2	63.9 100	All	1.2: 1 >, 5 = P 1.5: 2 >, 5 = P, 1 = V, 1 = Z
South East (Two applications ↓)	6	49.3	27.5 62.5	79.9 (3 trials)	68.9 85.7	94.4	84.1 98.3	82.4	59.1 92.0	Proline/0.72 L/ha	1.2: 3 = P 1.5: 1 >, 4 = P

*Direct comparison with Proline (P). ^Direct comparison with Vertisan (V). +Direct comparison to Zantara (Z)

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-151: Effectiveness of GF-3307 at 1.2 and 1.5 L/ha against Puccrt in winter wheat (TRZAW). Results from 15 trials conducted in the EPPO South-East climatic zone between 2014-2021. Assessment at 27-42 days after application.

EPPO Zone	Numbe r of trials	Untreated: Puccrt % infection		% control of Puccrt							Significantl y >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mea n	min- max	Mea n	min- max	Mea n	min- max	Mea n	min- max	Product/dos e	
South-East (1.5 L/ha)	15	36.9	7.0- 72.5	-	-	92.5	69.4 -100	85.7	59.1 -100	All^	3 >, 10 = P, 1 = V, 1 = Z
South-East* (1.5 L/ha)	13	38.0	7.0- 72.5	-	-	91.8	69.4 -100	83.5	59.1 -100	Proline	3 >, 10= P
South- East** (1.5 L/ha)	1	8.4	-	-	-	100	-	100	-	Vertisan	1 = V
South-East+ (1.5 L/ha)	1	50.0	-	-	-	94.4	-	99.5	-	Zantara	1 = Z
South-East* (1.2 L/ha)	11	36.8	7.0- 72.5	82.9	62.5 - 95.2	90.7	69.4 -100	82.6	59.1 -100	Proline	1 >, 10 = P
South-East (One application)	10	30.7	7.0- 72.5	84.0 (8 trials)	62.5 - 95.2	91.6	69.4 -100	87.3	63.9 -100	All^	1.2: 1 >, 7 = P 1.5: 2 >, 7 = P, 1 = V, 1 = Z
South-East* (Two applications)	6	49.3	27.5 - 62.5	79.9 (3 trials)	68.9 - 85.7	94.4	84.1 - 98.3	82.4	59.1 - 92.0	Proline	1.2: 3 = P 1.5: 1>, 4 = P

*Direct comparison to Proline (P) applied at 180-198 g prothioconazole/ha. ^Direct comparison with Vertisan (V) applied at 1.0 L/ha.

+Direct comparison to Zantara (Z) applied at 1.0 L/ha

^Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Vertisan at 1.0 L/ha and Zantara at 1.0 L/ha.

Summary and conclusions for the proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on the 13 15 EPPO South-East climatic zone trials demonstrating mean overall control of PuccRT in winter wheat of 91.9 92.5%, from an application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of PuccST PuccRT is fully supported. Where disease levels are low, a 1.2 L/ha dose of GF-3307 could be used, as this provided effective control of PuccST PuccRT (81.4% across nine trials) (82.9% across 11 trials at 1.2 L/ha).

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.3 Effectiveness of GF-3307 for the control of PuccST in wheat

This section addresses the efficacy of GF-3307, for the control of PuccST on wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-152 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 12.0-37.5 m ² EPPO North-East: 20-30 m ² EPPO South-East: 20-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 11 TRZAW EPPO North-East: 6 8 TRZAW EPPO North-East: 1 TRZAS EPPO South-East: 7 8 TRZAW
	Varieties per crop (number of trials)	EPPO Maritime: Akteur, Ambition, JB Asano (4), Patras (2), Santiago, Solstice, Substance (2) EPPO North-East (TRZAW): Arkadia, Bogatka (2), Fredis, Hondia, Tonacja, Zyta EPPO North-East (TRZAS): Tybalt EPPO South-East: Genius, GK Élet (3), Glosa Iridium, Miranda (2)
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-45 EPPO North-East: BBCH 39-56 EPPO South-East: BBCH 39-4749
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of PuccST applications were timed to cover these situations from commencing when there was a risk of infection with PuccST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 5-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PuccST is a prevalent disease.

Introduction

In total, 24 28 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccinia in winter wheat (TRZAW) and ~~one-on~~ spring wheat (TRZAS). To support the label claims, GF-3307 was tested at the proposed label rate of 1.5 L/ha in the EPPO Maritime zone trials and a range from 1.2 L/ha to 1.5 L/ha in the and EPPO North-East and South-East climatic zone trials, in accordance with the EPPO Standard PP 1/26, 'Foliar and ear diseases on cereals'.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (3), Germany (6) and the UK (2) in the EPPO Maritime climatic zone, Latvia (1) Poland (6 8) in the EPPO North-East climatic zone and Hungary (5) and Romania (2 3) in the EPPO South-East climatic zone, between 2014 and 2020 2021.

On the basis of the EPPO Standard PP 1/241 'Guidance on comparable climates', the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-15.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease. Puccinia is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 5 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6	150
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.25	281
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
Vertisan 200 EC	EC	200 g /L penthiopyrad	1.0	200

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0-1.25	225-281
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
Vertisan 200 EC	EC	200 g /L penthiopyrad	1.0	200

Experimental details

The ~~25~~ 28 efficacy trials were conducted to GEP, by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12m² and 37.5m². **Twenty-seven trials were on winter wheat and one trial on spring wheat.** In all trials, the treatments were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

In all trials, GF-3307 was applied as a single application at BBCH 31-56 of winter wheat. The treatments were typically sprayed when Puccst had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with Puccst or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were made on Leaf 1 or Leaf 2.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, 11 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccst in winter wheat at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 31-45 of the crop. The trials were conducted in Denmark (3), Germany (6) and the UK (2) in the EPPO Maritime climatic zone between 2014 -2019. The data included trials where Puccst was established before application (including on the leaves assessed for control in some trials) and trials where Puccst did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 or Leaf 2) so are considered to be a robust test of the product.

Across these 11 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of Puccst of 93.6% (range 87.5-100%), 25-41 days after one application, compared to 90.0% for the reference standards. In nine trials, GF-3307 was compared directly to the prothioconazole standard Proline and achieved mean control of 93.9% compared to mean control of 91.5% using Proline. In one trial, GF-3307 was compared directly to the bixafen + prothioconazole standard Aviator Xpro, and GF-3307 achieved 95.9% control, compared to 95.1% control using Aviator Xpro. In one other trial, GF-3307 was compared directly to the fluxapyroxad + metconazole standard Librax, and GF-3307 achieved 88.3% control, compared to 71.7% control using Librax. Across all trials, control of Puccst achieved by GF-3307 was not statistically different from the standards.

The results are summarised in Table 3.2-15328 and the the results of the individual trials are detailed in the BAD. Results in Table 3.2-15328 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-15328: Efficacy of GF-3307 applied at 1.5 L/ha for the control of Puccst in winter wheat (TRZAW)). Results from 11 trials conducted in the EPPO Maritime climatic zone between 2014-2020. Assessment at 25-41 days after a single application.

EPPO Zone	Number of trials	Untreated: PuccST % infection		% control of PuccST					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	11	24.9	6.1-65.0	93.6	87.5-100	90.0	71.7-100	All	9= P, 1 =A, 1 = L
Maritime*	9	28.1	7.4-65.0	93.9	87.5-100	91.5	81.9-100	Proline/0.72 L/ha	9 = P
Maritime ^	1	6.1	-	95.9	-	95.1	-	Aviator Xpro/1.25 L/ha	1 = A
Maritime #	1	15.0	-	88.3	-	71.7	-	Librax at 2.0 L/ha	1 = L

*Direct comparison to Proline (P), **Direct comparison to Aviator Xpro (A), ***Direct comparison to Librax (L)

*Direct comparison to Proline (P) applied at 198 g prothioconazole/ha, ^Direct comparison to Aviator Xpro (A) applied at 1.25 L/ha, Direct comparison to Librax (L) applied at 2.0 L/ha

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the 11 EPPO Maritime climatic zone trials, demonstrating mean overall control of Puccst in winter wheat of 93.6% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed label claims for control of Puccst is fully supported.

Proposed dose range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total ~~seven~~ **nine** small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccst in winter and spring wheat at the proposed dose range of 1.2-1.5 L/ha, following a single application applied at BBCH 37-56 of the crop. The trials were conducted in Latvia (1) and Poland (~~6~~ **8**) in the EPPO North-East climatic zone. ~~The data included trials where Puccst was established before application (including on the leaves assessed for control in some trials) and trials where Puccst did not develop until after application.~~ **The data included trials where Puccst was established at low levels on lower leaves before application and trials where Puccst did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 or Leaf 2) so are considered to be a robust test of the product.

Across ~~six~~ **eight** EPPO North-East climatic zone trials on winter wheat, GF-3307 at the maximum dose rate of 1.5 L/ha achieved mean control of Puccst of ~~92.1~~ **93.3%** (range 81.1-100%), 28-42 days after one application, compared to ~~79.8~~ **88.9%** control from the reference standards. In ~~five~~ **four** trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of ~~94.3~~ **97.0%**, compared to mean control of ~~87.8~~ **91.9%** using Proline (range ~~32.8~~ **74.1-100%**). In ~~three~~ **two** trials, GF-3307 was compared directly to the bixafen + prothioconazole standard Aviator Xpro, and achieved mean control of 93.0%, compared to mean control of 88.4% using Aviator Xpro (range ~~72.9~~ **72.9-100%**). In one trial, GF-3307 was compared directly to the penthiopyrad standard Vertisan, and GF-3307 achieved control of 81.1% compared to 78.5% using Vertisan.

Across ~~four~~ **six** EPPO North-East climatic zone trials on winter wheat, GF-3307 at the lower dose rate of 1.2 L/ha achieved mean control of Puccst of ~~90.2~~ **91.9%** (range 69.6-100%), compared to ~~95.7~~ **96.4%** (range 83.6-100%) for the 1.5 L/ha dose and ~~81.6~~ **93.1%** control (range ~~32.8~~ **72.9-100%**) for the ~~prothioconazole standard Proline~~ **the reference standards (Proline and Aviator Xpro).**

In addition, data from three trials in neighbouring countries within the EPPO Maritime climatic zone are also considered supportive of the proposed use. These three trials on winter wheat (all conducted in Germany) demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at 91.8% (range 87.5-100) at 1.5 L/ha, 90.0% control (range 84.0-100%) for the 1.2 L/ha dose and 87.6% control (range 81.9-98.0%) for the prothioconazole standard Proline. Combined with the ~~six~~ **eight** EPPO North-East climatic zone trials, these provide mean control of Puccst of ~~92.0~~ **93.0%** for 1.5 l/ha dose, across ~~9~~ **11** trials, compared to ~~82.4~~ **88.6%** control from the reference standards. In ~~7~~

nine of these trials where the 1.2 L/ha was applied this achieved ~~90.1~~ 91.2% control compared to ~~94.0~~ 94.9% from the 1.5 L/ha dose, which supports the proposed dose range of 1.2-1.5 L/ha in wheat. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-15429 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-15429 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-154: Effectiveness of GF-3307 at the proposed label rates of 1.2 and 1.5 L/ha against PuccST in winter wheat (TRZAW). Results from 6 trials in the EPPO North-East climatic zone plus three DE trials, conducted between 2014-2020. Assessment at 28-42 days after one application.

Trials, conducted between 2014-2020, Assessment at 20-42 days after one application											
EPPO Zone	Number of trials	Untreated: PuccST % infection		% control of PuccST							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North- East (1.5 L/ha)	6	22.2	6.4- 40.6	-	-	92.1	81.1- 100	79.8	32.8- 100	All	2>, 3=P, 1=V
North- East* (1.5 L/ha)	5	22.0	6.4- 40.6	-	-	94.3	83.6- 100	80.1	32.8- 100	Proline#	2>, 3=P
North- East** (1.5 L/ha)	1	23.3	-	-	-	81.1	-	78.5	-	Vertisan/1.0 L/ha	1=V
DE (1.2 and 1.5 L/ha)	3	28.6	20.0- 37.5	90.0	84.0- 100	91.8	87.5- 100	87.6	81.9- 98.0	Proline#	3=P (both doses)
North- East + DE (1.5 L/ha)	9	24.3	6.4- 40.6	-	-	92.0	81.1- 100	82.4	32.8- 100	All	2>, 6=P, 1=V
North- East (1.2 L/ha)	4	20.8	6.4- 40.6	90.2	69.6- 100	95.7	83.6- 100	81.6	32.8- 100	Proline#	1>, 3=P
North- East + DE (1.2 L/ha)	7	24.2	6.4- 40.6	90.1	69.6- 100	94.0	83.6- 100	84.2	32.8- 100	Proline#	1>, 6=P

*Direct comparison to Proline (P), **Direct comparison to Vertisan (V)

#Reference standards used based on prothioconazole applied at 180-198 g as/ha.

Table 3.2-155: Effectiveness of GF-3307 at 1.2 and 1.5 L/ha against PuccST in winter wheat (TRZAW). Results from 8 trials in the EPPO North-East climatic zone plus three DE trials, conducted between 2014-2021. Assessment at 28-42 days after one application.

EPPO Zone	Number of trials	Untreated: PUC CST % infection		% control of PUC CST							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North-East (1.5 L/ha)	8	23.2	6.4- 45.0	-	-	93.3	81.1- 100	88.9	72.9- 100	All^	1 >, 3 = P, 3 = A, 1 = V
North- East* (1.5 L/ha)	4	20.2	6.4- 40.6	-	-	97.0	88.7- 100	91.9	74.1- 100	Proline	1 >, 3 = P
North- East** (1.2 and 1.5 L/ha)	3	27.1	7.2- 45.0	86.6	69.6- 100	93.0	83.6- 100	88.4	72.9- 100	Aviator Xpro	3 = A (both doses)
North- East# (1.5 L/ha)	1	23.3	-	-	-	81.1	-	78.5	-	Vertisan	1 = V
DE (1.2 and 1.5 L/ha)*	3	28.6	20.0- 37.5	90.0	84.0- 100	91.8	87.5- 100	87.6	81.9- 98.0	Proline	3 = P (both doses)
North-East + DE (1.5 L/ha)	11	24.7	6.4- 45.0	-	-	93.0	81.1- 100	88.6	72.9- 100	All^	1 >, 6 = P, 3 = A, 1 = V
North-East (1.2 L/ha)	6	22.6	6.4- 45.0	91.9	69.6- 100	96.4	83.6- 100	93.1	72.9- 100	All^	3 = P, 3 = A
North-East + DE (1.2 L/ha)*	9	24.6	6.4- 45.0	91.2	69.6- 100	94.9	83.6- 100	91.3	72.9- 100	Proline	6 = P, 3 = A

*Direct comparison to Proline (P) applied at 180-198 g prothioconazole/ha, **Direct comparison to Aviator Xpro applied at 1.0 L/ha.

#Direct comparison to Vertisan (V) applied at 1.0 L/ha

^Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro applied at 1.0 L/ha and Vertisan at 1.0 L/ha

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). In this trial, the 1.5 L/ha dose of GF-3307 achieved 93.3% control of Puccst, compared to 93.3% for the 1.2 L/ha dose and 95.8% control using Proline.

The results are summarised in Table 3.2-1560 and results of the individual trials are detailed in the BAD.

Table 3.2-1560: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of Puccst in spring wheat (TRZAS) in 2016. Assessment at 32 days after a single application

wheat (PRZAS) in 2016: Assessment at 32 days after a single application											
EPPO Zone	Number of trials	Untreated: PuccST % infection		% control of PuccST							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	1	8.7	-	90.8	-	93.3	-	95.8	-	Proline/0.72 L/ha	= P (both doses)

P = Proline applied at 198 g prothioconazole/ha

Summary and conclusions for the proposed range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and only Puccst requires control, the lower dose of 1.2 L/ha is recommended. Based on data from 7 trials on winter wheat using the 1.2 L/ha dose rate of GF-3307 (four EPPO North-East climatic zone trials and three DE trials), demonstrating mean overall control of Puccst of 90.1-91.2% and one trial on spring wheat demonstrating 90.8% control, it is considered that the proposed claim for control of Puccst using GF-3307 at a dose rate of 1.2 L/ha on wheat is fully supported.

In high pressure mixed disease situations (or PYRNT also present or expected) the higher dose of 1.5 L/ha is recommended. Based on data from 9-11 trials on winter wheat using the 1.5 L/ha dose rate of GF-3307 (six EPPO North-East climatic zone trials and three DE trials), demonstrating mean overall control of Puccst of 92.0-93.0% and one trial on spring wheat demonstrating 93.3% control, it is considered that the proposed claim for control of Puccst using GF-3307 at a maximum dose rate of 1.5 L/ha on winter wheat is fully supported.

As all dose rates and both winter and spring wheat crops show very similar levels of control of this disease (90.0-93.3-96.4% across all data sets), it is considered that the claims on both crops at 1.2-1.5 L/ha are fully supported.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in wheat to offer grower flexibility to adjust to the disease conditions. The lower dose may be used earlier in the season or where pressure from Puccst is the main target disease and pressure from other disease such as PYRNT is lower. Where disease pressure is high the 1.5 L/ha dose will give excellent control of Puccst.

Proposed dose of 1.2-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

Seven EPPO small plot field trials were conducted to demonstrate the efficacy of GF-3307, for the control of Puccst in winter wheat, following a single application at BBCH 39-47 of the crop. The trials were conducted in Hungary (5) and Romania (2) in the EPPO South-East climatic zone. The data included trials where Puccst was established before application (including on the leaves assessed for control in some trials) and trials where Puccst did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1) so are considered to be a robust test of the product.

A single application of GF-3307 at 1.5 L/ha achieved mean control of 90.7-91.4% (range 82.3-100%) against Puccst across seven trials, compared to 88.3-89.1% for the reference standards. Compared directly to the various standards used, GF-3307 at 1.5 L/ha achieved 92.1-92.7% control,

compared to ~~88.8~~ **89.6%** for the prothioconazole standard Proline (mean of ~~six~~ **seven** trials) and 82.3% compared to 85.7% for the penthiopyrad standard Vertisan (one trial). The 1.2 L/ha dose rate achieved ~~84.6~~ **86.2%** control of Puccst (range 72.6-99.0%) across ~~five~~ **six** trials, compared to ~~93.5~~ **94.0%** for the 1.5 L/ha dose and ~~91.5~~ **92.0%** for the prothioconazole standard Proline.

The results are summarised in Table 3.2-1571 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1571 are shown across all trials for each dose first (~~shaded grey~~), before being shown orthogonally against the various standards.

~~Table 3.2-157: Effectiveness of GF-3307 at proposed label rates of 1.2 and 1.5 L/ha against Puccst in winter wheat (TRZAW). Results from 7 trials conducted in the EPPO South-East climatic zone between 2014-2020. Assessment at 28-49 days after one application~~

EPPO Zone	Number of trials	Untreated: PuccST % infection		% control of PuccST							Significantly >, =, < Standards
				GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
South- East (1.5 L/ha)	7	38.4	11.3- 63.8	-	-	90.7	82.3- 100	88.3	73.7- 100	All	2 >, 4 = P, 1 = V
South- East* (1.5 L/ha)	6	42.1	11.3- 63.8	-	-	92.1	85.1- 100	88.8	73.7- 100	Proline#	2 >, 4 = P
South- East^ (1.5 L/ha)	1	16.4	-	-	-	82.3	-	85.7	-	Vertisan/1.0 L/ha	1 = V
South- East* (1.2 L/ha)	5	37.8	11.3- 63.8	84.6	72.6- 99.0	93.5	85.1- 100	91.5	73.7- 100	Proline#	1 >, 4 = P

*Direct comparison with Proline (P)

^Direct comparison with Vertisan (V)

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-158: Effectiveness of GF-3307 at 1.2 and 1.5 L/ha against Puccst in winter wheat (TRZAW). Results from 8 trials conducted in the EPPO South-East climatic zone between 2014-2021. Assessment at 28-49 days after one application

EPPO Zone	Number of trials	Untreated: PuccST % infection		% control of PuccST							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
South- East (1.5 L/ha)	8	34.5	6.8- 63.8	-	-	91.4	82.3- 100	89.1	73.7- 100	All^	2 >, 5 = P, 1 =V
South- East* (1.5 L/ha)	7	37.1	6.8- 63.8	-	-	92.7	85.1- 100	89.6	73.7- 100	Proline	2 >, 5 = P
South- East# (1.5 L/ha)	1	16.4	-	-	-	82.3	-	85.7	-	Vertisan	1 = V
South- East* (1.2 L/ha)	6	32.6	6.8- 63.8	86.2	72.6- 99.0	94.0	85.1- 100	92.0	73.7- 100	Proline	1 >, 5 = P

*Direct comparison with Proline (P) applied at 180-198 g prothioconazole /ha. #Direct comparison with Vertisan (V) applied at 1.0 L/ha

^Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Vertisan at 1.0 L/ha

Summary and conclusions for the proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on the seven **eight** EPPO South-East climatic zone trials demonstrating mean overall control of Puccst in winter wheat of 90.7 **91.4%**, from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of Puccst is fully supported. Where disease levels are low, a 1.2 L/ha dose of GF-3307 could be used, as this provided effective control of Puccst (~~84.6%~~ **86.2%** based on **six** trials at 1.2 L/ha).

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.4 Effectiveness of GF-3307 for the control of Fusarium head blight (FUSASP) of winter wheat

This section addresses the effectiveness of GF-3307, for the control of fusarium head blight (FUSASP) on winter wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, 1.5 L/ha in in Poland (EPPO North-East climatic zone) and 1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-1592 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-30 m ² EPPO Maritime: 12.0-30 m ² EPPO North-East: 15.0 24.0m ² EPPO South-East: 22.5-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 10 TRZAW EPPO North-East: 7 TRZAW EPPO South-East: 3 TRZAW
	Varieties per crop	EPPO Maritime: JB Asano, Akteur, Altamira, Bernstein, Desamo, Grafton, Ilona, Muza, Naskov, Tobak. EPPO North-East: Artist, Euforia (2), Joker, Patras, Tobak, Zyta EPPO South-East: Altigo, Genius, MV Nador
Application	Crop stage (BBCH) at application	EPPO Maritime: BBCH 61-65 EPPO North-East: BBCH 61-65 ⁶⁹ EPPO South-East: BBCH 61-65
	Timing Pest stage at application (1)	Application was made to coincide with the most susceptible period of growth which was early to mid-flowering of the wheat
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% incidence (frequency) of infected ears, the average % severity of ear infection of all ears assessed and the Disease severity Index (DSI). The deoxynivalenol (DON) content of the harvested grain was determined Assessments for efficacy (% infection with FHB) were aimed at BBCH 83-85 when symptoms of FHB were most obvious. % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, Hagberg falling number, Hectolitre weight, protein content and other quality parameters,
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% incidence) were aimed at the BBCH 83-85 in winter wheat
Other relevant information	Natural / artificial	Natural infection and artificial inoculation
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where FHB is an abundant disease.

Introduction

In total, data from ± 20 field trials are presented in this section to demonstrate the effectiveness of

GF-3307, for the control of fusarium head blight (FUSASP) on winter wheat (TRZAW). GF-3307 was tested ~~at the proposed label rate of 1.5 L/ha,~~ **at 1.5, 1.25 and 1.2 L/ha**, in accordance with the EPPO Standard PP 1/26, ‘*Foliar and ear diseases on cereals*’

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials, in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (3), Germany (4), Denmark (1), France (1) and the UK (1) in the EPPO Maritime climatic zone, Poland (~~4~~ **7**) in the EPPO North-East climatic zone ~~between 2014 and 2016.~~ **and Hungary (3) in the EPPO South-East climatic zone between 2014 and 2021.**

On the basis of EPPO Standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. ~~For FUSASP, this submission includes data from the Maritime and North East EPPO climatic zones, which are representative of the proposed GAP in each region. FUSASP is an important disease in the wetter regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South East climatic zone, the climatic conditions are less conducive to the development of FUSASP, as hot dry weather reduces the rate of disease development. As a result, this is a relatively minor disease in this climatic zone. As with data for other diseases in this dossier, the trial results from Poland in the EPPO North-East climatic zone and Austria in the EPPO Maritime climatic zone, as neighbouring countries, are comparable to those from the EPPO South East climatic zone and it is considered this will also be the case for FUSASP. It is therefore considered that data from Poland and Austria can be used to support this use in the EPPO South East climatic zone.~~ **This submission includes data from each of these zones, so are representative of the proposed GAP.**

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-16.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Fusarium head blight (FHB) is a prevalent disease. For trial site and application details, see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 6 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.5	225
Proline 275	EC	275 g/L prothioconazole	0.72	198

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.25, 1.5	135, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	1.0	250

Experimental details

The 20 efficacy trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 12 m² and 36 m². To suppress foliar diseases during the growing season, cover sprays with fungicides were applied over the whole trial area. The trial treatments were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering a water volume between 200 and 300 L/ha.

GF-3307 at the rates tested and the reference product Proline were typically applied during the anthesis of the wheat crop as a single ‘ear wash’ spray applied between wheat growth stage BBCH 61 and BBCH 65 when the weather conditions for ear infections were favourable for FHB.

In some majority of trials *F.culmorum* and *F. graminearum* were artificially inoculated by spraying spore suspensions of the single species or both species in mixture close before or after the application of GF-3307 and the reference products (see Table 3.2-16033).

Table 3.2-16133 Trials with natural infections or artificial inoculations

Trial number	Country	Fusarium species used for artificial inoculation
DE15E7B018UB02C	Austria	FUSACU
DE16E7B032UB02C	Austria	Natural infection
DE16E7B032UB03C	Austria	FUSACU+GIBBZE
DE14E7B023UB01C	Germany	Natural infection
DE15E7B018UB01C	Germany	Natural infection
DE16E7B032FS01	Germany	FUSACU+GIBBZE
DE16E7B032UB01C	Germany	FUSACU
DK16E7B032KF02C	Denmark	FUSACU+GIBBZE
FR16E7B035MC01C	France	FUSACU
GB15E7B018EB01C	UK	FUSACU+GIBBZE
PL16E7B032AS01C	Poland	FUSACU
EA21E7B130F-DPF059	Poland	FUSASP
EA21E7B130F-DPF060	Poland	FUSASP
EA21E7B130F-DPF061	Poland	FUSASP
EA21E7B130F-DPF063	Poland	FUSASP
EA21WBN66001F-DPF016	Poland	FUSASP
EA21WBN66001F-DPF017	Poland	FUSASP
EA21WBN66001F-EAN009	Hungary	FUSASP
EA21WBN66001F-EAN010	Hungary	FUSASP
EA21WBN66001F-EAN011	Hungary	FUSASP

FUSACU = *F. culmorum*

GIBBZE = *Gibberella zeae*, also known by the name of its anamorph *F. graminearum*

FHB was assessed on 50-100 randomly selected ears per plot as % incidence (frequency) of infected ears and the average % severity of ear infection of all ears assessed. In addition for the 2021 trials the FHB index or Disease Severity Index (DSI) was also calculated. For trials proper to 2021 where this is not included in the trials report, this has been calculated based on the % incidence and % severity reported in the trials. The deoxynivalenol (DON) content of the harvested grain was determined in all trials using liquid chromatography procedures or ELISA tests. Assessments for efficacy (% infection with FHB) were aimed at BBCH 83-85 when symptoms of FHB were most obvious. Percentage control was calculated based on the severity of ear infection and FHB index (DSI), relative to the infection level present in the untreated control. The percent reduction of the mycotoxin deoxynivalenol (DON) was calculated relative to the contents present in the grain of the control plots.

The prevailing *Fusarium* species present in the trials were *F. graminearum* and *F. culmorum* which belong to the most damaging diseases in cereal crops (see Table 3.2-133). Both species contaminate human food and animal feed through the production of mycotoxins such as DON, DON derivatives and zearalenone that belong to a group of structurally similar fungal metabolites called trichothecenes. However, it needs to be noted, that the FHB intensity shown in the trials and mycotoxin accumulation

in the grain do not always closely correlate. Reasons might be that mycotoxins other than DON are produced by some *Fusarium* spp. that were not analysed or that head blight infections are present which are caused by pathogens such as *Microdochium nivale* that do not produce mycotoxins.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Ten GEP small plot field trials were conducted in order to determine the efficacy of GF-3307, for the control of FUSASP in winter wheat, following a single application, applied at BBCH 61-65 of the crop. The efficacy trials were conducted in in Austria (3), Germany (4), Denmark (1), France (1) and the UK (1) in the EPPO Maritime climatic zone. All assessments were conducted on the ear.

A single application of GF-3307 applied at 1.5 L/ha achieved mean control of 80.6% (range 71.0-92.0%) for FUSASP, 15-37 days after application. Applied in the same trials, the prothioconazole standard Proline achieved mean control of 74.8%. **Control based on the FHB Index (DSI) has also been calculated for these trials based on the % severity and % incidence (except for trial DK16E7B032KF02C, where % control based on the FHB index was included). GF-3307 applied at 1.5 L/ha achieved mean control of FUSAP based on the DSI of 88.6% compared to 87.2% for the prothioconazole standard Proline.**

The results are summarised in Table 3.2-1624 and individual trial results are detailed in the BAD.

~~Table 3.2-162 — Efficacy of GF-3307 applied at 1.5 L/ha for the control of FUSASP in winter wheat (TRZAW). Results from 10 trials conducted in the EPPO Maritime climatic zone between 2014 and 2016. Assessment at 15-37 days after one application.~~

EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP				
				GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)		Significantly >, =, < Standards
		Mean	min-max	Mean	min-max	Mean	min-max	
Maritime	10	31.2	5.7-93.8	80.6	71.0-92.0	74.8	47.1-83.0	2 >, 2 <, 6 = P

Table 3.2-163 Efficacy of GF-3307 applied at 1.5 L/ha for the control of FUSASP in winter wheat (TRZAW). Results from 10 trials conducted in the EPPO Maritime climatic zone between 2014 and 2016. Assessment at 15-37 days after one application.

EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP				
				GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)		Significantly >, =, < Standards
		Mean	min-max	Mean	min-max	Mean	min-max	
Maritime (severity)	10	31.2	5.7-93.8	80.6	71.0-92.0	74.8	47.1-83.0	2 >, 2 <, 6 = P
Maritime (DSI)	10	27.3	2.7-93.8	88.6	61.6-98.4	87.2	68.6-98.2	-

In addition to assessing the control of FUSASP, all trials included an assessment of the impact of the treatments on the deoxynivalenol (DON) content of the harvested grain. A single application of GF-3307 applied at 1.5 L/ha achieved a mean reduction of 67.9% for DON, 75-154 days after harvest. Applied in the same trials, the prothioconazole standard Proline achieved a mean reduction of 70.8%. **Additional factors, other than just FUSASP control, can have an influence on the DON levels at harvest (e.g. weather around harvest, sooty moulds and variety), therefore the reduction in DON levels does not always equate to the level of control of FUSASP in the growing crop. However, the data demonstrate that the reduction in DON content from GF-3307 at the 1.5 L/ha dose was comparable to the reference product.**

The results are summarised in Table 3.2-1645 and individual trial results are detailed in the BAD.

Table 3.2-1645 Efficacy of GF-3307 applied at 1.5 L/ha for the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from 10 trials conducted in the EPPO Maritime climatic zone between 2014 and 2016. Assessment at 75-154 days after application (after harvest).

EPPO Zone	Number of trials	Untreated control content DON mg/kg		% control reduction of DON				
				GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)		Significantly >, =, < Standards
		Mean	min-max	Mean	min-max	Mean	min-max	
Maritime	10	9.2	0.1-38.6	67.9	17.9-85.8	70.8	51.7-87.4	-

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the 10 EPPO Maritime climatic zone trials, demonstrating mean overall control of FUSASP in winter wheat of 80.6% (based on severity) or 88.6% (based on the DSI) and a reduction in DON content of 67.9%, when applied at flowering at the proposed dose rate of 1.5 L/ha, it is considered that the proposed label claim for control of FUSASP is fully supported.

Proposed maximum dose of 1.5 L/ha for Poland (EPPO North-East climatic zone)

One **Seven** GEP small plot field trials were conducted in order to determine the effectiveness of GF-3307, for the control of the FUSASP in winter wheat, following a single application applied at BBCH 61-65 **69** of the crop. The trial was conducted in Poland in the EPPO North-East climatic zone. Assessments were conducted on the ear.

A single application of GF-3307 applied at 1.5 L/ha achieved ~~83.6~~ **83.4%** control of FUSASP, ~~17 days after application based on severity, 17-28 days after application.~~ This compared to 79.1% for the prothioconazole standard Proline. This compared to 82.4% for the tebuconazole + prothioconazole standard **Prosaro**. The 1.2 L/ha dose delivered lower control of ~~68.3~~ **78.8%**.

~~In addition to this trial, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These four trials were conducted in Germany and demonstrate comparable control of FUSASP to the EPPO North East climatic zone data, with the 1.5 L/ha achieving 80.3%, compared to 71.6% for the prothioconazole standard Proline. Combined with the one EPPO North East climatic zone trial, these give overall control of FUSASP across the five trials of 80.9% for GF 3307 at 1.5 L/ha, compared to 73.1% for the prothioconazole standard Proline. The 1.2 L/ha dose delivered lower control of 69.6%. Details for these German trials are included in the EPPO Maritime climatic zone section, above.~~

In addition to this trial, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose. These four trials were conducted in Germany and demonstrate comparable control of FUSASP to the EPPO North-East climatic zone data, with the 1.5 L/ha achieving 80.3% control based on severity, compared to 83.8% for the tebuconazole + prothioconazole standard Prosaro. Combined with the seven EPPO North-East climatic zone trials, these give overall control of FUSASP based on severity across the 11 trials of 82.3% for GF-3307 at 1.5 L/ha, compared to 82.9% for the tebuconazole + prothioconazole standard Prosaro. The 1.2 L/ha dose delivered lower control of 74.9%. Details for these German trials are included in the EPPO Maritime climatic zone section, above.

Control based on the FHB Index (DSI) was included in the six 2021 Polish trials and has been calculated for all earlier trials based on the % severity and % incidence. GF-3307 applied at 1.5 L/ha achieved mean control of FUSAP based on the DSI of 92.1% for the seven EPPO North-East trials, 89.6% for the four DE trials and 93.1% for all 11 trials combined. This compares to 92.4%, 94.0% and 93.0% respectively for the tebuconazole + prothioconazole standard Prosaro.

The results are summarised in Table 3.2-16536 individual trial results are detailed in detailed in the BAD.

Table 3.2-165 Efficacy of GF 3307 applied at the proposed dose range of 1.2-1.5 L/ha for the control of FUSASP in winter wheat (TRZAW). Results from one trial in the EPPO North-East climatic zone and 4 DE trials, conducted between 2014 and 2016. Assessment at 17-37 days after one application.

EPPO-Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP						
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)		Significantly ≥, =, ≤ Standards
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
North-East	1	13.7	-	68.3	-	79.1	-	82.8	-	1=P
DE	4	47.8	8.5-93.8	69.9	57.0-83.7	71.6	47.1-80.6	83.8	75.9-90.1	2≥, 2<P
North-East+DE	5	41.0	8.5-93.8	69.6	57.0-83.7	73.1	47.1-80.6	83.6	75.9-90.1	2>, 2<, 1=P

Table 3.2-166 Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the control of FUSASP in winter wheat (TRZAW). Results from 7 trials conducted in the EPPO North-East climatic zone and four DE trials between 2014 and 2021. Assessment based on disease severity at 17-37 days after one application

between 2014 and 2021. Assessment based on disease severity at 17-37 days after one application										
EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP						
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)		Significantly >, =, < Standards
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
North-East (severity)	7	48.1	13.7-91.3	78.8#	66.1-97.6	83.4	50.1-100	82.4	53.4-96.7	1 <, 6 = PO
DE (severity)	4	47.8	8.5-93.8	69.9	57.0-83.7	80.3	71.0-92.0	83.8	75.9-90.1	1 <, 1 >, 2 = PO
North-East + DE (severity)	11	48.0	8.5-93.8	74.9##	57.0-97.6	82.3	50.1-100	82.9	53.4-96.7	2 <, 1 >, 8 = PO
North-East (DSI)	7	41.3	3.4-91.3	89.5#	73.9-99.8	92.1	63.1-100	92.4	66.5-98.9	1 <, 5 = PO
DE (DSI)	4	40.5	4.9-93.8	89.6	83.7-95.2	89.6	83.7-95.2	94.0	84.0-98.9	-
North-East + DE (DSI)	11	41.0	3.4-93.8	89.5	73.9-99.8	93.1	63.1-100	93.0	66.5-98.9	1 <, 5 = PO

#Based on 5 trials, ##Based on 9 trials

In addition to assessing the control of FUSASP, all trials included an assessment of the impact of the treatments on the deoxynivalenol (DON) content of the harvested grain. A single application of GF 3307 applied at 1.5 L/ha achieved a reduction of 74.9% for DON, 101 days after harvest in the one EPPO North-East climatic zone trials. This compared to 78.1% for the prothioconazole standard Proline. Combined with the four DE trials, an overall reduction of DON of 73.7% was achieved for the proposed dose compared to 73.3% for the prothioconazole standard Proline.

In addition to assessing the control of FUSASP, all trials included an assessment of the impact of the treatments on the deoxynivalenol (DON) content of the harvested grain. In three Polish trials, no DON was found, therefore the table below is based on results from four trials. A single application of GF-3307 applied at 1.5 L/ha achieved a reduction of 41.1% for DON, 101-134 days after application (after harvest) in the four EPPO North-East climatic zone trials. This compared to 43.4% for the tebuconazole + prothioconazole standard Prosaro. Combined with the four DE trials, an overall reduction of DON of 57.2% was achieved for the proposed dose compared to 58.6% for the tebuconazole + prothioconazole standard Prosaro. Additional factors, other than just FUSASP control, can have an influence on the DON levels at harvest (e.g. weather around harvest, sooty moulds and variety), therefore the reduction in DON levels does not always equate to the level of control of FUSASP in the growing crop. However, the data demonstrate that the reduction in DON content from GF-3307 at the maximum 1.5 L/ha dose was comparable to the reference product.

The results are summarised in Table 3.2-16737 and individual trial results are detailed in the BAD.

Table 3.2-167 — Efficacy of GF-3307 applied at the proposed dose range of 1.2-1.5 L/ha for the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from one trial in the EPPO North-East climatic zone and 4 DE trials, conducted between 2014 and 2016. Assessment at 76-154 days after harvest.

EPPO-Zone	Number of trials	Untreated control DON-mg/kg		% control of DON							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max		
North-East	1	0.3	-	68.6	-	74.9	-	78.1	-	-	
DE	4	10.9	0.1-38.6	67.3	58.3-75.1	73.4	58.3-85.8	72.2	58.3-85.5	-	
North-East + DE	5	8.8	0.1-38.6	67.5	58.3-75.1	73.7	58.3-85.8	73.3	58.3-85.5	-	

Table 3.2-168 Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from 7 trials conducted in the EPPO North-East climatic zone and four DE trials between 2014 and 2021. Assessment at 76-154 days after application (after harvest)

(after harvest)										
EPPO Zone	Number of trials	Untreated control DON mg/kg content		% reduction of DON						
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)		Significantly >, =, < Standards
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
North-East	4	3.7	0.3-5.6	68.6#	-	41.1	21.9-74.9	43.4	28.2-73.7	-
DE	4	10.9	0.1-38.6	67.3	58.3-75.1	73.4	58.3-85.8	73.9	58.3-85.8	-
North-East + DE	8	7.3	0.1-38.6	67.5##	58.3-75.1	57.2	21.9-85.8	58.6	28.2-85.8	-

#Based on one trial, ##Based on 5 trials

Summary and conclusions for maximum dose of 1.5 L/ha and proposed range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Based on one EPPO North East climatic zone trial and four trials from Germany, demonstrating mean overall control of FUSASP in winter wheat of 80.9% and a reduction in DON content of 73.7%, when applied at flowering at the proposed dose rate of 1.5 L/ha, it is considered that the proposed label claim for control of FUSASP is fully supported.

Note: Additional EPPO North East trials are being generated on FUSASP in 2021 and can submitted to support this claim if the the current data is not considered sufficient.

A dose range of 1.2-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions. The data for the 1.2 L/ha dose confirm that the lower 1.2 doses rate is not sufficient to control this disease and if control of this disease is required, the maximum dose rate of 1.5 L/ha will be required.

Based on seven EPPO North-East climatic zone trials and four trials from Germany, demonstrating mean overall control of FUSASP in winter wheat of 82.3% (based on severity) or 93.1% (based on the DSI) and a reduction in DON content of 57.2%, when applied at flowering at the proposed dose rate of 1.5 L/ha, it is considered that the proposed label claim for control of FUSASP is fully supported.

Control demonstrated by the maximum 1.5 L/ha dose was comparable to the tebuconazole + prothioconazole standard Prosaro at 82.9% control of FUSASP (based on severity) or 93.0% (based on the DSI) and a 58.6% reduction of DON.

A dose range of 1.2-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions. The data for the 1.2/1.25 L/ha dose confirm that the lower

1.2 L/ha dose rate is not sufficient to control this disease and if control of this disease is required, the maximum dose rate of 1.5 L/ha will be required.

~~Summary and conclusions for the proposed maximum dose of 1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone~~

No data are presented from the EPPO South East climatic zone using GF 3307 against this disease. FUSASP is an important disease in the wetter regions of the Central EU Authorization zone, where disease pressure is significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South East climatic zone, the climatic conditions are generally less conducive to the development of FUSASP, as hot dry weather reduces the rate of disease development. The climate in Poland and Austria, as neighbouring countries, is similar to the EPPO South East climatic zone (i.e., hot summers), but is slightly wetter than in the EPPO South East climatic zone. It is therefore considered that trials from Poland and Austria represent a more robust test of the product against FUSASP, so these data can be used to support use in the EPPO South East climatic zone. The trials from Germany summarised in the Maritime data set represent the worst case scenario and further support the maximum dose rate of 1.5 L/ha is required for control of FUSASP.

The results for FUSASP control are summarised in Table 3.2 165 individual trial results are detailed in detailed in the BAD.

~~Table 3.2 169 — Efficacy of GF 3307 at the proposed dose range of 1.2–1.5 L/ha against FUSASP in winter wheat (TRZAW). Results from one PL trial and 3 AT trials conducted in 2015 and 2016. Assessment at 15–25 days after one application.~~

15-25 days after one application										
EPPO-Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP						Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)		
		Mean n	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
PL	1	13.7	-	68.3	-	83.6	-	79.1	-	1=P
AT	3	18.4	5.7-29.3	68.7	51.2-81.1	81.0	79.0-83.1	80.8	78.9-83.0	3=P
AT+PL	4	17.3	5.7-29.3	68.6	51.2-81.0	81.7	79.0-83.6	80.4	78.9-83.0	4=P

The results of DON reduction are summarised in Table 3.2 167 and individual trial results are detailed in the BAD.

~~Table 3.2 170 — Efficacy of GF 3307 at the proposed dose range of 1.2–1.5 L/ha on the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from one PL trial and 3 AT trials conducted in 2015 and 2016. Assessment at 75–101 days after harvest.~~

EPPO Zone	Number of trials	Untreated control DON mg/kg		% control of DON						Significantly >, Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference (Proline 275 at 0.72 L/ha)		
		Mean n	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
PL	1	0.3	-	56.3	-	74.9	-	78.1	-	-
AT	3	12.0	9.3-16.4	67.9	64.5-70.5	74.0	66.4-84.4	79.3	73.9-87.4	-
AT+PL	4	9.1	0.3-16.4	65.0	56.3-70.5	74.2	66.4-84.4	79.0	73.9-87.4	-

~~Based on one Polish trial and three trials from Austria, demonstrating mean overall control of FUSASP in winter wheat of 81.7% and a reduction in DON content of 74.2%, when applied at~~

~~flowering at the proposed dose rate of 1.5 L/ha, it is considered that the proposed label claim for control of FUSASP is fully supported.~~

~~Control demonstrated by the maximum 1.5 L/ha dose was comparable to the prothioconazole reference standard Proline at 80.4% control of FUSASP and a 79.0% reduction of DON.~~

~~Across all disease claims on wheat a dose range of 1.2-1.5 L/ha will be proposed, as many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law. The data for the 1.2 L/ha dose confirm that the lower 1.2 doses rate is not sufficient to control this disease and if control of this disease is required, the maximum dose rate of 1.5 L/ha will be required.~~

Proposed maximum dose of 1.5 L/ha for the EPPO South-East climatic zone countries of the Central EU Authorisation zone

Three GEP small plot field trials were conducted in order to determine the effectiveness of GF-3307, for the control of the FUSASP in winter wheat, following a single application applied at BBCH 61-65 of the crop. The trials were conducted in Hungary in the EPPO South-East climatic zone. Assessments were conducted on the ear.

A single application of GF-3307 applied at 1.5 L/ha achieved 70.9% control of FUSASP based on severity, 15-25 days after application. This compared to 81.8% for the tebuconazole + prothioconazole standard Prosaro. The 1.2 L/ha dose delivered lower control of 66.3%.

FUSASP is an important disease in the wetter regions of the Central EU Authorization zone, where disease pressure is significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South-East climatic zone, the climatic conditions are generally less conducive to the development of FUSASP, as hot dry weather reduces the rate of disease development. The climate in Austria and Poland, as neighbouring countries, is similar to the EPPO South-East climatic zone (i.e., hot summers), but is slightly wetter than in the EPPO South-East climatic zone. It is therefore considered that trials from Austria and Poland represent a more robust test of the product against FUSASP, so these data can be used to support use in the EPPO South-East climatic zone

Eight trials were conducted in Austria and Poland and demonstrated comparable control of FUSASP to the EPPO South-East climatic zone data, with the 1.5 L/ha achieving 87.1% control based on severity, compared to 86.4% for the tebuconazole + prothioconazole standard Prosaro. Combined with the three EPPO South-East climatic zone trials, these give overall control of FUSASP based on severity across the 11 trials of 82.6% for GF-3307 at 1.5 L/ha, compared to 85.1% for the tebuconazole + prothioconazole standard Prosaro. The 1.2 L/ha dose delivered lower control of 72.7%. Details for these Austrian and Polish trials are included in the EPPO Maritime and North-East climatic zone sections, above.

Control based on the FHB Index (DSI) was included in the three 2021 Hungarian and four 2021 Polish trials and has been calculated for all earlier trials based on the % severity and % incidence. GF-3307 applied at 1.5 L/ha achieved mean control of FUSAP based on the DSI of 84.8% for the three EPPO South-East trials, 94.7% for the eight Austrian and Polish trials and 92.0% for all 11 trials combined. This compares to 92.4%, 95.9% and 95.0% respectively for the tebuconazole + prothioconazole standard Prosaro.

The results for FUSASP control are summarised in Table 3.2-1658 individual trial results are detailed in detailed in the BAD.

Table 3.2-171 Efficacy of GF-3307 at 1.2-1.5 L/ha against FUSASP in winter wheat (TRZAW). Results of the three (3) trials conducted in the EPPO South-East climatic zone, three (3) AT trials and five (5) PL trials between 2015 and 2021. Assessment based on disease severity at 15-28 days after one application

Trials between 2010 and 2021: Assessment based on disease severity at 15-20 days after one application										
EPPO Zone	Number of trials	Untreated control % infection FUSASP		% control of FUSASP						Significantly >, =, < Standards
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)		
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
South-East (severity)	3	39.0	15.0-79.5	66.3	46.0-76.7	70.9	54.1-86.0	81.8	67.9-89.1	3 = PO
AT + PL (severity)	8	36.4	5.7-91.3	75.0	51.2-97.6	87.1	79.0-100	86.4	75.9-96.7	8 = PO
South-East + AT + PL (severity)	11	37.1	5.7-91.3	72.7	46.0-97.6	82.6	54.1-100	85.1	67.9-96.7	11 = PO
South-East (DSI)	3	35.8	11.5-74.8	80.5	63.0-92.3	84.8	70.1-94.1	92.4	84.5-96.7	1 <, 2 = PO
AT + PL (DSI)	8	31.1	2.7-91.3	87.0	71.5-99.8	94.7	89.5-100	95.9	90.1-99.1	4 = PO
South-East + AT + PL (DSI)	11	32.4	2.7-91.3	85.2	63.0-99.8	92.0	70.1-100	95.0	84.5-99.1	1 <, 6 = PO

In addition to assessing the control of FUSASP, all trials included an assessment of the impact of the treatments on the deoxynivalenol (DON) content of the harvested grain. In two Polish trials, no DON was found, therefore the table below is based on results from nine trials. A single application of GF-3307 applied at 1.5 L/ha achieved a reduction of 75.4% for DON, 37-73 days after application (after harvest) in the three EPPO South-East climatic zone trials. This compared to 88.8% for the tebuconazole + prothioconazole standard Prosaro. Combined with the six Austrian and Polish trials, an overall reduction of DON of 64.2% was achieved for the proposed dose compared to 71.9% for the tebuconazole + prothioconazole standard Prosaro. Additional factors, other than just FUSASP control, can have an influence on the DON levels at harvest (e.g. weather around harvest, sooty moulds and variety), therefore the reduction in DON levels does not always equate to the level of control of FUSASP in the growing crop. However, the data demonstrate that the reduction in DON content from GF-3307 at the maximum 1.5 L/ha dose was comparable to the reference product.

The results of DON reduction are summarised in Table 3.2-1679 and individual trial results are detailed in the BAD.

Table 3.2-172 Efficacy of GF-3307 at 1.2-1.5 L/ha on the reduction of DON content of the harvested grain in winter wheat (TRZAW). Results from three (3) trials conducted in the EPPO South-East climatic zone, three (3) AT trials and five (5) PL trials between 2015 and 2021. Assessment at 37-132 days after application (after harvest)

EPPO Zone	Number of trials	Untreated content DON mg/kg		% reduction of DON						
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference (Prosaro at 1.0 L/ha)		Significantly >, =, < Standards
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
South-East	3	16.4	6.8-28.0	71.2	56.4-87.5	75.4	52.7-89.7	88.8	75.0-95.8	1 <, 2 = PO
AT + PL	6	7.7	0.3-16.4	70.7#	66.5-75.2	58.6	21.9-84.4	63.4	28.2-88.9	1 <, 1 = PO
South-East + AT + PL	9	10.6	0.2-28.0	70.9##	56.4-87.5	64.2	21.9-89.7	71.9	28.2-95.8	3 <, 3 = PO

#Based on four trials, ##Based on seven trials

Summary and conclusions for the proposed maximum dose of 1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on three EPPO South-East climatic zone trials and eight trials from Austria and Poland, demonstrating mean overall control of FUSASP in winter wheat of 82.6% (based on severity) or 92.0% (based on the DSI) and a reduction in DON content of 64.2%, when applied at flowering at the proposed dose rate of 1.5 L/ha, it is considered that the proposed label claim for control of FUSASP is fully supported.

Control demonstrated by the maximum 1.5 L/ha dose was comparable to the tebuconazole + prothioconazole standard Prosaro at 85.1% control of FUSASP (based on severity) or 95.0% (based on the DSI) and a 71.9% reduction of DON

Across all disease claims on wheat a dose range of 1.2-1.5 L/ha will be proposed, as many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law. The data for the 1.2/1.25 L/ha dose confirm that the lower 1.2 L/ha dose rate is not sufficient to control this disease and if control of this disease is required, the maximum dose rate of 1.5 L/ha will be required.

3.2.3.5 Effectiveness of GF-3307 for the control of PYRNTR in wheat

This section addresses the effectiveness of GF-3307 for the control of PYRNTR on winter and spring wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-173 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-36 m² EPPO Maritime: 17.5-30 m ² EPPO North-East: 4.3-36 m ² (one trial at 4.3 m ²) EPPO South-East: 12-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: TRZAW (7) EPPO North-East: TRZAW (6), TRZAS (± 2) EPPO South-East: TRZAW (6)
	Varieties per crop	EPPO Maritime: Winter wheat: Akteur, Colonia, Element, Patras (2), Ritmo, Smaragd, Tobak. EPPO North-East: Winter wheat: Arkadia, Artis, Hondia, Muszelka, Zentos (3) Spring wheat: Goplana, Zebra EPPO South-East: Winter wheat: Glosa (2), Iridium, Rubisko (3)
Application	Crop stage (BBCH) at application	EPPO Maritime: 1 application (BBCH 31-51), 2 applications (One DE trial: BBCH 30-32 and BBCH 39-41) EPPO North-East: 1 application (BBCH 35-51), 2 applications (One PL trial: BBCH 31 and BBCH 43-45 used in EPPO Maritime section only) EPPO South-East: 1 application (BBCH 31-41), 2 applications (One HU trial: BBCH 32-33 and BBCH 49-51) EPPO Maritime: BBCH 31-51 EPPO North-East: BBCH 35-51 EPPO South-East: 1 application (BBCH 31-41), 2 applications (One HU trial: BBCH 32-33 and BBCH 49-51)
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In all cases PYRNTR was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 (17 trials), 2 (3 trials) EPPO Maritime: One per crop EPPO North-East: One per crop EPPO South-East: One per crop (5 trials), Two per crop (one trial)
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas

		representative of those where the crop is grown commercially and where the key target pathogen is an abundant disease. PYRNTR was assessed as a secondary pathogen present at reliable levels.
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Introduction

~~In total, data from 20 field trials are presented in this section to demonstrate the minimum effective dose of GF 3307, for the control of PYRNTR in winter and spring wheat. GF 3307 was tested at 1.5 and 1.2 L/ha. The trials were performed in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’.~~

In total, data from ~~23~~ **21** field trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTR in winter wheat (TRZAW) and spring wheat (TRZAS). To support the label claims, GF-3307 was tested at the proposed label rate of 1.5 L/ha (EPPO Maritime zone), 1.2-1.5 L/ha (EPPO North-East) and 1.2 to 1.5 L/ha in EPPO South-East trials, in accordance with the EPPO Standard PP 1/26, ‘*Foliar and ear diseases on cereals*’.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (1), the Czech Republic (~~1~~ **2**) and Germany (~~5~~ **4**) in the EPPO Maritime climatic zone, Latvia (4) and Poland (~~3~~ **4**) in the EPPO North-East climatic zone and Hungary (1) and Romania (5) in the EPPO South-East climatic zone, between 2014 and ~~2020~~ **2021**. ~~Note: One Polish trial is used to support the EPPO Maritime uses only. As this trial was based on a two-dose regime, it is not used in the EPPO North-East section.~~

On the basis of the EPPO standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these EPPO climatic zones, which is representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The MED efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-17.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PYRNTR is an abundant disease. PYRNTR is a disease which multiplies rapidly at short cycles under warm climatic conditions such as found in the EPPO Maritime, North-East and South-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 7 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6 0.72	150 180
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0-1.25	225-281
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
Input	EC	160 g/L prothioconazole + 300 g/L spiroxamine	1.0	460

Experimental details

The ~~20~~ ~~23~~ ~~21~~ efficacy trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12 m² and 36 m². ~~Nineteen~~ ~~Twenty-one~~ trials were carried out on winter wheat and ~~one~~ ~~two~~ on spring wheat. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after each application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PYRNTR or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments used were generally on Leaf 1 to Leaf 4 as the highest available assessed leaf with sufficient infection in the untreated.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, seven EPPO Maritime climatic zone trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTR in winter wheat at the proposed label rate of 1.5 L/ha, following an application applied at BBCH 31-51 of the crop. The trials were conducted in Austria (1), the Czech Republic (~~4~~ ~~2~~) and Germany (~~5~~ ~~4~~). In addition to these EPPO Maritime climatic zone trials, ~~three~~ ~~four~~ Polish trials are also included as supporting data. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product.

~~One German trial and one supporting Polish trial were based on a two dose regime (DE16E7B004UB02C and PL14E7B014AS02C), however, PYRNTR did not develop in these trials until 19-33 days after the second application. In these trial the first application was applied at BBCH 30-32 of the crop and the second application was applied at BBCH 41-45. PYRNTR did not develop until 54-56 days after the first application, demonstrating how the disease can infect crops late in their development and this is considered to be beyond the protection period, the first application of GF-3307 could be expected to deliver, particularly as the assessed leaves (Leaf 1/Leaf 2) would not have been emerged at the time of the first application. For these trials, the results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. The results from these two dose trials (77% control for the DE trial and 88.0% for the PL trial) are within the dose range of the results from the single dose trials (75.2-92.4%) and confirm the conclusion that in the absence of disease in the crop before the second application, results from these trials are comparable to a single dose regime.~~

Note: In one German trial and one supporting Polish trial, the latest assessment timing after a single application was 16-22 days. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

Across the seven EPPO Maritime climatic zone trials, GF-3307 achieved mean control of PYRNTR of ~~82.0~~ ~~83.9~~% (range 75.2-92.4%), 22-62 days after one application, compared to ~~74.7~~ ~~84.5~~% for the reference standards. In ~~five~~ ~~two~~ trials, GF-3307 was compared directly to the prothioconazole standard Proline and achieved mean control of ~~81.8~~ ~~85.4~~%, compared to mean control of ~~70.5~~ ~~89.5~~% using Proline. In ~~one~~ ~~trial~~ ~~four~~ ~~trials~~, GF-3307 was compared directly to the bixafen + prothioconazole standard Aviator Xpro, and GF-3307 achieved ~~77.5~~ ~~82.4~~% control, compared to ~~86.6~~ ~~82.1~~% control using Aviator Xpro. In one other trial, GF-3307 was compared directly to the fluxapyroxad + metconazole standard Librax, and GF-3307 achieved 87.1% control, compared to 83.9% control using Librax. Across all trials, control of PYRNTR achieved by GF-3307 was higher than or not statistically different from the standards.

In addition to these EPPO Maritime climatic zone trials, three trials from Poland are also included. As Poland is a neighbouring country to the Czech Republic and a close neighbour to Austria, it is considered that the climatic conditions are similar, and these data can be used to support use in these countries. These trials demonstrated comparable control to that seen in the EPPO Maritime climatic zone trials, at ~~86.4~~ **90.4%** control (range 79.0-92.3%) from an application applied at BBCH 35-51, compared to ~~67.5~~ **77.7%** control for the ~~prothioconazole standard~~ **Proline reference standards (Proline and Aviator Xpro)**. Combined with the seven EPPO Maritime trials results, these gave overall control of PYRNTR of ~~83.3~~ **85.9%**, across 10 trials, compared to mean control of ~~81.3~~ **82.4%**, using the reference standards.

The results are summarised in Table 3.2-1741 and the the results of the individual trials are detailed in the BAD. Results in Table 3.2-1741 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-174: Efficacy of GF-3307 applied at 1.5 L/ha for the control of PYRNTR in winter wheat (TRZAW). Results from 7 trials in the EPPO Maritime climatic zone and three PL trials, conducted between 2014-2020. Assessment at 16-62 days after one application.

EPPO-Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	7	23.8	7.8-50.8	82.0	75.2-92.4	74.7	48.0-94.5	All	2>, 3 = P, 1 = A, 1 = L
Maritime*	5	29.6	14.9-50.8	81.8	75.2-92.4	70.5	48.0-94.5	Proline#	2>, 3 = P
Maritime**	1	10.3	-	77.5	-	86.6	-	Aviator Xpro/1.25 L/ha	1 = A
Maritime***	1	7.8	-	87.1	-	83.9	-	Librax at 2.0 L/ha	1 = L
PL	3	17.6	5.0-26.3	86.4	79.0-92.3	67.5	31.5-88.0	Proline#	1>, 2 = P
Maritime + PL	10	21.9	5.0-50.8	83.3	75.2-92.4	72.6	31.5-94.5	All	3>, 5 = P, 1 = A, 1 = L

*Direct comparison to Proline (P), **Direct comparison to Aviator Xpro (A), ***Direct comparison to Librax (L)

#Reference standards used based on prothioconazole applied at 180-198 g as/ha.

Table 3.2-175: Efficacy of GF-3307 applied at 1.5 L/ha for the control of PYRNTR in winter wheat (TRZAW). Results from seven (7) trials in the EPPO Maritime climatic zone and three (3) PL trials, conducted between 2014-2021. Assessment at 16-62 days after one application.

EPPO Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	7	24.0	7.8-50.8	83.9	75.2-92.4	84.5	73.6-94.5	All	2 = P, 4 = A, 1 = L
Maritime*	2	43.5	36.3-50.8	85.4	78.4-92.4	89.5	84.4-94.5	Proline	2 = P
Maritime^	4	18.2	10.3-31.0	82.4	75.2-90.8	82.1	73.6-86.6	Aviator Xpro	4 = A
Maritime#	1	7.8	-	87.1	-	83.9	-	Librax	1 = L
PL	3	19.7	11.3-26.3	90.4	79.0-100	77.7	59.4-84.2	All	1 = P, 1 >, 1 = A
Maritime + PL	10	22.7	7.8-50.8	85.9	75.2-100	82.4	59.4-94.5	All	3 = P, 1 >, 5 = A, 1 = L

*Direct comparison to Proline (P) applied at 198 g prothioconazole/ha, **Direct comparison to Aviator Xpro (A) applied at 1.0-1.25 L/ha, #Direct comparison to Librax (L) applied at 2.0 L/ha

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the seven EPPO Maritime climatic zone trials (mean control of ~~82.0~~ **83.9%**) and three trials from Poland (mean control of ~~86.4~~ **90.4%**), demonstrating mean overall control of PYRNTR in winter

wheat of ~~83.3~~ 85.9% (across all 10 trials), it is considered that the proposed claim for control of PYRNTR is fully supported.

Proposed maximum dose of 1.5 L/ha and dose range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total ~~six~~ eight small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTR in winter and spring wheat at the proposed maximum label rate (1.5 L/ha), following a single application applied at BBCH 35-51 of the crop. The trials were conducted in Latvia (4) and Poland (~~2~~ 4) in the EPPO North-East climatic zone. ~~The data included trials where PYRNTR was established before application (including on the leaves assessed for control in some trials) and trials where PYRNTR did not develop until after application.~~ The data included trials where PYRNTR was established at low levels on lower leaves before application and trials where PYRNTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 4), so are considered to be a robust test of the product. **Note:** In two trials, the latest assessment timing after a single application was 16-20 days. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

~~Across five EPPO North East climatic zone trials on winter wheat, GF 3307 at 1.5 L/ha achieved mean control of PYRNTR of 86.4% (range 79.0-93.3%), 16-42 days after one application, compared to 73.8% control for the prothioconazole standard Proline. In three trials, GF 3307 was applied at 1.2 L/ha and achieved mean control of PYRNTR of 78.4% (range 68.1-84.1%), compared to 65.7% for the prothioconazole standard Proline.~~

Across six EPPO North-East climatic zone trials on winter wheat, GF-3307 at 1.5 L/ha achieved mean control of PYRNTR of 88.7% (range 79.0-100%), 16-42 days after one application, compared to 81.3% control for the reference standards. In four trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of 88.2%, compared to mean control of 84.4% using Proline. In two trials, GF-3307 was compared directly to the bixafen + prothioconazole standard Aviator Xpro, and achieved mean control of 89.5%, compared to mean control of 75.1% using Aviator Xpro. In four trials, GF-3307 was applied at 1.2 L/ha and achieved mean control of PYRNTR of 79.8% (range 68.1-84.2%), compared to 78.9% for the reference standards.

In addition, data from ~~five~~ six trials in neighbouring countries within the EPPO Maritime climatic zone are also considered supportive of the proposed use. These ~~five~~ six trials on winter wheat (~~one~~ two Czech trials and four German trials) demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at ~~83.8~~ 85.0% mean control (range 75.2-92.4%) at 1.5 L/ha and ~~78.6~~ 80.6% mean control (range 64.0-~~86.2~~ 90.6%) at 1.2 L/ha dose. Combined with the ~~five~~ six EPPO North-East climatic zone trials, these provide mean control of PYRNTR of ~~85.1~~ 86.8% for the 1.5 L/ha dose, across ~~10~~ 12 trials, compared to ~~74.9~~ 82.7% control from the reference standards. In ~~eight~~ 10 trials where the 1.2 L/ha was included, this achieved ~~78.5~~ 80.3% control compared to ~~84.1~~ 86.4% for the 1.5 L/ha dose and ~~72.1~~ 82.0% for the reference standards, which supports the proposed dose range of 1.2-1.5 L/ha. Details for the Czech and German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-1762 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1762 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-176: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of PYRNTR in winter wheat (TRZAW). Results from 5 trials in the EPPO North-East climatic zone plus one CZ and 4 DE trials, conducted between 2014-2020. Assessment at 16-62 days after one application

EPPO Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North-East (1.5 L/ha)	5	16.7	10.6- 26.3	-	-	86.4	79.0- 93.3	73.8	31.5- 87.1	Proline#	2>, 3=P
CZ+DE (1.2 and 1.5 L/ha)	5	28.2	7.8- 50.8	78.6	64.0- 86.2	83.8	75.2- 92.4	76.0	48.0- 94.5	AllΔ	1>, 3=P, 1 =L (both doses)
North-East +CZ+DE (1.5 L/ha)	10	22.4	7.8- 50.8	-	-	85.1	75.2- 93.3	74.9	31.5- 94.5	AllΔ	3>, 6=P; 1=L
North-East (1.2 L/ha)	3	20.6	13.8- 26.3	78.4	68.1- 84.1	84.6	79.0- 92.3	65.7	31.5- 82.9	Proline#	1>, 2=P
North-East +CZ+DE (1.2 L/ha)	8	25.3	7.8- 50.8	78.5	64.0- 86.2	84.1	75.2- 92.4	72.1	31.5- 94.5	AllΔ	2>, 5=P; 1=L

P = Proline, L = Librax

^Reference standards used based on prothioconazole applied at 180-198 g as/ha, except one trial using Librax (L) at 2.0 L/ha

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-177: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of PYRNTR in winter wheat (TRZAW). Results from six (6) trials in the EPPO North-East climatic zone plus two (2) CZ and 4 DE trials, conducted between 2014-2021. Assessment at 16-62 days after one application

EPPO Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North-East (1.5 L/ha)	6	15.8	10.6- 26.3	-	-	88.7	79.0- 100	81.3	59.4- 90.8	All#	1 >, 3 = P, 1 >, 1 = A
North-East * (1.5 L/ha)	4	15.5	10.6- 26.3	-	-	88.2	82.6- 93.3	84.4	82.6- 87.1	Proline	1 >, 3 = P
North- East^ (1.5 L/ha)	2	16.5	11.3- 21.6	76.2	68.1- 84.2	89.5	79.0- 100	75.1	59.4- 90.8	Aviator Xpro	1 >, 1 = A
CZ + DE (1.2 and 1.5 L/ha)	6	26.2	7.8- 50.8	80.6	64.0- 90.6	85.0	75.2- 92.4	84.1	73.6- 94.5	All##	2=P, 3 = A, 1 = L (Both doses)
North-East +CZ + DE (1.5 L/ha)	12	21.0	7.8- 50.8	-	-	86.8	75.2- 100	82.7	59.4- 94.5	All##	1 >, 5=P, 1 > 4 = A, 1 = L
North-East (1.2 L/ha)	4	18.3	11.3- 26.3	79.8	68.1- 84.2	88.5	79.0- 100	78.9	59.4- 84.2	All#	2 = P, 1 > 1 = A
North-East + CZ + DE (1.2 L/ha)	10	23.0	7.8- 50.8	80.3	64.0- 90.6	86.4	75.2- 100	82.0	59.4- 94.5	All##	4 = P, 1 > 4 = A, 1 = L

*Direct comparison to Proline (P) applied at 198 g prothioconazole/ha, ^Direct comparison to Aviator Xpro (A) applied at 1.0 L/ha, L = Librax applied at 2.0 L/ha

#Reference standards used based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro at 1.0 L/ha

##Reference standards used based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro at 1.0 L/ha and Librax (L) at 2.0 L/ha.

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). In this trial, the 1.5 L/ha dose of GF-3307 achieved 78.6% control of PYRNTR, compared to 72.9% for the 1.2 L/ha dose and 67.6% control for the reference Proline.

In addition to data on winter wheat, two trials were conducted on spring wheat (TRZAS). In these trials, results were comparable to winter wheat, with the 1.5 L/ha dose of GF-3307 achieving 88.3%

control of PYRNTR, compared to 80.5% for the 1.2 L/ha dose and 75.3% control for the reference Proline.

The results are summarised in Table 3.2-1783 and results of the individual trials are detailed in the BAD.

Table 3.2-178: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of PYRNTR in spring wheat (TRZAS) in 2014. Assessment at 20 days after a single application

EPPO Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR						Significantly >>,<, Standards	
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North- East	1	13.1	-	72.9	-	78.6	-	67.6	-	Proline/0.72 L/ha	1 = P (both doses)

P = Proline

Table 3.2-179: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of PYRNTR in spring wheat (TRZAS) in 2014 and 2021. Assessment at 20-31 days after a single application

EPPO Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	2	16.7	13.1-20.3	80.5	72.9-88.0	88.3	78.6-98.0	75.3	67.6-83.0	Proline	2 = P (both doses)

P = Proline

Summary and conclusions for the proposed maximum dose of 1.5 L/ha and proposed range of 1.2–1.5 L/ha in the EPPO North-East climatic zone

Based on the 10 trials on winter wheat demonstrating mean overall control of PYRNTR of 85.1% (five EPPO North-East trials at 86.4% control and five CZ/DE trials at 83.8% control) from 1.5 L/ha and one EPPO North-East climatic zone trial on spring wheat demonstrating 78.6% control of PYRNTR, it is considered that the proposed claim for control of PYRNTR on winter and spring wheat is fully supported.

Data from three EPPO North-East trials and five CZ/DE trials on winter wheat demonstrate that the 1.2 L/ha dose achieved good control of PYRNTR at 78.5%. A single Polish trial on spring wheat demonstrated 72.9% control for the 1.2 L/ha dose. Although this is a more limited dataset, it does confirm that the 1.2 L/ha dose should deliver around 80% control of PYRNTR, where PYRNTR is not the main target or in low disease pressure situations.

Based on the 12 trials on winter wheat demonstrating mean overall control of PYRNTR of 86.8% (six EPPO North-East trials at 88.7% control and six CZ/DE trials at 85.0% control) from 1.5 L/ha and two EPPO North-East climatic zone trials on spring wheat demonstrating 88.3% control of PYRNTR, it is considered that the proposed claim for control of PYRNTR on winter and spring wheat is fully supported.

Data from four EPPO North-East trials and six CZ/DE trials on winter wheat demonstrate that the 1.2 L/ha dose achieved good control of PYRNTR at 80.3%. Two North-East climatic zone trials on spring wheat demonstrated comparable control of 80.5% control for the 1.2 L/ha dose. These data confirm that the proposed 1.2 L/ha dose should deliver around 80% control of PYRNTR, where PYRNTR is not the main target or in low disease pressure situations.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in wheat to offer grower flexibility to adjust to the disease conditions. The lower dose may be used earlier in the season or where pressure from PYRNTR is lower and SEPTTR or rusts are the main target disease. The 1.5 L/ha dose should be used in higher pressure PYRNTR situations or late season when applying to control *Fusarium* on the ears.

Proposed dose of 1.2-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

Six GEP small plot field trials were conducted to demonstrate the efficacy of GF-3307, for the control of PYRNTR in winter wheat, following a single application at BBCH 31-51 of the crop. The trials were conducted in Hungary (1) and Romania (5) in the EPPO South-East climatic zone. The data is based on trials where PYRNTR did not develop until after application. These trials can therefore be considered to be a robust test of both the curative properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 3), so are considered to be a robust test of the product. One trial was based on a two-dose regime (HU14E7B014AB01C), however, PYRNTR did not develop in the trial until 25 days after the second application. In this trial the first application was applied at BBCH 32-33 of the crop and the second application was applied at BBCH 49-51. PYRNTR did not develop until 47 days after the first application, demonstrating how the disease can infect crops late in their development and this is considered to be beyond the protection period, the first application of GF-3307 could be expected to deliver, particularly as the assessed leaf (Leaf 2) would not have been emerged at the time of the first application. For this trial, the results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. The results from this two-dose trial, at 90.0% for both doses, is within the dose range of the results from the single dose trials (1.2 L/ha: 74.6-96.8% and 1.5 L/ha: 88.6-97.3%) and confirm the conclusion that in the absence of disease in the crop before the second application, results from this trial is comparable to a single dose regime.

Across three trials, GF-3307 at 1.5 L/ha achieved mean control of 92.0% (range 88.6-94.3%) against PYRNTR, compared to 86.4% for the prothioconazole standard Proline. Across all six trials, GF-3307 at 1.2 L/ha achieved mean control of 87.1% (range 74.2-96.8%) against PYRNTR, compared to 88.5% for the reference standards. Compared directly to the various standards used, GF-3307 at 1.2 L/ha achieved 81.7% control compared to 86.4% for the prothioconazole standard Proline (mean of three trials), 90.2% control compared to 87.8% for the bixafen + prothioconazole standard Aviator Xpro (mean of two trials) and 96.8% compared to 96.3% for the prothioconazole + spiroxamine standard Input (one trial).

In addition to these trials from the EPPO South-East climatic zone, data are available from Austria (1 trial), the Czech Republic (~~1 trial~~ 2 trials) and Poland (~~2~~ 3 trials), which are neighbouring countries, bordering the EPPO South-East climatic zone. These countries have conditions that favour the development of PYRNTR (warmer/wetter conditions) more than the EPPO South-East climatic zone, which is reflected in the increased levels of disease in the trials (10.3-26.3%) compared to EPPO South-East climatic zone (5.2-10.0%). It is therefore considered that results from these trials can be considered a more challenging situation for PYRNTR control and can be used to support the claims for control of this disease in this zone. Data from these ~~four~~ six trials demonstrate similar levels of effectiveness and when combined with the EPPO South-East trials give ~~87.3~~ 89.1% control of PYRNTR for the 1.5 L/ha dose, compared to ~~75.6~~ 81.5% for the reference standards (across ~~7~~ 9 trials) and ~~83.4~~ 84.1% for the 1.2 L/ha dose, compared to ~~80.1~~ 83.1% for the reference standards (across ~~10~~ 12 trials).

The results are summarised in Table 3.2-1804 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1804 are shown across all trials for each dose first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2 180: Efficacy of GF 3307 applied at 1.2 and 1.5 L/ha for the control of PYRNTR in winter wheat (TRZAW. Results from 6 trials from the EPPO South-East climatic zone, two trials from Poland, one trial from Austria and one trial from the Czech Republic, conducted between 2014 and 2020. Assessment at 16-54 days after application.

EPPO Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR							Significantly >, =, < Standards
				GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
South-East (1.5 L/ha)#	3	7.2	5.2- 10.0	81.7	74.2- 90.0	92.0	88.6- 97.3	86.4	80.0- 94.3	Proline#	3=P
AT + CZ + PL (1.2 and 1.5 L/ha)	4	18.3	10.3- 26.3	77.9	68.1- 86.1	83.7	77.5- 92.3	67.5	31.5- 86.6	All	2>, 1=P, 1 =A
CZ + PL (1.2 and 1.5 L/ha)#	3	20.9	14.9- 26.3	79.0	68.1- 86.1	85.8	79.0- 92.3	61.1	31.5- 82.9	Proline#	2>, 1=P
AT (1.2 and 1.5 L/ha)*	1	10.3	-	74.7		77.5	-	86.6	-	Aviator Xpro/1.25 L/ha	1=A
South-East +AT + CZ + PL (1.5 L/ha)	7	13.5	5.2- 26.3	79.6	68.1- 90.0	87.3	77.5- 97.3	75.6	31.5- 94.3	All	2>, 4=P, 1=A
South-East (1.2 L/ha)	6	6.7	5.2- 10.0	87.1	74.2- 96.8	-	-	88.5	80.0- 96.3	All	2<, 1=P, 1 =I, 2=A
South-East (1.2 L/ha)*	2	5.9	5.8- 6.0	90.2	88.3- 92.1	-	-	87.8	87.0- 88.6	Aviator Xpro/1.0 L/ha	2=A
South-East (1.2 L/ha)^	1	6.5	-	96.8	-	-	-	96.3	-	Input/1.0 L/ha	1=I
South-East +AT + CZ + PL (1.2 L/ha)	10	11.3	5.2- 26.3	83.4	68.1- 96.8	-	-	80.1	31.5- 96.3	All	2<, 1>, 3= P, 1=I, 3= A

#Direct comparison with Proline (P), reference standards used based on prothioconazole applied at 180-198 g as/ha

*Direct comparison with Aviator Xpro (A)

^Direct comparison with Input (I)

Table 3.2-181: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of PYRNTR in winter wheat (TRZAW. Results from 6 trials from the EPPO South-East climatic zone, three trials in Poland, one trial in Austria and two trials from the Czech Republic, conducted between 2014 and 2021. Assessment at 16-54 days after application.

EPPO Zone	Number of trials	Untreated: PYRNTR % infection		% control of PYRNTR							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
South-East (1.5 L/ha)#	3	7.2	5.2- 10.0	81.7	74.2- 90.0	92.0	88.6- 97.3	86.4	80.0- 94.3	Proline#	3 = P
AT + CZ + PL (1.2 and 1.5 L/ha)	6	16.9	10.3- 26.3	81.1	68.1- 90.6	87.6	77.5- 100	79.0	59.4- 86.6	All^	1 = P, 1 >, 4= A (both doses)
PL (1.2 and 1.5 L/ha)#	3	19.7	11.3- 26.3	78.4	68.1- 84.2	90.4	79.0- 100	77.7	59.4- 90.8	All^	1 = P, 1 >, 1= A (both doses)
AT + CZ (1.2 and 1.5 L/ha)*	3	14.0	10.3- 16.7	83.8	74.7- 90.6	84.8	77.5- 90.8	84.9	82.7- 86.6	Aviator Xpro	3 = A (both doses)
South-East +AT + CZ + PL (1.5 L/ha)	9	13.6	5.2- 26.3	81.3	68.1- 90.6	89.1	77.5- 100	81.5	59.4- 94.3	All^	4 = P, 1 >, 4= A
South-East (1.2 L/ha)	6	6.7	5.2- 10.0	87.1	74.2- 96.8	-	-	88.5	80.0- 96.3	All^^	2 <, 1 = P, 1 = I, 2 = A
South-East (1.2 L/ha)*	2	5.9	5.8- 6.0	90.2	88.3- 92.1	-	-	87.8	87.0- 88.6	Aviator	2 = A
South-East (1.2 L/ha)**	1	6.5	-	96.8	-	-	-	96.3	-	Input	1 = I
South-East +AT + CZ + PL (1.2 L/ha)	12	11.8	5.2- 26.3	84.1	68.1- 96.8	-	-	83.1	59.4- 96.3	All^^	2 <, 2 = P, 1 >, 6 = A, 1 = I

#Direct comparison with Proline (P), reference standards used based on prothioconazole applied at 180-198 g as/ha

*Direct comparison with Aviator Xpro (A) applied at 1.0-1.25 L/ha

**Direct comparison with Input (I) applied at 1.0 L/ha

^Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro at 1.0-1.25 L/ha

^^Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro at 1.0-1.25 L/ha and Input at 1.0 L/ha

Summary and conclusions for the proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on the three EPPO South-East climatic zone trials and ~~four~~ **six** trials for neighbouring countries (AT, CZ and PL) demonstrating mean overall control of PYRNTR in winter wheat of ~~87.3~~ **89.1**%, from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of PYRNTR is fully supported. Where disease levels are low, a 1.2 L/ha dose of GF-3307 will provide effective control of PYRNTR, as demonstrated by the ~~87.1~~ **84.1**% control achieved across six EPPO South-East climatic zone trials **and six trials for neighbouring countries (AT, CZ and PL)** in low disease level situations (5.2-~~10.0~~ **26.3**% PYRNTR infection in the untreated).

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.6 Effectiveness of GF-3307 for the control of ERYSGT in wheat

This section addresses the effectiveness of GF-3307 for the control of ERYSGT on winter and spring wheat, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of ~~1.2-1.5 L/ha~~ 1.0-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-1825 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226 , 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-30 m² EPPO Maritime: 16-30 m ² EPPO North-East: 15-25 m ² EPPO South-East: 20-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: TRZAW (7) EPPO North-East: TRZAW (6), TRZAS (1) EPPO South-East: TRZAW (8)
	Varieties per crop	EPPO Maritime: Winter wheat: Akteur (2), Dagmar, Princeps, Tobak (3). EPPO North-East: Winter wheat: Arkadia, Artist, Bilanz, Julius, Zyta (2) Spring wheat: Harenda EPPO South-East: Winter wheat: Balaton (2), Basilio, Cellule, GK Csillag, Miranda (2), Rubisko
Application	Crop stage (BBCH) at application	EPPO Maritime: 1 application (BBCH 32-49), 2 applications (3 CZ trials: BBCH 31-32 and BBCH 37-49) EPPO North-East: BBCH 39-49 37-55 EPPO South-East: BBCH 32-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In all cases ERYSGT was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 (13 trials), 2 (three CZ trials) EPPO Maritime: One per crop (4 trials), Two per crop (3 trials) EPPO North-East: One per crop EPPO South-East: One per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where the key target pathogen is an abundant disease. ERYSGT was assessed as a secondary pathogen present at reliable levels.

Introduction

In total, data from 17 field trials are presented in this section to demonstrate the effectiveness of GF-3307, for the control of ERYSGT in winter and spring wheat. GF-3307 was tested at 1.5 and 1.2 L/ha. The trials were performed in accordance with the EPPO standard PP 1/225 ‘Minimum effective dose’. The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in the Czech Republic (6) and Germany (1) in the EPPO Maritime climatic zone, Poland (3) in the EPPO North East climatic zone and Hungary (5) and Romania (2) in the EPPO South East climatic zone, between 2014 and 2020. The trials were conducted in the Czech Republic (6) and Germany (1) in the EPPO Maritime climatic zone, Poland (7) in the EPPO North-East climatic zone and Hungary (5) and Romania (3) in the EPPO South-East climatic zone, between 2014 and 2021.

On the basis of the EPPO standard PP 1/241 ‘Guidance on comparable climates’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these EPPO climatic zones, which is representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-18

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGT is an abundant disease. ERYSGT is a disease which multiplies rapidly at short cycles under warm climatic conditions such as found in the EPPO Maritime, North-East and South-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 8 provides an overview on the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.6	150
Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
Input	EC	160 g/L prothioconazole + 300 g/L spiroxamine	1.0	460
Zantara	EC	50 g/L bixafen + 166 g/L tebuconazole	1.0	216

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	0.9, 1.0, 1.2, 1.5	135, 150, 180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0	225

Librax	EC	62.5 g/L fluxapyroxad + 45 g/L metconazole	2.0	215
Input	EC	160 g/L prothioconazole + 300 g/L spiroxamine	1.0	460
Zantara	EC	50 g/L bixafen + 166 g/L tebuconazole	1.0	216

Experimental details

The 17 22 MED trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12 m² and 30 m². Sixteen Twenty-one trials were carried out on winter wheat and one on spring wheat. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

In the EPPO South-East and North-East climatic zone trials, GF-3307 was applied as a single application at BBCH 32-4955 of winter wheat. The treatments were typically sprayed when ERYSGT had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

The EPPO Maritime climatic zone trials were set up to support both a single and two-dose regime and in many trials included both regimes. ERYSGT is generally a late season disease, that spreads quickly during periods of hot weather. Some of the trials were targeted specifically at ERYSGT and were based on a single application from BBCH 37-49, to provide mainly curative control of the disease. However, other trials were designed as general disease trials, with the first applications potentially applied too early for effective control of ERYSGT, followed by a second application. Three Czech trials which were based on a two-dose regime (CZ15E7B010PV01C, CZ15E7B041PV01C and CZ15E7B041PV04C) and ERYSGT did not develop until 11-25 days after the second application. In these trials, the first applications were made at BBCH 31-32 of the crop and the second applications were made at BBCH 37-45. ERYSGT did not develop in these trials until 26-48 days after the first application, demonstrating how the disease can infect crops late in their development, and this is considered to be beyond the expected protection period for the first application of GF-3307 (see summary of disease levels at application for these trials below). In addition, the assessed leaf (Leaf 2 and 3) had not emerged at the time of the first application (BBCH 31-32) and would not have been protected by that spray. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. For full site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Summary of disease levels at application in two-dose trials

	1 st Application timing (BBCH)	ERYSGT % infection at 1 st application	2 nd Application timing (BBCH)	ERYSGT % infection at 2 nd application	Days after 2 nd application ERYSGT found in trial (days after 1 st application)
CZ15E7B010PV01C	32	0% all leaves	43	0% all leaves	11 days (26 days)
CZ15E7B041PV01C	31-32	3.0% L6	37-39	0% L4	18 days (44 days)
CZ15E7B041PV03C	31	0% all leaves	43-45	0% all leaves	25 days (48 days)

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after each application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with ERYSGT or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments used were generally on Leaf 1 to Leaf 3 as the highest available assessed leaf with sufficient infection in the untreated.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Seven GEP small plot field trials were conducted in order to determine the effectiveness of GF-3307, for the control of ERYSGT in wheat, following a single application, applied at BBCH 32-49 of the crop. The trials were conducted in the Czech Republic (6) and Germany (1) in the EPPO Maritime climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (mostly Leaf 3), so are considered to be a robust test of the product. Results for three CZ trials are based on a two-dose regime. In these trials ERYSGT did not develop until 11-25 days after the second application, 16-48 days after the first application, which is beyond the protection period the first application of GF-3307 could be expected to deliver. It is also considered that as the first application was at BBCH 31-32 of the crop, the assessed leaf (Leaf 3 or Leaf 3) had not emerged at this timing. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime. **Note:** In one trial, the latest assessment timing after a single application was 11 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

Across the seven EPPO Maritime climatic zone trials, GF-3307 achieved mean control of ERYSGT of 88.9% (range 64.7-100%), 11-34 days after application, compared to 84.4 92.2% for the reference standards. In ~~six~~ four trials, GF-3307 was compared directly to the prothioconazole standard Proline and achieved mean control of 92.9 93.2%, compared to mean control of 86.4 99.5% using Proline. In two trials, GF-3307 was compared directly to the bixafen + prothioconazole standard Aviator Xpro, and GF-3307 achieved 92.5% control, compared to 87.8% control using Aviator Xpro. In one trial, GF-3307 was compared directly to the fluxapyroxad + metconazole standard Librax, and GF-3307 achieved 64.7% control, compared to 72.1% control using Librax. Across all trials, control of ERYSGT achieved by GF-3307 was higher than or not statistically different from the standards.

In addition to these EPPO Maritime climatic zone trials, ~~three trials~~ six winter wheat trials from Poland are also included (~~two TRZAW and one TRZAS~~). As Poland is a neighbouring country to the Czech Republic and a close neighbour to Austria, it is considered that the climatic conditions are similar and these data can be used to support use in these countries. These trials demonstrated comparable control to that seen in the EPPO Maritime climatic zone trials, at 87.3 94.0% control (range 85.5-88.3 94.0%) from an application applied at BBCH 37-4955, compared to 87.0 90.4% control for the prothioconazole standard Proline. Combined with the seven EPPO Maritime trials results, these gave overall control of ERYSGT of 88.4 91.2%, across 10 13 trials, compared to mean control of 85.2 91.4%, using the reference standards.

The results are summarised in Table 3.2-18346 and the the results of the individual trials are detailed in the BAD. Results in Table 3.2-18346 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards/crops.

~~Table 3.2-183: Efficacy of GF-3307 applied at 1.5 L/ha for the control of ERYSGT in winter wheat (TRZAW). Results from 7 trials in the EPPO Maritime climatic zone and 3 PL trials, conducted between 2014-2020. Assessment at 11-44 days after application.~~

2014-2020: Assessment at 1-4 days after application:									
EPPO-Zone	Number of trials	Untreated: ERYSGT-% infection		% control of ERYSGT					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	7	11.5	7.9-17.0	88.9	64.7-100	84.4	46.9-100	All	2>, 4=P, 1=L
Maritime*	6	10.6	7.9-14.9	92.9	86.3-100	86.4	46.9-100	Proline#	2>, 4=P
Maritime**	1	17.0	-	64.7	-	72.1	-	Librax at 2.0 L/ha	1=L
PL	3	8.8	7.0-11.5	87.3	85.5-88.3	87.0	79.4-91.9	Proline#	3=P
PL (TRZAW)	2	7.8	7.0-8.0	88.2	88.0-88.3	90.8	89.6-91.9	Proline#	2=P

PL (TRZAS)	1	11.5	-	85.5	-	79.4	-	Proline#	1 = P
Maritime + PL	10	10.7	7.0-17.0	88.4	64.7-100	85.2	46.9-100	All	2 >, 7 = P 1 = L

*Direct comparison to Proline (P), **Direct comparison to Librax (L)

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

Table 3.2-184: Efficacy of GF-3307 applied at 1.5 L/ha for the control of ERYSGT in winter wheat (TRZAW). Results from seven (7) trials in the EPPO Maritime climatic zone and six (6) PL trials, conducted between 2014-2021. Assessment at 11-44 days after application.

EPPO Zone	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
Maritime	7	11.5	7.9-17.0	88.9	64.7-100	92.2	72.1-100	All	4 = P, 1 <, 1 = A 1 = L
Maritime*	4	9.2	7.9-14.9	93.2	86.3-100	99.5	97.9-100	Proline*	4 = P
Maritime^	2	13.4	11.9-14.9	92.5	90.4-94.6	87.8	80.2-95.3	Aviator Xpro	1 <, 1 = A
Maritime#	1	17.0	-	64.7	-	72.1	-	Librax	1 = L
PL	6	10.8	6.0-17.5	94.0	87.5-100	90.4	73.8-100	Proline	6 = P
Maritime + PL	13	11.2	6.0-17.5	91.2	64.7-100	91.4	72.1-100	All	10 = P, 1 <, 1 = A 1 = L
Maritime + PL (One application)	10	12.0	6.0-17.5	90.0	64.7-100	89.0	72.1-100	All	7 = P, 1 <, 1 = A 1 = L
Maritime* (Two applications)	3	8.3	7.9-9.0	95.4	92.5-100	99.3	97.9-100	Proline	3 = P

*Direct comparison to Proline (P) applied at 180-198 g prothioconazole/ha, ^Direct comparison to Aviator Xpro (A) applied at 1.0 L/ha, #Direct comparison to Librax (L) applied at 2.0 L/ha

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the seven EPPO Maritime climatic zone trials (mean control of 82.0%) and three trials from Poland (mean control of 86.4%), demonstrating mean overall control of ERYSGT in winter and spring wheat of 83.3% (across all 10 trials), it is considered that the proposed claim for control of ERYSGT is fully supported. Based on the seven EPPO Maritime climatic zone trials (mean control of 88.9%) and seven trials from Poland (mean control of 92.8%), demonstrating mean overall control of ERYSGT in winter and spring wheat of 90.8% (across all 14 trials), it is considered that the proposed claim for control of ERYSGT is fully supported.

Proposed dose range of 1.2-1.5 L/ha 1.0-1.5 L/ha for Poland (EPPO North-East climatic zone)

Three-Seven GEP small plot field trials were conducted in order to determine the effectiveness of GF-3307, for the control of the ERYSGT in winter wheat and spring wheat, following a single application applied at BBCH 39-49 37-55 of the crop. The trials were conducted in Poland (3 7) in the EPPO North-East climatic zone. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1, Leaf 2 or Leaf 3), so are considered to be a robust test of the product.

Across two EPPO North-East climatic zone trials on winter wheat, GF-3307 at 1.5 L/ha achieved mean control of ERYSGT of 88.2% (range 88.0-88.3%), 21-42 days after one application, compared to 88.4% for the 1.2 L/ha dose and 90.8% control for the prothioconazole standard Proline. Across six EPPO North-East climatic zone trials on winter wheat, GF-3307 at the maximum dose of 1.5 L/ha achieved mean control of ERYSGT of 94.0% (range 87.5-100%), 21-42 days after one application, compared to 89.4% for the 1.2 L/ha dose, 82.6% for the 0.9/1.0 L/ha dose and 90.4% control for the prothioconazole standard Proline.

In addition, data from four trials in neighbouring countries within the EPPO Maritime climatic zone are also considered supportive of the proposed use. These four trials on winter wheat (three Czech trials and one German trial) demonstrate 84.0% mean control at 1.5 L/ha and 75.5% mean control at 1.2 L/ha dose (across four trials) and 77.5% for the 1.0 L/ha dose (across three trials). Combined with the five EPPO North-East climatic zone trials, these provide mean control of ERYSGT of 85.4% for 1.5 L/ha dose, across six trials, compared to 79.1% control from the reference standards. In five trials where the 1.2 L/ha was applied this achieved 80.6% control compared to 85.2% for the 1.5 L/ha dose and 74.9% for the reference standards, which supports the proposed dose range of 1.2-1.5 L/ha in wheat. Details for the Czech and German trials are in the EPPO Maritime climatic zone section, above. Combined with the six EPPO North-East climatic zone trials, these provide mean control of ERYSGT of 90.0% for 1.5 L/ha dose, across 10 trials, compared to 89.0% control from the reference standards. In nine trials where the 1.2 L/ha was applied, this dose achieved 84.8% control compared to 90.4% for the 1.5 L/ha dose and 87.8% for the reference standards, In nine trials where the 0.9/1.0 L/ha was applied, this dose achieved 80.9% control compared to 92.8% for the 1.5 L/ha dose and 90.9% for the reference standards. It is considered that these data supports the proposed dose range of 1.0-1.5 L/ha in wheat. Details for the Czech and German trials are in the EPPO Maritime climatic zone section, above. The results are summarised in Table 3.2-18547 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-18547 are shown across all trials first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-185: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of ERYSGT in winter wheat (TRZAW). Results from two trials in the EPPO North-East climatic zone plus three CZ and one DE trials, conducted between 2014-2020. Assessment at 11-44 days after one application

EPPO Zone	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North-East (1.2 and 1.5 L/ha)	2	7.5	7.0- 8.0	88.4	87.1- 89.7	88.2	88.0- 88.3	90.8	89.6- 91.9	Proline#	2 = P (both doses)
CZ + DE (1.5 L/ha)	4	13.9	11.9- 17.0	-	-	84.0	64.7- 94.6	73.2	46.9- 100	AHΔ	2 >, 1 = P, 1 = L
North-East +CZ + DE (1.5 L/ha)	6	11.8	7.0- 17.0	-	-	85.4	64.7- 94.6	79.1	46.9- 100	AHΔ	2 >, 3 = P, 1 = L
CZ + DE (1.2 L/ha)	3	14.6	11.9- 17.0	75.5	64.7- 88.7	83.2	64.7- 94.6	64.3	46.9- 73.8	Proline#	2 > P, 1 = L
North-East +CZ + DE (1.2 L/ha)	5	11.8	7.0- 17.0	80.6	64.7- 89.7	85.2	64.7- 94.6	74.9	46.9- 91.9	AHΔ	2 >, 2 = P, 1 = L

P = Proline.

#Reference standards used based on prothioconazole applied at 180-198 g as/ha

^Reference standards used based on prothioconazole applied at 180-198 g as/ha and one trial where Librax (L) at 2.0 L/ha.

Table 3.2-186: Efficacy of GF-3307 applied at 0.9-1.5 L/ha for the control of ERYSGT in winter wheat (TRZAW). Results from six (6) trials in the EPPO North-East climatic zone plus three (3) CZ and one (1) DE trials, conducted between 2014-2021. Assessment at 11-44 days after one application

DE trials, conducted between 2014-2021. Assessment at 11-44 days after one application													
EPPO Zone	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT								Significantly >, =, < Standards	
				GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max		
North- East (All doses)	6	10.8	6.0- 17.5	82.6	57.5- 100	89.4	72.5- 100	94.0	87.5- 100	90.4#	73.8- 100	6 = P	
CZ + PL (All doses)	4	13.9	11.9- 17.0	77.6	71.6- 88.8	75.5	64.7- 88.7	84.0	64.7- 94.6	86.9^^	72.1- 100	1 = P, 1 = L 1 <, 1 = A	
North- East DE (1)+ CZ(3) + PL(6) (1.5 L/ha dose)	10	12.0	6.0- 17.5	-	-	-	-	90.0	64.7- 100	89.0^^	72.1- 100	7 = P, 1 = L 1 <, 1 = A	
North- East DE (1)+ CZ(2) + PL(6) (1.2 L/ha dose)	9	12.1	6.0- 17.5	-	-	84.8	64.7- 100	90.4	64.7- 100	87.8^^	72.1- 100	6 = P, 1 = L 1 <, 1 = A	
North- East(6) + CZ(3) (1.0 L/ha dose)	9	11.5	6.0- 17.5	80.9	57.5- 100	-	-	92.8	86.3- 100	90.9^	73.8- 100	7 = P, 1 <, 1 = A	

#Reference standards used based on prothioconazole (P) applied at 180-198 g as/ha

^Reference standards used based on prothioconazole (P) applied at 198 g as/ha, Aviator Xpro (A) at 1.0 L/ha and Librax (L) at 2.0 L/ha

^^Reference standards used based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro (A) at 1.0 L/ha.

In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). In this trial, the 1.5 L/ha dose of GF-3307 achieved 69.7% control of ERYSGT, compared to 85.5% for the 1.5

~~L/ha dose and 79.6% control using Proline.~~ In addition to data on winter wheat, one trial was conducted on spring wheat (TRZAS). In this trial, the 1.5 L/ha dose of GF-3307 achieved ~~69.7%~~ **85.5%** control of ERYSGT, compared to ~~85.5%~~ **69.7%** for the ~~1.5~~ **1.2** L/ha dose, ~~58.0%~~ **for the 1.0 L/ha dose** and ~~79.6%~~ **79.4%** control using Proline.

The results are summarised in Table 3.2-18748 and results of the individual trials are detailed in the BAD.

~~Table 3.2-187: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of ERYSGT in spring wheat (TRZAS) in 2020. Assessment at 28 days after a single application~~

EPPO Zone	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT							Significantly ≥, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North- East	1	11.5	-	69.7	-	85.5	-	79.4	-	Proline/0.72 L/ha	1=P (both doses)

P = Proline

Table 3.2-188: Efficacy of GF-3307 applied at 1.0-1.5 L/ha for the control of ERYSGT in spring wheat (TRZAS) in 2020. Assessment at 28 days after a single application

EPPO Zone	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT						Significantly >, =, < Standards
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline/0.72 L/ha
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean
North-East	1	11.5	-	58.0	-	69.7	-	85.5	-	79.4

P = Proline

Summary and conclusions for the proposed maximum dose of 1.5 L/ha and proposed range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Six trials on winter wheat demonstrate mean overall control of ERYSGT of 85.4% (two EPPO North-East trials at 88.2% control and four CZ/DE trials at 84.0% control) from 1.5 L/ha and one EPPO North-East climatic zone trial on spring wheat demonstrates 85.5% control of ERYSGT. In addition, the data on winter triticale in this dossier demonstrate comparable levels of control ERYSGT of 91.4% for the 1.5 L/ha dose across five EPPO North East trials (see section 3.2.3.10). It is therefore considered that the proposed claim for control of ERYSGT on winter and spring wheat is fully supported.

Data from two EPPO North East trials and three CZ/DE on winter wheat demonstrate that the 1.2 L/ha dose achieved good control of ERYSGT at 80.6%. This trend is also further supported by 5 trials from the EPPO South East (Table 3.2-189). A single Polish trial on spring wheat demonstrated 69.7% control for the 1.2 L/ha dose. Although this is a more limited data set, it does confirm that the 1.2 L/ha dose recommended for control of wheat foliar diseases should deliver around 80% control of ERYSGT, where ERYSGT is not the main target or in low disease pressure situations. Data from 5 Polish trials on winter triticale in this dossier further support this, demonstrating comparable levels of ERYSGT control of 83.7% for the 1.2 L/ha dose and 91.4% for the 1.5 L/ha dose across five EPPO North-East trials (see section 3.2.3.10).

Note: Additional EPPO North East trials are being generated on ERYSGT in 2021 and can submitted to support this claim if the current data is not considered sufficient, although data presented from 5 trials in wheat and 5 trials in triticale from this EPPO zone and 5 trials from the South East EPPO clearly support the dose range of 1.2-1.5 L/ha for control of mildew in wheat.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in wheat to offer grower flexibility to adjust to the disease conditions. The lower dose may be used earlier in the season or where pressure from ERYSGT is lower and SEPTTR and rusts are the main target disease. The 1.5 L/ha dose should be used in higher pressure situations.

Summary and conclusions for the proposed range of 1.0-1.5 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and only ERYSGT requires control, the lower dose of 1.0 L/ha is recommended. Based on data from six EPPO North-East climatic zone and three CZ trials on winter wheat using the 0.9/1.0 L/ha dose rate of GF-3307, demonstrating mean overall control of SEPTTR of 80.9%, it is considered that the proposed claim for control of ERYSGT using GF-3307 at a dose rate of 1.0 L/ha on winter wheat is fully supported.

In mixed disease situations, the 1.2 L/ha dose is recommended. Based on data from six EPPO North-East climatic zone, two CZ and one DE trials on winter wheat using the 1.2 L/ha dose rate of GF-3307, demonstrating mean overall control of ERYSGT of 84.8%, it is considered that the proposed claim for control of ERYSGT using GF-3307 at a dose rate of 1.2 L/ha on winter wheat is fully supported

In high pressure mixed disease situations (or FUSASP also present or expected) the higher dose of 1.5 L/ha may be recommended. Based on data from six EPPO North-East climatic zone, three CZ and one DE trials on winter wheat using the 1.5 L/ha dose rate, demonstrating mean overall control of ERYSGT of 90.0%, it is considered that the proposed claim for control of ERYSGT using GF-3307 at a maximum dose rate of 1.5 L/ha on winter wheat is fully supported.

Results from spring wheat were limited (one EPPO North-East climatic zone trial), however this trial demonstrated a similar dose response, which the 1.5 L/ha dose rate achieving the highest level of control (85.5%).

A dose range of 1.0-1.5 L/ha will be proposed for diseases of wheat to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

~~Seven~~ **Eight** GEP small plot field trials were conducted to demonstrate the efficacy of GF-3307, for the control of ERYSGT in winter wheat, following a single application at BBCH 32-49 of the crop. The trials were conducted in Hungary (5) and Romania (~~2~~ **3**) in the EPPO South-East climatic zone. ~~The data included trials where ERYSGT was established before application (including on the leaves assessed for control in some trials) and trials where ERYSGT did not develop until after application.~~ **The data included trials where ERYSGT was established at low levels on lower leaves before application and trials where ERYSGT did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on the highest leaf with sufficient disease levels (Leaf 1 to Leaf 3), so are considered to be a robust test of the product.

Across ~~six~~ **seven** trials, GF-3307 at 1.5 L/ha achieved mean control of ~~89.2~~ **86.9%** (range ~~83.9~~ **73.1-92.7%**) against ERYSGT, compared to ~~93.6~~ **89.3%** for the reference standards. Compared directly to the various standards used, GF-3307 at 1.5 L/ha achieved ~~91.4~~ **87.8%** control compared to ~~91.7~~ **86.0%** for the prothioconazole standard Proline (mean of ~~four~~ **five** trials) and 84.8% compared to 97.5% for the bixafen + tebuconazole standard Zantara (two trials).

Across ~~five~~ **six** trials, GF-3307 at 1.2 L/ha achieved mean control of ~~86.5~~ **83.6%** (range ~~78.9~~ **69.3-91.5%**) against ERYSGT, compared to ~~92.6~~ **87.7%** for the reference standards. Compared directly to the various standards used, GF-3307 at 1.2 L/ha achieved ~~85.2~~ **82.0%** control compared to ~~91.7~~ **86.0%** for the prothioconazole standard Proline (mean of ~~four~~ **five** trials) and 91.5% compared to 96.5% for the prothioconazole + spiroxamine standard Input (one trial).

In addition to these trials from the EPPO South-East climatic zone, data are available from the Czech Republic (three trials), which neighbours the EPPO South-East climatic zone and has similar climatic conditions that encourage the development of ERYSGT (warm/humid weather in late spring/early summer). Data from these three trials demonstrate similar levels of effectiveness (84.8% control for the 1.5 L/ha dose and 80.9% control for the 1.2 L/ha dose) and when combined with the EPPO South-East trials give ~~89.6~~ **88.0%** control of ERYSGT for the 1.5 L/ha dose, compared to ~~86.9~~ **90.0%** for the reference standards (across ~~nine~~ **10** trials) and ~~84.9~~ **82.9%** for the 1.2 L/ha dose, compared to ~~83.4~~ **87.7%** for the reference standards (across ~~seven~~ **nine** trials).

The results are summarised in Table 3.2-18949 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-18949 are shown across all trials for each dose first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-189: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of ERYSGT in winter wheat (TRZAW. Results from 7 trials in the EPPO South-East climatic zone and three from the Czech Republic, conducted between 2017 and 2020. Assessment at 11-39 days after application.

Experiment conducted between 2017 and 2020: Assessment at 11-35 days after application.											
EPPO Zone	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
South-East (1.5 L/ha)	6	17.2	12.0-25.0	-	-	89.2	83.9-92.7	93.6	87.7-98.0	All	4=P, 2=Z
South-East# (1.2 and 1.5 L/ha)	4	17.1	12.0-25.0	85.2	78.6-91.5	91.4	89.4-92.7	91.7	87.7-95.6	Proline#	4=P
South-East (1.5 L/ha)*	2	17.2	15.6-28.8	-	-	84.8	83.9-85.6	97.5	96.9-98.0	Zantara/1.0 L/ha	2=Z
CZ (1.5 L/ha)	3	12.9	11.9-14.9	-	-	90.4	86.3-94.6	73.6	46.9-100	Proline#	2>, 1=P
South-East + CZ (1.5 L/ha)	9	15.7	11.9-25.0	-	-	89.6	83.9-94.6	86.9	46.9-100	All	2>, 5=P, 2=Z
South-East (1.2 L/ha)	5	19.2	12.0-27.5	86.5	78.9-91.5	-	-	92.6	87.7-96.5	All	4=P, 1=I
South-East (1.2 L/ha)^	1	27.5	-	91.5	-	-	-	96.5	-	Input/1.0 L/ha	1=I
CZ (1.2 L/ha)#	2	13.4	11.9-14.9	80.9	73.0-88.7	-	-	60.4	46.9-73.8	Proline#	2>P
South-East + CZ (1.2 L/ha)	7	17.5	11.9-27.5	84.9	73.0-91.5	-	-	83.4	46.9-96.5	All	2>, 4=P, 1=I

#Direct comparison with Proline (P), Reference standards used based on prothioconazole applied at 180-198 g as/ha

*Direct comparison with Zantara (Z)

^Direct comparison with Input (I)

Table 3.2-190: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of ERYSGT in winter wheat (TRZAW. Results from 8 trials in the EPPO South-East climatic zone and three from the Czech Republic, conducted between 2017 and 2021. Assessment at 11-49 days after one application.

Republiec, conducted between 2017 and 2021: Assessment at 11-45 days after one application.											
EPPO Zone	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
South-East (1.5 L/ha)	7	16.2	10.5- 25.0	-	-	86.9	73.1- 92.7	89.3	63.3- 98.0	All^	1 >, 4 = P, 2 = Z
South- East# (1.2 and 1.5 L/ha)	5	15.8	10.5- 25.0	82.0	69.3- 91.5	87.8	73.1- 92.7	86.0	63.3- 95.6	Proline#	1 >, 4 = P
South-East (1.5 L/ha)*	2	17.2	15.6- 28.8	-	-	84.8	83.9- 85.6	97.5	96.9- 98.0	Zantara/1.0 L/ha	2 = Z
CZ (1.5 L/ha)	3	12.9	11.9- 14.9	-	-	90.4	86.3- 94.6	91.8	80.2- 100	All	1= P 1 <, 1 = A
South-East + CZ (1.5 L/ha)	10	15.2	10.5- 25.0	-	-	88.0	73.1- 94.6	90.0	63.3- 100	All^^	1 >, 5 = P, 2 = Z, 1 <, 1 = A
South-East (1.2 L/ha)	6	17.8	10.5- 27.5	83.6	69.3- 91.5	-	-	87.7	63.3- 96.5	All^^^	1 >, 4 = P, 1 =I
South-East	1	27.5	-	91.5	-	-	-	96.5	-	Input/1.0	1 = I

(1.2 L/ha)**										L/ha	
CZ (1.2 L/ha)***	2	13.4	11.9-14.9	80.9	73.0-88.7	-	-	87.8	80.2-95.3	Aviator Xpro /1.0 L/ha	1 <, 1 = A
South-East + CZ (1.2 L/ha)	8	16.7	10.5-27.5	82.9	69.3-91.5	-	-	87.7	63.3-96.5	All^^^^	1 >, 5 = P, 1 <, 1 = A, 1 = I

#Direct comparison with Proline (P), Reference standards used based on prothioconazole applied at 180-198 g as/ha

*Direct comparison with Zantara (Z) **Direct comparison with Input (I), ***Direct comparison with Aviator Xpro (A)

^Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Zantara at 1.0 L/ha

^^Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro at 1.0 L/ha and Zantara at 1.0 L/ha

^^^Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Input at 1.0 L/ha

^^^^Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro at 1.0 L/ha and Input at 1.0 L/ha

Summary and conclusions for the proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on the six **seven** EPPO South-East climatic zone trials and three trials for a neighbouring country (CZ) demonstrating mean overall control of ERYSGT in winter wheat of ~~89.6~~ **88.0**%, from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of ERYSGT is fully supported. Where disease levels are low, a 1.2 L/ha dose of GF-3307 will provide effective control of ERYSGT, as demonstrated by the ~~84.9~~ **82.9**% control achieved across ~~five~~ **six** EPPO South-East climatic zone trials and two Czech trials **at 1.2 L/ha**.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.7 Effectiveness of GF-3307 for the control of Puccinia on winter rye

This section addresses the efficacy of GF-3307, for the control of Puccinia on winter rye, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and in Poland (EPPO North-East climatic zone).

Table 3.2-191 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-30 m ² EPPO North-East: 24-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 12 SECCW EPPO North-East: 3 5 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Minello, Palazzo (8), Recrut, Visello (2) EPPO North-East: Bono, Brasetto, Dankowskie Diament, Kier, SU Performer
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 32-59 EPPO North-East: BBCH 37-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of Puccinia applications were timed to cover these situations from commencing when there was a risk of infection with Puccinia or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop
	Spray volumes	200-230 300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were approximately 2-3 and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia is a prevalent disease.

Introduction

In total, 15 17 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccinia on winter rye (SECCW). To support the label claims, GF-3307 was tested at the proposed label rates of 1.2 and 1.5 L/ha, in accordance with the EPPO Standard PP 1/26, 'Foliar and ear diseases on cereals'.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (12) in the EPPO Maritime climatic zone and Poland (3 5) in the EPPO North-East climatic zone, between 2015 and 2017.

On the basis of the EPPO Standard PP 1/241 'Guidance on comparable climates', the trials included

in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in countries listed in Table 3.2-19.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where Puccinia striiformis (Puccre) is a prevalent disease. Puccre is a disease which multiplies rapidly at short cycles under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 9 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.25	281

Experimental details

The ~~15~~ **17** efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 20m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and ~~230~~ **300** L/ha.

In all the trials, GF-3307 was applied as a single application at BBCH 32-59 of winter rye. The treatments were typically sprayed when Puccre had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with Puccre or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were conducted on Leaf 1 or Leaf 2 as the highest leaf or the leaf with the highest level of infection.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total 12 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccre in winter rye at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 32-59 of the crop. The trials were conducted in Germany (12) in the EPPO Maritime climatic zone between 2015 and 2017. ~~The data includes trials where Puccre was established before~~

application and trials where Puccre did not develop until after application. The data includes trials where Puccre was established at low levels on lower leaves before application and trials where Puccre did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments were conducted on Leaf 1 or Leaf 2, as the highest leaf or the leaf with the highest level of infection, so are considered to be a robust test of the product.

Across these 12 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of Puccre of 89.5% (range 82.5-100%), 33-56 days after one application, compared to 88.4% control using the reference standards. In 10 trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of 89.6%, compared to mean control of 88.1% using Proline. In two trials, GF-3307 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3307 achieved mean control of 88.8%, compared to mean control of 90.2% using Aviator Xpro. Across all trials there were no statistically significant difference between the levels of control of Puccre achieved by GF-3307 and the reference standards.

The results are summarised in Table 3.2-1921 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1921 are shown across all trials first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-1921: Efficacy of GF-3307 applied at 1.5 L/ha for the control of Puccre in winter rye (SECCW). Results from 12 trials conducted in the EPPO Maritime climatic zone between 2015 - 2017. Assessment at 33-56 days after a single application.

Assessment at 35-50 days after a single application.									
EPPO Zone	Number of trials	Untreated: PuccRE % infection		% control of PuccRE					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
Maritime	12	19.6	5.0- 74.0	89.5	82.5-100	88.4	78.7- 100	All	10 = P; 2 = A
Maritime*	10	15.5	5.0- 41.2	89.6	82.5-100	88.1	78.7- 100	Proline 275/0.72 L/ha	10 = P
Maritime**	2	40.5	7.0- 74.0	88.8	85.7- 91.9	90.2	85.7- 94.6	Aviator Xpro/1.25 L/ha	2 = A

*Direct comparison to Proline (P)

**Direct comparison to Aviator Xpro (A)

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the 12 EPPO Maritime climatic zone trials, demonstrating mean overall control of Puccre in winter rye of 89.5% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed label claim for control of Puccre is fully supported.

Proposed maximum dose of 1.5 L/ha and proposed range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, three five small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccre in winter rye, at the proposed label maximum label rate of 1.5 L/ha, following a single application applied at BBCH 37-52 of the crop. The trials were conducted in Poland (3 5) in the EPPO North-East climatic zone. The data were from trials where Puccre did not develop until after application. These trials can therefore be considered to be a robust test of the protectant properties of GF-3307. Assessments across all trials were on Leaf 1. This leaf had high levels of Puccre infection, so is considered to be a robust test of the product.

Across the three five EPPO North-East climatic zone trials, GF-3307 at 1.2 L/ha achieved mean control of Puccre of 67.4 77.4% (range 54.7-77.8-100%) and 77.1 84.7% (range 69.0-84.7-100%) using the 1.5 L/ha dose, 41-49 days after one application. Control by both dose rates was comparable to that achieved by the prothioconazole standard Proline at 73.8 83.3% (range 66.2-86.3-100%).

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. Ten trials were conducted in Germany demonstrating comparable control of Puccre of 89.6% at the 1.5 L/ha rate (range 82.5-

100%) and 83.3% control at the 1.2 L/ha rate (range 71.4-95.0%). Combined with the ~~three~~ **five** EPPO North-East climatic zone trials, these gave overall control of Puccre of ~~86.7~~ **88.0%** at the maximum 1.5 L/ha rate and ~~79.6~~ **81.3%** at the 1.2 L/ha rate, across ~~13~~ **15** trials, compared to Proline which achieved mean control of ~~84.8~~ **86.5%**. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-1932 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1932 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

~~Table 3.2-193: Efficacy of GF-3307 applied at the dose rate range of 1.2-1.5 L/ha for the control of Puccre in winter rye (SECCW). Results from 3 trials conducted in the EPPO North-East climatic zone in 2016 plus 10 DE trials conducted between 2015 and 2017. Assessment at 33-56 days after a single application~~

Application											
EPPO Zone	Number of trials	Untreated: Puccre % infection		% control of Puccre							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	3	32.8	18.1-49.1	67.4	54.7-77.8	77.1	69.0-84.7	73.8	66.2-86.3	Proline/0.72 L/ha	1.2 L/ha: 1 >, 1 =, 1 < P 1.5 L/ha: 2 >, 1 = P
DE	10	15.5	5.0-41.2	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100	Proline/0.72 L/ha	10 = P Both doses
North-East + DE	13	19.5	5.0-49.1	79.6	54.7-95.0	86.7	69.0-100	84.8	66.2-100	Proline/0.72 L/ha	1.2 L/ha: 1 >, 11 =, 1 < P 1.5 L/ha: 2 >, 11 = P

Proline = P

Table 3.2-194: Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the control of Puccre in winter rye (SECCW). Results from 5 trials conducted in the EPPO North-East climatic zone in 2016 and 2021, plus 10 DE trials conducted between 2015 and 2017. Assessment at 33-56 days after a single application

EPPO Zone	Number of trials	Untreated: PuccRE % infection		% control of PuccRE							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	5	26.2	8.8-49.1	77.4	54.7-100	84.7	69.0-100	83.3	66.2-100	Proline*	1.2 L/ha: 1 >, 3 =, 1 < P 1.5 L/ha: 2 >, 3 = P
DE	10	15.5	5.0-41.2	83.3	71.4-95.0	89.6	82.5-100	88.1	78.7-100	Proline*	10 = P Both doses
North-East + DE	15	19.0	5.0-49.1	81.3	54.7-100	88.0	69.0-100	86.5	66.2-100	Proline*	1.2 L/ha: 1 >, 13 =, 1 < P 1.5 L/ha: 2 >, 13 = P

*Proline (P) applied at 180-198 g as/ha

Summary and conclusions for maximum dose of 1.5 L/ha and proposed range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Based on the ~~three~~ **five** EPPO North-East climatic zone trials (mean control of ~~77.1~~ **84.7%**) and 10 trials from Germany (mean control of 89.6%), demonstrating mean overall control of Puccre in winter rye of ~~88.9~~ **88.9%**, from a single application of GF-3307 at 1.5 L/ha across ~~13~~ **15** trials, it is considered that the proposed claim for control of Puccre in winter triticale is fully supported.

Data from these trials demonstrate that the 1.2 L/ha dose achieved ~~79.6~~ **81.3%** of Puccre and confirm that the 1.2 L/ha dose recommended for control of other diseases on rye (RHYNSE) should

deliver good control of PUCCRE, where PUCCRE is not the main target disease or not at high pressure.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in rye to offer growers flexibility to adjust to the disease conditions.

3.2.3.8 Effectiveness of GF-3307 for the control of RHYNSE in winter rye

This section addresses the efficacy of GF-3307, for the control of RHYNSE on winter rye, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1.2-1.5 L/ha Poland (EPPO North-East climatic zone).

Table 3.2-195 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 20-30 m ² EPPO North-East: 19.6-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 10 SECCW EPPO North-East: 5 6 SECCW
	Varieties per crop (number of trials)	EPPO Maritime: Minello, Palazzo (6), Recrut, Visello (2) EPPO North-East: Bono, Brasetto , Dankowskie Diament (2), Kier, Palazzo
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 32-59 EPPO North-East: BBCH 37-59
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of RHYNSE applications were timed to cover these situations from commencing when there was a risk of infection with RHYNSE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop
	Spray volumes	200- 230 300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were conducted 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease.

Introduction

In total ~~15~~ 16 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of RHYNSE in winter rye (SECCW). To support the label claims, GF-3307 was tested at the proposed label rates of 1.2 and 1.5 L/ha, in accordance with the EPPO Standard PP 1/26, 'Foliar and ear diseases on cereals'.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (10) in the EPPO Maritime climatic zone and Poland (~~5~~ 6) in the EPPO North-East climatic zone, between 2015 and 2017.

On the basis of the EPPO Standard PP 1/241 'Guidance on comparable climates', the trials included

in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-20.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is a prevalent disease. RHYNSE is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 10 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72	180
Aviator Xpro 225EC	EC	75 g/L bixafen + 150 g/L prothioconazole	1.25	281

Experimental details

The ~~15~~ **16** efficacy trials were conducted to GEP, by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 19.6m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 ~~and 230~~ **300** L/ha.

In the all trials, GF-3307 was applied as a single application at BBCH 32-59 of winter rye. The treatments were typically sprayed when RHYNSE had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were already senesced to a high degree in both treated and untreated plots, were excluded from summarization. Assessments were conducted on Leaf 1, Leaf 2 or Leaf 3 as the highest leaf or the leaf with the highest level of infection.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, 10 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of RHYNSE in winter rye, at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 32-59 of the crop. The trials were conducted in Germany (10) in the EPPO Maritime climatic zone, between 2015 and 2017. ~~The data included trials where RHYNSE was established before application and trials where RHYNSE did not develop until after application.~~ **The data included**

trials where RHYNSE was established at low levels on lower leaves before application and trials where RHYNSE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments were on Leaf 1 or Leaf 2 (and one trial on Leaf 3), as these leaves had high levels of RHYNSE infection, so was considered to be a robust test of the product.

Across these 10 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of RHYNSE of 90.7% (range 75.0-100%), 33-56 days after one application, compared to 85.9% control by the reference standards. In eight trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of 89.9%, compared to mean control of 83.2% using Proline. In two trials, GF-3307 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro, and GF-3307 achieved mean control of 94.0%, compared to mean control of 96.5% using Aviator Xpro. Across all trials, control was statistically higher for GF-3307 or there were no statistical differences between control of RHYNSE achieved by GF-3307 and the standards.

The results are summarised in Table 3.2-1964 and the results of the individual trials are detailed the BAD. Results in Table 3.2-1964 are shown across all trials first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-1964: Efficacy of GF-3307 applied at 1.5 L/ha for the control of RHYNSE in winter rye (SECCW). Results from 10 trials conducted in the EPPO Maritime climatic zone between 2015 and 2017. Assessment at 33-56 days after a single application.

EPPO Zone	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
Maritime	10	15.7	6.8- 27.0	90.7	75.0- 100	85.9	59.3- 100	All	1 >, 7 = P, 2 = A
Maritime*	8	15.3	6.8- 27.0	89.9	75.0- 100	83.2	59.3- 100	Proline/0.72 L/ha	1 >, 7 = P
Maritime**	2	17.0	14.0- 20.0	94.0	92.9- 95.0	96.5	92.9- 100	Aviator Xpro/1.25 L/ha	2 = A

*Direct comparison to Proline (P)

**Direct comparison to Aviator Xpro (A)

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the 10 EPPO Maritime climatic zone trials, demonstrating mean overall control of RHYNSE in winter rye of 90.7%, from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed label claim for control of RHYNSE is fully supported.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, ~~five~~ **six** small plot GEP trials were conducted in the EPPO North-East climatic zone to demonstrate the efficacy of GF-3307 for the control of RHYNSE in winter rye at the proposed label rates of 1.2 L/ha and 1.5 L/ha, following a single application applied at BBCH 37-59 of the crop. The trials were conducted in Poland (~~5~~ **6**) in the EPPO North-East climatic zone. ~~The data included trials where RHYNSE was established before application (including on the leaves assessed for control in some trials) and trials where RHYNSE did not develop until after application.~~ **The data included trials where RHYNSE was established at low levels on lower leaves before application and trials where RHYNSE did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments were conducted on Leaf 1 or Leaf 2, as the highest leaf with the highest level of infection.

Across the ~~five~~ **six** EPPO North-East climatic zone trials, GF-3307 at 1.2 L/ha achieved mean control of RHYNSE of ~~76.0~~ **75.7%** (range 63.5-93.8%) and ~~81.5~~ **81.1%** (range 68.1-97.6%) using the maximum 1.5 L/ha dose, ~~35-42~~ **43** days after one application. Control by both dose rates was higher than that achieved by the prothioconazole standard Proline at ~~68.6~~ **70.7%** (range 56.0-~~77.3~~ **81.3%**).

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. Eight trials were conducted in

Germany demonstrating 89.9% control of RHYNSE at the 1.5 L/ha rate (range 75.0-100%) and 84.5% control at the 1.2 L/ha rate (range 68.2-100%). Combined with the ~~five~~ **six** EPPO North-East climatic zone trials, these gave overall control of RHYNSE of ~~87.6~~ **86.1**% at the maximum 1.5 L/ha rate and ~~81.2~~ **80.7**% at the 1.2 L/ha rate, across ~~13~~ **14** trials, compared to Proline which achieved mean control of ~~80.1~~ **77.9**%. Details for the German trials are in the EPPO Maritime climatic zone section, above. The results are summarised in Table 3.2-1975 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-1975 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-197: Efficacy of GF-3307 applied at the dose rate range of 1.2-1.5 L/ha for the control of RHYNSE in winter rye (SECCW). Results from 5 trials conducted in the EPPO North-East climatic zone in 2016 plus 6 DE trials conducted between 2015 and 2017. Assessment at 33-56 days after a single application

EPPO Zone	Number of trials	Untreated: RHYNSE-% infection		% control of RHYNSE							Significantly ≥,=,< Standards
				GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Reference-standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North- East	5	13.1	5.0- 28.4	76.0	63.5- 93.8	81.5	68.1- 97.6	68.6	56.0- 77.3	Proline/0.72 L/ha	1.2 L/ha: 1 >, 3 =, 1 < P 1.5 L/ha: 1 >, 4 = P
DE	8	15.3	6.8- 27.0	84.5	68.2- 100	89.9	75.0- 100	83.2	59.3- 100	Proline/0.72 L/ha	1.2 L/ha: 1 >, 6 = P, 1 < P 1.5 L/ha: 2 >, 7 = P
North- East+ DE	13	14.8	5.0- 28.4	81.2	63.5- 100	87.6	68.1- 100	80.1	56.0- 100	Proline/0.72 L/ha	1.2 L/ha: 2 >, 9 =, 2 < P 1.5 L/ha: 2 >, 11 = P

Proline = P

Table 3.2-198: Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the control of RHYNSE in winter rye (SECCW). Results from 6 trials conducted in the EPPO North-East climatic zone in 2016 and 2021, plus 6 DE trials conducted between 2015 and 2017. Assessment at 33-56 days after a single application

EPPO Zone	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East	6	17.6	5.0-40.0	75.7	63.5-93.8	81.1	68.1-97.6	70.7	56.0-81.3	Proline*	1.2 L/ha: 1 >, 3 =, 1 < P 1.5 L/ha: 1 >, 4 = P
DE	8	15.3	6.8-27.0	84.5	68.2-100	89.9	75.0-100	83.2	59.3-100	Proline*	1.2 L/ha: 1 >, 6 = P, 1 < P 1.5 L/ha: 2 >, 7 = P
North-East + DE	14	16.3	5.0-40.0	80.7	63.5-100	86.1	68.1-100	77.9	56.0-100	Proline*	1.2 L/ha: 2 >, 9 =, 2 < P 1.5 L/ha: 2 >, 11 = P

*Proline (P) applied at 1080-198 g as/ha

Summary and conclusions for the proposed dose rate range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and the only disease requiring control is RHYNSE, the lower dose of 1.2 L/ha provides effective control. Based on ~~five~~ **six** EPPO North-East climatic RHYNSE trials and eight trials from Germany demonstrating mean overall control of RHYNSE in winter rye of ~~81.3~~ **80.7**% from a single application of GF-3307 applied at 1.2 L/ha, it is considered that the proposed claim for control of RHYNSE at the lower dose rate of 1.2 L/ha is fully supported.

In mixed disease situations (PUCCRE also present or expected) the higher dose of 1.5 L/ha is recommended. Based on ~~five~~ **six** EPPO North-East climatic zone trials and eight trials from Germany demonstrating mean overall control of RHYNSE in winter rye of ~~87.6~~ **86.1**% from a single application of GF-3307, it is considered that the proposed claim for control of RHYNSE at a maximum dose rate of 1.5 L/ha is also fully supported.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in rye to offer growers flexibility to adjust to the disease conditions.

3.2.3.9 Effectiveness of GF-3307 for the control of SEPTSP in winter triticale

This section addresses the efficacy of GF-3307, for the control of SEPTTR and SEPTSP (often mixed populations present in triticale) on winter triticale, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and in Poland (EPPO North-East climatic zone).

Table 3.2-199 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 17.5-30 m ² EPPO North-East: 15.0-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 7 TTLWI EPPO North-East: 6 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: Adverda, Agostino (2), Aveo, Grenado, Talendro (2) EPPO North-East: Grenado (2), Magnat (2), Remiko, Tulus
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 33-51 EPPO North-East: BBCH 33-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of SEPTSP applications were timed to cover these situations from commencing when there was a risk of infection with SEPTSP or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were made at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease.

Introduction

In total, 13 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of SEPTSP in winter triticale (TTLWI). To support the label claims, GF-3307 was tested at the proposed label rates of 1.5 L/ha (EPPO Maritime climatic zone) and 1.2-1.5 L/ha (EPPO North-East climatic zone), in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (7) in the EPPO Maritime

climatic zone and Poland (6) in the EPPO North-East climatic zone, between 2015 and 2020.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates*', the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-21.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where SEPTSP is a prevalent disease. SEPTSP is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 11 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.8	200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	1.0	250

Experimental details

The 13 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 230 L/ha.

In all the trials, GF-3307 was applied as a single application, at BBCH 33-52 of winter triticale. The treatments were typically sprayed when SEPTSP had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with SEPTSP or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were on Leaf 1, Leaf 2 or Leaf 3 (one result).

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, seven small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of SEPTSP in winter triticale at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 33-51 of the crop. The trials were conducted in Germany (7) in the EPPO Maritime climatic zone, between 2015-2020. ~~The data included trials where SEPTSP was established before application (including on the leaves assessed for control in some trials) and trials where SEPTSP did not develop until after application.~~ **The data included trials where SEPTSP was established at low levels on lower leaves before application and trials where SEPTSP did not develop**

until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on either Leaf 1 or Leaf 2, as these leaves had high levels of SEPTSP infection, so was considered to be a robust test of the product. Across these seven EPPO Maritime climatic zone trials, GF-3307 achieved mean control of SEPTSP of 91.5% (range 82.3-100%), 27-50 days after one application, compared to mean control of 81.8% from the reference standards. In five trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of 90.6%, compared to mean control of 77.4% using Proline. In two trials, GF-3307 was compared directly to the tebuconazole + prothioconazole standard, Prosaro, where GF-3307 achieved mean control of 93.9%, compared to mean control of 93.0% using Prosaro. Across all trials there were no statistical differences between the levels of control of SEPTSP achieved by GF-3307 and the standards.

In addition to these trials, data from neighbouring countries in the EPPO North-East climatic zone are available and can also be considered supportive of the proposed use. The six trials conducted in Poland demonstrated comparable control to that seen in the EPPO Maritime climatic zone trials, at 85.9% (range 76.0-100%). Combined with the seven EPPO Maritime trials results, these gave overall control of SEPTSP of 88.9%, across 13 trials, compared to mean control of 81.3%, using the reference standards. Details for the Polish trials are in the EPPO North-East climatic zone section, below.

The results are summarised in Table 3.2-20057 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-20057 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-20057: Efficacy of GF-3307 applied at 1.5 L/ha for the control of SEPTSP in winter triticale (TTLWI). Results from 7 trials in the EPPO Maritime climatic zone and 6 trials in PL, conducted between 2015 and 2020. Assessment at 21-50 days after a single application.

EPPO Zone/ Country	Number of trials	Untreated: SEPTSP % infection		% control of SEPTSP					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
Maritime	7	21.7	5.8- 47.5	91.5	82.3-100	81.8	63.4- 100	All	5 = P, 2 = PO
Maritime*	5	26.4	7.8- 47.5	90.6	82.3-100	77.4	63.4- 96.9	Proline/0.72 L/ha	5 = P
Maritime**	2	10.1	5.8- 14.3	93.9	87.7-100	93.0	56.0- 100	Prosaro/1.0 L/ha	2 = PO
PL	6	15.3	7.0- 33.8	85.9	76.0-100	80.6	58.3- 100	All	2>, 2= P, 2 = PO
PL*	4	19.1	8.9- 33.8	82.4	76.0- 94.2	73.8	58.3- 86.5	Proline/0.72 L/ha	2>, 2= P
PL**	2	7.8	7.0-8.6	92.9	85.8-100	94.2	88.4- 100	Prosaro/1.0 L/ha	2 = PO
Maritime + PL	13	18.8	5.8- 47.5	88.9	76.0-100	81.2	58.3- 100	All	1>, 8= P, 4 =PO

*Direct comparison to Proline (P)

**Direct comparison to Prosaro (PO)

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the seven EPPO Maritime climatic zone trials (mean control of 91.5%) and six trials from Poland (mean control of 85.9%), demonstrating mean overall control of SEPTSP in winter triticale of 88.9% (across all 13 trials), from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of SEPTSP is fully supported.

In addition, data on wheat in section 3.2.3.1 also demonstrate effective control of SEPTTR (92.7%) across 13 EPPO Maritime climatic zone trials and are considered to support this proposed claim/use on triticale.

Proposed maximum dose of 1.5 L/ha and proposed range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, six small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of SEPTSP in winter triticale, at the proposed maximum label rate of 1.5 L/ha, following a single application applied at BBCH 33-52 of the crop. The trials were conducted in Poland (6) in the EPPO North-East climatic zone. The data included trials where SEPTSP was established **at low levels on lower leaves** before application and trials where SEPTSP did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on Leaf 1, Leaf 2 or Leaf 3, as this leaf had high levels of SEPTSP infection, so was considered to be a robust test of the product.

Across all six EPPO North-East climatic zone trials, GF-3307 at the maximum dose rate of 1.5 L/ha achieved mean control of SEPTSP of 85.9% (range 76.0-100%), 21-43 days after one application. Control was higher than that achieved by the prothioconazole standard Proline at 80.6% (range 58.3-100%). In three EPPO North-East climatic zone trials, GF-3307 at the lower dose rate of 1.2 L/ha achieved mean control of SEPTSP of 72.3% (range 68.6-74.5%).

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. At the 1.5 L/ha dose rate of GF-3307, seven trials were conducted in Germany and demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at 91.5% (range 82.3-100%). Combined with the six EPPO North-East climatic zone trials, these gave overall control of SEPTSP of 88.9%, across 13 trials, using the 1.5 L/ha dose rate of GF-3307, compared to 81.2% using the reference standards. At the 1.2 L/ha dose rate of GF-3307, four trials were conducted in Germany, achieving mean control of 75.1% (range 69.2-90.3%). Combined with the three EPPO North-East climatic zone trials, these gave overall control of SEPTSP of 73.9%, across seven trials, at the 1.2 L/ha dose rate, compared to 73.3% control using the reference standards. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-20158 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-20158 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-201: Efficacy of GF-3307 applied at the dose rate range of 1.2-1.5 L/ha for the control of SEPTSP in winter triticale (TTLWI). Results from 6 trials in the EPPO North-East climatic zone and 7 trials in DE, conducted between 2015 and 2020. Assessment at 21-50 days after a single application.

EPPO Zone/ Country	Number of trials	Untreated: SEPTSP % infection		% control of SEPTSP							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
North-East (1.5 L/ha)	6	15.3	7.0- 33.8	-	-	85.9	76.0-100	80.6	58.3- 100	All	2>, 2= P, 2 = PO
North-East* (1.5 L/ha)	4	19.1	8.9- 33.8	-	-	82.4	76.0- 94.2	73.8	58.3- 86.5	Proline/0.72 L/ha	2>, 2= P
North-East** (1.5 L/ha)	2	7.8	7.0-8.6	-	-	92.9	85.8-100	94.2	88.4- 100	Prosaro/1.0 L/ha	2 = PO
DE (1.5 L/ha)	7	21.7	5.8- 47.5	-	-	91.5	82.3-100	81.8	63.4- 100	All	5 = P 2 = PO
DE* (1.5 L/ha)	5	26.4	7.8- 47.5	-	-	90.6	82.3-100	77.4	63.4- 96.9	Proline/0.72 L/ha	5 = P
DE** (1.5 L/ha)	2	10.1	5.8- 14.3	-	-	93.9	87.7-100	93.0	56.0- 100	Prosaro/1.0 L/ha	2 = PO
North-East + DE (1.5 L/ha)	13	18.8	5.8- 47.5	-	-	88.9	76.0-100	81.2	58.3- 100	All	1>, 8= P 4 =PO
North-East (1.2 L/ha)	3	17.9	8.9- 33.8	72.3	68.6- 74.5	78.4	76.0- 81.6	74.3	58.3- 86.5	Proline/0.72 L/ha	1>, 1=, 1 < P
DE (1.2 L/ha)	4	25.0	7.8- 47.5	75.1	69.2- 90.3	88.2	82.3-100	72.5	63.4- 87.1	Proline/0.72 L/ha	4 = P
North-East + DE (1.2 L/ha)	7	22.0	7.8- 47.5	73.9	68.6- 90.3	84.0	76.0-100	73.3	58.3- 87.1	Proline/0.72 L/ha	1>, 5=, 1 < P

*Direct comparison to Proline (P)

** Direct comparison to Prosaro (PO)

Summary and conclusions for maximum dose of 1.5 L/ha and proposed range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Based on the six EPPO North-East climatic zone trials (mean control of 85.9%) and seven trials from Germany (mean control of 91.5%), demonstrating mean overall control of SEPTSP in winter triticales of 88.9% across 13 trials, from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of SEPTSP in winter triticales is fully supported.

Data from three Polish and four German trials demonstrate that the 1.2 L/ha dose achieved 73.9% control of SEPTSP. Although this is a more limited dataset, it does confirm that the 1.2 L/ha dose recommended for control of other diseases on triticales should deliver reasonable control of SEPTSP, where SEPTSP is not the main target.

In addition, data on wheat in section 3.2.3.1 also demonstrate effective control of SEPTTR (92.6% control for the 1.5 L/ha dose and 86.2% control for the 1.2 L/ha dose) across 12/11 EPPO North-East climatic zone trials and are considered to support this proposed claim/use on triticales.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in triticales to offer growers flexibility to adjust to the disease conditions.

3.2.3.10 Effectiveness of GF-3307 for the control of ERYSGT in winter triticale

This section addresses the efficacy of GF-3307, for the control of ERYSGT on winter triticale, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone).

Table 3.2-202 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 17.5-30 m ² EPPO North-East: 15.0-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: § 4 TTLWI EPPO North-East: § 6 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: Agostino, Aveo, Cedrico, Gernado, Talentro EPPO North-East: Grenado (2), Magnat, Remiko (2)
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 33-49 (single application), BBCH 32-33 and BBCH 41-49 in one DE trial. EPPO North-East: BBCH 33-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of ERYSGT applications were timed to cover these situations from commencing when there was a risk of infection with ERYSGT or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 (9 trials), 2 (1 DE trial) EPPO Maritime: one per crop EPPO North-East: one per crop
	Spray volumes	150-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were made at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGT is a prevalent disease.

Introduction

In total, 10 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of ERYSGT in winter triticale (TTLWI). To support the label claims, GF-3307 was tested at the proposed label rates of 1.5 L/ha (EPPO Maritime climatic zone) and 1.2-1.5 L/ha (EPPO North-East climatic zone), in accordance with the EPPO Standard PP 1/26, 'Foliar and ear diseases on cereals'. The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (§ 4) in the EPPO Maritime

climatic zone and Poland (§ 6) in the EPPO North-East climatic zone, between 2015 and ~~2020~~ 2021. On the basis of the EPPO Standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-22.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGT is a prevalent disease. ERYSGT is a disease which multiplies rapidly, at short cycles, under warm climatic conditions, such as are found in the Maritime and North-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 12 provides an overview of the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.72-0.8	180-200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	1.0	250
Wirtuoz 520 EC in sequence with Artea	EC	320 g/L prochloraz + 160 g/L tebuconazole + 40 g/L proquinazid	1.0	520
	EC	80 g/L cyproconazole + 250 g/L propiconazole	0.5	165

Experimental details

The 10 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 150 and 300 L/ha.

In all the trials, GF-3307 was applied at BBCH 33-49 of winter triticale. The treatments were typically sprayed when ERYSGT had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with ERYSGT or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were on Leaf 1, Leaf 2, Leaf 3 or the whole plant.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, five **four** small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of ERYSGT in winter triticale at the proposed label rate of 1.5 L/ha, following an application applied at BBCH 33-49 of the crop. The trials were conducted in Germany (5 **4**) in the EPPO Maritime climatic zone, between 2015 and 2020. ~~The data included trials where ERYSGT was established before application (including on the leaves assessed for control in some trials) and trials where ERYSGT did not develop until after application.~~ **The data included trials where ERYSGT was established at low levels on lower leaves before application and trials where ERYSGT did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across the majority of trials were on either Leaf 2 or Leaf 3 as these leaves had high levels of ERYSGT infection, so was considered to be a robust test of the product. Assessment in one trial was on the whole plant. **Note:** In one trial only a 14 day assessment is available for ERYSGT, as the disease was not found at later assessments.

~~Results for one trial were based on a two application regime (EA20F9B007F DPE012). In this trial, the first application was applied at BBCH 32-33 of the crop. However, ERYSGT did not develop in this trial until the timing of second application (23 days after the first application) and only at a low level at the bottom of the plant (0.5% on Leaf 4). As the assessed leaf (Leaf 2) would not have been emerged at the time of the first application, it is considered that would have not been protected by the application. It is therefore considered that control of ERYSGT after two applications is comparable to a single application dose regime, so has been included.~~

Across these **five four** EPPO Maritime climatic zone trials, GF-3307 achieved mean control of ERYSGT of ~~86.7~~ **83.4%** (range 65.3-100%), 14-43 days after application, compared to mean control of ~~82.1~~ **77.7%** from the reference standards. In two trials, GF-3307 was compared directly to the prothioconazole standard Proline, and both products achieved mean control of 85.1%. In ~~three~~ **two** trials, GF-3307 was compared directly to the tebuconazole + prothioconazole standard, Prosaro, where GF-3307 achieved mean control of ~~87.8~~ **81.8%**, compared to mean control of ~~80.1~~ **70.2%** using Prosaro. Across all trials there were no statistical differences between the levels of control of ERYSGT achieved by GF-3307 and the standards.

In addition to these trials, data from neighbouring countries in the EPPO North-East climatic zone are available and can also be considered supportive of the proposed use. The **five six** trials conducted in Poland demonstrated comparable control to that seen in the EPPO Maritime climatic zone trials, at ~~91.4~~ **91.8%** (range 65.5-99.3%). Combined with the **five four** EPPO Maritime trials results, these gave overall control of ERYSGT of ~~89.1~~ **88.4%**, across 10 trials, compared to mean control of ~~86.9~~ **85.4%**, using the reference standards. Details for the Polish trials are in the EPPO North-East climatic zone section, below.

The results are summarised in Table 3.2-2030 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-2030 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

~~Table 3.2-203: Efficacy of GF-3307 applied at 1.5 L/ha for the control of ERYSGT in winter triticale (TTLWI). Results from 5 trials in the EPPO Maritime climatic zone and 5 PL trials, conducted between 2015 and 2020. Assessment at 14-43 days after application.~~

EPPO Zone/ Country	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT					Significantly >,<= Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
Maritime	5	19.3	5.0- 36.3	86.7	63.5- 100	82.1	40.4- 100	All	2=P, 3=PO
Maritime [±]	2	35.2	34.1- 36.3	85.1	84.885.3	85.1	79.3- 90.9	Proline/0.72 L/ha	2=P
Maritime ^{±±}	3	8.8	5.0- 13.0	87.8	63.5- 100	80.1	40.4- 100	Prosaro/1.0 L/ha	3=PO
PL	5	14.9	7.8	91.4	65.5	91.7	70.3	All	4=P, 1=W/A

			29.4		99.3		100		
PL*	4	15.5	7.8- 29.4	89.4	65.5- 99.3	89.7	70.3- 99.3	Proline/0.72 L/ha	4 = P
PL#	1	12.8	-	99.2	-	100	-	Wirtuoz + Artea#	1 = W/A
Maritime + PL	10	17.1	5.0- 36.3	89.1	63.5- 100	86.9	40.4- 100	All	6 = P, 3 = PO, 1 = W/A

*Direct comparison to Proline (P)

**Direct comparison to Prosaro (PO)

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha (W/A)

Table 3.2-204: Efficacy of GF-3307 applied at 1.5 L/ha for the control of ERYSGT in winter triticale (TTLWI). Results from four trials in the EPPO Maritime climatic zone and six PL trials, conducted between 2015 and 2021. Assessment at 14-43 days after application.

EPPO Zone/ Country	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
Maritime	4	22.1	5.0- 36.3	83.4	63.5- 100	77.7	40.4- 100	All	2 = P, 2 = PO
Maritime*	2	35.2	34.1- 36.3	85.1	84.885.3	85.1	79.3- 90.9	Proline	2 = P
Maritime^	2	9.0	5.0- 13.0	81.8	63.5- 100	70.2	40.4- 100	Prosaro	2 = PO
PL	6	14.9	7.8- 31.9	91.8	65.5- 99.3	90.6	70.3- 100	All	1 >, 4 = P, 1 = W/A
PL*	5	15.5	7.8- 31.9	90.3	65.5- 99.3	88.8	70.3- 99.3	Proline	1 >, 4 = P
PL#	1	12.8	-	99.2	-	100	-	Wirtuoz + Artea#	1 = W/A
Maritime + PL	10	19.5	5.0- 36.3	88.4	63.5- 100	85.4	40.4- 100	All	1 >, 6 = P, 2 = PO, 1 = W/A

*Direct comparison to Proline (P) applied at 180-200 g as/ha

^Direct comparison to Prosaro (PO) applied at 1.0 L/ha

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha (W/A)

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on the ~~five~~ **four** EPPO Maritime climatic zone trials (mean control of ~~86.7~~ **83.4%**) and ~~five~~ **six** trials from Poland (mean control of ~~91.4~~ **91.8%**), demonstrating mean overall control of ERYSGT in winter triticale of ~~89.1~~ **88.4%** (10 trials), from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of ERYSGT is fully supported.

In addition, data on wheat in section 3.2.3.6 also demonstrate effective control of ERYSGT (88.9%) across seven EPPO Maritime climatic zone trials and are considered to support this proposed claim/use on triticale.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, ~~five~~ **six** small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of ERYSGT in winter triticale, at the proposed label rates of 1.2 L/ha and 1.5 L/ha, following a single application applied at BBCH 33-49 of the crop. The trials were conducted in Poland (~~5~~ **6**) in the EPPO North-East climatic zone. ~~The data included trials where ERYSGT was established before application and trials where ERYSGT did not develop until after application.~~ **The data included trials where ERYSGT was established at low levels on lower leaves before application and trials where ERYSGT did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on Leaf 1 or leaf 2, as this leaf had high levels of ERYSGT infection, so was considered to be a robust test of the product.

Across all ~~five~~ **six** EPPO North-East climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of ERYSGT of ~~91.4~~ **91.8%** (range 65.5-99.3%) and mean control of ~~83.7~~ **84.2%** (range 59.1-96.1%) using the 1.2 L/ha dose, ~~27-34~~ **42** days after one application. Control by the maximum dose rate was

comparable to that achieved by the ~~prothioconazole standard Proline~~ at 91.7% ~~reference standards~~ (Proline at 180-200 g as/ha and Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha), at 90.6% (range 70.3-100%).

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. At the 1.5 L/ha dose rate of GF-3307, four trials were conducted in Germany based on a single dose of GF-3307 and demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at 89.1% (range 63.5-100%). Combined with the ~~five~~ **six** EPPO North-East climatic zone trials, these gave overall control of ERYSGT of ~~87.8~~ **88.4**%, across ~~nine~~ **10** trials, using the 1.5 L/ha dose rate of GF-3307, compared to ~~85.5~~ **85.4** % using the reference standards. At the 1.2 L/ha dose rate of GF-3307, one trial was conducted in Germany, achieving control of 86.2%. Combined with the ~~five~~ **six** EPPO North-East climatic zone trials, these gave overall control of ERYSGT of ~~84.2~~ **84.5**%, across ~~six~~ **seven** trials, at the 1.2 L/ha dose rate, compared to ~~91.6~~ **90.7**% control using the reference standards. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-2051 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-2051 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards.

Table 3.2-205: Efficacy of GF-3307 applied at the dose rate range of 1.2-1.5 L/ha for the control of ERYSGT in winter triticale (TTLWI). Results from 5 trials in the EPPO North-East climatic zone and 4 DE trials, conducted between 2015 and 2020. Assessment at 14-43 days after a single application.

EPPO Zone/ Country	Number of trials	Untreated: ERYSGT % infection		% control of ERYSGT							Significantl y > , = , < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference-standard			
		Mea n	min- max	Mea n	min- max	Mea n	min- max	Mea n	min- max	Product/dos e	
North-East*	5	14.9	7.8-29.4	83.7	59.1-96.1	91.4	65.5-99.3	91.7	70.3-100	All	4=P, 1=W
North-East*	4	15.5	7.8-29.4	80.7	59.1-91.5	89.4	65.5-99.3	89.7	70.3-99.3	Proline/0.72 L/ha	4=P
North-East#	1	12.8	-	96.1	-	99.2	-	100	-	Wirtuoz + Artea#	1=W/A
DE (1.5 L/ha)	4	22.1	5.0-36.3	-	-	89.1	63.5-100	86.9	40.4-100	All	
DE (1.5 L/ha)*	2	35.2	34.1-36.3	-	-	85.1	84.885.3	85.1	79.3-90.9	Proline/0.72 L/ha	2=P
DE (1.5 L/ha)**	2	9.0	5.0-13.0	-	-	81.8	63.5-100	77.7	40.4-100	Prosaro/1.0 L/ha	2=PO
DE (1.2 L/ha)	1	34.1	-	86.2	-	85.3	-	90.9	-	Proline/0.72 L/ha	1=P
North-East + DE (1.5 L/ha)	9	18.1	5.0-36.3	-	-	87.8	63.5-100	85.5	40.4-100	All	6=P, 2=PO, 1=W/A
North-East + DE (1.2 L/ha)	6	18.1	7.8-34.1	84.2	59.1-96.1	90.4	65.5-99.3	91.6	70.3-100	All	5=P, 1<W/A

*Direct comparison to Proline (P)

**Direct comparison to Prosaro (PO)

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha (W/A)

Table 3.2-206: Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the control of ERYSGT in winter triticale (TTLWI). Results from six trials in the EPPO North-East climatic zone and 4 DE trials, conducted between 2015 and 2021. Assessment at 14-43 days after a single application.

Conducted between 2015 and 2021. Assessment at 14-45 days after a single application.											
EPPO Zone/ Countr y	Nume r of trials	Untreated: ERYSGT % infection		% control of ERYSGT							Significantl y >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mea n	min- max	Mea n	min- max	Mea n	min- max	Mea n	min- max	Product/dos e	
North- East*	6	14.9	7.8- 31.9	84.2	59.1 - 96.1	91.8	65.5- 99.3	90.6	70.3 -100	All	1 >, 4 = P, 1 = W
North- East*	5	15.5	7.8- 31.9	81.8	59.1 - 91.5	90.3	65.5- 99.3	88.8	70.3 - 99.3	Proline	1 >, 4 = P
North- East#	1	12.8	-	96.1	-	99.2	-	100	-	Wirtuoz + Arteas#	1 = W/A
DE (1.5 L/ha)	4	22.1	5.0- 36.3	-	-	89.1	63.5- 100	86.9	40.4 -100	All	
DE (1.5 L/ha)*	2	35.2	34.1 - 36.3	-	-	85.1	84.885. 3	85.1	79.3 - 90.9	Proline	2 = P
DE (1.5 L/ha)**	2	9.0	5.0- 13.0	-	-	81.8	63.5- 100	77.7	40.4 -100	Prosaro	2 = PO
DE (1.2 L/ha)	1	34.1	-	86.2	-	85.3	-	90.9	-	Proline	1 = P
North- East + DE (1.5 L/ha)	10	19.5	5.0- 36.3	-	-	88.4	63.5- 100	85.4	40.4 -100	All	1 >, 6 = P, 2 = PO, 1 = W/A
North- East + DE (1.2 L/ha)	7	20.1	7.8- 34.1	84.5	59.1 - 96.1	90.9	65.5- 99.3	90.7	70.3 -100	All	6 = P, 1< W/A

*Direct comparison to Proline (P) applied at 180-200 g as/ha

^Direct comparison to Prosaro (PO) at 1.0 L/ha.

Summary and conclusions for the proposed rate range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and only control of ERYSGT is required, the lower dose of 1.2 L/ha is considered sufficient. ~~Five~~ **Six** EPPO North-East climatic zone trials (mean control of ~~83.7~~ **84.2**%) and one trial from Germany (86.2%) at this dose rate, demonstrated mean overall control of ERYSGT in winter triticale of ~~84.2~~ **84.5**% from a single application of GF-3307. Based on these triticale trials and supported by data from two EPPO North-East climatic zone trials on winter wheat, which achieved comparable mean control of 88.4% of ERYSGT using the 1.2 L/ha dose, it is considered that the proposed claim for control of ERYSGT, at a dose rate of 1.2 L/ha in winter triticale, is supported.

In mixed disease situations where ERYSGT and other diseases such as SEPTSP occur, the higher dose of 1.5 L/ha is recommended. Based on ~~five~~ **six** EPPO North-East climatic zone trials (mean control of ~~91.4~~ **91.8**%) and four trials from Germany (mean control of 89.1%) at this dose rate, demonstrated mean overall control of ERYSGT in winter triticale of ~~87.8~~ **88.4**%, from a single application of GF-3307, it is considered that the proposed claim for control of ERYSGT, at a dose rate of 1.5 L/ha in winter triticale, is fully supported.

In addition, data on wheat in section 3.2.3.6 also demonstrate effective control of ERYSGT (94.0% control for the 1.5 L/ha dose and 89.4% control for the 1.2 L/ha dose) across six EPPO North-East climatic zone trials and are considered to support this proposed claim/use on triticale.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in triticale to offer growers flexibility to adjust to the disease conditions.

3.2.3.11 Effectiveness of GF-3307 for the control of PuccST in winter triticale

This section addresses the efficacy of GF-3307, for the control of PuccST on winter triticale, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone and 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone).

Table 3.2-207 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO Maritime: 18-25 m ² EPPO North-East: 25-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: 10 TTLWI EPPO North-East: 8 TTLWI
	Varieties per crop (number of trials)	EPPO Maritime: KWS Avea, SU Agendus (2), Talento (2), Talendro, Tender (4) EPPO North-East: Grenado (2), Magnat (3), Trismart, Twingo, Witon
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 37-51 EPPO North-East: BBCH 33-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of PuccST applications were timed to cover these situations from commencing when there was a risk of infection with PuccST or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: One per crop EPPO North-East: One per crop
	Spray volumes	200-230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were made at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PuccST is a prevalent disease.

Introduction

In total, 18 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of PuccST in winter triticale (TTLWI). To support the label claims, GF-3307 was tested at the proposed label rates of 1.2 L/ha and 1.5 L/ha, in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Germany (10) in the EPPO Maritime climatic zone and Poland (8) in the EPPO North-East climatic zone, between 2015 and 2020.

On the basis of the EPPO Standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from both of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-23.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where Puccst is a prevalent disease. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 13 provides an overview of the geographical distribution of the MED trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline 275	EC	275 g/L prothioconazole	0.72	198
Proline 250	EC	250 g/L prothioconazole	0.8	200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	1.0	250

Experimental details

The 18 efficacy trials were conducted to GEP and followed the appropriate EPPO standards, by officially recognized efficacy testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 18m² and 30m². The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers, equipped with conventional or low drift flat fan nozzles, delivering water volumes between 200 and 230 L/ha.

In all the trials, GF-3307 was applied as a single application at BBCH 33-52 of winter triticale. The treatments were typically sprayed when Puccst had established on the lower leaves, to stop the disease from further development. For further site and application details of individual trials, see Appendix 3 and Appendix 4 of the BAD.

Assessments for efficacy (% infection) were conducted approximately 2-3 weeks and 4-6 weeks after application and/or at BBCH 75. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with Puccst or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were on either Leaf 1 or Leaf 2.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, 10 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccst in winter triticale at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 35-51 of the crop. The trials were conducted in Germany (10) in the EPPO Maritime climatic zone between 2015-2020. ~~The data included trials where Puccst was established before application (including on the leaves assessed for control in some trials) and trials where Puccst did not develop until after application.~~ **The data included trials where Puccst was established at low levels on lower leaves before application and trials where Puccst did not develop**

until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on either Leaf 1 or Leaf 2, as these leaves had high levels of Puccst infection, so was considered to be a robust test of the product. **Note:** In one trial only a 17 day assessment is available for Puccst, as the disease was not found at levels >5.0% at later assessments.

Across these 10 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of Puccst of 90.0% (range 81.8-100%), 17-53 days after one application, compared to mean control of 89.7% from the reference standards. In nine trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of 89.1% compared to mean control of 88.8% using Proline. In one trial, GF-3307 was compared directly to the tebuconazole + prothioconazole standard, Prosaro and both products achieved 98.1% control. Across all trials, control of Puccst achieved by GF-3307 was not statistically different from the standards.

The results are summarised in Table 3.2-2083 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-2083 are shown across all trials first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-2083: Efficacy of GF-3307 applied at 1.5 L/ha for the control of Puccst in winter triticale (TTLWI). Results from 10 trials conducted in the EPPO Maritime zone between 2015 and 2020.

Assessment at 17-53 days after a single application.

Assessment at 17-25 days after a single application.									
EPPO Zone/ Country	Number of trials	Untreated: PuccST % infection		% control of PuccST					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min- max	Product/dose	
Maritime	10	37.0	6.0- 96.5	90.0	81.8- 100	89.7	73.9- 100	All	9 = P, 1 = PO
Maritime*	9	35.1	6.0- 96.5	89.1	81.8- 100	88.8	73.9- 100	Proline/0.72 L/ha	9 = P
Maritime**	1	53.8	-	98.1	-	98.1	-	Prosaro/1.0 L/ha	1 = PO

**Direct comparison to Proline (P) applied at 198-200 g as/ha

**Direct comparison to Prosaro (PO)

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on 10 EPPO Maritime climatic zone trials demonstrating mean overall control of Puccst in winter triticale of 90.0% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of Puccst in winter triticale is fully supported.

In addition, data on wheat in section 3.2.3.3 also demonstrate effective control of Puccst (93.6%) across 11 EPPO Maritime climatic zone trials and are considered to support this proposed claim/use on triticale.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, eight small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of Puccst in winter triticale at the proposed label rates of 1.2 L/ha and 1.5 L/ha, following a single application applied at BBCH 33-52 of the crop. The trials were conducted in Poland (8) in the EPPO North-East climatic zone. The data includes trials where Puccst was established at low levels on lower leaves before application and trials where Puccst did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments across all trials were on either Leaf 1 or Leaf 2, as these leaves had high levels of Puccst infection, so were considered to be a robust test of the product.

Across the eight EPPO North-East climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of Puccst of 89.5% (range 82.4-96.0%), 38-45 days after one application. In six trials, GF-3307 was compared directly to the prothioconazole standard Proline, and achieved mean control of 90.0% compared to mean control of 55.9% using Proline. In two trials, GF-3307 was compared directly to the tebuconazole + prothioconazole standard, Prosaro, where GF-3307 achieved control of 87.9%, compared to 84.6% from Prosaro. Across all trials, control of Puccst achieved by GF-3307 was higher than or not statistically different from the standards. In three EPPO North-East climatic zone

trials, GF-3307 at 1.2 L/ha achieved mean control of PuccST of 76.4% (range 73.9-79.0%), which was higher than that achieved by the prothioconazole standard Proline, at 55.9%.

In addition to these trials, data from neighbouring countries in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed use. At the 1.5 L/ha dose rate of GF-3307, eight trials were conducted in Germany based on a single dose of GF-3307 and demonstrated comparable control to that seen in the EPPO North-East climatic zone trials, at 88.5% (range 81.8-100%). Combined with the eight EPPO North-East climatic zone trials, these gave overall control of PuccST of 89.0%, across 16 trials, using the 1.5 L/ha dose rate of GF-3307, compared to 75.9% using the reference standards. At the 1.2 L/ha dose rate of GF-3307, these German trials achieved 85.0% control. Combined with the three EPPO North-East climatic zone trials at this dose rate, these gave overall control of PuccST of 82.6%, across 11 trials, at the 1.2 L/ha dose rate, compared to 79.8% control using the prothioconazole standard Proline. Details for the German trials are in the EPPO Maritime climatic zone section, above.

The results are summarised in Table 3.2-2094 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-2094 are shown across all trials first (shaded grey), before being shown orthogonally against the various standards.

Table 3.2-2094: Efficacy of GF-3307 applied at the dose rate range of 1.2-1.5 L/ha for the control of PuccST in winter triticale (TTLWI). Results from 8 trials in the EPPO North-East climatic zone and 8 DE trials conducted between 2015 and 2020 Assessment at 28-53 days after a single application.

EPPO Zone	Number of trials	Untreated: PUC CST % infection		% control of PUC CST							Significantly >, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
North-East (1.5 L/ha)	8	26.1	7.1-50.0	-	-	89.5	82.4-96.0	63.0	36.6-87.4	All	6 > P 2 = PO
North-East* (1.5 L/ha)	6	24.0	7.1-50.0	-	-	90.0	82.4-96.0	55.9	36.6-73.7	Proline/0.72 L/ha	6 > P
North-East** (1.5 L/ha)	2	32.3	22.0-42.5	-	-	87.9	83.0-92.9	84.6	81.8-87.4	Prosaro/1.0 L/ha	2 = PO
DE (1.2 and 1.5 L/ha)	8	38.1	6.0-96.5	85.0	75.0-100	88.5	81.8-100	88.8	73.9-100	Proline/0.72 L/ha	1.2: 1 <, 7 = P 1.5: 8 = P
North-East + DE (1.5 L/ha)	16	32.1	6.0-96.5	-	-	89.0	81.8-100	75.9	36.6-100	All	6 > P, 8 = P 2 = PO
North-East (1.2 L/ha)	3	31.4	7.1-50.0	76.4	73.9-79.0	85.0	82.4-89.4	55.9	36.6-73.7	Proline/0.72 L/ha	2 >, 1 = P
North-East + DE (1.5 L/ha)	11	36.2	6.0-96.5	82.6	73.9-100	87.5	81.8-100	79.8	36.6-100	Proline/0.72 L/ha	2 >, 1 <, 8 = P

*Direct comparison to Proline (P)

**Direct comparison to Prosaro (PO)

Summary and conclusions for the proposed range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Where disease pressure is low and only control of PuccST is required, the lower dose of 1.2 L/ha is considered sufficient. Three EPPO North-East climatic zone trials (mean control of 76.4%) and 8 trials from Germany (85.0%) at this dose rate, demonstrated mean overall control of PuccST in winter triticale of 82.6% from a single application of GF-3307.

In mixed disease situations where PuccST and other diseases such as SEPTSP occur, the higher dose of 1.5 L/ha is recommended. Based on eight EPPO North-East climatic zone trials (mean control of 89.5%) and eight trials from Germany (mean control of 88.5%) at this dose rate, demonstrated mean overall control of PuccST in winter triticale of 89.0%, from a single application of GF-3307, it is

considered that the proposed claim for control of Puccst, at a dose rate of 1.5 L/ha in winter triticale, is fully supported.

In addition, data on wheat in section 3.2.3.3 also demonstrate effective control of Puccst (93.3% control for the 1.5 L/ha dose across eight EPPO North-East climatic zone trials and 86.6% control for the 1.2 L/ha dose across three EPPO North-East climatic zone trials) and are considered to support this proposed claim/use on triticale.

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in triticale to offer growers flexibility to adjust to the disease conditions.

zRMS comments:

During the commenting period the applicant had submitted 3 additional trials in the spring triticale (TTLSO) from Poland (the North-Eastern EPPO zone) and proposed that the use in control of Puccrt and Pyrntr in spring triticale could be authorized, based on extrapolation of data, concerning the same pathogens, from winter wheat. The submitted summary has been pasted below:

Effectiveness of GF-3307 for the control of Pyrntr and Puccrt in spring triticale

This section addresses the efficacy of GF-3307, for the control of Pyrntr and Puccrt on spring triticale, when applied at the proposed label rate of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone).

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	EPPO North-East: Pyrntr: 15.0 m ² Puccrt: 25 m ²
	Number of replications	4
Crop	Trials per crop	EPPO North-East: 3 TTLSO
	Varieties per crop (number of trials)	Pyrntr (2) Mikaro, Milewo Puccrt (1) Hugo
Application	Crop stage (BBCH)* at application	Pyrntr: BBCH 45-49 47 Puccrt: BBCH 57-59
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of Pyrntr and Puccrt applications were timed to cover these situations from commencing when there was a risk of infection or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	EPPO North-East: one per crop
	Spray volumes	Pyrntr 200 L/ha Puccrt 230 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre

		weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were made at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were conducted approximately 3-4 weeks after application.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGT is a prevalent disease.

Introduction

In total, 3 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTR (2 trials) and Puccrt (1 trial) in spring triticale (TTLSo). To support the label claims, GF-3307 was tested at the proposed label rates of 1.2-1.5 L/ha (EPPO North-East climatic zone), in accordance with the EPPO Standard PP 1/26, '*Foliar and ear diseases on cereals*'.

The trials were carried out by Corteva contractor companies, all of which followed the EPPO Standards and are officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Poland (3) in the EPPO North-East climatic zone in 2021 and 2022.

On the basis of the EPPO Standard PP 1/241 '*Guidance on comparable climates*', the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime and North-East EPPO climatic zones, as described in EPPO Standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-22.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where diseases in triticale are prevalent, often later in the season in spring triticale. Puccrt and PYRNTR are diseases which multiply rapidly, at short cycles, under optimal climatic conditions, such as are found in the North-East EPPO climatic zones. For trial site and application details see individual trial reports.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	1.0	250

Experimental details

The 3 efficacy trials were conducted to GEP by officially recognized efficacy testing organisations and followed the appropriate EPPO Standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15 and 25 m². The treatments in all trials were applied using self-propelled, bicycle precision small plot sprayers, equipped with conventional flat fan nozzles, delivering water volumes at 200 -230 L/ha.

In these spring triticale trials, GF-3307 was applied at BBCH 45-49 to PYRNTR trials and BBCH 57-59 for the single PUCCRT trial. The treatments were sprayed before disease had established as a preventative treatment. The 1.2 L/ha and 1.5 L/ha doses were only included in one of the three trials and was not included in the other 2 trials as these protocols concentrated on other products and the GF-3307 1.5 L/ha dose was included as an internal standard

Assessments for efficacy (% infection) were conducted approximately 4 weeks after application. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PYRNTR or PUCCRT or leaves which were already senesced to a high degree in both treated and untreated plots were excluded from summarization. Assessments were on Leaf 1 and Leaf 2 and the data is presented respectively, on the key leaf (Leaf 1) with highest infection at the time of assessment which was late in the season because of infection occurring later with applications at B45-59.

Results

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

Two small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTR in spring triticale, at 1.5 L/ha, following a single application applied at BBCH 45-49 of the crop. In the PUCCRT trial the application was made at BBCH 57-59 and 1.2 and 1.5 L/ha. The trials were conducted in Poland (3) in the EPPO North-East climatic zone. The data against PYRNTR and PUCCRT is further supported by efficacy data presented against the same diseases in winter wheat where read across is possible. These trials can therefore be considered to confirm activity of GF-3307 against these diseases in spring triticale. Assessment data is presented on leaf 1 as this leaf had highest levels of infection as disease appeared later in the crop development.

Mean control of 94.6% from a single trial against PUCCRT using the 1.5 L/ha dose, 26 days after one application. Control by the maximum dose rate was higher than that achieved by the reference standard Prosaro 1 l/ha that delivered 81.4% control with 15% infection on leaf 1 in the untreated (Table 3.2-210). The lower range dose of 1.2L/ha was not present in these trials, though data presented on wheat shows comparable control of moderate levels of PUCCRT from 1.2 and 1.5 L/ha doses.

GF-3307 at 1.5 L/ha achieved mean control of PYRNTE of 91.2% (range 84.23-98.21%) from two trials compared to a mean control of 86.3% (range 75.1-97.44%) from Prosaro at 1.0 L/ha. [The lower dose of 1.2 L/ha was only included in one trial and achieved 63.7% control vs 84.23% for the 1.5L dose and 75.1% for Prosaro, but there was no statistically significant difference between treatments (Table 3.2-1B)]. Data presented for barley shows good control of PYRNTE in barley and other diseases in cereals at 1.2 L/ha.

Use on spring triticale in the EPPO North-East zone includes a dose of 1.2 to 1.5 L/ha. The maximum 1.5 L/ha dose rate is supported by 3 harvested spring triticale trials and one trial at 1.2 L/ha (yield in spring triticale is further supported by 10 EPPO North-East zone trials and nine trials from the EPPO Maritime zone/DE in winter triticale). A summary of the yield and quality data from 3 of these efficacy trials at the 1.5 L/ha dose rate is presented in Table 3.2-1C.

A single application of GF-3307 at 1.2 and 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The yield increases found with the 1.5 L/ha dose rate was similar to the reference Prosaro with a mean yield of 6.87 and 6.7 respectively, delivering a 110.7%, increase for GF-3307@ 1.5 L/ha compared to the untreated. In the trial where GF-3307 was present at 1.2 and 1.5 L/ha the yield was equivalent at 8.5 T/ha compared to 8.3 T/ha with Prosaro and 7.8 T/ha in the untreated.

The results are summarised in Table 3.2-1A and 3.2-1B and 3.2-1C

Table 3.2-211 Effectiveness of GF-3307 at the proposed label rates of 1.2 and 1.5 L/ha against Puccin (TTLSO). Results from 1 trial conducted in the EPPO Maritime and North-East climatic zones between 2015-2020. Assessment at 26 days after one application.

EPPO Zone	Country	Trial number	Application timing (BBCH)	Days after application	Plant part evaluated	Untreated SEPTSP % infection		GF-3307			GF-3307		Prosaro 250g as/ha 1.0 L/ha			Significantly >, =, < Standards	
								180g as/ha			225g as/ha						
								1.2 L/ha			1.5 L/ha						
North-East	Poland	PL22G1C013F-ASF08C	57-59	26 DAA	L1	15.0	a	-	-	-	0.5 0.8	c	94.6	2.8	bc	81.4	1.5>= PO

PO = Prosaro

Table 3.2-1B Effectiveness of GF-3307 at the proposed label rates of 1.2 and 1.5 L/ha against PYRNTR in spring triticale (TTLSO). Results from 2 trials conducted in the EPPO North-East climatic zones between 2022. Assessment at 24-26 days after one application.

EPPO Zone	Country	Trial number	Application timing (BBCH)	Days after application	Plant part evaluated	Untreated SEPTSP % infection		GF-3307			GF-3307			Prosaro 250g as/ha 1.0 L/ha			Significantly >, =, < Standards
								180g as/ha			225g as/ha						
								1.2 L/ha			1.5 L/ha						
North-East	Poland	EA21E7B055F-DPF048	45-47	26 DAA	L1	10.2	a	3.75	b	63.71	1.56	b	84.23	2.5	b	75.1	1.5 =PO
North-East	Poland	EA21G1C004F-DPF006	45-49	24 DAA	L1 L2	7.1	a				0.125	e	98.21	0.188	e	97.44	1.5 = PO
North-East		1.5 L/ha dose			min	7.81					84.3			75.1			
					max	10.2					98.2			97.44			
					n trials	2					2			2			
North-East		1.2 L/ha dose		24-26 DAA	Mean	8.65					91.2			86.3			
					n trials	1		1			1			1			
					Mean	10.2		63.7			84.3			75.1			

PO = Prosaro

Table 3.2-1C Yield (T/ha) of GF-3307 at the proposed label rates of 1.2 and 1.5 L/ha against PYRNTR in spring triticale (TTLSO). Results from 3 trials conducted in the EPPO North-East climatic zones between 2021 and 2022.

EPPO Zone	Country	Trial number	Application timing (BBCH)	Days after application	Plant part evaluated	Untreated T/ha		GF-3307			GF-3307			Prosaro 250g as/ha 1.0 L/ha			Significantly >, =, < Standards
								180g as/ha			225g as/ha						
								1.2 L/ha			1.5 L/ha						
North-East	Poland	EA21E7B055F-DPF048	45-47	93 61 DAA	grain	7.8	a	8.5	b	106% 109%	8.5	b	105% 108%	8.3	b	103 105%	1.5 =PO
North-East	Poland	EA21G1C004F-DPF006	45-49	128 DAA	grain	5.2	a				5.5	a	106%	5.6	a	108%	1.5 = PO
North-East	Poland	PL22G1C013F-ASF08C	57-59	104 DAA	grain	5.4	a				6.6	a	121.3 %	6.2	a	114%	1.5 = PO
North-East		1.5 L/ha dose			min	5.2					8.5			8.3			
					max	7.8					6.6			5.6			
					n trials	3					3			3			
North-East		1.2 L/ha dose		24-26 DAA	Mean	6.13					6.86		6.7				
					n trials	1		1		1		1					
					Mean	7.8		8.5		8.5		8.3					

PO = Prosaro

Summary and conclusions for the proposed rate range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

A dose range is proposed on the Polish label of 1.2-1.5 L/ha for control of diseases in spring triticale to offer growers flexibility to adjust to the disease conditions. The data presented supports the proposed uses.

zRMS comments:

The data submitted was accepted by zRMS; the summaries have been verified against the original trial reports and corrected. The use can be supported. The respective amendments have been introduced into the GAP table and product label either.

3.2.3.12 Effectiveness of GF-3307 for the control of RAMUCC in barley

This section addresses the efficacy of GF-3307 for the control of RAMUCC on winter and spring barley, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-212 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	21.3-30 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (5), Spring barley (5)
	Varieties per crop	EPPO Maritime: Winter barley: California, Lomerit, SU Vireni, Sandra (2). Spring barley: Grace (3), Laurikka, Milford
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-51
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of <i>Ramularia collo-cygni</i> (RAMUCC) application was timed to cover this situation from commencing when there was a risk of infection with RAMUCC or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: one per crop
	Spray volumes	200 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RAMUCC is an abundant disease.

Introduction

In total, data from 10 field trials are presented in this section, to demonstrate the effectiveness of GF-3307, for the control of RAMUCC in winter and spring barley. To support the label claims for each EPPO zone, GF-3307 was tested at 1.2 and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, 'Foliar and ear diseases on cereals'.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (2), Germany (8) in the EPPO Maritime

climatic zone between 2017 and 2019.

On the basis of the EPPO standard PP 1/241 ‘*Guidance on comparable climates*’, the trials included in the dossier have been grouped and summarised by EPPO climatic zone. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data for the control of RAMUCC from Germany which is within both the EPPO Maritime climatic zone and the Central EU Authorization zone. RAMUCC is an important disease in the EPPO Maritime climatic zone of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. It is considered that data from Germany are a robust test of the product. In the EPPO North-East and South-East climatic zones, the climatic conditions are less conducive to the development of RAMUCC and is considered more of a secondary disease in these regions. This is reflected in the trials programme for GF-3307, where RAMUCC was either not found or the disease levels were low (<5%). It is therefore considered that these data from Germany (EPPO Maritime climatic zone) fully support the claims for control of RAMUCC across the whole Central* EU Authorization zone.

zRMS comments:

*Please, see the zRMS comments on RAMUCC data, by the end of this chapter.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-24. All testing facilities used for the efficacy trials were GEP compliant.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where RAMUCC is an abundant disease. RAMUCC is a disease which multiplies rapidly at short cycles, under warm climatic conditions, such as are found in the EPPO Maritime climatic zone. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 14 provides an overview on the geographical distribution of the trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2 , 1.25, 1.5	180 , 187.5, 225
Proline	EC	250 g/L prothioconazole	0.8	200
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0	225

Experimental details

The 10 efficacy trials were conducted by officially recognized testing organisations, to GEP and followed the appropriate EPPO standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 21.3 m² and 30 m². Five trials were carried out on winter barley and five on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles, delivering a water volume of 200 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of the crop. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RAMUCC or leaves which were senesced to a high degree in treated and untreated plots were excluded from the

summary tables. Assessments were generally conducted on Leaf 1 or Leaf 2, with one on Leaf 3 and one on 'Mid-Leaf'.

Results

In total, 10 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of RAMUCC in winter and spring barley at the proposed label rate, following a single application, applied between BBCH 31-51 of the crop. The trials were conducted in Denmark (2) and Germany (8) in the EPPO Maritime climatic zone, on winter and spring barley. In the majority of trials RAMUCC did not develop until after application and these trials can therefore be considered to be a robust test of the protectant properties of GF-3307. Assessment were on the highest leaf or the leaf with the highest level of infection and were generally on Leaf 1 or Leaf 2. This is considered to be a robust test of the product. **Note:** Results from 5 trials were based on a slightly higher dose rate of 1.25 L/ha (trials highlighted in the BAD). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lower label dose of 1.2 L/ha for EPPO zones North East and South East. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

Across these 10 EPPO Maritime climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of RAMUCC in winter and spring barley of 84.6% (range 65.8-97.9%), 18-41 days after one application. When compared directly with the reference standards, GF-3307 at 1.5 L/ha demonstrated 82.6% control, which was in excess of the control achieved by the prothioconazole standard Proline at 71.2% (range 45.0-92.7%), across 8 trials. Across two trials, GF-3307 at 1.5 L/ha and the bixafen + prothioconazole standard Aviator Xpro both demonstrated 92.5% control of RAMUCC.

The dataset includes five trials from use on winter barley (HORVW) and five trials from use on spring barley (HORVS). Results on both crops are comparable (83.8% control on HORVW and 85.4% control on HORVS). It is therefore considered that all 10 trials fully support use in both winter and spring barley crops.

Although no data are available from the EPPO North-East and South-East climatic zones, data from neighbouring countries (DE) in the EPPO Maritime climatic zone are available and can also be considered supportive of the proposed dose in these zones. In these 8 German trials, GF-3307 applied at 1.5 L/ha achieved mean control of 83.8% (83.8% on HORVW and 83.7% on HORVS), compared to lower control of 75.1% (range 45.0-95.1%) for the reference standards (Proline and Aviator Xpro). Across five DE trials, GF-3307 applied at ~~1.2~~ 1.25 L/ha achieved mean control of 81.4% (83.8% on HORVW and 80.1% on HORVS), compared to lower control of 68.2% (range 45.0-92.7%) for the prothioconazole standard Proline.

The results are summarised in Table 3.2-21366 the results of the individual trials are detailed in the BAD. Results in Table 3.2-21366 are shown across all trials first (~~shaded grey~~), before being shown orthogonally against the various standards and for spring and winter barley.

Table 3.2-21366: Efficacy of GF-3307 for the control of RAMUCC in winter and spring barley from 10 trials conducted in the EPPO Maritime climate zone between 2017 and 2019. Assessment at 18-41 days after application

after application											
EPPO Zone/Crop	Nume r of trials	Untreated: RAMUCC % infection		% control of RAMUCC							Significantl y >, =, < Standards
				GF-3307 1.2 L/ha GF-3307 1.25 L/ha		GF-3307 1.5 L/ha		Reference standard			
		Mea n	min- max	Mea n	min- max	Mea n	min- max	Mea n	min- max	Product/dos e	
Maritime (all trials)	10	46.3	5.0- 99.0	-	-	84.6	65.8 - 97.9	75.5	45.0 - 95.1	All	1 >, 7 = P 2 = A
Maritime* (all crops)	8	41.1	5.0- 88.8	-	-	82.6	65.5 - 96.3	71.2	45.0 - 92.7	Proline/0.8 L/ha	1 >, 7 = P
Maritime* * (HORVW)	2	67.4	35.9 - 99.0	-	-	92.5	87.1 - 92.9	92.5	89.9 - 95.1	Aviator Xpro/ 1.0 L/ha	2 = A
Maritime (HORVW)	5	55.0	7.1- 99.0	-	-	83.8	65.5 - 97.9	83.1	63.0 - 95.1	All	1 >, 2 = P 2 = A
Maritime (HORVS)	5	37.7	5.0- 74.5	-	-	85.4	76.3 - 93.7	67.8	45.0 - 86.3	Proline/0.8 L/ha	5 = P
DE only (all crops) 1.5 L/ha	8	47.4	5.0- 99.0	-	-	83.8	65.5 - 97.9	75.1	45.0 - 95.1	All	1 >, 5 = P 2 = A
DE only (HORVW) 1.5 L/ha	5	55.0	7.1- 99.0	-	-	83.8	65.5 - 97.9	83.1	63.0 - 95.1	All	1 >, 2 = P 2 = A
DE only (HORVS) 1.2 +1.5 L/ha	3	34.8	5.0- 51.8	80.1	74.9 - 90.0	83.7	76.3 - 90.0	61.7	45.0 - 71.1	Proline/0.8 L/ha	3 = P (both doses)
DE only (HORVW) 1.2 L/ha	2	78.0	7.1- 88.8	83.5	77.0 - 96.3	84.2	72.0 - 96.3	77.9	63.0 - 92.7	Proline/0.8 L/ha	2 = P
DE only (all crops) 1.2 L/ha	5	40.0	5.0- 88.8	81.4	74.9 - 90.0	83.9	72.0 - 96.3	68.2	45.0 - 92.7	Proline/0.8 L/ha	5 = P

*Direct comparison to Proline (P), **Direct comparison to Aviator Xpro (A)

Summary and conclusions for the proposed dose of 1.5 L/ha in the EPPO Maritime climatic zone

Data from the 10 EPPO Maritime climatic zone trials demonstrate mean overall control of RAMUCC in barley of 84.6% using a single application of 1.5 L/ha GF-3307. Results on both winter and spring crops are comparable (83.8% control on HORVW and 85.4% control on HORVS). It is therefore considered that all 10 trials fully support the proposed claims for control of RAMUCC in winter and spring barley.

Summary and conclusions for the proposed dose of 1.5 L/ha in the EPPO North-East climatic zone

This submission includes data from the EPPO Maritime climatic zone only. RAMUCC is an important disease in the maritime regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. It is considered that data from this region are a robust (and worst case) test of the product.

Although no data is not presented from the North East EPPO zone the data on other barley diseases clearly shows the product is selective in barley and that the results from neighbouring countries for other diseases mirror those obtained from trials in the North East EPPO zone. 8 trials from neighbouring countries (DE) in the EPPO Maritime climatic zone are available and can be considered

supportive of the proposed use for control of this disease in Poland/EPPO North-East climatic zone. RAMUCC is a currently a disease of low significance in Poland, but could become more important in future years. RAMUCC a disease that develops in similar conditions to PYRNTE and has the same risk factors which include infected seed, infected barley trash, volunteers, susceptible varieties, high humidity/rainfall and mild temperatures in spring and summer. As control of PYRNTE requires a dose of 1.2 - 1.5 L/ha for effective control (see section PYRNTE section) and both diseases are likely to occur in a crop at the same time and represent a high disease pressure situations, the maximum dose of 1.5 L/ha is also recommended for control of RAMUCC. A dose range of 1.2-1.5 L/ha can be recommended, based on data from five German trials on barley demonstrating mean overall control of RAMUCC of 81.4% for the ~~1.2~~ 1.25 L/ha dose rate.

The data from 8 German trials on winter and spring barley using the 1.5 L/ha dose rate of GF-3307, demonstrate mean overall control of RAMUCC of 83.8% (83.8% control on HORVW and 85.4% control on HORVS). As control on both winter and spring crops is shown to be comparable, both for this disease and other diseases in this dossier, it is considered that these data fully support the proposed claim for control of RAMUCC using GF-3307 at the maximum dose rate of 1.5 L/ha on winter and spring barley crops.

A dose range of 1.2-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions. However, if high pressure situations of RAMUCC and/or PYRNTE is found in the crop or expected, the maximum dose rate of 1.5 L/ha is recommended.

Summary and conclusions for the proposed dose rate range of 1.2-1.5 L/ha in the EPPO South-East climatic zone

No data are available from the EPPO South-East climatic zone for this disease. However, this submission includes data from Germany in the EPPO Maritime climatic zone. RAMUCC is an important disease in the maritime regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. It is considered that data from Germany are a robust (and worst case) test of the product. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of RAMUCC and this is a relatively minor disease in this region. This is reflected in the trials programme for GF-3307, where RAMUCC was either not found or disease levels were low (<5%) in trials from this region. Data for other diseases in this dossier have shown a high degree of comparability in control achieved by GF-3307 across all three EPPO climatic zones of the Central EU Authorization zone. It is therefore considered that these data from Germany (EPPO Maritime climatic zone) fully support the claims for control of RAMUCC across the whole Central EU Authorization zone, including the EPPO South-East climatic zone.

Data from neighbouring countries (DE) in the EPPO Maritime climatic zone are available and can be considered supportive of the proposed use in the EPPO South-East climatic zone. Where disease pressure is low and only RAMUCC requires control, the lower dose of 1.2 L/ha is recommended, based on data from five German trials on barley demonstrating mean overall control of RAMUCC of 81.4% ~~for this dose rate~~ at 1.25 L/ha. These results were higher than the prothioconazole reference standard at 68.2%.

In high pressure mixed disease situations (PYRNTE also present or expected, see PYRNTE section) the higher dose of 1.5 L/ha is recommended. Based on data from 8 German trials on barley using the 1.5 L/ha dose rate of GF-3307, demonstrating mean overall control of RAMUCC of 83.8%, it is considered that the proposed claim for control of RAMUCC using GF-3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley is supported. These results were higher than the prothioconazole reference standard at 75.1%.

It is considered that the proposed dose rate range of 1.2-1.5 L/ha will deliver robust control of this disease under a wide range of environmental conditions in the EPPO South-East climatic zone (dependent on disease pressure).

zRMS comments:

Indeed, the dossier does not include any trials that would show efficacy data on RAMUCC from the NE EPPO zone. On the contrary, it includes one efficacy trial from the SE EPPO zone, HU18F9B029AB01C. That trial might perhaps offer some outlook of the situation if not for the generally low efficacy level across almost all the treatments at 14 DAAA (including test item and the standard Proline, 44% and 43% respectively, L3), and the fact that the next observations had followed the second application - 28 DAAA = 14 DAAB.

Since HU18F9B029AB01C is also geographically detached from the Maritime zone data set, it is acceptable that this trial is not used in summaries concerned with RAMUCC (otherwise its other data cover only PUCCHD), but the zRMS considers its results worth sample-demonstrating, for the cMSs in the SE EPPO zone:

Trial HU18F9B029AB01C; RAMUCC in HORVW			Efficacy (%)	
DAA	UNCK % PESSEV	Leaf layer	GF-3307 at 1.5L/ha	Proline 250 at 0.8L/ha
14 DAA, 0 DAB	26,0	L 3-4	49,3	41,8
28 DAA, 14 DAB	39,5	L 2-4	72,4	64,2
28 DAA, 14 DAB	68,1	L 1-2	61,6	71,5

The cMSs Romania and Slovakia are kindly invited to consider individually whether the approval of the use against RAMUCC in barley in their countries is possible based solely on the Maritime zone data. In Poland, the use cannot be approved for the absence of the NE zone data. Although the importance of the pathogen in Poland had been claimed local and minor, back in the 2017, it may not necessarily remain so in the future. According to CABI Invasive Species Compendium <https://www.cabi.org/isc/datasheet/46723> (modified 16 Nov. 2021, accessed July 2022) the pathogen is reported from HU, SK, AT, CZ, DE, DK, Scandinavian Peninsula and from LT, with no data from PL and RO.

3.2.3.13 Effectiveness of GF-3307 for the control of RHYNSE in barley

This section addresses the effectiveness of GF-3307 for the control of RHYNSE on winter and spring barley, when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed label dose range of ~~1.2-1.5 L/ha~~ 1.0-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed label dose range of ~~1.2-1.5 L/ha~~ 1.0-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-21467 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	15-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (9), Spring barley (4) EPPO North-East: Winter barley (6 7), Spring barley (4)
	Varieties per crop	EPPO Maritime: Winter barley: Casino, Etincel (2), KWS Glacier, Hennriette, Lomerit, Maris Otter, KWS Meridian, Sebastian Spring barley: Concerto, Propino, Salome, Sebastian EPPO North-East: Winter barley: Bartosz, Bazant, Carola, Kobuz, Kosmos, Padura, Zenek. Spring barley: Blask, Iron, KWS Vermont, Nokia
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH)* at application	EPPO Maritime: BBCH 31-51 EPPO North-East: BBCH 31-52
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of <i>Rhynchosporium secalis</i> (RHYNSE) application was timed to cover this situation from commencing when there was a risk of infection with RHYNSE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: one per crop EPPO North-East: one per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is an abundant disease.

Introduction

In total, data from ~~23~~ 24 field trials were conducted to demonstrate the efficacy of GF-3307, for the control of RHYNSE in winter and spring barley. To support the label claims, GF-3307 was tested at ~~the proposed label rates of 1.2 L/ha and 1.5 L/ha,~~ 1.0, 1.2/1.25 L/ha and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, '*Foliar and ear diseases on cereals*'. **Note: Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East.**

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Belgium (1), France (4), Germany (4) and UK (4) in the EPPO Maritime climatic zone, also Latvia (1) and Poland (~~9~~ 10) in the EPPO North-East climatic zone between 2017 and ~~2020~~ 2021.

On the basis of the EPPO standard PP 1/241 '*Guidance on comparable climates*', the trials included in the dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. This submission includes data from the EPPO Maritime and North-East climatic zones, which are representative of the proposed GAP in each region. RHYNSE is an important disease in the wetter regions of the Central EU Authorization zone, where disease levels are significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of RHYNSE, as hot dry weather reduces the rate of disease development. As a result, this is a more minor disease in this region. As with data for other diseases in this dossier, the trial results from Poland in the EPPO North-East climatic zone, as a neighbouring country, are comparable to those from the EPPO South-East climatic zone and it is considered this will also be the case for RHYNSE. It is therefore considered that data from Poland can be used to support this use in the EPPO South-East climatic zone.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-25.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where RHYNSE is an abundant disease. RHYNSE is a disease which multiplies rapidly at short cycles under wet climatic conditions, such as are found in the EPPO Maritime and North-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 15 provides an overview on the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.25, 1.5	135, 180, 187.5, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8	150-200
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	0.8-1.0	180-225

Experimental details

The 24 efficacy trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15 m² and 36 m². ~~Fifteen~~ Sixteen trials were carried out on winter barley and eight on spring barley. The treatments in all trials were applied using self-

propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 - 300 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after application and/or at BBCH 75 of barley. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with RHYNSE or leaves which were senesced to a high degree in treated and untreated plots were excluded from summary tables. Assessments used were Leaf 1, Leaf 2 or Leaf 3, as the highest assessed leaf in the trial or the leaf with high levels of disease.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, 13 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of RHYNSE in winter and spring barley at the proposed label rate following a single application applied at BBCH 31-51 of the crop. The trials were conducted in Belgium (1), France (4), Germany (4) and UK (4) in the EPPO Maritime climatic zone between 2017 -2019. ~~The data includes trials where RHYNSE was established before application (including on the leaves assessed for control in some trials) and trials where RHYNSE did not develop until after application.~~ **The data includes trials where RHYNSE was established at low levels on lower leaves before application and trials where RHYNSE did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessment across all trials are on Leaf 2 and this is considered to be a robust test of the product. **Note:** In seven trials, the latest assessment timing after a single application was used at 17-28 days after application. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

Across these 13 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of RHYNSE in winter and spring barley of 88.1% (range 75.1-100%), 17-35 days after application, which was comparable to level of control achieved by the prothioconazole standard Proline at 82.2% (range 43.1-100%).

The dataset includes nine trials on winter barley (HORVW) and four trials on spring barley (HORVS). Results on both crops are comparable (89.1% control on HORVW and 85.8% control on HORVS). Winter barley can be considered to be the more challenging situation, as RHYNSE can become established in the crop over the winter months and is therefore more difficult to eradicate. As 89.1% control has been achieved in winter barley, it is considered that all 13 trials fully support use in both winter and spring barley crops.

The results are summarised in Table 3.2-21568 the results of the individual trials are detailed in the BAD. Results in Table 3.2-21568 are shown across all trials first (~~shaded~~), before being shown orthogonally for spring and winter barley.

Table 3.2-21568: Efficacy of GF-3307 applied at 1.5 L/ha for the control of RHYNSE in winter and spring barley from 13 trials conducted in the EPPO Maritime climate zone between 2017 and 2019. Assessment 17-35 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE				Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Proline 0.8 L/ha		
		Mean	min-max	Mean	min-max	Mean	min-max	
Maritime (All trials)	13	14.1	5.0-39.8	88.1	75.1-100	82.2	43.1-100	13 = P
Maritime (HORVW)	9	12.7	5.2-39.8	89.1	76.7-100	81.4	43.1-100	9 = P
Maritime (HORVS)	4	17.2	5.0-32.5	85.8	75.1-95.8	83.8	80.0-88.2	4 = P

P = Proline

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on data from the 13 EPPO Maritime climatic zone trials demonstrating mean overall control of RHYNSE in barley of 88.1% from a single application at a dose rate of 1.5 L/ha, it is considered that the proposed claims for control of RHYNSE in winter and spring barley are fully supported.

Proposed dose range of ~~1.2-1.5 L/ha~~ **1.0-1.5 L/ha** for Poland (EPPO North-East climatic zone)

~~Ten~~ **Eleven** efficacy trials were conducted to demonstrate the efficacy of GF-3307 for the control of RHYNSE in winter and spring barley at the proposed label rates of 1.2 and 1.5 L/ha **at 1.0 to 1.5 L/ha**, following a single application applied at BBCH 31-52 of the crop. The trials were conducted in Latvia (1) and Poland (9 ~~10~~) on both winter and spring barley. ~~The data include trials where RHYNSE was established before application (including on the leaves assessed for control in some trials) and trials where RHYNSE did not develop until after application.~~ **The data include trials where RHYNSE was established at low levels on lower leaves before application and trials where RHYNSE did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessment across all trials is on Leaf 1-3 and is considered to be a robust test of the product. **Note:** In two trials, the latest assessment timing after a single application was used at 14-18 days after application. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

Across all 10 ~~11~~ EPPO North-East climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of RHYNSE in winter and spring barley of 95.6 ~~96.0~~ (94.1 ~~94.9~~ on HORVW and 97.9% on HORVS) at 14-43 days after one application (range 88.7-100%), ~~which is higher than the level of control achieved by the prothioconazole standard Proline at 83.7% (range 48.5-100%)~~ **which is comparable to the level of control achieved by the bixafen + prothioconazole standard Aviator Xpro at 92.6% (range 78.7-100%).** At a dose rate of ~~1.2 L/ha~~ **1.2/1.25 L/ha**, only slightly lower control of ~~92.1~~ **92.9**% (89.4 ~~90.9~~ on HORVW and 96.3% on HORVS) was achieved (range 80.0-100%). **Note:** Results from 8 trials were based on a slightly higher dose rate of 1.25 L/ha (~~trials highlighted in the BAD~~). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lower label dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

At the lower dose rate of 1.0 L/ha, GF-3307 achieved 84.4% control compared to the bixafen + prothioconazole standard Aviator Xpro at 91.8% (range 78.7-100%).

~~The EPPO North East climatic zone dataset includes six trials from use on winter barley (HORVW) and four trials from use on spring barley (HORVS). Combining the six EPPO North East climatic zone trials on winter barley with two from a neighbouring country (DE) gives 94.7% control of RHYNSE on winter barley at the maximum 1.5 L/ha dose and 91.4% control at the lower 1.2 L/ha dose, across 8 trials, which is higher than the level of control achieved by the prothioconazole standard Proline at 84.2%.~~

The EPPO North-East climatic zone dataset includes seven trials from use on winter barley (HORVW) and four trials from use on spring barley (HORVS). Combining the seven EPPO North-East climatic zone trials on winter barley with two from a neighbouring country (DE) gives 95.3% control of RHYNSE on winter barley across nine trials at the maximum 1.5 L/ha dose, 92.3% control at the 1.2/1.25 L/ha dose and 89.6% for the lower 1.0 L/ha dose rate (8 trials)

~~The results are summarised in Table 3.2-216 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-216 are shown across all trials first before being shown orthogonally for spring and winter barley.~~

The results are summarised in Table 3.2-216 and Table 3.2-218. The results of the individual trials are detailed in Table 3.2-220 and Table 3.2-221. Results in Table 3.2-216 and Table 3.2-218. are shown across all trials first before being shown orthogonally for spring and winter barley.

Table 3.2-216: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of RHYNSE in winter and spring barley from 10 trials conducted in the EPPO North-East climatic zone plus 2 DE trials between 2017 and 2020. Assessment at 14-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE						Significantly >, =, < Standards
				GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Proline 0.6-0.8 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North-East (all trials)	10	13.9	5.6-35.0	92.1	80.0- 100	95.6	88.7- 100	83.7	48.5- 100	2 > P, 8 = P (both doses)
North-East + DE (all trials)	12	12.3	5.6-35.0	93.9	80.0- 100	96.3	88.7- 100	87.3	48.5- 100	2 > P, 10 = P (both doses)
North-East (HORVW)	6	16.4	5.6-35.0	89.4	80.0- 99.1	94.1	88.7- 100	79.2	48.5- 100	2 > P, 4 = P (both doses)
North-East (HORVS)	4	10.1	5.6-17.8	96.3	87.5- 100	97.9	92.1- 100	90.4	80.2- 100	4 = P (both doses)
North-East + DE (HORVW)	8	14.4	5.6-35.0	91.4	80.0- 100	94.7	88.7- 100	84.2	48.5- 100	2 > P, 6 = P (both doses)

P = Proline

Table 3.2-217: Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the control of RHYNSE in winter and spring barley from 11 trials conducted in the EPPO North-East climatic zone plus 2 DE trials between 2017 and 2021. Assessment at 14-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE						Significantly >, =, < Standards
				GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North-East (all trials)	11	14.5	5.6-35.0	92.9	80.0- 100	96.0	88.7- 100	92.6	78.7- 100	1.2: 1 >, 2 <, 8 = A 1.5: 3 >, 8 = A
DE (HORVW)	2	8.2	7.6-8.8	97.4	94.7- 100	96.7	93.4- 100	98.9	97.7- 100	2 = A (All doses)
North-East + DE (all trials)	13	13.5	5.6-35.0	93.5	80.0- 100	96.1	88.7- 100	93.5	78.7- 100	1.2: 1 >, 2 <, 10 = A 1.5: 3 >, 10 = A
North-East (HORVW)	7	17.0	5.6-35.0	90.9	80.0- 100	94.9	88.7- 100	91.7	80.0- 100	1.2: 1 >, 2 <, 4 = A 1.5: 2 >, 5 = A
North-East (HORVS)	4	10.1	5.6-17.8	96.3	87.5- 100	97.9	92.1- 100	94.1	78.7- 100	1.2: 4 = A 1.5: 1 >, 3 = A
North-East + DE (HORVW)	9	15.1	5.6-35.0	92.3	80.0- 100	95.3	88.7- 100	93.3	80.0- 100	1.2: 1 >, 2 <, 6 = A 1.5: 2 >, 7 = A

A = Aviator Xpro

Table 3.2-218: Efficacy of GF-3307 applied at 1.0 L/ha for the control of RHYNSE in winter and spring barley from 10 trials conducted in the EPPO North-East climatic zone plus 2 DE trials between 2017 and 2021. Assessment at 14-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE				Significantly >, =, < Standards
				GF-3307 1.0 L/ha		Aviator Xpro 0.8-1.0 L/ha		
		Mean	min-max	Mean	min-max	Mean	min-max	
North-East (all trials)	10	12.5	5.6-22.5	84.4	59.2-99.2	91.8	78.7-100	1 >, 3 <, 6 = A
DE (HORVW)	2	8.2	7.6-8.8	97.4	94.7-100	98.9	97.7-100	2 = A
North-East + DE (all trials)	11	12.2	5.6-22.5	86.5	59.2-100	92.4	78.7-100	1 >, 3 <, 8 = A
North-East (HORVW)	6	14.0	5.6-22.5	87.0	78.0-99.1	90.3	80.0-100	1 >, 2 <, 3 = A
North-East (HORVS)	4	10.1	5.6-17.8	80.4	59.2-99.2	94.1	78.7-100	1 <, 3 = A
North-East + DE (HORVW)	8	12.6	5.6-22.5	89.6	78.0-100	92.4	80.0-100	1 >, 2 <, 5 = A

A = Aviator Xpro

Summary and conclusions for the proposed dose rate range of 1.2-1.5 L/ha 1.0-1.5 L/ha in the EPPO North-East climatic zone

~~Where disease pressure is low and only RHYNSE requires control, the lower dose of 1.2 L/ha is recommended. Based on data from 8 trials on winter barley using the 1.2 L/ha dose rate of GF-3307, demonstrating mean overall control of RHYNSE of 91.4% (six EPPO North East climatic zone trials and two German trials) plus four EPPO North East climatic zone trials on spring barley, demonstrating 96.3% control of RHYNSE, it is considered that the proposed claim for control of RHYNSE using GF-3307 at a dose rate of 1.2 L/ha on winter and spring barley is fully supported.~~

~~In high pressure mixed disease situations (PYRNTE also present or expected) the higher dose of 1.5 L/ha is recommended. Based on data from 8 trials on winter barley using the 1.5 L/ha dose rate of GF-3307, demonstrating mean overall control of RHYNSE of 94.7% (six EPPO North East climatic zone trials and two German trials) plus four EPPO North East climatic zone trials on spring barley, demonstrating 97.9% control of RHYNSE, it is considered that the proposed claim for control of RHYNSE using GF-3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley is fully.~~

~~A dose range of 1.2-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.~~

Where disease pressure is low and only RHYNSE requires control, the lower dose of 1.0 L/ha is recommended. Based on data from eight trials on winter barley using the 1.0 L/ha dose rate of GF-3307, demonstrating mean overall control of RHYNSE of 89.6% (six EPPO North-East climatic zone trials and two German trials) plus four EPPO North-East climatic zone trials on spring barley, demonstrating 80.4% control of RHYNSE, it is considered that the proposed claim for control of RHYNSE using GF-3307 at a dose rate of 1.0 L/ha on winter and spring barley is fully supported.

In mixed disease situations (other diseases also present) the 1.2 L/ha dose is recommended. Based on data from nine trials on winter barley using the 1.2/1.25 L/ha dose rate of GF-3307, demonstrating mean overall control of RHYNSE of 92.3% (seven EPPO North-East climatic zone trials and two German trials) plus four EPPO North-East climatic zone trials on spring barley, demonstrating 96.3% control of RHYNSE, it is considered that the proposed claim for control of RHYNSE using GF-3307 at a 1.2 L/ha dose rate on winter and spring barley is fully supported.

In high pressure mixed disease situations (PYRNTE also present or expected) the higher dose of 1.5 L/ha is recommended. Based on data from nine trials on winter barley using the 1.5 L/ha dose rate of GF-3307, demonstrating mean overall control of RHYNSE of 95.3% (seven EPPO North-East climatic zone trials and two German trials) plus four EPPO North-East climatic zone trials on spring barley, demonstrating 97.9% control of RHYNSE, it is considered that the proposed claim for control of RHYNSE using GF-3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley is fully supported. A dose range of 1.0-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.

Summary and conclusions for the proposed dose range of 1.2-1.5 L/ha 1.0-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

No data are presented from the EPPO South-East climatic zone on RHYNSE. This submission includes data from Poland in the EPPO North-East climatic zone at the same dose rate as is proposed for the EPPO South-East climatic zone. RHYNSE is an important disease in the wetter regions of the Central EU Authorization zone, where disease pressure is significantly higher than in other areas, due to the climatic conditions that encourage the development of this disease. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of RHYNSE, as hot dry weather reduces the rate of disease development. As a result, RHYNSE is a more minor disease in this region. The climate in Poland, as a neighbouring country, is similar to the EPPO South-East climatic zone (i.e., hot summers), but is slightly wetter than in the EPPO South-East climatic zone. It is therefore considered that trials from Poland represent a more robust test of the product against RHYNSE, so these data can be used to support use in the EPPO South-East climatic zone.

Table 3.2-219: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of RHYNSE in winter and spring barley in 9 Polish trials conducted between 2017 – 2020. Assessment at 14-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE						Significantly >=, < Standards
				GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Proline 0.6-0.8 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
Poland (all trials)	9	14.7	5.6-35.0	91.4	80.0- 100	95.1	88.7- 100	81.9	48.5- 100	2 > P, 7 = P (both doses)
Poland (HORVW)	5	18.3	5.6-35.0	87.4	80.0- 96.6	92.9	88.7- 97.2	75.0	48.5- 100	2 > P, 3 = P (both doses)
Poland (HORVS)	4	10.1	5.6-17.8	96.3	87.5- 100	97.9	92.1- 100	90.4	80.2- 100	4 = P (both doses)

P = Proline. The results of the individual trials are detailed in the BAD.

Table 3.2-220: Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the control of RHYNSE in winter and spring barley in 10 Polish trials conducted between 2017 - 2021. Assessment at 14-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE						Significantly >, =, < Standards
				GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
Poland (all trials)	10	15.3	5.6-35.0	92.2	80.0- 100	95.6	88.7- 100	91.8	78.7- 100	1.2: 1 >, 2 <, 7 = A 1.5: 3 >, 7 = A
Poland (HORVW)	6	18.7	5.6-35.0	89.5	80.0- 100	94.1	88.7- 100	90.3	80.0- 100	1.2: 1 >, 2 <, 3 = A 1.5: 2>, 4 = A
Poland (HORVS)	4	10.1	5.6-17.8	96.3	87.5- 100	97.9	92.1- 100	94.1	78.7- 100	1.2: 4 = A 1.5: 1 >, 3 = A

A = Aviator Xpro, The results of the individual trials are detailed in Table 3.2-220

Table 3.2-221: Efficacy of GF-3307 applied at 1.0 L/ha for the control of RHYNSE in winter and spring barley from 9 trials conducted in the EPPO North-East climatic zone between 2017 and 2021. Assessment at 14-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: RHYNSE % infection		% control of RHYNSE				Significantly >, =, < Standards
				GF-3307 1.0 L/ha		Aviator Xpro 0.8-1.0 L/ha		
		Mean	min-max	Mean	min-max	Mean	min-max	
Poland (all trials)	9	13.1	5.6-22.5	82.7	59.2-99.2	90.9	78.7-100	1 >, 3 <, 5 = A
Poland (HORVW)	5	15.5	5.6-22.5	84.6	78.0-98.5	88.4	80.0-93.7	1 >, 2 <, 2 = A
Poland (HORVS)	4	10.1	5.6-17.8	80.4	59.2-99.2	94.1	78.7-100	1 <, 3 = A

A = Aviator Xpro. The results of the individual trials are detailed in Table 3.2-221.

~~These nine Polish trial results demonstrate that the proposed maximum dose of 1.5 L/ha provides excellent control of RHYNSE (mean of 95.1 %), which is higher than the level of control achieved by the prothioconazole standard Proline at 81.9% and comparable across both winter and spring barley (92.9% on HORVW and 97.9% on HORVS). It is considered that the proposed claim for control of RHYNSE in barley in the EPPO South East climatic zone is fully supported by the data from these nine trials. The lower dose of 1.2 L/ha also provided good levels of control of RHYNSE (91.4%) and it is considered this dose rate can be used in lower disease situations, in the EPPO South East climatic zone, as has been demonstrated for other diseases.~~

Where disease pressure is low and only RHYNSE requires control, the lower dose of 1.0 L/ha is recommended. Based on data from nine Polish trials on barley using the 1.0 L/ha dose rate of GF-3307 demonstrating mean overall control of RHYNSE of 82.7% control (84.6% control from 5 trials on HORVW and 80.4% control from 4 trials on HORVS), it is considered that the proposed claim for control of RHYNSE using GF-3307 at a dose rate of 1.0 L/ha on winter and spring barley in the EPPO South-East climatic zone is fully supported.

In moderate pressure mixed disease situations (other diseases also present) the 1.2 L/ha dose is recommended. Based on data from 10 Polish trials on barley using the 1.2/1.25 L/ha dose rate of GF-3307 demonstrating mean overall control of RHYNSE of 92.2% control (89.5% control from 6 trials on HORVW and 96.3% control from 4 trials on HORVS), it is considered that the proposed claim for control of RHYNSE using GF-3307 at a 1.2 L/ha dose rate on winter and spring barley in the EPPO South-East climatic zone is fully supported.

In high pressure mixed disease situations (PYRNTE also present or expected) the higher dose of 1.5 L/ha is recommended. Based on data from 10 Polish trials on barley using the 1.5 L/ha dose rate of GF-3307 demonstrating mean overall control of RHYNSE of 95.6% control (94.1% control from 6 trials on HORVW and 97.9% control from 4 trials on HORVS), it is considered that the proposed claim for control of RHYNSE using GF-3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley in the EPPO South-East climatic zone is fully supported.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.14 Effectiveness of GF-3307 for the control of PYRNTE in barley

This section addresses the efficacy of GF-3307 for the control of PYRNTE on winter and spring barley when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed label dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and the proposed dose range of 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-222 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	15-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (10) EPPO North-East: Winter barley (5 7), Spring barley (7) EPPO South-East: Winter barley (5 11), Spring barley (2 3)
	Varieties per crop	EPPO Maritime: Winter barley: Arcanda, California, Etincel (3), KWS Meridian (2), Sandra, Tonic, Yatzy EPPO North-East: Winter barley: Bartosz, Bazant, Kosmos, SU Jule, KWS Meridian, Padura, Zenek. Spring barley: Iron (2), Nokia, Ringo, Tocada (2), KWS Vermont EPPO South-East: Winter barley: Calypso, Cardinal, Casanova (2), SU Ellen, KWS Meridian (2), Obzor (2), Planet, Vanessa Spring barley: Bojos, Conchita, Xanadu
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH) at application	BBCH 32-52 EPPO Maritime: BBCH 32-49 EPPO North-East: BBCH 32-52 EPPO South-East: BBCH 37-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. For the control of <i>Pyrenophora teres</i> (PYRNTE) application was timed to cover this situation from commencing when there was a risk of infection with PYRNTE or when the disease started to develop on the lower leaf levels to applications against established infection.
	Number of applications	± EPPO Maritime: one per crop EPPO North-East: one per crop EPPO South-East: one per crop
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas

		representative of those where the crop is grown commercially and where PYRNTE is an abundant disease..
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Introduction

~~In total 29 field trials were conducted to demonstrate the efficacy of GF 3307, for the control of PYRNTE in winter and spring barley. To support the label claims, GF 3307 was tested at the proposed label rates of 1.2 L/ha and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, ‘Foliar and ear diseases on cereals’.~~

In total 38 field trials were conducted to demonstrate the efficacy of GF-3307, for the control of PYRNTE in winter and spring barley. To support the label claims, GF-3307 was tested at 1.2/1.25 L/ha and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, ‘Foliar and ear diseases on cereals’. **Note:** Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (2), Belgium (1), France (3) Germany (4) in the EPPO Maritime climatic zone, also Latvia (2) and Poland (10-12) in the EPPO North-East climatic zone, and Bulgaria (2), and Hungary (5) Hungary (7) and Romania (5) in the EPPO South-East climatic zone, between 2017 and 2019 2021.

On the basis of the EPPO standard PP 1/241 ‘Guidance on comparable climates’, the trials included in this dossier have been grouped and summarised by EPPO climatic zone. EPPO climatic zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-26.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PYRNTE is an abundant disease. PYRNTE is a disease which multiplies rapidly at short cycles under warm climatic conditions, such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 16 provides an overview on the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.25, 1.5	180, 187.5, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8	150-200
Aviator Xpro	EC	75 g/L bixafen + 150 g/L prothioconazole	1.0	225

Experimental details

The ~~29~~ 38 efficacy trials were conducted to GEP and followed the appropriate EPPO standards, by officially recognized efficacy testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15 m² and 36 m². ~~Twenty trials~~ Twenty-eight were carried out on winter barley and ~~nine~~ 10 on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

Assessments for efficacy (% infection) were targeted at 2-3 weeks after each application and/or at BBCH 75 of barley. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PYRNTE or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessments were generally ~~on Leaf 1 and Leaf 2, with one on Leaf 3,~~ on Leaf 1, Leaf 2 or Leaf 3, as the highest assessed leaf in the trial or the leaf with high levels of disease.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total 10 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTE in barley at the proposed label rate of 1.5 L/ha, following a single application applied at BBCH 32-49 of the crop. The trials were conducted in Austria (2), Belgium (1), Germany (4) and France (3) in the EPPO Maritime climatic zone between 2017 -2019. ~~The data includes trials where PYRNTE was established before application (including on the leaves assessed for control in some trials) and trials where PYRNTE did not develop until after application.~~ The data includes trials where PYRNTE was established at low levels on lower leaves before application and trials where PYRNTE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessment across the majority of trials was on Leaf 2, as this leaf had high infection levels of PYRNTE and is considered to be a robust test of the product.

Across these 10 EPPO Maritime climatic zone trials, GF-3307 achieved mean control of PYRNTE in winter barley of 84.7% (range 72.0-100%), 30-48 days after application. In 8 trials, GF-3307 was compared directly to the prothioconazole standard Proline and GF-3307 achieved mean control of 81.6% compared to mean control of 80.2% using Proline. In two trials with high disease levels (mean of 71.0% on Leaf 2), GF-3307 was compared directly to the bixafen + prothioconazole standard, Aviator Xpro. GF-3307 achieved mean control of 97.4% compared to mean control of 94.4% using Aviator Xpro.

All data were from use on winter barley (HORVW). PYRNTE is a more significant disease of winter barley, as infection can become well established in the over-wintering crop. As data from other EPPO zones for PYRNTE demonstrates comparable levels of control of PYRNTE in winter and spring crops (see below) and data on other diseases in the EPPO Maritime climatic zone have shown comparable levels of control using GF-3307 in both winter and spring crops, it is considered that these data are fully supportive of the claim for control of PYRNTE in spring barley (HORVS).

The results are summarised in Table 3.2-2234 the results of the individual trials are detailed in the BAD. Results Table 3.2-2234 are shown across all trials first (~~shaded~~), before being shown orthogonally against the two reference standards.

Table 3.2-2234: Efficacy of GF-3307 applied at 1.5 L/ha for the control of PYRNTE in barley from 10 trials conducted in the EPPO Maritime climatic zone between 2017 and 2019. Assessment at 28-48 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: PYRNTE % infection		% control of PYRNTE					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min-max	Mean	min-max	Product/dose	
Maritime (HORVW)	10	39.3	5.4- 99.0	84.7	72.0-100	83.0	71.0-95.9	All	8 = P, 2 = A
Maritime* (HORVW)	8	31.4	5.4- 73.3	81.6	72.0-88.3	80.2	71.0-86.0	Proline/0.8 L/ha	8 = P
Maritime** (HORVW)	2	71.0	43.0- 99.0	97.4	94.7-100	94.4	92.9-100	Aviator Xpro/1.0 L/ha	2 = A

*Direct comparison to Proline (P)

**Direct comparison to Aviator Xpro (A)

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on 10 EPPO Maritime climatic zone trials demonstrating mean overall control of PYRNTE in winter barley of 84.7% from a single application at a dose rate of 1.5 L/ha, it is considered that the proposed label claims for control of PYRNTE in winter and spring barley are fully supported.

Proposed dose range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total ~~12~~ **14** small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTE in winter and spring barley, at the proposed label rates of 1.2 and 1.5 L/ha, following a single application applied at BBCH 32-52 of the crop. The trials were conducted in Latvia (2) and Poland (~~10~~ **12**) in the EPPO North-East climatic zone on both winter and spring barley. ~~The data include trials where PYRNTE was established before application (including on the leaves assessed for control in some trials) and trials where PYRNTE did not develop until after application.~~ **The data include trials where PYRNTE was established at low levels on lower leaves before application and trials where PYRNTE did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessment across all trials is on the highest leaf (generally Leaf 1 or Leaf 2). **Note:** In one trial (PL18E7B009AS02C), the latest assessment timing after a single application was 16 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP, but assessments after the first application are considered valid to support the GAP.

~~Across all 12 EPPO North-East climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of PYRNTE in winter and spring barley of 87.5% (85.2% on HORVW and 89.2% on HORVS) at 16-43 days after one application (range 79.6-100%), which is higher than the level of control achieved by the prothioconazole standard Proline at 72.2% (range 42.4-95.7%). At a dose rate of 1.2 L/ha, very good control of 82.0% (80.7% on HORVW and 83.0% on HORVS) was achieved (range 67.9-95.7%).~~ **Note:** Results from nine trials were based on a slightly higher dose rate of 1.25 L/ha (trials highlighted in the BAD). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lower label dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

Across all 14 EPPO North-East climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of PYRNTE in winter and spring barley of 85.8% (82.5% on HORVW and 89.2% on HORVS) at 16-43 days after one application (range 67.6-100%), which is comparable to control achieved by the prothioconazole + bixafen standard Aviator Xpro at 85.5% (range 66.7-100%). At a dose rate of 1.2/1.25 L/ha, very good control of 80.6% (78.2% on HORVW and 83.0% on HORVS) was achieved (range 61.8-95.7%). **Note:** Results from nine trials were based on a slightly higher dose rate of 1.25 L/ha. As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lower label dose of 1.2 L/ha. This also aligns with the label dose range

proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

~~The EPPO North East climatic zone dataset includes five trials from use on winter barley (HORVW) and seven trials from use on spring barley (HORVS). Combining the five EPPO North East climatic zone trials on winter barley with three from a neighbouring country (DE) gives an overall mean of 88.4% control of PYRNTE on winter barley at the maximum 1.5 L/ha dose across 8 trials, compared to the reference standards at 74.6% (67.9% for the prothioconazole standard Proline across six trials and 94.4% for the bixafen + prothioconazole standard Aviator Xpro, across two trials) and 81.1% control at the lower 1.2 L/ha dose, across 6 winter barley trials.~~

The EPPO North-East climatic zone dataset includes seven trials from use on winter barley (HORVW) and seven trials from use on spring barley (HORVS). Combining the seven EPPO North-East climatic zone trials on winter barley with three from a neighbouring country (DE) gives an overall mean of 85.9% control of PYRNTE on winter barley at the maximum 1.5 L/ha dose across 10 trials, compared to the reference standard at 88.3% and 78.8% control at the lower 1.2/1.25 L/ha dose, across eight winter barley trials.

The results are summarised in

Table 3.2-~~224~~5 and the results of the individual trials are detailed in the BAD. Results in

Table 3.2-~~224~~5 are shown across all trials first before being shown orthogonally for spring and winter barley.

Table 3.2-224: Efficacy of GF-3307 applied at rate range of 1.2 and 1.5 L/ha for the control of PYRNTE in winter and spring barley from 12 trials conducted in the EPPO North-East climatic zone plus 3 in DE between 2017 and 2020. Assessment at 16-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: PYRNTE % infection		% control of PYRNTE						Significantly >,=,< Standards
				GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Proline 0.6-0.8 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North-East (all trials)	12	17.4	5.0-30.6	82.0	67.9- 95.7	87.5	79.6- 100	72.2	42.4- 95.7	1.2: 4 >, 7 =, 1 < P 1.5: 5 >, 7 = P
North-East (HORVW)	5	16.4	5.0-29.4	80.7	72.1- 87.3	85.2	80.0- 91.4	66.0	48.4- 85.4	1.2: 2 >, 2 =, 1 < P 1.5: 2 >, 3 = P
North-East (HORVS)	7	18.1	5.5-30.6	83.0	67.9- 95.7	89.2	79.6- 100	76.6	42.4- 95.7	1.2: 2 >, 5 = P 1.5: 3 >, 4 = P
North-East + DE (HORVW)	8	37.2	5.0-99.0	81.1#	72.1- 87.3	88.4	80.0- 100	74.6	48.4- 95.9	1.5: 2 >, 4 = P 2 = A

P = Proline, A = Aviator Xpro #Results from 6 trials only

Table 3.2-225: Efficacy of GF-3307 applied at 1.2 - 1.5 L/ha for the control of PYRNTE in winter and spring barley from 14 trials conducted in the EPPO North-East climatic zone plus 3 in DE between 2017 - 2021. Assessment at 16-43 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: PYRNTE % infection		% control of PYRNTE						Significantly >, =, < Standards
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Aviator Xpro 0.8-1.0 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North-East (all trials)	14	19.5	5.0-36.4	80.6	61.8- 95.7	85.8	67.6- 100	85.5	66.7- 100	14 = A (both doses)
North-East (HORVW)	7	20.9	5.0-36.4	78.2	61.8- 87.3	82.5	67.6- 91.4	85.8	66.7- 97.5	7 = A (both doses)
North-East (HORVS)	7	18.1	5.5-30.6	83.0	67.9- 95.7	89.2	79.6- 100	85.2	69.6- 100	7 = A (both doses)
North-East + DE (HORVW)	10	36.2	5.0-99.0	78.8#	61.8- 87.3	85.9	67.6- 100	88.3	66.7- 97.5	10 = A (both doses)
North-East + DE (all trials)	17	28.7	5.0-99.0	80.7##	61.8- 95.7	87.2	67.6- 100	87.0	66.7- 100	17 = A (both doses)

A = Aviator Xpro #Results from 8 trials only. ##Results from 15 trials only.

Summary and conclusions for the proposed dose rate range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

Based on data from 8 10 trials on winter barley using the 1.5 L/ha dose rate of GF-3307 demonstrating mean overall control of PYRNTE of 88.4 85.9% (five seven EPPO North-East climatic zone trials and three German trials) plus seven EPPO North-East climatic zone trials on spring barley demonstrating 89.2% control of PYRNTE, it is considered that the proposed claim for control of PYRNTE using GF-3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley is fully supported. Where disease pressure is low and only PYRNTE requires control, the lower dose of 1.2 L/ha is recommended. Based on data from 6 eight trials on winter barley using the 1.2 L/ha-1.2/1.25 L/ha dose rate of GF-3307, demonstrating mean overall control of PYRNTE of 81.1-78.8% (five seven EPPO North-East climatic zone trials and one German trial) plus seven EPPO North-East climatic zone trials on spring barley, demonstrating 83.0% control, it is considered that the proposed claim for control of PYRNTE using GF-3307 at a dose rate of 1.2 L/ha on winter and spring barley is fully supported.

A dose range of 1.2-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions. However, if PYRNTE is found in the crop or expected, the maximum dose rate of 1.5 L/ha is recommended.

Proposed dose of 1.2-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

~~Seven Fourteen GEP small plot field trials were conducted to demonstrate the efficacy of GF 3307 for the control of PYRNTE in winter and spring barley, at the proposed label rate following a single application at BBCH 37-49 of the crop. The trials were conducted in Bulgaria (2) and Hungary (5) in the EPPO South East climatic zone, on winter and spring barley. The data include trials where PYRNTE was established before application (including on the leaves assessed for control in some trials) and trials where PYRNTE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF 3307. Assessments were on Leaf 1 or Leaf 2, as these leaves had high infection levels of PYRNTE and are considered to be a robust test of the product.~~

Fourteen GEP small plot field trials were conducted to demonstrate the efficacy of GF-3307 for the control of PYRNTE in winter and spring barley, at 1.2-1.5 L/ha following a single application at BBCH 37-49 of the crop. The trials were conducted in Bulgaria (2), Hungary (7) and Romania (5) in the EPPO South-East climatic zone, on winter and spring barley. The data include trials where PYRNTE was established at low levels on lower leaves before application and trials where PYRNTE did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments were on Leaf 1, Leaf 2 or Leaf 3, as these leaves had high infection levels of PYRNTE and are considered to be a robust test of the product.

~~From these seven trials conducted in the EPPO South East climatic zone, a single application of GF 3307 at 1.5 L/ha applied between BBCH 37-49 achieved mean control of 87.2% (87.2% on HORVW and 87.3% on HORVS) against PYRNTE on barley (range 81.1-96.9%). The 1.2 L/ha dose achieved mean control of 77.3% (75.5% on HORVW and 81.6% on HORVS) across the same trials (range 70.0-87.8%). These results are comparable to the level of control achieved by the prothioconazole standard Proline at 81.9% (range 71.3-92.9%). **Note:** Results from six trials were based on a slightly higher dose rate of 1.25 L/ha (trial highlighted in the BAD.). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lower label dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.~~

From these 14 trials conducted in the EPPO South-East climatic zone, a single application of GF-3307 at 1.5 L/ha applied between BBCH 37-49 achieved mean control of 86.4% (86.1% on HORVW and 87.8% on HORVS) against PYRNTE on barley (range 80.1-96.9%). The 1.2/1.25 L/ha dose achieved mean control of 77.5% (75.9% on HORVW and 83.7% on HORVS) across the same trials (range 69.5-88.1%). These results are comparable to the level of control achieved by the prothioconazole standard Proline at 79.6% (range 69.1-92.9%). **Note:** Results from six trials were based on a slightly higher dose rate of 1.25 L/ha (trial highlighted in the BAD). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lower label dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

The dataset includes ~~five~~ 11 trials from use on winter barley (HORVW) and ~~two~~ three trials from use on spring barley (HORVS). Winter barley can be considered to be the more challenging situation, as PYRNTE can become established in the crop over the winter months and cause higher infection levels. As results on both crops are comparable, it is considered that all data support use across both crops. The results are summarised in Table 3.2-2266 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-2266 are shown across all trials first before being shown orthogonally for spring and winter barley.

Table 3.2-226: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of PYRNTE in winter and spring barley from 7 trials conducted in the EPPO South-East climatic zone between 2017 and 2020. Assessment at 30-46 days after application.

EPPO Zone/Crop	Number of trials	Untreated: PYRNTE % infection		% control of PYRNTE						Significantly > , = , < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
South East (all trials)	7	26.6	10.0- 40.0	77.3	70.0- 87.8	87.2	81.1- 96.9	81.9	71.3- 92.9	1 > P, 6 = P (both doses)
South East (HORVW)	5	25.8	10.0- 40.0	75.5	70.0- 87.8	87.2	81.1- 96.9	83.4	74.1- 92.9	5 = P (both doses)
South East (HORVS)	2	28.8	21.3- 36.3	81.6	79.9- 83.2	87.3	87.0- 87.6	78.1	71.3- 84.8	1 > P, 1 = P (both doses)

P = Proline

Table 3.2-227: Efficacy of GF-3307 applied at 1.2 - 1.5 L/ha for the control of PYRNTE in winter and spring barley from 14 trials conducted in the EPPO South-East climatic zone between 2017 and 2021. Assessment at 28-46 days after application.

EPPO Zone/Crop	Number of trials	Untreated: PYRNTE % infection		% control of PYRNTE						Significantly >, =, < Standards
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
South-East (all trials)	14	21.5	5.0-42.5	77.5	69.5- 88.1	86.4	80.1- 96.9	79.6	69.1- 92.9	1.2: 2 > P, 12 = P 1.5: 5 > P, 9 = P
South-East (HORVW)	11	21.3	5.0-42.5	75.9	69.5- 87.8	86.1	80.1- 96.9	79.9	69.1- 92.9	1.2: 11 = P 1.5: 3 > P, 8 = P
South-East (HORVS)	3	22.4	9.5-36.3	83.7	79.9- 88.1	87.8	87.0- 88.9	78.6	71.3- 84.8	2 > P, 1 = P (both doses)

P = Proline

Summary and conclusions for the proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on the seven EPPO South-East climatic zone trials demonstrating mean overall control of PYRNTE in barley of 87.2% from a single application of GF-3307 at 1.5 L/ha, it is considered that the claim for control of PYRNTE is fully supported. Where disease levels are low, the 1.2 L/ha dose could be used, as this provided effective control of PYRNTE in this situation (77.3%).

Based on the 14 EPPO South-East climatic zone trials demonstrating mean overall control of PYRNTE in barley of 86.4% from a single application of GF-3307 at 1.5 L/ha (86.1% control across 11 trials on HORVW and 87.8% control across 3 trials on HORVS), it is considered that the claim for control of PYRNTE is fully supported. Where disease levels are low, the 1.2 L/ha dose could be used, as this provided effective control (77.5%) of PYRNTE in this situation (75.9% control across 11 trials on HORVW and 83.7% control across 3 trials on HORVS at 1.2/1.25 L/ha).

Across all trials, the level of control of PYRNTE achieved by GF-3307, at both dose rates tested, was higher or not statistically different from the standards. Results on both winter and spring crops are comparable and it is therefore considered that all data fully support use on both winter and spring crops.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.15 Effectiveness of GF-3307 for the control of PUCCHD in barley

This section addresses the efficacy of GF-3307 for the control of PUCCHD on winter and spring barley when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, ~~at the proposed dose range of 1.2-1.5 L/ha~~ 1.0-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and 1.0-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-2287 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	15-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (7), Spring barley (4) EPPO North-East: Winter barley (+ 2), Spring barley (6) EPPO South-East: Winter barley (+ 4), Spring barley (2)
	Varieties per crop	EPPO Maritime: Winter barley: Frigg, Hannelore, Lomerit, KWS Meridian, KWS Tonic (2), Wootan Spring barley: Vendela, Chapau, Odyssey, Ovation (2) EPPO North-East: Winter barley: Bazant , Kosmos Spring barley: Blask, Iron, Nokia, Propino, Ringo, Tocada EPPO South-East: Winter barley: Antonella, Astaire , Cardinal , SU Ellen Spring barley: Kangoo, Tango
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH) at application	BBCH 31-52: one application BBCH 31-39 and BBCH 45-59 two applications (Five EPPO Maritime trials and one EPPO South-East trial) EPPO Maritime: BBCH 31-49 (one application); BBCH 31-39 and BBCH 45-59 two applications (5 x two application trials) EPPO North-East: BBCH 32-52 EPPO South-East: BBCH 31-49 (one application); BBCH 31-32 and BBCH 47-49 two applications (1 SK two application trial)
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In many trials PUCCHD was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	4 (15 trials) — 2 (Five EPPO Maritime trials and one EPPO South-East trial) EPPO Maritime: one per crop (6 trials); two per crop (5 trials) EPPO North-East: one per crop (all trials) EPPO South-East: one per crop (4 trials); two per crop (1 SK trial)
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of

		known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCHD is an abundant disease.
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Introduction

~~In total, 21 field trials were conducted to demonstrate the efficacy of GF 3307, for the control of PUCCHD in winter and spring barley. To support the label claims, GF 3307 was tested at the proposed label rates of 1.0 L/ha, 1.2 L/ha and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, 'Foliar and ear diseases on cereals'.~~

In total, 25 field trials were conducted to demonstrate the efficacy of GF-3307, for the control of PUCCHD in winter and spring barley. To support the label claims, GF-3307 was tested at 1.0, 1.2/1.25 L/ha and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, 'Foliar and ear diseases on cereals'. **Note:** Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Austria (1), Belgium (1), Czech Republic (1), Denmark (2), France (1) Germany (2) and UK (3) in the EPPO Maritime climatic zone, Latvia (2) and Poland (5 6) in the EPPO North-East climatic zone, and Hungary (4 3), Romania (1) and Slovakia (2) in the EPPO South-East climatic zone, between 2017 and 2020 2021.

On the basis of the EPPO standard PP 1/241 'Guidance on comparable climates', the trials included in the dossier have been grouped and summarised by EPPO zone. EPPO zones have been defined by taking considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these zones, which are representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-27.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where PUCCHD is an abundant disease. PUCCHD is a disease which multiplies rapidly at short cycles, under warm climatic conditions such as are found in the Maritime, North-East and South-East EPPO climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 17 provides an overview on the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.5	150, 180, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8	150-200
Delaro*	SC	175 g/L prothioconazole + 150 g/L trifloxystrobin	0.75	244

*One HU trial only

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.0, 1.2, 1.25, 1.5	150, 180, 187.5, 225
Proline 250	EC	250 g/L prothioconazole	0.72-0.8	180-200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	0.75	188

Experimental details

The 24 25 efficacy trials were conducted to GEP, by officially recognized testing organisations, following the appropriate EPPO standards. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 15 m² and 36 m². Nine Thirteen trials were carried out on winter barley and 12 trials on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

Depending on the time of appearance of the disease within the season and the speed of progression of PUCCHD infections, the treatments were applied typically when diseases had established, to stop further development of the disease. Five of the trials in the EPPO Maritime climatic zone and one trial in the EPPO South-East climatic zone were based on a two-application regime (CZ18E7B007PV02C, DE18E7B007UB01C, DE18E7B007UB4C, GB17E7B046RH01, GB17E7B049RH02 and SK18E7B008PV02C). In these trials PUCCHD did not develop until 17-31 days after the second application. The first applications were applied at BBCH 31-39 of the crop (in April/May) and the second applications were applied at BBCH 47-59 (in May/June). PUCCHD in these trials did not develop until 28-42 days after the first application and this is considered to be beyond the protection period the first application of GF-3307 could be expected to deliver (see summary of diseases levels at application for these trials below). In addition, the assessed leaf (Leaf 2) was not emerged at the time of the first application in some of these trials and would not have been protected by that spray. For these trials, results after two applications were used, as it is considered that the second application is comparable to a single application dose regime. For full site and application details of individual trials see Appendix 3 and Appendix 4 of the BAD.

Summary of disease levels at application in two-dose trials

Trial number	Crop	1 st Application timing (BBCH)	PUCCHD % infection at 1 st application	2 nd Application timing (BBCH)	PUCCHD % infection at 2 nd application	Days after 2 nd application PUCCHD found in trial (days after 1 st application)
CZ18E7B007PV02C	HORVS	31-32	0% all leaves	47-49	0% all leaves	28 days (42 days)
DE18E7B007UB01C	HORVW	37-39	0% all leaves	55-59	0% all leaves	20 days (33 days)
DE18E7B007UB4C	HORVW	32	0% all leaves	49-51	0% all leaves	17 days (34 days)
GB17E7B046RH01	HORVS	37	0% all leaves	49	0% all leaves	21 days (28 days)
GB17E7B049RH02	HORVS	37	0% all leaves	45-49	0% all leaves	31 days (40 days)
SK18E7B008PV02C	HORVS	31-32	0% all leaves	47-49	0% all leaves	26 days (42 days)

Assessments for efficacy (% infection) were targeted at 2-3 weeks and 4-6 weeks after each application and/or at BBCH 75 of winter barley. Percentage control was calculated by leaf level relative to the infection level present in the untreated control. Leaves showing less than 5% infection with PUCCHD or leaves which were senesced to a high degree in treated and untreated plots, were excluded from the summary tables. Assessment were generally on Leaf 1 or Leaf 2, with a couple on Leaf 3.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, 11 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of PUCCHD in winter and spring barley, at the proposed label rate following an application applied at BBCH 32-59. The trials were conducted in Austria (1), Belgium (1), Czech Republic (1), Denmark (2), France (1) Germany (2) and UK (3) in the EPPO Maritime climatic zone between 2017 - 2019. ~~The data included trials where PUCCHD was established before application (including on the leaves assessed for control in some trials) and trials where PUCCHD did not develop until after application.~~ The data included trials where PUCCHD was established at low levels on lower leaves before application and trials where PUCCHD did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessment across the majority of trials was on Leaf 2, as this leaf had high infection levels of PUCCHD and is considered to be a robust test of the product.

Results for five trials are based on a two-dose regime. In these trials PUCCHD did not develop until 17-31 days after the second application, 28-42 days after the first application, which is beyond the protection period the first application of GF-3307 could be expected to deliver. For these trials, results after two applications have been used, as it is considered that the second application is comparable to a single dose regime.

Across these 11 EPPO Maritime climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of PUCCHD in winter and spring barley of 93.9% (range 78.9-100%), 20-36 days after application, which was identical to the control achieved by the prothioconazole standard Proline at 93.9% (range 81.3-100%).

The dataset includes seven trials from use on winter barley (HORVW) and four trials from use on spring barley (HORVS). Results on both crops are comparable (95.7% control on HORVW and 90.8% control on HORVS). It is therefore considered that all 11 trials fully support use in both winter and spring barley crops.

In addition to these data from the EPPO Maritime Climatic zone, data are available from Poland, which is a neighbouring country. Poland has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of PUCCHD. Data from six trials are available that demonstrate comparable levels of control following a single application: 96.6%, compared to 90.8% for the standard Proline and Prosaro (tebuconazole + prothioconazole). Combined with the six EPPO Maritime Climatic zone trials based on a single dose gives 94.4% overall control of PUCCHD across 12 trials, 95.5% control on HORVW across seven trials and 93.0% control on HORVS across five trials.

The results are summarised in Table 3.2-229 the results of the individual trials are detailed in the BAD. Results in Table 3.2-229 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley.

Table 3.2-229: Efficacy of GF-3307 applied at 1.5 L/ha for the control of PUCCHD in winter and spring barley from 11 trials conducted in the EPPO Maritime climatic zone between 2017 and 2019. Assessment at 20-36 days after application.

EPPO Zone/Crop	Number of trials	Untreated: PUCCHD % infection		% control of PUCCHD					Significantly ≥, =, < Standards
				GF 3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min-max	Mean	min-max	Product/dose	
Maritime (HORVW)	11	25.2	7.7-76.7	93.9	78.9-100	93.9	81.3-100	Proline/0.8 L/ha	11 = P
Maritime (HORVW)	7	15.5	7.7-23.8	95.7	78.9-100	95.4	83.4-100	Proline/0.8 L/ha	7 = P
Maritime (HORVS)	4	42.0	12.3- 76.7	90.8	83.7-99.2	91.3	81.3-100	Proline/0.8 L/ha	4 = A

P = Proline

Table 3.2-230: Efficacy of GF-3307 applied at 1.5 L/ha for the control of PUCCHD in winter and spring barley from 11 trials conducted in the EPPO Maritime climatic zone plus six (6) PL trials between 2017-2021. Assessment at 20-38 days after application.

2021 Assessment at 20-30 days after application									
EPPO Zone/Crop	Number of trials	Untreated: PUCCHD % infection		% control of PUCCHD					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min- max	Mean	min-max	Product/dose	
Maritime (HORVW)	11	25.2	7.7- 76.7	93.9	78.9-100	93.9	81.3-100	Proline/0.8 L/ha	11 = P
Maritime (HORVW)	7	15.5	7.7- 23.8	95.7	78.9-100	95.4	83.4-100	Proline/0.8 L/ha	7 = P
Maritime (HORVS)	4	42.0	12.3- 76.7	90.8	83.7- 99.2	91.3	81.3-100	Proline/0.8 L/ha	4 = A
PL (All crops) Single application	6	21.2	5.5- 47.5	96.6	89.9-100	90.8	80.3-100	All^	3 = P, 1 >, 2 = PO
Maritime + PL (All crops) Single application	12	17.8	5.5- 47.5	94.4	78.9-100	91.1	80.3-100	All^	9 = P, 1 >, 2 = PO
Maritime + PL (HORVW) Single application	7	19.8	7.7- 47.5	95.5	78.9-100	93.2	83.4-100	All^	6 = P, 1 = PO
Maritime + PL (HORVS) Single application	5	15.0	5.5- 31.9	93.0	83.7-100	88.2	80.3-98.4	All^	3 = P, 1 >, 1 = PO

^Reference standards used based on Proline 250 (P) applied at 0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on 11 EPPO Maritime climatic zone trials demonstrating mean overall control of PUCCHD in barley of 93.9% from a single application of 1.5 L/ha GF-3307, it is considered that the proposed claims for control of PUCCHD in winter and spring barley are fully supported.

Eleven EPPO Maritime climatic zone trials demonstrate mean overall control of PUCCHD in barley of 93.9% from application of GF-3307 at 1.5 L/ha. In addition, data are available from 12 single dose trials (Six EPPO Maritime climatic zone trials and six Polish trials, demonstrating mean overall control of PUCCHD in barley of 94.4 from a single application of 1.5 L/ha GF-3307 (93.4% on HORVW across 8 trials and 91.6% on HORVS across 6 trials). It is therefore considered that the proposed claim for control of PUCCHD using the 1.5 L/ha dose of GF-3307 in winter and spring barley, is fully supported.

Proposed dose range of 1.2-1.5 L/ha 1.0-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, ~~seven~~ **eight** small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of PUCCHD in winter and spring barley at ~~the proposed label rates of 1.2 and 1.5 L/ha~~ **1.0-1.5 L/ha**, following a single application applied at BBCH 37-52 of the crop. The trials were conducted in Latvia (2) and Poland (5 ~~6~~) in the EPPO North-East climatic zone on both winter and spring barley. ~~The data included trials where PUCCHD was established before application (including on the leaves assessed for control in some trials) and trials where PUCCHD did not develop until after application.~~ **The data included trials where PUCCHD was established at low levels on lower leaves before application and trials where PUCCHD did not develop until after application.** These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. Assessments on Leaf 1 or Leaf 2 data were available and the leaf with the highest level of disease was used.

~~Across all 7 EPPO North East climatic zone trials, GF 3307 at 1.5 L/ha achieved mean control of PUCCHD in winter and spring barley of 96.9% (98.1% on HORVW and 96.7% on HORVS) at 21-37 days after one application (range 89.9-100%), which is higher than the level of control achieved by the prothioconazole standard Proline at 88.8% (range 71.4-100%). At a dose rate of 1.2 L/ha, only slightly lower control of 92.6% (96.0% on HORVW and 92.0% on HORVS) was achieved (range 79.6-100%).~~

Across all eight EPPO North-East climatic zone trials, GF-3307 at the maximum dose rate of 1.5 L/ha achieved mean control of PUCCHD in winter and spring barley of 97.3% (99.1% on HORVW and 96.7% on HORVS) at 21-38 days after one application (range 89.9-100%), which is higher than the level of control achieved by the reference standards at 92.0% (range 80.3-100%). At a dose rate of 1.2/1.25 L/ha, only slightly lower control of 93.5% (98.0% on HORVW and 92.0% on HORVS) was achieved (range 79.6-100%). **Note:** Results from six trials were based on a slightly higher dose rate of 1.25 L/ha ~~(trials highlighted in the BAD)~~. As this is within 4% of the proposed label dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lowest label dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

At the lower dose rate of 1.0 L/ha, GF-3307 achieved 86.2% control (range 77.6-97.1%). When compared directly with the various standards used (Proline 250 and Prosaro) control by all three doses was comparable to the reference standards.

~~The EPPO North East climatic zone dataset includes one trial from use on winter barley (HORVW) and six trials from use on spring barley (HORVS). Although data from eight trials is not available on winter and/or spring barley, combining the seven EPPO North East climatic zone on winter and spring barley with one on winter barley from a neighbouring country (DE) gives 97.1% control of PUCCHD on barley at the maximum 1.5 L/ha dose and 93.5% control at the lower 1.2 L/ha dose, across 8 trials. As comparability of control between winter and spring crops has been demonstrated for both this disease and the other diseases in this dossier, it is considered that these eight trials fully support use of GF 3307 on winter and spring barley~~

The EPPO North-East climatic zone dataset includes two trials from use on winter barley (HORVW) and six trials from use on spring barley (HORVS). Although data from eight trials is not available on winter and/or spring barley, combining the eight EPPO North-East climatic zone on winter and spring barley with one on winter barley from a neighbouring country (DE) gives 97.4% control of PUCCHD on barley at the maximum 1.5 L/ha dose, 94.2% control at the 1.2/1.25 L/ha dose and 86.2% control for the 1.0 L/ha dose, across seven trials. As comparability of control between winter and spring crops has been demonstrated for both this disease and the other diseases in this dossier, it is considered that these nine trials fully support use of GF-3307 on winter and spring barley

The results are summarised in Table 3.2-23179 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-23179 are shown across all trials first before being shown orthogonally for spring and winter barley.

~~Table 3.2-231: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of PUCCHD in winter and spring barley from 7 trials conducted in the EPPO North-East climatic zone plus one DE trial, between 2017 and 2020. Assessment at 21-37 days after a single application.~~

EPPO Zone/Crop	Number of trials	Untreated: PUCCHD-%	% control of PUCCHD			Significantly >, =,<
			GF-3307	GF-3307	Proline	

		infection		1.2 L/ha		1.5 L/ha		0.6-0.8 L/ha		Standards
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
North-East (all trials)	7	17.4	5.5-47.5	92.6	79.6-100	96.9	89.9-100	88.8	71.4-100	2>P, 5=P (both doses)
North-East (HORVW)	1	47.5	-	96.0	-	98.1	-	84.8	-	1=P (both doses)
North-East (HORVS)	6	12.4	5.5-31.9	92.0	79.6-100	96.7	89.9-100	89.5	71.4-100	2>P, 4=P (both doses)
North-East + DE (all trials)	8	18.1	5.5-47.5	93.5	79.6-100	97.1	89.9-100	89.9	71.4-100	2>P, 6=P (both doses)
North-East + DE (HORVW)	2	35.4	23.3-47.5	97.8	96.0-99.5	98.3	98.1-98.4	91.4	84.8-97.9	2=P (both doses)

P=Proline

Table 3.2-232: Efficacy of GF-3307 applied at 1.0-1.5 L/ha for the control of PUCCHD in winter and spring barley from 8 trials conducted in the EPPO North-East climatic zone plus one (1) DE trial, between 2017 and 2021. Assessment at 21-38 days after a single application.

Between 2017 and 2021. Assessment at 21-38 days after a single application.												
EPPO Zone/ Crop	Numbe r of trials	Untreated: PUCCHD % infection		% control of PUCCHD								Significantl y >, =, < Standards
				GF-3307 1.0 L/ha		GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference standards		
		Mea n	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North-East (all trials)	8	17.4	5.5- 47.5	86.2#	77.6- 97.1	93.5	79.6- 100	97.3	89.9- 100	92.0^	80.3- 100	1.0: 1>, 1 < 2 = P, 1>, 2= PO 1.2/1.5: 1 >, 4 = P, 1 >, 2 = PO
North- East* (all trials)	5	16.9	5.5- 47.5	84.9	77.6- 94.1	90.4	79.6- 100	96.0	89.9- 100	91.4	84.4- 100	1.0: 1 >, 1 <, 2= P 1.2: 1 >, 4 = P 1.5: 1 >, 4 = P
North- East** (all trials)	3	18.3	5.5- 31.9	87.9	82.5- 97.1	98.7	97.6- 100	99.5	98.6- 100	92.9	80.3- 100	1 >, 2 = PO (All doses)
North-East (HORVW)	2	34.2	20.8- 47.5	88.3	82.5- 94.1	98.0	96.0- 100	99.1	98.1- 100	92.4	84.8- 100	1 > P, 1 = PO (All doses)
North-East (HORVS)	6	12.4	5.5- 31.9	85.3	77.6- 97.1	92.0	79.6- 100	96.7	89.9- 100	91.9	80.3- 100	1.0: 1 <, 2 = P, 1 >, 1 = PO 1.2/1.5: 4 = P, 1 >, 1 = PO
North-East + DE (HORVW)	3	30.5	23.3- 47.5	-	-	98.5	96.0- 100	98.8	98.1- 100	94.2	84.8- 100	1 > 1 = P, 1 = PO Both doses
North-East + DE (all trials)	9	18.0	5.5- 47.5	86.2#	77.6- 97.1	94.2	79.6- 100	97.4	89.9- 100	92.6	80.3- 100	1.0: 1>, 1 <, 2 = P, 1>, 2= PO 1.2/1.5: 1 >, 5 = P, 1 >, 2 = PO

#7 Trials only

*Direct comparison to Proline (P)

**Direct comparison to Prosaro (PO)

^Reference standards used based on Proline 250 (P) applied at 0.72-0.8 L/ha.

^^Reference standards used based on Proline 250 (P) applied at 0.72-0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

Summary and conclusions for the proposed dose rate range of ~~1.2-1.5 L/ha~~ 1.0-1.5 L/ha in the EPPO North-East climatic zone

~~PUCCHD is a secondary target disease for GF 3307. Where disease pressure is low and only PUCCHD requires control, the lower dose of 1.2 L/ha is recommended. Based on data from eight trials on winter and spring barley using the 1.2 L/ha dose rate of GF 3307, demonstrating mean overall control of PUCCHD of 93.5% (seven EPPO North-East climatic zone trials and one German trial), it is considered that the proposed claim for control of PUCCHD using GF 3307 at a dose rate of 1.2 L/ha on winter and spring barley is fully supported.~~

~~In high pressure mixed disease situations (PYRNTE also present or expected) the higher dose of 1.5 L/ha is recommended. Based on data from eight trials on winter and spring barley using the 1.5 L/ha dose rate of GF 3307, demonstrating mean overall control of PUCCHD of 97.1% (seven EPPO North-East climatic zone trials and one German trial), it is considered that the proposed claim for control of PUCCHD using GF 3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley is fully supported.~~

PUCCHD is a secondary target disease for GF-3307. Where disease pressure is low and only PUCCHD requires control, the lower dose of 1.0 L/ha is recommended. Based on data from seven EPPO North-East climatic zone trials on barley using the 1.0 L/ha dose rate of GF-3307, demonstrating mean overall control of PUCCHD of 86.2%, it is considered that the proposed claim for control of PUCCHD using GF-3307 at a dose rate of 1.0 L/ha on winter and spring barley is fully supported.

In mixed disease situations (other diseases also present) the 1.2 L/ha dose is recommended. Based on data from nine trials on barley using the 1.2/1.25 L/ha dose rate of GF-3307, demonstrating mean overall control of PUCCHD of 94.2% (eight EPPO North-East climatic zone trials and one German trial), it is considered that the proposed claim for control of PUCCHD using GF-3307 at a 1.2 L/ha dose rate on winter and spring barley is fully supported.

In high pressure mixed disease situations (PYRNTE also present or expected) the higher dose of 1.5 L/ha is recommended. Based on data from nine trials on barley using the 1.5 L/ha dose rate of GF-3307, demonstrating mean overall control of PUCCHD of 97.4% (eight EPPO North-East climatic zone trials and one German trial), it is considered that the proposed claim for control of PUCCHD using GF-3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley is fully supported.

A dose range of ~~1.2-1.5 L/ha~~ 1.0-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose rate range of 1.0-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

~~Three GEP small plot field trials were conducted to demonstrate the efficacy of GF 3307 for the control of PUCCHD in winter and spring barley, at the proposed label rates following a single application applied at BBCH 31-49 of the crop. The trials were conducted in Hungary (1) and Slovakia (2) in the EPPO South-East climatic zone, on winter and spring barley. Assessment across all trials was on Leaf 2 or Leaf 3, as these leaves had the highest infection levels of PUCCHD and were considered to be a robust test of the product.~~

Six GEP small plot field trials were conducted to demonstrate the efficacy of GF-3307 for the control of PUCCHD in winter and spring barley at 1.0-1.5 L/ha, following a single application applied at BBCH 31-49 of the crop. The trials were conducted in Hungary (3), Romania (1) and Slovakia (2) in the EPPO South-East climatic zone, on winter and spring barley. Assessment across all trials was on Leaf 1, Leaf 2 or Leaf 3, as these leaves had the highest infection levels of PUCCHD and were considered to be a robust test of the product.

One trial was based on a two-application regime (SK18E7B008PV02C), where PUCCHD did not develop in the trial until 26 days after the second application. In this trial the first application was applied at BBCH 31-32 of the crop (in May) and the second application was applied at BBCH 47-59 (in June). PUCCHD in this trial did not develop until 46 days after the first application, demonstrating how the disease can infect crops late in their development and this is considered to be beyond the protection period the first application of GF-3307 could be expected to deliver. It is also considered that as the first application was at BBCH 31-32 of the crop, the assessed leaf (Leaf 2) had not emerged

at this timing. For this trial, the results after two applications have been used, as it was considered that the second application was comparable to a single dose regime. **Note:** Results from two trials were based on a slightly higher dose rate of 1.25 L/ha (trial highlighted in the BAD.). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single result for the proposed lower label dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

~~From these three trials conducted in the EPPO South East climatic zone, a single application of GF 3307 at 1.5 L/ha, applied between BBCH 31-49 achieved mean control of 92.4% (range 89.5-95.3%) of PUCCHD on barley, 14-26 days after application. The 1.2 L/ha dose achieved 90.9% (range 88.2-93.5%) across two trials and the 1.0 L/ha dose achieved 84.9% control (range 76.3-93.5%) across the same two trials. These results were comparable to the levels of control achieved by the prothioconazole standard Proline at 91.5% across two trials and the prothioconazole + trifloxystrobin standard Delaro at 98.9% in one trial.~~

From these six trials conducted in the EPPO South-East climatic zone, a single application of GF-3307 at 1.5 L/ha, applied between BBCH 31-49 achieved mean control of 92.0% (range 89.0-95.9%) of PUCCHD on barley, 14-42 days after application. The 1.2/1.25 L/ha dose achieved 90.3% (range 88.0-93.5%) across five trials and the 1.0 L/ha dose achieved 85.3% control (range 76.3-93.5%) across the same five trials. These results were comparable to the levels of control achieved by the prothioconazole standard Proline (applied 180-200 g as /ha) at 92.4%.

In addition to these data from the EPPO South-East Climatic zone, data are available from Poland, which is a neighbouring country. Poland has similar climatic conditions in late stages of the crop/summer that encourage the development of PUCCHD (hot and dry weather). ~~Data from five trials are available that demonstrate comparable levels of control: 95.9% for the 1.5 L/ha dose, 93.7% for the 1.2 L/ha dose and 86.9% for the 1.0 L/ha dose, compared to 86.0% for the prothioconazole standard Proline.~~ Data from six trials based on a single application are available that demonstrate comparable levels of control: 96.6% for the 1.5 L/ha dose, 94.8% for the 1.2/1.25 L/ha dose and 86.2% for the 1.0 L/ha dose, compared to 92.8% for the reference standards (Proline 250 and Prosaro). Combining these six Polish trials with the five EPPO South-East Climatic zone based on a single application demonstrates 94.2% control of PUCCHD for the 1.5 L/ha dose across 11 trials, 92.7% for the 1.2/1.25 L/ha dose and 85.0% for the 1.0 L/ha dose across 10 trials, compared to 90.9% for the reference standards (Proline 250 and Prosaro).

~~The dataset includes two trial from use on winter barley (HORVW) and six trials from use on spring barley (HORVS).~~ The dataset (EPPO South-East and Poland trials combined) includes six trials from use on winter barley (HORVW) and six trials from use on spring barley (HORVS). Results on both crops are comparable, and it is therefore considered that all data fully support use on both winter and spring crops.

The results are summarised in Table 3.2-2330 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-2330 are shown across all trials first before being shown orthogonally for spring and winter barley and the reference standards.

~~Table 3.2-233: Efficacy of GF-3307 applied at 1.0, 1.2 and 1.5 L/ha for the control of PUCCHD in winter and spring barley in 2018. Assessment at 14-26 days after application.~~

EPPO Zone/ Crop	Number of trials	Untreated: PUCCHD-% infection		% control of PUCCHD								Significantly >, =, < Standards
				GF-3307 1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
South-East (all-crops)	3	13.0	7.6- 16.9	-	-	-	-	92.4	89.5- 95.3	93.7	84.2- 98.8	2 = P 1 = D
South-East (HORVW)	1	14.5	-	-	-	-	-	92.3	-	98.0*	-	1 = D
South-East (HORVS)	2	12.3	7.6- 16.9	84.9	76.3- 93.5	90.9	88.2- 93.5	92.4	89.5- 95.3	91.5**	84.2- 98.8	2 = P (all-doses)
Poland (all-crops)	5	22.0	5.5- 47.5	86.9	77.6- 97.1	93.7	87.2- 98.4	95.9	89.9- 100	86.0	71.4- 92.9	2 > P, 3 = P (all-doses)
Poland (HORVW)	1	47.5	-	94.1	-	96.0	-	98.1	-	84.8	-	1 > P (all-doses)
Poland	4	15.6	5.5-	85.1	77.6-	93.1	87.2-	95.4	89.9-	86.3	71.4-	1 > P, 3 = P

(HORVS)			31.9		97.1		98.4		100		92.9	(all doses)
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*Delaro (D) applied at 0.75 L/ha. **Proline (P) applied at 0.6-0.8 L/ha.

Table 3.2-234: Efficacy of GF-3307 applied at 1.0-1.5 L/ha for the control of PUCCHD in winter and spring barley. Results from six trials in the EPPO South-East climatic zone plus six PL trials conducted between 2018-2021. Assessment at 14-42 days after application.

EPPO Zone/ Crop	Numbe r of trials	Untreated: PUCCHD % infection		% control of PUCCHD								Significantl y >, =, < Standards
				GF-3307 1.0 L/ha		GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference standards		
		Mea n	min- max	Mea n	min- max	Mea n	min- max	Mea n	min- max	Mean	min- max	
South- East (all crops)	6	10.8	5.3- 16.9	-	-	-		92.0	89.0 - 95.9	92.4^	84.2 - 98.8	6 = P
South- East (all crops)	5	10.1	5.3- 16.9	85.3	76.3 - 93.5	90.3	88.0 - 93.5	91.9	89.0 - 95.9	91.3^	84.2 - 98.8	5 = P (all doses)
South- East (HORVW)	4	10.1	5.3- 14.5	-	-	-	-	91.8	89.0 - 95.9	92.9^	89.0 - 98.0	4 = P
South- East (HORVW)	3	8.7	5.3- 11.4	85.5	79.6 - 91.9	90.0	88.0 - 93.0	91.6	89.0 - 95.9	91.2^	89.0 - 95.5	3 = P (all doses)
South- East (HORVS)	2	12.3	7.6- 16.9	84.9	76.3 - 93.5	90.9	88.2 - 93.5	92.4	89.5 - 95.3	91.5^	84.2 - 98.8	2 = P (all doses)
Poland (all crops)	6	21.2	5.5- 47.5	86.2	77.6 - 97.1	94.8	87.2 -100	96.6	89.9 -100	92.8^ ^	84.8 -100	1.2/1.5: 1 >, 2 = P, 1 >, 2 = PO; 1.0: 1 <, 1 >, 1 = P, 1 >, 2 = PO
Poland (HORVW)	2	34.2	20.8 - 47.5	88.3	82.5 - 94.1	98.0	96.0 -100	99.1	98.1 -100	92.4^ ^	84.8 -100	1 > P, 1 = PO (all doses)
Poland (HORVS)	4	15.6	5.5- 31.9	85.1	77.6 - 97.1	93.1	87.2 - 98.4	95.4	89.9 -100	89.9^ ^	80.3 - 98.4	1.2/1.5: 2 = P, 1 >, 1 = PO; 1.0: 1 <, 1 = P, 1 >, 1 = PO
South- East + PL (all crops) Single dose	11	16.0	5.3- 47.5	85.0#	76.3 - 97.1	92.7#	87.2 -100	94.2	89.0 -100	90.9^ ^	80.3 -100	1.2/1.5: 1 >, 7 = P, 1 >, 2 = PO; 1.0: 1 <, 1 >, 5 = P, 1 >, 2 = PO

#Results from 10 trials only

^Reference standards used based on Proline 250 (P) applied at 0.72-0.8 L/ha.

^^Reference standards used based on Proline 250 (P) applied at 0.72-0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

Summary and conclusions for the proposed dose range of 1.0-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Based on ~~three~~ **six** EPPO South-East climatic zone trial results, demonstrating mean overall control of PUCCHD in barley of ~~92.4~~ **92.0%** from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of PUCCHD is fully supported. The 1.5 L/ha dose is considered to be appropriate for situations where other diseases such as PYRNTE are present/expected or where season long control is required. In other situations, a lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated ~~90.9~~ **90.3%** control **across five trials at 1.2/1.25 L/ha**. For low disease risk situations, the lowest dose in the proposed range of 1.0 L/ha is considered appropriate, as this demonstrated ~~84.9~~ **85.3%** control **across five trials**.

~~Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the later stages of the crop/summer that encourage the development of PUCCHD (hot and dry weather). Data from these trials (a mix of HORVS and HORVW trials)~~

~~demonstrate comparable levels of control: 95.9% for the 1.5 L/ha dose, 93.7% for the 1.2 L/ha dose and 86.9% for the 1.0 L/ha dose.~~

~~Across all trials, the level of control of PUCCHD achieved by GF-3307, at all three dose rates tested, was higher or not statistically different from the standards.~~

Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the later stages of the crop/summer that encourage the development of PUCCHD (hot and dry weather). Data from these trials (a mix of HORVS and HORVW trials) demonstrate comparable levels of control: 96.6% for the 1.5 L/ha dose, 94.8% for the at 1.2/1.25 L/ha dose and 86.2% for the 1.0 L/ha dose.

Across all trials, the level of control of PUCCHD achieved by GF-3307, at all three dose rates tested (94.2% for the 1.5 L/ha dose, 92.7% for the at 1.2/1.25 L/ha and 85.0% for the 1.0 L/ha dose), was higher or not statistically different from the reference standards (90.9%). Results on both winter and spring crops are comparable and it is therefore considered that all data fully support use on both winter and spring crops.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.16 Effectiveness of GF-3307 for the control of ERYSGH in barley

This section addresses the efficacy of GF-3307 for the control of ERYSGH on winter and spring barley when applied at the proposed label rate of 1.5 L/ha in the EPPO Maritime climatic zone countries of the Central EU Authorisation zone, the proposed dose range of 1.2-1.5 L/ha in Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) and 1.2-1.5 L/ha in the EPPO South-East climatic zone countries of the Central EU Authorisation zone.

Table 3.2-2351 Details on trial methodology

Guidelines	General guidelines	EPPO PP 1/135, 1/152, 1/181, 1/226, 1/214, 1/223
	Specific guidelines	EPPO PP 1/26
Experimental design	Plot design	RCB
	Plot size	12-36 m ²
	Number of replications	4
Crop	Trials per crop	EPPO Maritime: Winter barley (7 6), Spring barley (3) EPPO North-East: Winter barley (5), Spring barley (5) EPPO South-East: Winter barley (2), Spring barley (2)
	Varieties per crop	EPPO Maritime: Winter barley: California, Cassia, Cervoise, Frigg, Hennriette, Infinity, Lomerit, Spring barley: Avalon, Grace (2) EPPO North-East: Winter barley: Carola (3), Meridian, Zenek Spring barley: Blask, Iron, Propino, Stratus, Tocada EPPO South-East: Winter barley: SE Ellen, Astaire Spring barley: Xanadu, Kangoo
	Sowing period	Winter barley: September-October Spring barley: March-May
Application	Crop stage (BBCH)* at application	BBCH 30-52: one application BBCH 32 and BBCH 49 two applications (one UK trial) EPPO Maritime: BBCH 31-41 EPPO North-East: BBCH 31-52 EPPO South-East: BBCH 31-49
	Timing Pest stage at application	GF-3307 has both protectant and curative properties. In all cases ERYSGH was assessed as a secondary pathogen. Applications were timed to commenced when was a risk of infection with the target pathogen or the target pathogen started to develop on the lower leaf levels to applications against established infection.
	Number of applications	1 (21 trials) 2 (1 UK trial) EPPO Maritime: one application EPPO North-East: one application EPPO South-East: one application
	Spray volumes	200-300 L/ha
Assessment	Assessment types	% infection (severity) of foliar diseases by leaf level, % crop injury (phytotoxicity effects such as chlorosis, necrosis, stunting), green leaf area, yield amount (T/ha) corrected to 86% dry matter, in selected trials yield parameters such as grain moisture at harvest, 1000 grain weight, hectolitre weight and other quality parameters, germination ability of seeds collected
	Assessment dates for efficacy and crop selectivity	Assessments for crop selectivity were aimed at 1 and 2 weeks after application and at every assessment timing for efficacy. Assessments for efficacy (% infection) were aimed at the timing of application, 2-3, 4-6 weeks after application and/or at BBCH 75.
Other relevant information	Natural / artificial inoculation	Natural infection
	Field / Greenhouse	All trials were carried out in the field, trial sites were selected on the basis of known pest pressure, favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially and where the key target pathogen is an abundant disease. ERYSGH was assessed as a secondary pathogen present at reliable levels.

Introduction

~~In total, 22 field trials were conducted to demonstrate the efficacy of GF 3307 for the control of ERYSGH in winter and spring barley. To support the label claims, GF 3307 was tested at the proposed label rates of 1.2 L/ha, and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, 'Foliar and ear diseases on cereals'.~~

In total, 23 field trials were conducted to demonstrate the efficacy of GF-3307 for the control of ERYSGH in winter and spring barley. To support the label claims, GF-3307 was tested at 1.2/1.25 L/ha and 1.5 L/ha, in accordance with the EPPO standard PP 1/26, 'Foliar and ear diseases on cereals'. **Note:** Results from some trials were based on a 1.25 L/ha dose rate instead of 1.2 L/ha (trials highlighted in the BAD). As these doses are within 10% of each other (actual 4% difference), the data has been combined to support the 1.2 L/ha dose rate in the EPPO North-East and South-East.

The trials were carried out by Dow AgroSciences, contractor companies and Official Research Institutes, all of which followed the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in Denmark (1), France (1), Germany (6) and United Kingdom (2 1) in the EPPO Maritime climatic zone, Latvia (5) and Poland (5) in the EPPO North-East climatic zone and Hungary (1 3) and Slovakia (1) in the EPPO South-East climatic zone, between 2017 and 2020.

On the basis of the EPPO standard PP 1/241 'Guidance on comparable climates', the trials included in this dossier have been grouped and summarised by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The Central EU Authorisation Zone covers countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO standard PP 1/241. This submission includes data from each of these zones, which is representative of the proposed GAP.

Materials and Methods

Testing facilities or organisations

The efficacy trials were carried out by the testing facilities in the countries listed in Table 3.2-28.

Sites

Trial sites were selected on the basis of known pest pressure, favourable agronomic and environmental factors, in areas representative of those where the crop is grown commercially and where ERYSGH is an abundant disease. ERYSGH is a disease which multiplies rapidly at short cycles under warm and humid climatic conditions, such as are found in the EPPO Maritime, North-East and South-East climatic zones. For trial site and application details see Appendix 3 and Appendix 4 of the BAD. Figure 3.2 - 18 provides an overview on the geographical distribution of the efficacy trials across the EU countries involved.

Formulations applied and rates

Test-product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.5	180, 225
Proline	EC	250 g/L prothioconazole	0.6-0.8	150-200

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	50 g/L fenpicoxamid + 100 g/L prothioconazole	1.2, 1.25, 1.5	180, 187.5, 225
Proline 250	EC	250 g/L prothioconazole	0.8	200
Prosaro	EC	125 g /L tebuconazole + 125 g /L prothioconazole	0.75	188

Experimental details

The ~~22~~ 23 efficacy trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and plot sizes ranging between 12 m² and 36 m². Thirteen trials were carried out on winter barley and ~~eight~~ 10 on spring barley. The treatments in all trials were applied using self-propelled, bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 200 and 300 L/ha.

Assessments for efficacy (% infection) were targeted 2-3 weeks after each application and/or at BBCH 75 of winter barley. Percentage control was calculated by leaf level, relative to the infection level present in the untreated control. Leaves showing less than 5% infection with ERYSGH or leaves which were senesced to a high degree in treated and untreated plots were excluded from the summary tables. Assessments used were generally on Leaf 2, Leaf 3, or Leaf 4 as the highest available assessed leaf with sufficient infection in the untreated.

Results

Proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

In total, ~~10~~ 9 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of ERYSGH in winter and spring barley, at the proposed label rate of 1.5 L/ha, following application at BBCH 30-55. The trials were conducted in Denmark (1), Germany (6), France (1) and the UK (~~2~~ 1) between 2017 -2019. ~~The data included trials where ERYSGH was established before application (including on the leaves assessed for control in some trials) and trials where ERYSGH did not develop until after application.~~ The data included trials where ERYSGH was established at low levels on lower leaves before application and trials where ERYSGH did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. ERYSGH is a disease that establishes early in the crop on the lower leaves, therefore the majority of results for this disease are from lower leaves (Leaf 3 and Leaf 4). **Note:** In one trial, the latest assessment timing after a single application was 18 days. Later assessments in this trial followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP.

~~Results for one trial were based on a two application regime (GB18E7B007EB02C). In this trial, the first application was applied at BBCH 31-32. However, ERYSGH did not develop in this trial until 21 days after the second application (35 days after the first application). This timing is beyond the protection period a single application of GF 3307 could be expected to deliver and as the first application was at BBCH 31-32 of the crop, the assessed leaf (Leaf 2) had not emerged at this timing. It is therefore considered that control of ERYSGH after two applications is comparable to a single application dose regime, so has been included.~~

Across these ~~10~~ 9 EPPO Maritime climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of ERYSGH in winter and spring barley of ~~96.3~~ 95.9% (range 80.0-100%), 18-~~40~~42 days after application, which was comparable to the control achieved by the prothioconazole standard Proline at ~~96.2~~ 95.8% (range 69.1-100).

The dataset includes ~~seven~~ six trials from use on winter barley (HORVW) and three trials from use on spring barley (HORVS). Results on both crops are comparable (~~95.4~~ 94.6% control on HORVW and 98.6% control on HORVS). It is therefore considered that all ~~10~~ nine trials fully support use in both winter and spring barley crops.

In addition to these data from the EPPO Maritime Climatic zone, data are available from Poland, which is a neighbouring country. Poland has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of ERYSGH (warm and humid weather). Data from five trials are available that demonstrate comparable levels of control: 86.5%, compared to 82.9% for the standards, Proline and Prosaro (tebuconazole + prothioconazole) after a single application. Combined with the EPPO Maritime Climatic zone data gives 92.6% overall control of ERYSGH across 14 trials, 93.4% control on HORVW across eight trials and 91.4% control on HORVS across six trials.

The results are summarised in Table 3.2-236 the results of the individual trials are detailed in the BAD. Results in Table 3.2-236 are shown across all trials first (~~shaded grey~~), before being shown orthogonally for spring and winter barley.

~~Table 3.2-236: Efficacy of GF-3307 applied at 1.5 L/ha for the control of ERYSGH in winter and spring barley from 10 trials conducted in the EPPO Maritime climatic zone between 2017 and 2019. Assessment at 18-40 days after application.~~

EPPO Zone/Crop	Number of trials	Untreated: ERYSGH % infection		% control of ERYSGH					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min-max	Mean	min-max	Product/dose	
Maritime (All crops)	10	15.9	5.8-60.0	96.3	80.0-100	96.2	69.1-100	Proline/0.8 L/ha	10 = P
Maritime (HORVW)	7	16.7	5.8-60.0	95.4	80.0-100	95.2	69.1-100	Proline/0.8 L/ha	7 = P
Maritime (HORVS)	3	14.0	5.8-30.0	98.6	95.7-100	98.6	95.7-100	Proline/0.8 L/ha	7 = A

P = Proline

Table 3.2-237: Efficacy of GF-3307 applied at 1.5 L/ha for the control of ERYSGH in winter and spring barley from 9 trials conducted in the EPPO Maritime climatic zone and five PL trials between 2017-2020. Assessment at 16-42 days after one application.

EPPO Zone/Crop	Number of trials	Untreated: ERYSGH % infection		% control of ERYSGH					Significantly >, =, < Standards
				GF-3307 1.5 L/ha		Reference standard			
		Mean	min- max	Mean	min-max	Mean	min-max	Product/dose	
Maritime (All crops)	9	16.9	5.8- 60.0	95.9	80.0-100	95.8	69.1-100	Proline 250/0.8 L/ha	9 = P
Maritime (HORVW)	6	18.1	5.8- 60.0	94.6	80.0-100	94.4	69.1-100	Proline 250/0.8 L/ha	6 = P
Maritime (HORVS)	3	14.0	5.8- 30.0	98.6	95.7-100	98.6	95.7-100	Proline 250/0.8 L/ha	3 = A
PL (All crops)	5	15.3	8.3- 23.3	86.5	75.8-93.9	82.9	73.5-90.1	All^	2= P, 3 = PO
Maritime + PL (All crops)	14	16.2	5.8- 60.0	92.6	75.8-100	91.2	69.1-100	All^	11= P, 3 = PO
Maritime + PL (HORVW)	8	17.5	5.8- 60.0	93.4	80.0-100	91.8	69.1-100	All^	7= P, 1 = PO
Maritime + PL (HORVS)	6	14.6	5.8- 30.0	91.4	75.8-100	90.4	73.5-100	All^	4= P, 2 = PO

^Reference standards used based on Proline 250 (P) applied at 0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

Summary and conclusions for the proposed dose of 1.5 L/ha for EPPO Maritime climatic zone countries of the Central EU Authorisation zone

Based on ~~10~~ **nine** EPPO Maritime climatic zone trials **and five Polish trials**, demonstrating mean overall control of ERYSGH in barley of ~~96.3~~ **92.6%** from a single application of 1.5 L/ha GF-3307 (**93.4% on HORVW across 8 trials and 91.6% on HORVS across 6 trials**), it is considered that the proposed claim for control of ERYSGH using the 1.5 L/ha dose of GF-3307 in winter and spring barley, is fully supported.

Proposed dose rate range of 1.2-1.5 L/ha for Poland (EPPO North-East climatic zone)

In total, 10 small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of ERYSGH in winter and spring barley at ~~the proposed label rate range of 1.2-1.5 L/ha~~, following a single application applied at BBCH 31-52. The trials were conducted in Latvia (5) and Poland (5) in the EPPO North-East climatic zone on both winter and spring barley. ~~The data included trials where ERYSGH was established before application (including on the leaves assessed for control~~

in some trials) and trials where ERYSGH did not develop until after application. The data included trials where ERYSGH was established at low levels on lower leaves before application and trials where ERYSGH did not develop until after application. These trials can therefore be considered to be a robust test of both the curative and protectant properties of GF-3307. The results for this disease are from a range of leaves (Leaf 1 to Leaf 4) as the highest available assessed leaf with sufficient infection in the untreated. **Note:** In four trials, the latest assessment timing after a single application was used at 16-20 days after application. Later assessments in these trials followed a second application (with disease present in the crop at both applications) and are not considered valid to support the proposed GAP. In another trial only a 14 day assessment is available for ERYSGH, as the disease was not found at later assessments.

Across all 10 EPPO North-East climatic zone trials, GF-3307 at 1.5 L/ha achieved mean control of ERYSGH in winter and spring barley of 89.8% (91.1% on HORVW and 88.5% on HORVS) at 14-37 days after one application (range 75.8-100%), which is higher than the level of control achieved by the prothioconazole standard Proline at 84.2% (range 48.8-100%). which is comparable to the control achieved by the reference standard at 89.9% (range 73.5-100%). When compared directly to the reference standard, GF-3307 at 1.5 L/ha achieved mean control of ERYSGH of 89.6% compared to Proline 250 at 90.9% across seven trials and 90.3% compared to 87.5% for Prosaro across three trials. At a dose rate of 1.2 L/ha, only slightly lower control of 86.3% (88.4% on HORVW and 84.2% on HORVS) was achieved (range 63.6-100%). At a dose rate of 1.2/1.25 L/ha, only slightly lower control of 86.3% (88.4% on HORVW and 84.2% on HORVS) was achieved (range 63.6-100%). When compared directly to the reference standard, GF-3307 at 1.2/1.25 L/ha achieved mean control of ERYSGH of 84.8% compared to Proline 250 at 90.9% across seven trials and 89.7% compared to 87.5% for Prosaro across three trials. **Note:** Results from nine trials were based on a slightly lower dose rate of 1.2 L/ha (trials highlighted in the BAD). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single results for the proposed lower dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

The EPPO North-East climatic zone dataset includes five trials from use on winter barley (HORVW) and five trials from use on spring barley (HORVS). Combining the 10 EPPO North-East climatic zone trials on winter and spring barley with six from a neighbouring country (DE) gives 92.9% control of ERYSGH on winter barley at the maximum 1.5 L/ha dose across 8 trials and 90.0% control at the lower 1.2 L/ha 1.2/1.25 L/ha dose, across 6 winter barley trials; 92.3% control of ERYSGH on spring barley at the maximum 1.5 L/ha dose and 88.7% control at the lower 1.2 L/ha 1.2/1.25 L/ha dose, across 8 trials.

The results are summarised in Table 3.2-2383 and the results of the individual trials are detailed in the BAD. Results in Table 3.2-2383 are shown across all trials first before being shown orthogonally for spring and winter barley.

Table 3.2-238: Efficacy of GF-3307 applied label rate range of 1.2-1.5 L/ha against ERYSGH in winter and spring barley from 10 trials conducted in the EPPO North-East climatic zone plus 6 DE trials between 2017 and 2020. Assessment at 14-42 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: ERYSGH % infection		% control of ERYSGH						Significantly ≥, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North-East (all trials)	10	11.5	5.6-23.3	86.3	63.6- 100	89.8	75.8- 100	84.2	48.8- 100	2 > P, 8 = P (both doses)
North-East (HORVW)	5	10.5	5.6-21.6	88.4	76.8- 98.8	91.1	84.5- 96.7	87.5	68.2- 100	1 > P, 4 = P (both doses)
North-East (HORVS)	5	12.4	5.9-23.3	84.2	63.6- 100	88.5	75.8- 100	80.8	48.8- 100	1 > P, 4 = P (both doses)
North-East + DE (HORVW)	8	10.5	5.6-21.6	90.0#	76.8- 98.8	92.9	84.5- 100	91.9	68.2- 100	1 > P, 7 = P (both doses)
North-East +	8	13.0	5.8-30.0	88.7	63.6-	92.3	75.8-	87.5	48.8-	1 > P, 7 = P

DE (HORVS)					100		100		100	(both doses)
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P = Proline. #Results from 6 trials only

Table 3.2-239: Efficacy of GF-3307 applied at 1.2-1.5 L/ha against ERYSGH in winter and spring barley from 10 trials conducted in the EPPO North-East climatic zone plus 6 DE trials between 2017 and 2020. Assessment at 14-42 days after a single application.

EPPO Zone/Crop	Number of trials	Untreated: ERYSGH % infection		% control of ERYSGH						Significantly >, =, < Standards
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference standards		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
North-East (all trials)	10	11.5	5.6- 23.3	86.3	63.6- 100	89.8	75.8- 100	89.9^	73.5- 100	1 > P, 6 = P, 3 = PO (both doses)
North-East* (all trials)	7	8.0	5.6- 10.9	84.8	63.6- 100	89.6	75.8- 100	90.9	73.5- 100	1 > P, 6 = P, (both doses)
North- East** (all trials)	3	19.6	23.8- 23.3	89.7	84.8- 93.5	90.3	86.8- 93.9	87.5	82.8- 90.1	3 = PO (both doses)
North-East (HORVW)	5	10.5	5.6- 21.6	88.4	76.8- 98.8	91.1	84.5- 96.7	91.8^	78.3- 100	1 > P, 3 = P, 1 = PO (both doses)
North-East (HORVS)	5	12.4	5.9- 23.3	84.2	63.6- 100	88.5	75.8- 100	87.9^	73.5- 100	3 = P, 2 = PO (both doses)
North-East + DE (HORVW)	8	10.5	5.6- 21.6	90.0#	76.8- 98.8	92.9	84.5- 100	94.5^	78.3- 100	1 > P, 6 = P, 1 = PO (both doses)
North-East + DE (HORVS)	8	13.0	5.8- 30.0	88.7	63.6- 100	92.3	75.8- 100	91.9^	73.5- 100	6 = P, 2 = PO (both doses)

#Results from 6 trials only

*Direct comparison to Proline 250 (P) applied at 0.8 L/ha.

**Direct comparison to Prosaro (PO) applied at 0.75 L/ha.

[^]Reference standards used based on Proline 250 (P) applied at 0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

Summary and conclusions for the proposed dose rate range of 1.2-1.5 L/ha in the EPPO North-East climatic zone

ERYSGH is a secondary target disease for GF-3307. Where disease pressure is low and only ERYSGH requires control, the lower dose of 1.2 L/ha is recommended. Based on data from five EPPO North-East climatic zone trials on winter barley demonstrating mean overall control of ERYSGH of 88.4% at 1.2/1.25 L/ha and eight trials on spring barley demonstrating mean overall control of ERYSGH of 88.7% at 1.2/1.25 L/ha (five EPPO North-East climatic zone trials and three German trials), it is considered that the proposed claim for control of ERYSGH using GF-3307 at a dose rate of 1.2 L/ha on winter and spring barley is fully supported.

In high pressure mixed disease situations (PYRNTE also present or expected) the maximum dose of 1.5 L/ha is recommended. Based on data from eight trials on winter barley using the maximum 1.5 L/ha dose rate of GF-3307, demonstrating mean overall control of ERYSGH of 92.9% (five EPPO North-East climatic zone trials and three German trials) and eight trials on spring barley demonstrating mean overall control of ERYSGH of 92.3% (five EPPO North-East climatic zone trials and three German trials), it is considered that the proposed claim for control of ERYSGH using GF-3307 at a maximum dose rate of 1.5 L/ha on winter and spring barley is fully supported.

A dose range of 1.2-1.5 L/ha will be proposed for all diseases of barley to offer growers flexibility so they can adjust dose according to the conditions.

Proposed dose of 1.2-1.5 L/ha for South-East climatic zone countries of the Central EU Authorisation zone

Two Four small plot GEP trials were conducted to demonstrate the efficacy of GF-3307 for the control of ERYSGH in winter and spring barley at the proposed label rates following a single application applied at BBCH 31-33-49 of the crop. The trials were conducted in Hungary (± 3) and Slovakia (1) in

the EPPO South-East climatic zone on winter and spring barley. The results for this disease are from Leaf 1, Leaf 2 and or Leaf 3, as the highest available assessed leaf with sufficient infection in the untreated. **Note:** Results from two trials were based on a slightly higher dose rate of 1.25 L/ha (trial highlighted in the BAD.). As this is within 4% of the proposed dose of 1.2 L/ha, the results have been combined to give a single results for the proposed lower label dose of 1.2 L/ha. This also aligns with the label dose range proposed in wheat, rye and triticale of 1.2-1.5 L/ha which will simplify and add consistency to the label for ease of use by growers.

From these trials conducted in the EPPO South-East climatic zone, at higher disease levels (mean of 31.4%), a single application of GF-3307 at 1.5 L/ha, applied between BBCH 31-33 achieved mean control of 87.385.9% (range 81.9-92.8%) for ERYSGH on barley, 21-46 days after application. The 1.2 L/ha 1.2/1.25 L/ha dose achieved 86.281.8% (range 81.069.0-91.5%) across the same two trials. These results are comparable to the levels of control achieved by the prothioconazole standard Proline at 87.381.6% (range 86.369.0-88.3%).

In addition to these data from the EPPO South-East Climatic zone, data are available from Poland, which is a neighbouring country. Poland has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of ERYSGH (warm and humid weather). Data from five trials are available that demonstrate comparable levels of control: 86.5% for the 1.5 L/ha dose, 83.6% for the 1.2 L/ha 1.2/1.25 L/ha dose, compared to 71.5% for the prothioconazole standard Proline 82.9% for the reference standards (Proline 250 and Prosaro).

The majority of data were generated from use on spring barley (HORVS). Results in this dossier from both the Maritime and North East EPPO climatic zones have shown comparable results between winter and spring barley for the control of ERYSGH, and data on other diseases encountered in this EPPO climatic zone have shown comparable levels of effectiveness on both crops. Therefore, it is considered that these data also support claims for control of ERYSGH on winter barley (HORVW) in the EPPO South East climatic zone.

Results from both the South-East and North-East EPPO climatic zones have shown comparable results between winter and spring barley for the control of ERYSGH, and data on other diseases encountered in this EPPO climatic zone have shown comparable levels of effectiveness on both crops. Therefore, it is considered that all trials support claims for control of ERYSGH on both winter and spring barley crops in the EPPO South-East climatic zone.

The results are summarised in Table 3.2-2404, the results of the individual trials are detailed in the BAD. Results in Table 3.2-2404 are shown across all trials first (shaded grey), before being shown orthogonally for spring and winter barley.

Table 3.2-240: Efficacy of GF-3307 applied at 1.2 and 1.5 L/ha for the control of ERYSGH in spring barley. Results from two trials in the EPPO South-East climatic zone plus five PL trials conducted between 2018-2020. Assessment at 16-46 days after one application.

EPPO Zone/Crop	Number of trials	Untreated: ERYSGH % infection		% control of ERYSGH						Significantly ≥, =, < Standards
				GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Proline 0.6-0.8 L/ha		
		Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max	
South-East (HORVS)	2	32.1	20.8- 43.3	86.2	81.0- 91.5	87.3	81.9- 92.8	87.3	86.3- 88.3	2=P (both doses)
Poland (all crops)*	5	15.3	8.3-23.3	83.6	63.6- 93.5	86.5	75.8- 93.9	71.5	48.8- 88.8	2>, 3=P (both doses)
Poland (HORVW)*	2	15.9	9.5-21.6	88.0	85.2- 90.8	89.8	85.7- 93.9	73.3	68.2- 78.3	1>, 1=P (both doses)
Poland (HORVS)*	3	15.1	8.3-23.3	80.6	63.6- 93.5	84.3	75.8- 90.3	70.4	48.8- 88.8	1>, 2=P (both doses)

P=Proline.

Table 3.2-241: Efficacy of GF-3307 applied at 1.2-1.5 L/ha for the control of ERYSGH in spring barley. Results from four trials in the EPPO South-East climatic zone plus five PL trials conducted between 2018-2021. Assessment at 16-46 days after one application.

2021: Assessment at 10-16 days after one application:										
EPPO Zone/Crop	Number of trials	Untreated: ERYSGH % infection		% control of ERYSGH						Significantly >, =, < Standards
				GF-3307 1.2 -1.25 L/ha		GF-3307 1.5 L/ha		Reference standards		
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
South-East* (all crops)	4	20.8	8.0-43.3	81.8	69.0-91.5	85.9	81.9-92.8	81.6	69.0-88.3	1>, 3 = P (both doses)
South-East* (HORVW)	2	9.6	8.0-11.1	77.3	69.0-85.5	84.4	84.0-84.8	75.9	69.0-82.8	2 = P (both doses)
South-East* (HORVS)	2	32.1	20.8-43.3	86.2	81.0-91.5	87.3	81.9-92.8	87.3	86.3-88.3	1>, 1 = P (both doses)
Poland (all crops)	5	15.3	8.3-23.3	83.6	63.6-93.5	86.5	75.8-93.9	82.9^	73.5-90.1	2 = P, 3 = PO (both doses)
Poland (HORVW)	2	15.9	9.5-21.6	88.0	85.2-90.8	89.8	85.7-93.9	84.0^	78.3-89.6	1 = P, 1 = PO (both doses)
Poland (HORVS)	3	15.1	8.3-23.3	80.6	63.6-93.5	84.3	75.8-90.3	82.1^	73.5-90.1	1 = P, 2 = PO (both doses)

*Direct comparison to Proline 250 (P) applied at 0.6-0.8 L/ha.

^Reference standards used based on Proline 250 (P) applied at 0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

Summary and conclusions for the proposed dose range of 1.2-1.5 L/ha for EPPO South-East climatic zone countries of the Central EU Authorisation zone

Two EPPO South-East climatic zone trials achieved mean overall control of ERYSGH in spring barley of 86.2-87.3% from a single application of GF-3307 at 1.2-1.5 L/ha, which is comparable to the levels of control achieved by the prothioconazole standard (87.3%).

Based on four EPPO South-East climatic zone trial results, demonstrating mean overall control of ERYSGH in barley of 85.9% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of ERYSGH is fully supported. The 1.5 L/ha dose is considered to be appropriate for situations where other diseases such as PYRNTE are present/expected or where season long control is required. In other situations, a lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated 81.8% control at 1.2/1.25 L/ha across these four trials.

Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of ERYSGH (warm and humid weather). Data from these trials (a mix of HORVS and HORVW trials) demonstrate comparable levels of control: 86.5% for the 1.5 L/ha dose and 83.6% for the 1.2 L/ha dose, compared to 71.5% for the prothioconazole standard Proline. Data from these trials (a mix of HORVS and HORVW trials) demonstrate comparable levels of control: 86.5% for the 1.5 L/ha dose and 83.6% for the 1.2/1.25 L/ha dose, compared to 82.9% for the reference standards (Proline 250 and Prosaro).

Across all trials, the level of control of ERYSGH achieved by GF-3307, at both dose rates tested, was higher or not statistically different from the standards. Results on both winter and spring crops are comparable and it is therefore considered that all data fully support use on both winter and spring crops.

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

3.2.3.17 Yield in effectiveness trials

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

In total ~~232~~ 267 effectiveness trials are included in this dossier: ~~107~~ 129 trials on winter wheat (TRZAW), ~~3~~ 4 trials on spring wheat (TRZAS), ~~17~~ 19 trials on winter rye (SECCW), 32 trials on winter triticale (TTLWI), ~~45~~ 54 trials on winter barley (HORVW) ~~28~~ and 29 trials on spring barley (HORVS). The majority of trials were harvested and yield and quality assessed (Thousand grain weight/TGW and Specific weight/hectolitre weight/HLW). **Note:** TGW and particularly HLW, were not assessed in all harvested trials. The results from these trials split by crop and EPPO zone are summarised in the following tables. Trials supporting the various target diseases have been combined for each crop, as many trials included more than one disease, even at levels below the threshold for assessment (5%). These results therefore reflect the benefits of the use of GF-3307 for general disease control in each crop. Results for GF-3307 are shown against the reference standards used in each disease section.

All results in this section are based on yield/quality assessments after a single dose of GF-3307. A number of trials were harvested after two applications. The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD.

Winter wheat (TRZAW)

Results – EPPO Maritime climatic zone

Of the ~~47~~ 49 EPPO Maritime climatic zone effectiveness trials on winter wheat generated between 2014-~~2020~~2021, the impact on grain yield after a single dose of GF-3307 was assessed in ~~37~~ 40 trials. One trial (DE15E7B014UB02C) were not harvested. ~~Nine~~ Eight trials only have results after two applications. The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD and show comparable yield increases.

In these ~~37~~ 40 trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of ~~22.7~~ 22.3%, relative to the untreated. These trials also achieved an 10.0% increase in thousand grain weight (TGWT), relative to the untreated and a ~~2.2~~ 2.3% increase in hectolitre weight (HLW). Results for the standards were comparable.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-2425 to ~~Table 3.2-2447~~. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-242: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated-control		Relative yield (Untreated = 100%)					
				GF-3307		Reference standard			
				225 g-as/ha					
				1.5 L/ha					
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
TRZAW	37	7.5	3.6-11.1	122.7	95.0-257.2	120.7	97.0-199.6	All	
TRZAW*	28	7.7	3.6-11.1	125.0	65.0-257.2	121.5	97.0-199.6	Proline*	
TRZAW**	7	6.7	5.0-8.7	115.5	103.3-150.1	119.0	99.5-153.1	Aviator Xpro/1.25 L/ha	
TRZAW***	2	8.2	8.0-8.4	116.0	115.3-116.8	116.7	114.7-118.7	Librax/2.0 L/ha	

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Table 3.2-243: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated-control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	36	40.6	27.9-54.4	110.0	98.4-143.0	107.4	92.1-139.1	All
TRZAW*	28	40.3	27.9-54.4	110.6	98.4-143.0	107.1	92.1-133.8	Proline/0.72 L/ha
TRZAW**	7	41.0	32.9-45.5	108.2	100.8-134.4	108.6	99.0-139.1	Aviator Xpro/1.25 L/ha
TRZAW***	4	48.4	-	105.7	-	106.1	-	Librax/2.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Table 3.2-244: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated-control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference-standard		
				225 g-as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	24	72.1	60.2-82.8	102.2	98.9-112.1	101.3	87.2-111.0	All
TRZAW*	18	71.5	60.2-78.3	102.0	98.9-112.1	100.7	87.2-111.0	Proline/0.72 L/ha
TRZAW**	3	75.0	66.1-82.8	103.2	100.2-110.1	103.1	99.7-110.5	Aviator Xpro/1.25 L/ha
TRZAW***	4	68.8	-	100.9	-	102.7	-	Librax/2.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Table 3.2-245: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

ETFO Maritime climatic zone efficacy trials								
Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
		1.5 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	40	7.6	3.6-11.1	122.3	95.0-257.2	120.7	97.0-199.6	All
TRZAW*	23	7.7	3.6-11.1	127.5	95.0-257.2	124.0	97.0-199.6	Proline*
TRZAW**	15	7.4	5.0-10.5	116.3	103.3-150.1	116.1	99.5-153.1	Aviator Xpro/1.0-1.25 L/ha
TRZAW***	2	8.2	8.0-8.4	116.0	115.3-116.8	116.7	114.7-118.7	Librax/2.0 L/ha

*Direct comparison to Proline applied at 198 g prothioconazole/ha

**Direct comparison to Aviator Xpro at 1.0-1.25 L/ha

***Direct comparison to Librax

Table 3.2-246: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

(TRZAW) in EPTO Maritime climatic zone efficacy trials								
Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
		1.5 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	39	40.8	27.9-54.4	110.0	98.4-143.0	107.4	92.1-139.1	All
TRZAW*	23	39.3	27.9-52.3	111.6	98.4-143.0	107.8	92.1-133.8	Proline*
TRZAW**	15	42.6	28.7-54.4	107.8	100.8-134.4	107.9	98.2-139.1	Aviator Xpro/1.0-1.25 L/ha
TRZAW***	1	48.4	-	105.7	-	106.1	-	Librax/2.0 L/ha

*Direct comparison to Proline applied at 198 g prothioconazole/ha

**Direct comparison to Aviator Xpro at 1.0-1.25 L/ha

***Direct comparison to Librax

Table 3.2-247: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on winter wheat (TRZAW) in EPPO Maritime climatic zone efficacy trials

(TRZAW) in EPFO Maritime climatic zone efficacy trials								
Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
		1.5 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	27	72.4	60.2-82.8	102.3	98.9-112.1	101.4	87.2-111.0	All
TRZAW*	13	70.5	60.2-77.3	102.1	98.9-112.1	100.3	87.2-111.0	Proline*
TRZAW**	13	74.5	66.1-82.8	102.7	99.1-110.1	102.4	98.7-110.5	Aviator Xpro/1.0-1.25 L/ha
TRZAW***	1	68.8	-	100.9	-	102.7	-	Librax/2.0 L/ha

*Direct comparison to Proline applied at 198 g prothioconazole/ha

**Direct comparison to Aviator Xpro at 1.0-1.25 L/ha

***Direct comparison to Librax

Results – EPPO North-East climatic zone

Of the ~~25~~ **38** EPPO North-East climatic zone effectiveness trials on winter wheat (TRZAW) and ~~three~~ **four** trials on spring wheat (TRZAS) generated between 2014-~~2020~~**2021**, the impact on grain yield after a single dose of GF-3307 was assessed in ~~23~~ **38** trials. ~~Five~~ **Four** winter wheat trials (PL14E7B014AS01C, ~~PL14E7B014AS02C~~—PL14E7B014AS03C, PL15E7B041AS01C and PL15E7B041AS02C) only have results after two applications (although the results used for effectiveness were based on assessment after the first application). The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD and show comparable yield increases.

All ~~23~~ **38** trials included the maximum dose rate of 1.5 L/ha and there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of ~~17.1~~ **17.5**%, relative to

the untreated across 20 34 winter wheat trials and 19.9 20.2% increase in three four spring wheat trials. These trials also achieved a 4.2 5.9% increase in thousand grain weight (TGWT) for winter wheat and 6.9 6.7% increase for spring wheat and a 1.0 3.9% increase in hectolitre weight (HLW) for winter wheat and 0.2 0.6% increase for spring wheat. Results for the standards were comparable.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-24888 to Table 3.2-2500. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-248: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on wheat in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF 3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	20	6.9	4.3-11.9	117.1	105.7-137.7	113.4	103.0-128.1	All
TRZAW*	16	6.6	4.9-9.2	116.6	105.7-137.7	112.0	103.0-123.7	Proline*
TRZAW**	3	9.4	7.2-11.9	113.0	110.6-115.9	115.6	112.1-119.4	Aviator Xpro/1.25 L/ha
TRZAW***	1	4.3	-	136.9	-	128.1	-	Vertisan/1.0 L/ha
TRZAS	3	4.8	3.8-6.5	119.9	116.2-122.9	118.1	107.0-126.8	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Aviator Xpro, *Direct comparison to Vertisan

Table 3.2-249: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on wheat in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated-control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference-standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	20	44.8	35.9-54.5	104.2	99.4-114.3	104.2	99.8-114.8	All
TRZAW*	16	44.0	35.9-51.1	104.5	99.0-114.7	104.5	99.8-114.8	Proline*
TRZAW**	3	47.4	41.3-51.3	102.8	102.0-103.9	102.9	101.8-103.7	Aviator Xpro/1.25 L/ha
TRZAW***	1	48.7	-	104.0	-	103.5	-	Vertisan/1.0 L/ha
TRZAS	3	33.9	31.3-36.4	106.9	98.2-118.9	103.1	98.7-107.2	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Aviator Xpro, *Direct comparison to Vertisan

Table 3.2-250: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on wheat in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated-control		Relative HLW (Untreated = 100%)				
				GF 3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	3	76.0	74.8-76.8	101.0	100.5-101.5	99.5	98.7-100.4	Proline*
TRZAS	1	66.3	-	100.2	-	97.5	-	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Table 3.2-251: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on wheat in EPPO North-East climatic zone efficacy trials

Climate Zone efficacy trials								
Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
		1.5 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	34	6.5	3.8-11.9	117.5	96.2-144.5	115.1	90.0-151.8	All
TRZAW*	19	6.4	4.9-9.2	118.2	105.7-142.1	114.1	101.3-139.1	Proline*
TRZAW**	7	7.3	3.8-11.9	119.1	106.5-144.5	119.3	106.2-148.8	Aviator Xpro/1.0-1.25 L/ha
TRZAW+	7	6.3	4.0-10.8	111.1	96.2-133.3	112.0	90.0-151.8	Prosaro at 1.0 L/ha
TRZAW***	1	4.3	-	136.9	-	128.1	-	Vertisan/1.0 L/ha
TRZAS	4	4.9	3.8-6.5	120.2	116.2-122.9	117.4	107.0-126.8	Proline*

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

Direct comparison to Aviator Xpro, *Direct comparison to Vertisan, +Prosaro applied at 1.0 L/ha

Table 3.2-252: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on wheat in EPPO North-East climatic zone efficacy trials

North-East climatic zone (maize trials)								
Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	31	43.0	32.7-54.5	105.9	99.4-133.7	105.8	99.0-131.8	All
TRZAW*	19	43.5	36.0-51.1	105.0	99.4-114.3	104.4	99.6-114.8	Proline*
TRZAW+	4	35.8	32.7-39.7	113.0	100.7-133.7	112.9	100.5-131.8	Prosaro at 1.0 L/ha
TRZAW**	7	45.0	41.3-54.5	104.8	102.0-110.3	105.8	99.0-116.1	Aviator Xpro/1.0-1.25 L/ha
TRZAW***	1	48.7	-	104.0	-	103.5	-	Vertisan/1.0 L/ha
TRZAS	4	34.1	31.3-36.4	106.7	98.2-118.9	102.6	98.7-107.2	Proline*

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

Direct comparison to Aviator Xpro, *Direct comparison to Vertisan, +Prosaro applied at 1.0 L/ha

Table 3.2-253: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on wheat in EPPO North-East climatic zone efficacy trials

North-East Climate Zone efficacy trials								
Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
		1.5 L/ha						
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	17	73.3	61.5-82.7	103.9	98.7-119.1	103.5	97.3-119.1	All
TRZAW*	7	74.2	66.4-77.0	103.9	99.5-115.0	103.1	98.1-115.0	Proline*
TRZAW+	6	69.6	61.5-80.3	104.8	98.7-119.1	105.2	97.3-119.1	Prosaro at 1.0 L/ha
TRZAW**	4	77.3	71.5-82.7	102.8	101.0-107.5	101.7	97.5-107.5	Aviator Xpro/1.0-1.25 L/ha
TRZAS	2	68.0	66.3-69.7	100.6	100.2-101.0	98.8	97.5-100.0	Proline*

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

Direct comparison to Aviator Xpro, *Direct comparison to Vertisan, +Prosaro applied at 1.0 L/ha

Use on wheat in the EPPO North-East zone includes a lower dose of 1.2 L/ha. This dose rate is supported by 30 35 winter wheat trials (48 25 EPPO North-East zone trials and 12 10 trials from the EPPO Maritime zone: CZ and DE) and three four spring wheat trials (EPPO North-East zone). A summary of the yield and quality data from 33 37 of these efficacy trials at the 1.2 L/ha dose rate is presented in Table 3.2-2541 to Table 3.2-2563. One DE trial (DE15E7B025AS01) and one CZ trial (CZ18E7B017PV01C) were not harvested.

A single application of GF-3307 at 1.2 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 1.5 L/ha dose rate, with a mean yield increase of 14.8 21.9 17.3-22.9%, relative to the untreated across 30-33 winter wheat trials and 16.5

16.4% increase in three four spring wheat trials. These trials also achieved a 4.4-11.0-5.0-10.0% mean increase in thousand grain weight (TGWT) for winter wheat and 3.2-3.6 % increase for spring wheat and a 0.2-2.2-0.1-3.0% mean increase in hectolitre weight (HLW) for winter wheat and 0.4-0.7% increase for spring wheat. Results for the standards were comparable.

Table 3.2-254: Impact of GF-3307 on grain yield when applied at 1.2 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	18	7.0	4.9-11.9	114.8	104.3-138.1	112.7	103.0-123.7	All
TRZAW*	NE	15	6.5	4.9-9.2	115.1	104.3-138.3	112.1	103.0-123.7	Proline*
TRZAW**	NE	3	9.4	7.2-11.9	113.1	111.3-114.2	115.6	112.1-119.4	Aviator Xpro/1.25 L/ha
TRZAW	MAR	12	8.1	4.1-11.1	121.9	95.7-241.9	118.8	97.0-199.6	All
TRZAW*	MAR	9	8.3	4.1-11.1	121.9	95.7-241.9	117.2	97.0-199.6	Proline*
TRZAW**	MAR	2	6.9	6.4-7.5	124.7	105.1-144.2	126.3	99.5-153.1	Aviator Xpro/1.25 L/ha
TRZAW#	MAR	1	8.4	-	116.1	-	118.7	-	Librax/2.0 L/ha
TRZAS	NE	3	4.8	3.8-6.5	116.5	108.4-122.9	128.1	107.0-126.8	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Table 3.2-255: Impact of GF-3307 on grain quality (TGWT) when applied at 1.2 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF 3307		Reference-standard		
					180 g as/ha				
			1.2 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	18	44.3	35.9-54.5	104.4	99.0-114.7	104.2	99.8-114.8	All
TRZAW*	NE	15	43.7	35.9-51.1	104.8	99.0-114.7	104.5	99.8-114.8	Proline*
TRZAW***	NE	3	47.4	41.3-51.3	102.4	100.5-104.8	102.9	101.8-103.7	Aviator Xpro/1.25 L/ha
TRZAW	MAR	12	41.7	28.7-54.4	111.0	98.3-141.2	109.0	92.1-139.1	All
TRZAW*	MAR	9	41.6	28.7-54.4	110.2	98.3-141.2	106.6	92.1-133.8	Proline*
TRZAW**	MAR	2	38.9	32.9-44.9	117.7	102.4-132.9	121.3	103.4-139.1	Aviator Xpro/1.25 L/ha
TRZAW#	MAR	1	48.4	-	104.9	-	106.1	-	Librax/2.0 L/ha
TRZAS	NE	3	33.9	31.3-36.4	103.2	98.3-107.5	103.1	98.7-107.2	Proline/0.72 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Table 3.2-256: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO Zone	Number of trials	HLW (kg) untreated control	Relative HLW (Untreated = 100%)	
				GF-3307	Reference standard
				180 g as/ha	
				1.2 L/ha	

			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	3	76.0	74.8-76.8	100.2	99.4-101.1	99.5	98.7-100.4	Proline*
TRZAW	MAR	10	73.1	65.6-78.3	102.2	98.5-110.9	100.8	87.2-110.5	All
TRZAW*	MAR	8	72.7	65.6-78.3	101.3	98.5-106.2	99.7	87.2-106.7	Proline*
TRZAW**	MAR	2	75.0	74.5-75.4	106.0	101.1-110.9	105.5	100.5-110.5	Aviator Xpro/1.25 L/ha
TRZAS	NE	1	66.3	-	100.4	-	97.5	-	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

Table 3.2-257: Impact of GF-3307 on grain yield when applied at 1.2 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	25	6.6	3.8-11.9	117.3	98.4-114.6	115.6	101.3-148.8	All
TRZAW*	NE	18	6.4	4.9-9.2	117.6	104.3-139.4	114.2	101.3-139.1	Proline*
TRZAW**	NE	7	7.3	3.8-11.9	116.7	98.4-141.6	119.3	106.2-148.8	Aviator Xpro/1.0-1.25 L/ha
TRZAW	MAR	8	8.8	4.1-11.1	122.9	95.7-241.9	118.0	97.0-199.6	All
TRZAW*	MAR	4	8.1	4.1-11.1	138.7	95.7-241.9	127.3	97.0-199.6	Proline*
TRZAW**	MAR	4	9.4	8.4-10.5	107.2	102.4-116.1	108.6	101.7-118.7	Aviator Xpro/1.0 L/ha
TRZAS	NE	4	4.9	3.8-6.5	116.4	108.4-122.9	117.4	107.0-126.8	Proline*

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Table 3.2-258: Impact of GF-3307 on grain quality (TGWt) when applied at 1.2 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

North East climatic zone and DE and CE efficacy trials									
Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
			1.2 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	25	43.7	36.0-54.5	105.0	99.0-114.7	104.7	99.0-116.1	All
TRZAW*	NE	18	43.2	36.0-51.1	104.7	99.0-114.7	104.3	99.6-114.8	Proline*
TRZAW***	NE	7	45.0	41.3-51.3	105.7	100.5-112.7	105.8	99.0-116.1	Aviator Xpro/1.0-1.25 L/ha
TRZAW	MAR	8	43.7	30.8-54.4	110.0	98.3-141.2	106.2	92.1-133.8	All
TRZAW*	MAR	4	37.5	30.8-47.7	119.2	105.3-141.2	110.2	92.1-133.8	Proline*
TRZAW**	MAR	4	49.8	44.7-54.4	100.8	98.3-104.9	102.1	98.2-106.1	Aviator Xpro/1.0 L/ha
TRZAS	NE	4	34.1	31.3-36.4	103.6	98.3-107.5	102.6	98.7-107.2	Proline/0.72 L/ha

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Table 3.2-259: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO Zone	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
			1.2 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	11	75.3	66.4-82.7	103.0	99.4-113.0	102.6	97.5-115.0	Proline*
TRZAW*	NE	7	74.2	66.4-77.0	103.2	99.4-113.0	103.1	98.1-115.0	Proline*
TRZAW***	NE	4	77.3	71.5-82.7	102.6	100.0-108.0	101.7	97.5-107.5	Aviator Xpro/1.0-1.25 L/ha
TRZAW	MAR	7	73.7	65.6-78.3	100.1	98.5-101.4	98.4	87.2-103.0	All
TRZAW*	MAR	4	71.9	65.6-77.3	100.6	99.3-101.4	97.4	87.2-103.0	Proline*
TRZAW**	MAR	3	76.2	72.8-78.3	99.5	98.5-100.9	99.7	98.7-100.9	Aviator Xpro/1.0 L/ha
TRZAS	NE	2	68.0	66.3-69.7	100.7	100.4-101.0	98.8	97.5-100.0	Proline*

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

***Direct comparison to Librax

Use on wheat in the EPPO North-East zone includes a lower dose of 1.0 L/ha. A summary of the yield and quality data from 12 efficacy trials at the 0.9/1.0 L/ha dose rate (9 EPPO North-East zone trials and 3 trials from the EPPO Maritime zone: CZ and DE and one spring wheat trial from the EPPO North-East zone).

A single application of GF-3307 at 0.9/1.0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 1.5 and 1.2 L/ha dose rates, with a mean yield increase of 11.1-20.8%, relative to the untreated across 12 winter wheat trials and 8.1% increase in one spring wheat trials. These trials also achieved a 3.8-6.4% mean increase in thousand grain weight (TGWT) and a 3.1-4.2% mean increase in hectolitre weight (HLW) for winter wheat. Results for the standards were comparable.

Table 3.2-260: Impact of GF-3307 on grain yield when applied at 0.9-1.0 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					135-150 g as/ha				
					0.9-1.0 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	9	6.1	5.1-7.5	120.8	104.1-145.3	119.1	103.0-148.8	All
TRZAW*	NE	8	6.1	5.1-7.7	117.7	104.1-130.4	115.4	103.0-124.1	Proline*
TRZAW**	NE	1	6.1	-	145.3	-	148.8	-	Aviator Xpro/1.0-1.25 L/ha
TRZAW	MAR	3	7.0	6.0-8.4	111.1	107.7-113.7	118.7	118.5-119.0	Aviator Xpro/1.0 L/ha
TRZAS	NE	1	4.6	-	108.1	-	107.0	-	Proline*

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

Table 3.2-261: Impact of GF-3307 on grain quality (TGWT) when applied at 0.9-1.0 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference standard		
					135-150 g as/ha				
			0.9-1.0 L/ha		Mean	min-max	Mean	min-max	Mean
TRZAW	NE	9	43.8	36.0-48.9	103.8	99.0-112.1	104.6	99.6-111.3	All
TRZAW*	NE	8	44.0	36.0-48.9	102.8	99.0-108.8	103.8	99.6-107.8	Proline*
TRZAW***	NE	1	42.8	-	112.1	-	111.3	-	Aviator Xpro/1.0-1.25 L/ha
TRZAW	MAR	3	38.7	28.7-48.4	106.4	103.1-109.1	108.6	106.1-110.7	Aviator Xpro/1.0 L/ha
TRZAS	NE	1	31.1	-	99.4	-	98.7	-	Proline/0.72 L/ha

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

Table 3.2-262: Impact of GF-3307 on grain quality (HLW) when applied at 0.9-1.0 L/ha on wheat in EPPO North-East climatic zone and DE and CZ efficacy trials

ETFO North-East climatic zone and DE and CZ efficacy trials									
Crop	EPPO Zone	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
					GF-3307		Reference standard		
					135-150 g as/ha				
					0.9-1.0 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	NE	5	74.1	71.5-76.8	104.2	100.0-108.2	103.2	98.7-107.5	Proline*
TRZAW*	NE	4	74.8	73.2-76.8	103.2	100.0-106.9	102.1	98.7-106.5	Proline*
TRZAW**	NE	1	71.5	-	108.2	-	107.5	-	Aviator Xpro/1.0-1.25 L/ha
TRZAW	MAR	2	69.2	67.4-70.9	103.1	101.0-105.1	103.1	101.1-105.0	Aviator Xpro/1.0 L/ha
TRZAS	NE	1	65.2	-	98.3	-	97.5	-	Proline*

*Direct comparison to Proline applied at 180-198 g prothioconazole/ha

**Direct comparison to Aviator Xpro

Results – EPPO South-East climatic zone

Of the ~~35~~ 42 EPPO South-East climatic zone effectiveness trials on winter wheat generated between 2014-~~2020~~2021, the impact on grain yield after a single dose of GF-3307 was assessed in ~~27~~ 34 trials. Three trials (HU14E7B026LM01, HU16E7B029AB04 and HU16E7B030AB01) were not harvested. Five trials (HU14E7B014AB01C, HU15E7B012AB02, HU15E7B012AB01C, HU15E7B012AB02C, HU15E7B040AB02C) only have results after two applications. The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD and show comparable yield increases.

In these ~~35~~ 34 trials there were no significant negative effects noted in any trial. Twenty-seven trials were based on the maximum dose rate of 1.5 L/ha. A single application of GF-3307 at 1.5 L/ha, in the presence of disease had a positive impact on grain yield across the majority of trials, with a mean yield increase of ~~16.5~~ 15.2%, relative to the untreated. These trials also achieved a ~~3.8~~ 3.2% mean increase in thousand grain weight (TGWT), relative to the untreated and a ~~0.4~~ 1.9% mean increase in hectolitre weight (HLW). The 1.2 L/ha dose rate was included in ~~23~~ 27 trials. In these trials, a single application of GF-3307 at 1.2 L/ha, in the presence of disease, had a positive impact on grain yield, with a mean yield increase of ~~13.2~~ 12.1%, relative to the untreated. These trials also achieved a ~~3.7~~ 3.3% mean increase in thousand grain weight (TGWT) and a 1.0% mean increase in hectolitre weight (HLW). The 1.0 L/ha dose rate is supported by ~~seven~~ eight trials. In ~~six~~ seven of these trials (one trial only had results after two applications, although the results used for effectiveness were based on assessment after the first application), a single application of GF-3307 at ~~1.0 L/ha~~ 0.9/1.0 L/ha, in the presence of

disease, had a positive impact on grain yield, with a mean yield increase of ~~15.8~~ **15.2%**, relative to the untreated. These trials also achieved a ~~4.6~~ **4.0%** mean increase in thousand grain weight (TGW) and a ~~1.4~~ **1.3%** mean increase in hectolitre weight (HLW). **Note:** Some EPPO Maritime and North-East climatic zone trials were used to support some claims. Results in the EPPO Maritime and North-East climatic zone above show comparable increases in yield and quality for ~~both the 1.2 and 1.5 L/ha~~ **all doses**.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-2637 to ~~Table 3.2-2682~~. The individual trial results are detailed in Appendix 5 of the BAD.

~~Table 3.2-263: Impact of GF-3307 on grain yield when applied at 1.2 and 1.5 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials~~

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated =100%)						
				GF-3307		GF-3307		Reference standard		
				180 g as/ha		225 g as/ha				
				1.2 L/ha		1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	20	4.9	2.6-9.0	-	-	116.5	96.1-145.1	114.6	100.0-140.5	All
TRZAW*	16	4.9	2.6-9.0	115.8	104.8-134.6	118.7	96.1-145.1	116.1	103.3-140.5	Proline*
TRZAW**	2	3.7	2.9-4.5	-	-	107.2	96.6-117.8	106.7	100.0-113.3	Vertisan/1.0 L/ha
TRZAW***	2	6.5	5.9-7.1	-	-	108.3	104.7-111.9	110.0	104.7-111.9	Zantara/1.0 L/ha
TRZAW	23	4.8	2.6-9.0	113.2	93.5-138.9	-	-	113.9	103.3-140.5	All
TRZAW*	16	4.9	2.6-9.0	115.8	104.8-134.6	-	-	116.1	103.3-140.5	Proline*
TRZAW#	3	4.8	4.0-5.1	108.4	103.8-112.6	-	-	107.7	104.2-110.6	Aviator Xpro/1.0 L/ha
TRZAW##	4	4.5	3.0-6.7	111.1	104.5-118.3	-	-	109.4	104.2-116.2	Input/1.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Vertisan. *Direct comparison to Zantara

#Direct comparison to Aviator Xpro. ##Direct comparison to Input

~~Table 3.2-264: Impact of GF-3307 on grain quality (TGW) when applied at 1.2 and 1.5 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials~~

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)						
				GF-3307		GF-3307		Reference standard		
				180 g as/ha		225 g as/ha				
				1.2 L/ha		1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	20	42.7	37.2-56.8	-	-	103.8	94.4-118.6	103.2	96.4-114.1	All
TRZAW*	16	43.4	37.3-56.8	-	-	103.7	94.4-118.6	103.1	96.4-114.1	Proline*
TRZAW**	2	39.5	37.2-41.7	-	-	103.3	101.6-105.0	100.9	98.9-102.9	Vertisan/1.0 L/ha
TRZAW***	2	40.0	39.6-40.4	-	-	104.5	103.5-105.5	105.8	105.2-106.3	Zantara/1.0 L/ha
TRZAW	23	43.0	36.4-56.8	103.7	93.2-119.5	-	-	103.1	96.4-114.1	All
TRZAW*	16	43.4	37.3-56.8	103.9	93.2-119.5	-	-	103.1	96.4-114.1	Proline*
TRZAW#	3	41.4	39.8-42.5	103.8	101.9-107.5	-	-	103.8	101.7-107.8	Aviator Xpro/1.0 L/ha
TRZAW##	4	42.3	36.4-48.1	103.1	100.5-105.5	-	-	102.5	100.2-104.4	Input/1.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Vertisan. *Direct comparison to Zantara

#Direct comparison to Aviator Xpro. ##Direct comparison to Input

~~Table 3.2-265: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 and 1.5 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials~~

Crop	Number of trials	HLW (kg) untreated control	Relative HLW (Untreated = 100%)		
			GF-3307		Reference standard
			180 g as/ha	225 g as/ha	

				1.2 L/ha		1.5 L/ha				Product/dose
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	
TRZAW*	11	74.2	63.6-81.7	-	-	100.4	95.4-102.6	100.7	96.7-102.7	Proline*
TRZAW	18	72.9	62.4-81.7	101.0	95.9-105.2	-	-	101.1	96.7-105.5	All
TRZAW*	11	74.2	63.6-81.7	100.4	95.9-102.6	-	-	100.7	96.7-102.7	Proline*
TRZAW#	3	68.7	62.4-75.3	102.6	101.2-105.2	-	-	102.6	101.2-105.5	Aviator Xpro/1.0 L/ha
TRZAW##	4	72.3	63.6-80.4	101.6	100.2-102.9	-	-	101.1	100.0-101.8	Input/1.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Vertisan. *Direct comparison to Zantara

#Direct comparison to Aviator Xpro. ##Direct comparison to Input

Table 3.2-266: Impact of GF-3307 on grain yield when applied 1.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated-control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				150 g as/ha				
				1.0 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	6	4.7	2.6-6.8	115.8	104.8-134.6	118.2	108.0-140.5	Proline®

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha#Direct comparison to Aviator Xpro. ##Direct comparison to Input

Table 3.2-267: Impact of GF-3307 on grain quality (TCWT) when applied at 1.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	TCW (g) untreated-control		Relative TCW (Untreated = 100%)				
				GF-3307		Reference-standard		
				150 g as/ha				
				1.0 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	6	41.9	39.7-47.7	104.6	100.5-109.8	103.8	100.0-108.7	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Table 3.2-268: Impact of GF-3307 on grain quality (HLW) when applied at 1.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated-control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference-standard		
				150 g as/ha				
				1.0 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW*	3	74.1	70.6-76.8	101.4	101.0-102.0	102.0	101.2-102.7	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Table 3.2-269: Impact of GF-3307 on grain yield when applied at 1.2 and 1.5 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)						
				GF-3307		GF-3307		Reference standard		
				180 g as/ha		225 g as/ha				
		1.2 L/ha		1.5 L/ha		Mean	min-max	Product/dose		
TRZAW	27	5.3	2.6-9.0	-	-	115.2	96.1-145.1	113.7	100.0-147.7	All
TRZAW*	20	5.0	2.6-9.0	-	-	116.3	96.1-145.1	114.1	100.8-140.5	Proline*
TRZAW++	3	7.4	5.1-8.6	-	-	118.1	101.0-144.7	117.8	101.0-147.7	Prosaro/1.0 L/ha
TRZAW**	2	3.7	2.9-4.5	-	-	107.2	96.6-117.8	106.7	100.0-113.3	Vertisan/1.0 L/ha
TRZAW***	2	6.5	5.9-7.1	-	-	108.3	104.7-111.9	110.0	104.7-111.9	Zantara/1.0 L/ha
TRZAW	27	4.9	2.6-9.0	112.1	93.5-138.9	-	-	112.7	100.8-140.5	All
TRZAW*	20	5.0	2.6-9.0	112.8	93.5-138.9	-	-	114.1	100.8-140.5	Proline*
TRZAW#	3	4.8	4.0-5.1	108.4	103.8-112.6	-	-	107.7	104.2-110.6	Aviator Xpro/1.0 L/ha
TRZAW##	4	4.5	3.0-6.7	111.1	104.5-118.3	-	-	109.4	104.2-116.2	Input/1.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Vertisan. *Direct comparison to Zantara

#Direct comparison to Aviator Xpro. ##Direct comparison to Input, ++ Direct comparison to Prosaro

Table 3.2-270: Impact of GF-3307 on grain quality (TGW) when applied at 1.2 and 1.5 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)						
				GF-3307		GF-3307		Reference standard		
				180 g as/ha		225 g as/ha				
		1.2 L/ha		1.5 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	27	42.4	34.2-56.8	-	-	103.2	94.4-118.6	103.8	96.4-128.0	All
TRZAW*	20	43.4	34.2-56.8	-	-	103.2	94.4-118.6	102.8	96.4-114.1	Proline*
TRZAW++	3	39.4	35.5-46.7	-	-	110.9	101.0-128.0	110.9	101.0-128.0	Prosaro/1.0 L/ha
TRZAW**	2	39.5	37.2-41.7	-	-	103.3	101.6-105.0	100.9	98.9-102.9	Vertisan/1.0 L/ha
TRZAW***	2	40.0	39.6-40.4	-	-	104.5	103.5-105.5	105.8	105.2-106.3	Zantara/1.0 L/ha
TRZAW	27	43.0	34.2-56.8	103.3	93.2-119.5	-	-	102.9	96.4-114.1	All
TRZAW*	20	43.4	34.2-56.8	103.3	93.2-119.5	-	-	102.8	96.4-114.1	Proline*
TRZAW#	3	41.4	39.8-42.5	103.8	101.9-107.5	-	-	103.8	101.7-107.8	Aviator Xpro/1.0 L/ha
TRZAW##	4	42.3	36.4-48.1	103.1	100.5-105.5	-	-	102.5	100.2-104.4	Input/1.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Vertisan. *Direct comparison to Zantara

#Direct comparison to Aviator Xpro. ##Direct comparison to Input, ++ Direct comparison to Prosaro

Table 3.2-271: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 and 1.5 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)						
				GF-3307		GF-3307		Reference standard		
				180 g as/ha		225 g as/ha				
		1.2 L/ha		1.5 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	17	73.6	61.7-81.7	-	-	101.9	95.4-122.7	102.1	96.7-123.3	All
TRZAW*	15	74.0	63.6-81.7	-	-	100.6	95.4-102.6	100.8	96.7-102.7	Proline*
TRZAW++	2	70.7	61.7-79.7	-	-	111.5	100.3-122.7	111.6	99.9-123.3	Prosaro/1.0 L/ha
TRZAW	22	73.0	62.4-81.7	101.0	95.9-105.2	-	-	101.1	96.7-105.5	All
TRZAW*	15	74.0	63.6-81.7	100.5	95.9-102.6	-	-	100.8	96.7-102.7	Proline*
TRZAW#	3	68.7	62.4-75.3	102.6	101.2-105.2	-	-	102.6	101.2-105.5	Aviator Xpro/1.0 L/ha
TRZAW##	4	72.3	63.6-80.4	101.6	100.2-102.9	-	-	101.1	100.0-101.8	Input/1.0 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Vertisan. *Direct comparison to Zantara

#Direct comparison to Aviator Xpro. ##Direct comparison to Input, ++ Direct comparison to Prosaro

Table 3.2-272: Impact of GF-3307 on grain yield when applied 0.9-1.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

In ETCO South-East climate zone efficacy trials								
Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				135-150 g as/ha				
				0.9-1.0 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TRZAW	7	4.7	2.6-6.8	115.2	104.8-134.6	117.4	108.0-140.5	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Table 3.2-273: Impact of GF-3307 on grain quality (TGW) when applied at 0.9-1.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Wheat (TRZAW) in DFG South-East climatic zone efficacy trials								
Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				135-150 g as/ha				
		0.9-1.0 L/ha		Mean	min-max	Mean	min-max	Product/dose
TRZAW	7	42.0	39.7-47.7	104.0	100.5-109.8	103.4	100.0-108.7	Proline*

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Table 3.2-274: Impact of GF-3307 on grain quality (HLW) when applied at 0.9-1.0 L/ha on winter wheat (TRZAW) in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)					
				GF-3307		Reference standard			
				135-150 g as/ha					
				0.9-1.0 L/ha					
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
TRZAW*	4	74.0	70.6-76.8	101.3	101.0-102.0	101.8	101.2-102.7	Proline*	

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Summary and conclusion

GF-3307 at the proposed label rates of 1.5 L/ha in the EPPO Maritime climatic zone, 1.2-1.5 L/ha in the EPPO North-East climatic zone or 1.0-1.5 L/ha in the EPPO South-East climatic zone had an overall positive effect on grain yield and quality of wheat crops treated in the presence of disease. GF-3307 at 1.5 L/ha in the EPPO Maritime climatic zone, 0.9-1.5 L/ha in the EPPO North-East climatic zone or 0.9-1.5 L/ha in the EPPO South-East climatic zone had an overall positive effect on grain yield and quality of wheat crops treated in the presence of disease.

Winter rye (SECCW)

Results – EPPO Maritime climatic zone

Of the 12 EPPO Maritime climatic zone effectiveness trials on winter rye generated between 2015-2017, the impact on grain yield after a single dose of GF-3307 was assessed in 11 trials. One trial (DE17G1C012UB03C) was not harvested.

In these 11 trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 17.3%, relative to the untreated. These trials also achieved a 6.2% increase in thousand grain weight (TGWT), relative to the untreated. No trials were assessed for hectolitre weight (HLW). Results for the standards were comparable. A summary of the yield and quality data from efficacy trials is presented in Table 3.2-2753 and Table 3.2-2764. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-2753: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter rye (SECCW) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	11	7.1	5.2-9.8	117.3	101.0-134.4	114.1	100.0-126.5	All
SECCW*	10	7.0	5.2-9.8	118.9	108.0-134.4	115.5	105.0-126.5	Proline/0.72 L/ha
SECCW**	1	8.4	-	101.0	-	100.0		Aviator Xpro/1.25 L/ha

*Direct comparison to Proline. **Direct comparison to Aviator Xpro

Table 3.2-2764: Impact of GF-3307 on grain quality (TGWT) when applied at 2.0 L/ha on winter rye (SECCW) in EPPO Maritime climatic zone efficacy trials

(SECCW) in LTPG Maritime climate zone efficacy trials								
Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	11	29.2	22.3-40.0	106.2	100.0-120.4	105.5	100.7-119.3	All
SECCW*	10	28.2	22.3-34.1	106.8	101.3-120.4	105.8	100.7-119.3	Proline/0.72 L/ha
SECCW**	1	40.0	-	100.0	-	102.5	-	Aviator Xpro/1.25 L/ha

*Direct comparison to Proline. **Direct comparison to Aviator Xpro

Results – EPPO North-East climatic zone

All ~~five~~ **seven** EPPO North-East climatic zone effectiveness trials on winter rye generated in 2016 **and** 2021 were assessed for the impact on grain yield after a single dose of GF-3307 at the 1.5 L/ha dose rate. In these ~~five~~ **seven** trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 2.0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of ~~14.3~~ **15.8**%, relative to the untreated and a ~~3.4~~ **3.6**%

increase in thousand grain weight (TGWT). No trials were assessed for hectolitre weight (HLW). Two 2021 trials were assessed for hectolitre weight (HLW) and demonstrated a 6.0% increase over the untreated. Results for the standards were comparable.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-2775 and to Table 3.2-2787. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-277: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated-control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
		1.5 L/ha						
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW*	5	5.1	3.6-7.3	114.3	107.5-128.1	115.7	107.1-138.3	Proline/0.72 L/ha

*Direct comparison to Proline

Table 3.2-278: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated=100%)					
				GF-3307		Reference standard			
				225 g as/ha					
				1.5 L/ha					
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose	
SECCW*	5	31.2	28.7-35.8	103.4	101.0-106.8	103.7	100.1-107.5	Proline/0.72 L/ha	

*Direct comparison to Proline

Table 3.2-279: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

BIO-NORTH EAST Climate Zone efficacy trials								
Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
		1.5 L/ha		Mean	min-max	Mean	min-max	Product/dose
SECCW	7	5.2	3.6-7.3	115.8	107.5-128.1	116.6	107.1-138.3	Proline*

*Proline 250 or 275 applied at 180-198 g as/ha

Table 3.2-280: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	7	31.3	28.7-35.8	103.6	101.0-106.8	103.9	100.1-107.5	Proline*

*Proline 250 or 275 applied at 180-198 g as/ha

Table 3.2-281: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	2	63.3	59.3-67.3	106.0	102.6-109.4	104.4	102.2-105.9	Proline*

*Proline 250 or 275 applied at 180-198 g as/ha

Use on rye in the EPPO North-East zone includes a lower dose of 1.2 L/ha. This dose rate is supported by 15 17 winter rye harvested trials (5 seven EPPO North-East zone trials and 10 trials from the EPPO Maritime zone/DE).

A summary of the yield and quality data from these efficacy trials at the 1.2 L/ha dose rate is presented in Table 3.2-2828 and to Table 3.2-283.

A single application of GF-3307 at 1.2 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 1.5 L/ha dose rate, with a mean yield increase of 9.0 12.0-17.1%, relative to the untreated. These trials also achieved a 0.3 1.5-5.8% mean increase in thousand grain weight (TGWT). Two 2021 trials were assessed for hectolitre weight (HLW) and demonstrated a 6.0% increase over the untreated. Results for the standards were comparable.

Table 3.2-282: Impact of GF-3307 on grain yield when applied at 1.2 L/ha on winter rye (SECCW) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference-standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	NE	5	5.1	3.6-7.3	109.0	101.7-116.1	115.7	107.1-138.3	Proline/0.72 L/ha
SECCW	MAR	10	7.0	5.2-9.8	117.1	106.1-131.2	115.5	105.0-126.5	Proline/0.72 L/ha

Table 3.2-283: Impact of GF-3307 on grain quality (TGWT) when applied at 1.2 L/ha on winter rye (SECCW) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference-standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	NE	5	31.2	28.7-28.7	100.3	98.5-101.8	103.7	100.1-107.5	Proline/0.72 L/ha
SECCW	MAR	10	28.2	22.3-34.1	105.8	101.2-120.0	105.8	100.7-119.3	Proline/0.72 L/ha

Table 3.2-284: Impact of GF-3307 on grain yield when applied at 1.2 L/ha on winter rye (SECCW) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	NE	7	5.2	3.6-7.3	112.0	101.7-124.4	116.6	107.1-138.3	Proline*
SECCW	MAR	10	7.0	5.2-9.8	117.1	106.1-131.2	115.5	105.0-126.5	Proline/0.72 L/ha

*Proline 250 or 275 applied at 180-198 g as/ha

Table 3.2-285: Impact of GF-3307 on grain quality (TGWT) when applied at 1.2 L/ha on winter rye (SECCW) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	NE	7	31.3	28.7-35.8	101.5	98.5-105.5	103.9	100.1-107.5	Proline*
SECCW	MAR	10	28.2	22.3-	105.8	101.2-	105.8	100.7-	Proline/0.72 L/ha

				34.1		120.0		119.3	
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*Proline 250 or 275 applied at 180-198 g as/ha

Table 3.2-286: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 L/ha on winter rye (SECCW) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				180 g as/ha				
				1.2 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
SECCW	2	63.3	59.3-67.3	104.3	101.5-107.1	104.4	102.2-105.9	Proline*

*Proline 250 or 275 applied at 180-198 g as/ha

Summary and conclusion

GF-3307 at the proposed label rates of 1.5 L/ha in the EPPO Maritime climatic zone and 1.2-1.5 L/ha in the EPPO North-East climatic zone had an overall positive effect on grain yield and quality of winter rye crops treated in the presence of disease.

Winter triticale (TTLWI)

Results – EPPO Maritime climatic zone

Of the 17 16 EPPO Maritime climatic zone effectiveness trials on winter triticale generated between 2015-2020, the impact on grain yield after a single dose of GF-3307 was assessed in 13 trials. Two trials (DE15E7B034UB03C and EA20E7B018F-DNZ057) were not harvested. ~~Two trials (EA20F9B007F-DPE012 and EA20F9B007F-DPE013)~~ **One trial (EA20F9B007F-DPE013)** only ~~have~~ **has** results after two applications (although the results used for effectiveness were based on assessment after the first application). The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD and show comparable yield increases.

In these 13 trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 18.4%, relative to the untreated. These trials also achieved a 5.1% increase in thousand grain weight (TGWT), relative to the untreated and a 3.1% increase in hectolitre weight (HLW). Results for the standards were comparable.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-28711 to Table 3.2-2893. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-28711: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter triticale (TTLWI) in EPPO Maritime climatic zone efficacy trials

ERFC Maritime climate zone efficacy trials								
Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	13	6.8	2.7-9.3	118.4	103.3-139.6	114.5	100.9-135.7	All
TTLWI*	10	6.5	2.7-9.3	121.5	108.4-139.6	117.3	100.9-135.7	Proline*
TTLWI**	3	7.8	6.4-8.6	107.9	103.3-117.3	105.5	103.4-109.6	Prosaro/1.0 L/ha

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

**Direct comparison to Prosaro

Table 3.2-28812: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on winter triticale (TTLWI) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	9	41.0	31.2-54.6	105.1	93.7-114.4	104.1	100.0-108.1	All
TTLWI*	7	41.6	31.2-54.6	104.5	93.7-114.4	103.6	100.0-108.1	Proline*
TTLWI**	2	39.3	37.9-40.7	107.3	103.2-111.4	105.7	103.9-107.4	Prosaro/1.0 L/ha

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

**Direct comparison to Prosaro

Table 3.2-2893: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on winter triticales (TTLWI) in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	5	72.4	67.8-74.8	103.1	101.0-107.4	103.0	100.7-105.9	All
TTLWI*	4	72.4	67.8-74.8	103.4	101.0-107.4	103.2	100.7-105.9	Proline*
TTLWI**	1	72.4	-	101.9	-	101.9	-	Prosaro/1.0 L/ha

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

**Direct comparison to Prosaro

Results – EPPO North-East climatic zone

All 15 16 EPPO North-East climatic zone effectiveness trials on winter triticales generated between 2016 and 2020/2021 were assessed for the impact on grain yield after a single dose of GF-3307 at the 1.5 L/ha dose rate.

In these 15 16 trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 15.3 14.9%, relative to the untreated. These trials also achieved a 5.2 5.1% mean increase in thousand grain weight (TGW), relative to the untreated and a 0.6 0.5% increase in hectolitre weight (HLW). Results for the standards were comparable.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-2904 to Table 3.2-2926. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-290: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter triticales (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number-of trials	Yield (t/ha) untreated-control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	15	6.1	4.1-8.3	115.3	98.7-126.9	114.0	102.4-122.9	All
TTLWI*	11	6.0	4.5-7.5	116.9	109.5-126.9	115.0	108.6-122.9	Proline*
TTLWI**	3	6.2	4.1-8.3	114.6	106.3-122.7	114.5	108.9-119.5	Prosaro/1.0 L/ha
TTLWI#	1	7.2	-	98.7	-	102.4	-	Wirtuoz/Artesa

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

**Direct comparison to Prosaro

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-291: Impact of GF-3307 on grain quality (TGW) when applied at 1.5 L/ha on winter triticales (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number-of trials	TGW (g) untreated-control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference-standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	13	37.3	28.4-53.7	105.2	102.0-113.5	105.3	100.0-111.6	All
TTLWI*	9	40.8	33.8-53.7	105.7	102.0-113.5	104.8	100.0-111.6	Proline*
TTLWI**	3	29.4	28.4-30.2	104.6	102.1-107.3	106.6	104.6-110.5	Prosaro/1.0 L/ha
TTLWI#	1	29.2	-	102.8	-	106.2	-	Wirtuoz/Artea#

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

**Direct comparison to Prosaro

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-292: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on winter triticales (TTLWI) in EPPO North-East climatic zone efficacy trials

Relative HLW (Untreated = 100%)				
Crop	Number of trials	HLW (kg) untreated control	GF-3307	Reference standard
			225 g as/ha	
			1.5 L/ha	

		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	7	64.8	59.9-68.1	100.6	95.8-103.1	100.8	96.5-104.6	All
TTLWI*	4	65.4	59.9-68.1	100.8	95.8-103.1	100.8	96.5-104.6	Proline*
TTLWI**	3	64.0	63.7-64.5	100.2	99.6-100.7	101.0	100.0-101.9	Prosaro/1.0 L/ha

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

**Direct comparison to Prosaro

Table 3.2-293: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	16	6.0	4.1-8.3	114.9	98.7-126.9	113.9	102.4-122.9	All
TTLWI*	12	5.9	4.5-7.5	116.4	109.5-126.9	114.8	108.6-122.9	Proline*
TTLWI**	3	6.2	4.1-8.3	114.6	106.3-122.7	114.5	108.9-119.5	Prosaro/1.0 L/ha
TTLWI#	1	7.2	-	98.7	-	102.4	-	Wirtuoz/Arteaz

*Direct comparison to Proline applied at 180-200 g prothioconazole/ha

**Direct comparison to Prosaro

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-294: Impact of GF-3307 on grain quality (TGW) when applied at 1.5 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	14	36.8	28.4-53.7	105.1	102.0-113.5	105.2	100.0-111.6	All
TTLWI*	10	39.7	30.4-53.7	105.4	102.0-113.5	104.6	100.0-111.6	Proline*
TTLWI**	3	29.4	28.4-30.2	104.6	102.1-107.3	106.6	104.6-110.5	Prosaro/1.0 L/ha
TTLWI#	1	29.2	-	102.8	-	106.2	-	Wirtuoz/Artea#

*Direct comparison to Proline applied at 180-200 g prothioconazole/ha

**Direct comparison to Prosaro

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-295: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	8	64.9	59.9-68.1	100.5	95.8-103.1	100.8	96.5-104.6	All
TTLWI*	5	65.5	59.9-68.1	100.7	95.8-103.1	100.6	96.5-104.6	Proline*
TTLWI**	3	64.0	63.7-64.5	100.2	99.6-100.7	101.0	100.0-101.9	Prosaro/1.0 L/ha

*Direct comparison to Proline applied at 180-200 g prothioconazole/ha

**Direct comparison to Prosaro

Use on triticale in the EPPO North-East zone includes a lower dose of 1.2 L/ha. This dose rate is supported by 18 19 harvested winter triticale trials (nine 10 EPPO North-East zone trials and nine trials from the EPPO Maritime zone/DE). A summary of the yield and quality data from 18 19 of these efficacy trials at the 1.2 L/ha dose rate is presented in Table 3.2-2967 to Table 3.2-2989.

A single application of GF-3307 at 1.2 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 1.5 L/ha dose rate, with a mean yield increase of 12.2 11.3-19.1%, relative to the untreated. These trials also achieved a 4.8 4.5-6.6% mean

increase in thousand grain weight (TGWT) and a 2-6 3.0-3.7% mean increase in hectolitre weight (HLW). Results for the standards were comparable.

Table 3.2-296: Impact of GF-3307 on grain yield when applied at 1.2 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	NE	9	6.0	4.5-7.5	112.2	98.7-121.4	113.7	102.4-122.9	All
TTLWI*	NE	8	5.9	4.5-7.5	113.8	108.6-121.4	115.1	110.3-122.9	Proline*
TTLWI#	NE	1	7.2	-	98.7	-	102.4	-	Wirtuoz/Artea#
TTLWI*	MAR	9	6.9	4.5-9.3	119.1	106.0-134.5	117.5	100.9-135.7	Proline*

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-297: Impact of GF-3307 on grain quality (TGWT) when applied at 1.2 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated-control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	NE	7	40.1	29.2-53.7	104.8	98.8-114.1	105.3	100.0-111.6	All
TTLWI*	NE	6	41.9	33.8-53.7	105.5	98.8-114.1	105.1	100.0-111.6	Proline*
TTLWI#	NE	1	29.2	-	100.6	-	106.2	-	Wirtuoz/Artea#
TTLWI*	MAR	6	42.8	31.2-54.6	106.6	97.3-115.7	103.6	100.0-108.1	Proline*

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-298: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI*	NE	1	59.9	-	102.6	-	104.6	-	Proline*
TTLWI*	MAR	3	74.0	74.3-74.8	103.7	101.7-106.1	104.1	101.5-105.9	Proline*

*Direct comparison to Proline applied at 198-200 g prothioconazole/ha

Table 3.2-299: Impact of GF-3307 on grain yield when applied at 1.2 L/ha on winter triticale (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	NE	10	5.9	4.2-7.5	113.1	98.7-121.4	113.6	102.4-122.9	All
TTLWI*	NE	9	5.7	4.2-7.5	114.7	108.6-121.4	114.8	110.3-122.9	Proline*
TTLWI#	NE	1	7.2	-	98.7	-	102.4	-	Wirtuoz/Artea#
TTLWI*	MAR	9	6.9	4.5-9.3	119.1	106.0-134.5	117.5	100.9-135.7	Proline*

*Direct comparison to Proline applied at 180-200 g prothioconazole/ha

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-300: Impact of GF-3307 on grain quality (TGWT) when applied at 1.2 L/ha on winter triticales (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI	NE	8	38.9	29.2-53.7	104.5	98.8-114.1	105.0	100.0-111.6	All
TTLWI*	NE	7	40.3	30.4-53.7	105.1	98.8-114.1	104.8	100.0-111.6	Proline*
TTLWI#	NE	1	29.2	-	100.6	-	106.2	-	Wirtuoz/Artea#
TTLWI*	MAR	6	42.8	31.2-54.6	106.6	97.3-115.7	103.6	100.0-108.1	Proline*

*Direct comparison to Proline applied at 180-200 g prothioconazole/ha

#Direct comparison to Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

Table 3.2-301: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 L/ha on winter triticales (TTLWI) in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
TTLWI*	NE	2	62.9	59.9-65.8	103.0	102.6-103.3	102.4	100.2-104.6	Proline*
TTLWI*	MAR	3	74.0	74.3-74.8	103.7	101.7-106.1	104.1	101.5-105.9	Proline*

*Direct comparison to Proline applied at 180-200 g prothioconazole/ha

Summary and conclusion

GF-3307 at the proposed label rates of 1.5 L/ha in the EPPO Maritime climatic zone and 1.2-1.5 L/ha in the EPPO North-East climatic zone had an overall positive effect on grain yield and quality of winter triticales crops treated in the presence of disease.

Winter barley (HORVW) and Spring barley (HORVS)

Results – EPPO Maritime climatic zone

Of the ~~30~~ 29 EPPO Maritime climatic zone effectiveness trials on winter barley and 14 trials on spring barley generated between 2017-2019, the impact on grain yield after a single dose of GF-3307 was assessed in 25 trials (17 winter barley and 8 spring barley). Two winter barley (DE17E7B045UB11C and GB17E7B046RH02) and three spring barley trials (GB17E7B049RH02, EA19E7B004F-DIT02 and EA19F9B025F-DNZ01) were not harvested. ~~Fourteen~~ Thirteen trials (~~11~~ 10 winter barley and 3 spring barley trials) only have results after two applications. The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD and show comparable yield increases.

In these 25 trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 13.6% on winter barley and 11.7 on spring barley, relative to the untreated. These trials also achieved an 7.0% increase in thousand grain weight (TGWT), relative to the untreated on winter barley and 3.9% increase on spring barley. A 2.3% increase in hectolitre weight (HLW) for winter barley and 1.4% increase for spring barley were also found. Results for the standards were comparable.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-30220 to Table 3.2-30422. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-30220: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on barley in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
Mean	min-max	Mean	min-max	Mean	min-max	Product/dose		
HORVW	17	7.4	3.6-10.3	113.6	99.3-135.5	114.1	99.5-141.2	All
HORVW*	15	7.2	3.6-10.3	113.7	99.3-135.5	114.5	99.5-141.2	Proline/0.8 L/ha
HORVW**	2	8.6	7.9-9.3	113.4	113.3-113.5	111.0	110.8-119.1	Aviator Xpro/1.0 L/ha
HORVS	8	6.1	2.8-8.8	111.7	103.6-122.5	110.8	106.0-123.1	Proline/0.8 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison to Aviator Xpro

Table 3.2-30321: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on barley in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	14	42.5	27.9-53.4	107.0	90.7-118.7	106.9	93.1-135.7	Proline/0.8 L/ha
HORVS	8	44.6	38.0-53.7	103.9	98.1-115.0	104.6	100.8-116.7	Proline/0.8 L/ha

Table 3.2-30422: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on barley in EPPO Maritime climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	15	64.0	56.1-75.3	102.3	96.2-106.0	101.8	96.9-105.2	All
HORVW*	13	63.3	56.1-75.3	102.2	96.2-106.0	101.7	96.9-105.2	Proline/0.8 L/ha
HORVW**	2	68.4	66.9-69.9	102.9	102.9-102.9	101.9	101.8-102.0	Aviator Xpro/1.0 L/ha
HORVS	6	66.2	60.6-71.8	101.4	100.4-102.4	100.8	98.8-102.8	Proline/0.8 L/ha

*Direct comparison to Proline applied at 150-198 g prothioconazole/ha

Direct comparison to Aviator Xpro *Direct comparison to Librax

Results – EPPO North-East climatic zone

Of the 9 11 EPPO North-East climatic zone effectiveness trials on winter barley and 10 trials on spring barley generated between 2017-2020~~2021~~, the impact on grain yield after a single dose of GF-3307 was assessed in 14 16 trials (5 7 winter barley and 9 spring barley). Five trials (4 winter barley and one spring barley trial) only have results after two applications (although the results used for effectiveness were based on assessment after the first application). The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD and show comparable yield increases.

In these 14 16 trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of 14.6 17.0% on winter barley and 16.8 on spring barley, relative to the untreated. These trials also achieved an 7.1 8.7% increase in thousand grain weight (TGWT), relative to the untreated on winter barley and 6.0% increase on spring barley. A 3.6% increase in hectolitre weight (HLW) for winter barley and a 1.9% increase in hectolitre weight (HLW) for spring barley was also found. Results for the standards were comparable.

A summary of the yield and quality data from efficacy trials is presented in ~~Table 3.2-3053~~ to ~~Table 3.2-3076~~. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-305: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated-control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	5	7.5	5.0-10.8	114.6	97.1-120.9	110.6	98.4-120.1	Proline*
HORVS	9	4.7	3.5-7.1	116.8	101.5-136.9	113.2	91.7-143.9	Proline*

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-306: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated-control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	5	39.4	33.9-45.1	107.1	101.8-144.8	106.5	102.7-114.2	Proline*
HORVS	9	42.2	29.0-60.5	106.0	102.0-113.0	105.8	98.6-113.8	Proline*

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-307: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated-control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference-standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	3	57.8	54.6-59.6	100.0	97.3-103.2	100.7	99.5-103.0	Proline*
HORVS	7	58.2	54.1-66.2	101.9	99.0-106.5	100.3	99.5-102.4	Proline*

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-308: Impact of GF-3307 on grain yield when applied at 1.5 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	7	7.1	5.0-10.8	117.0	97.1-131.0	110.5	98.4-124.7	All
HORVW*	4	6.4	5.0-7.4	119.0	116.7-120.9	113.7	108.7-120.1	Proline*
HORVW**	3	8.0	5.1-10.8	114.2	97.1-131.1	106.2	91.0-116.7	Prosaro/ 0.75 L/ha
HORVS	9	4.7	3.5-7.1	116.8	101.5-136.9	115.0	91.7-143.9	All
HORVS*	7	4.9	3.5-7.1	113.7	101.5-134.4	112.9	91.7-143.9	Proline*
HORVS**	2	4.1	3.6-4.5	127.5	118.1-136.9	122.6	106.1-139.0	Prosaro/ 0.75 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Table 3.2-309: Impact of GF-3307 on grain quality (TGWT) when applied at 1.5 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	7	38.3	25.9-45.2	108.7	101.8-121.2	106.3	102.3-114.2	All
HORVW*	4	39.1	33.9-45.1	108.4	104.5-114.8	107.5	104.8-114.2	Proline*
HORVW**	3	37.3	25.9-45.2	109.0	101.8-121.2	104.7	102.3-107.7	Prosaro/ 0.75 L/ha
HORVS	9	42.2	29.0-60.5	106.0	102.0-113.0	106.2	98.6-113.8	All
HORVS*	7	43.8	29.0-60.5	105.7	102.0-113.0	105.9	98.6-113.8	Proline*
HORVS**	2	36.9	31.9-41.8	106.9	106.2-107.6	107.5	106.3-108.7	Prosaro/ 0.75 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Table 3.2-310: Impact of GF-3307 on grain quality (HLW) when applied at 1.5 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				225 g as/ha				
				1.5 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	5	57.6	53.8-60.8	103.6	97.3-109.1	102.7	99.5-107.6	All
HORVW*	2	57.1	54.6-59.6	98.4	97.3-99.5	99.6	99.5-99.7	Proline*
HORVW**	3	57.9	53.8-60.8	107.1	103.2-109.1	104.8	102.4-107.6	Prosaro/ 0.75 L/ha
HORVS	7	58.1	54.1-66.2	103.2	99.0-109.7	102.2	99.5-108.9	All
HORVS*	5	56.5	54.1-60.5	103.3	99.0-109.7	101.6	99.5-108.9	Proline*
HORVS**	2	62.2	58.2-66.2	103.1	102.0-104.2	103.7	103.3-104.0	Prosaro/ 0.75 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Use on barley in the EPPO North-East zone includes a lower dose of 1.2 L/ha. This dose rate is supported by the 14 16 EPPO North-East zone trials detailed above and trials from the EPPO Maritime zone (Germany and the Czech Republic) using a dose rate of 1.2-1.25 L/ha. Five of the German trials were yielded after a single application. A summary of the yield and quality data from 19 of these efficacy trials at the 1.2 L/ha 1.2/1.25 L/ha dose rate is presented in Table 3.2-311 to Table 3.2-313.

A single application of GF-3307 at 1.2 L/ha 1.2/1.25 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 1.5 L/ha dose rate, with a mean yield increase of 6.5 9.8-21.4%, relative to the untreated across 7 nine winter barley trials and 13.0-14.3% increase in 12 spring barley trials. These trials also achieved a 6.1 6.7-10.0.0% mean increase in thousand grain weight (TGW) for winter barley and 3.8-4.0% increase for spring barley and a 2.9 4.2% 4.2-4.5% mean increase in hectolitre weight (HLW) for winter barley and 0.8-1.8% increase for spring barley. Results for the standards were comparable.

Table 3.2-311: Impact of GF-3307 on grain yield when applied at 1.2 L/ha on barley in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	NE	5	7.5	5.0-10.8	106.5	92.7-115.1	110.6	98.4-120.1	Proline*
HORVW	MAR	2	6.7	5.6-7.8	121.4	117.4-125.3	128.2	120.8-135.7	Proline/0.8 L/ha
HORVS	NE	9	4.7	3.5-7.1	114.3	98.5-144.7	113.2	91.7-143.9	Proline*
HORVS	MAR	3	7.0	5.1-8.0	113.0	107.4-122.5	112.4	106.9-123.1	

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-312: Impact of GF-3307 on grain quality (TGW) when applied at 1.2 L/ha on barley in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated-control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
					1.2 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	NE	5	39.4	33.9-45.1	106.1	101.7-113.1	106.5	102.7-114.2	Proline*
HORVW	MAR	2	42.1	38.9-45.4	110.0	108.1-111.9	122.7	109.6-135.7	Proline/0.8 L/ha
HORVS	NE	9	42.2	29.0-60.5	104.0	97.8-112.3	105.8	98.6-113.8	Proline*
HORVS	MAR	3	45.4	38.8-53.7	103.8	94.6-115.3	108.0	102.0-116.7	Proline/0.8 L/ha

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-313: Impact of GF-3307 on grain quality (HLW) when applied at 1.2 L/ha on barley in EPPO North-East climatic zone and DE efficacy trials

North-East climatic zone and 12E efficacy trials									
Crop	EPPO Zone	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
					GF-3307		Reference standard		
					180 g as/ha				
			1.2 L/ha		Mean	min-max	Mean	min-max	Mean
HORVW	NE	3	57.8	54.6-59.6	102.9	100.0-106.1	100.7	99.5-103.0	Proline*
HORVW	MAR	1	62.8	-	104.2	-	105.2	-	Proline/0.8 L/ha
HORVS	NE	7	58.2	54.1-66.2	100.8	99.2-103.1	100.3	99.5-102.4	Proline*
HORVS	MAR	2	67.8	65.1-70.5	101.8	100.9-102.8	101.8	100.8-102.8	Proline/0.8 L/ha

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-314: Impact of GF-3307 on grain yield when applied at 1.2-1.25 L/ha on barley in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO zone	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
					GF-3307		Reference standard		
					180-187.5 g as/ha				
			1.2-1.25 L/ha		Mean	min-max	Mean	min-max	Mean
HORVW	NE	7	7.1	5.0-10.8	109.8	92.7-121.4	110.5	98.4-124.7	All
HORVW*	NE	4	6.4	5.0-7.4	110.0	101.5-115.1	113.7	108.7-120.1	Proline*
HORVW**	NE	3	8.0	5.1-10.8	109.6	92.7-121.4	106.2	91.0-116.7	Prosaro/ 0.75 L/ha
HORVW	MAR	2	6.7	5.6-7.8	121.4	117.4-125.3	128.2	120.8-135.7	Proline/0.8 L/ha
HORVS	NE	9	4.7	3.5-7.1	114.3	98.5-144.7	115.0	91.7-143.9	All
HORVW*	NE	7	4.9	3.5-7.1	113.2	98.5-144.7	112.9	91.7-143.9	Proline*
HORVW**	NE	2	4.1	3.6-4.5	118.4	112.0-124.7	122.6	106.1-139.0	Prosaro/ 0.75 L/ha
HORVS	MAR	3	7.0	5.1-8.0	113.0	107.4-122.5	112.4	106.9-123.1	

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Table 3.2-315: Impact of GF-3307 on grain quality (TGWT) when applied at 1.2-1.25 L/ha on barley in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
					GF-3307		Reference standard		
					180-187.5 g as/ha				
					1.2-1.25 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	NE	7	38.3	25.9-45.2	106.7	101.7-113.1	106.3	102.3-114.2	All
HORVW*	NE	4	39.1	33.9-45.1	107.2	103.6-113.1	107.5	104.8-114.2	Proline*
HORVW**	NE	3	37.3	25.9-45.2	106.2	101.7-112.1	104.7	102.3-107.7	Prosaro/ 0.75 L/ha
HORVW	MAR	2	42.1	38.9-45.4	110.0	108.1-111.9	122.7	109.6-135.7	Proline/0.8 L/ha
HORVS	NE	9	42.2	29.0-60.5	104.0	97.8-112.3	106.2	98.6-113.8	All
HORVW*	NE	7	43.8	29.0-60.5	103.8	97.8-112.3	105.9	98.6-113.8	Proline*
HORVW**	NE	2	36.9	31.9-41.8	104.9	103.6-106.1	107.5	106.3-108.7	Prosaro/ 0.75 L/ha
HORVS	MAR	3	45.4	38.8-	103.8	94.6-	108.0	102.0-	Proline/0.8 L/ha

				53.7		115.3		116.7	
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*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Table 3.2-316: Impact of GF-3307 on grain quality (HLW) when applied at 1.2-1.25 L/ha on barley in EPPO North-East climatic zone and DE efficacy trials

Crop	EPPO Zone	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
					GF-3307		Reference standard		
					180-187.5 g as/ha				
					1.2-1.25 L/ha				
			Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	NE	5	57.6	53.8-60.8	104.5	100.0-107.7	102.7	99.5-107.6	All
HORVW*		2	57.1	54.6-59.6	101.3	100.0-102.5	99.6	99.5-99.7	Proline*
HORVW**		3	57.9	53.8-60.8	106.6	106.0-107.7	104.8	102.4-107.6	Prosaro/ 0.75 L/ha
HORVW	MAR	1	62.8	-	104.2	-	105.2	-	Proline/0.8 L/ha
HORVS	NE	7	58.1	54.1-66.2	102.1	99.2-109.7	102.2	99.5-108.9	All
HORVW*	NE	5	56.5	54.1-60.5	102.1	99.2-109.7	101.6	99.5-108.9	Proline*
HORVW**	NE	2	62.2	58.2-66.2	102.1	101.1-103.1	103.7	103.3-104.0	Prosaro/ 0.75 L/ha
HORVS	MAR	2	67.8	65.1-70.5	101.8	100.9-102.8	101.8	100.8-102.8	Proline/0.8 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Use on barley in the EPPO North-East zone includes a lower dose of 1.0 L/ha. This dose rate is supported by EPPO North-East zone trials used for this dose rate. A summary of the yield and quality data from 10 efficacy trials used to support the 1.0 L/ha dose is presented below

A single application of GF-3307 at 1.0 L/ha, in the presence of disease, had a positive impact on grain yield across all trials. The increases found were similar to the 1.2 and 1.5 L/ha dose rates, with a mean yield increase of 7.1%, relative to the untreated across four winter barley trials and 11.1% increase in six spring barley trials. These trials also achieved a 8.0% mean increase in thousand grain weight (TGWT) for winter barley and 4.3% increase for spring barley and a 3.1% mean increase in hectolitre weight (HLW) for winter barley and 1.7% increase for spring barley. Results for the standards were comparable.

Table 3.2-317: Impact of GF-3307 on grain yield when applied at 0.9-1.0 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)				
				GF-3307		Reference standard		
				1.35-150 g as/ha				
		0.9-1.0 L/ha		Mean	min-max	Mean	min-max	Product/dose
HORVW	4	6.8	5.0-10.8	107.1	97.0-111.1	107.7	91.0-120.1	All
HORVW*	2	5.7	5.0-6.4	110.3	109.4-111.1	114.4	108.7-120.1	Proline*
HORVW**	2	8.0	5.1-10.8	103.9	97.0-110.7	100.9	91.0-110.8	Prosaro/ 0.75 L/ha
HORVS	6	4.3	3.5-6.0	111.1	100.4-123.7	113.4	91.7-139.0	All
HORVW*	4	4.4	3.5-6.0	107.7	100.4-113.0	108.9	91.7-116.4	Proline*
HORVW**	2	4.1	3.6-4.5	118.0	112.2-123.7	122.6	106.1-139.0	Prosaro/ 0.75 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Table 3.2-318: Impact of GF-3307 on grain quality (TGWT) when applied at 0.9-1.0 L/ha on barley in EPPO North-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)				
				GF-3307		Reference standard		
				1.35-150 g as/ha				
				0.9-1.0 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	4	36.5	25.9-45.1	108.0	102.6-112.1	107.3	102.3-114.2	All
HORVW*	2	39.5	33.9-45.1	109.6	107.1-112.1	109.5	104.8-114.2	Proline*
HORVW**	2	33.4	25.9-40.9	106.3	102.6-110.0	105.0	102.3-107.7	Prosaro/ 0.75 L/ha
HORVS	6	38.8	29.0-60.5	104.3	101.6-110.3	106.4	98.6-1123.8	All
HORVW*	4	39.7	29.0-60.5	104.4	101.6-110.3	105.8	98.6-113.8	Proline*
HORVW**	2	36.9	31.9-41.8	104.1	103.7-104.4	107.5	106.3-108.7	Prosaro/ 0.75 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha

**Direct comparison with Prosaro at 0.75 L/ha

Table 3.2-319: Impact of GF-3307 on grain quality (HLW) when applied at 0.9-1.0 L/ha on barley in EPPO North-East climatic zone E efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)				
				GF-3307		Reference standard		
				1.35-150 g as/ha				
				0.9-1.0 L/ha				
		Mean	min-max	Mean	min-max	Mean	min-max	Product/dose
HORVW	3	57.5	53.8-59.6	103.1	99.3-106.3	103.9	99.7-107.6	All
HORVW*	1	59.6	-	99.3	-	99.7	-	Proline*
HORVW**	2	56.5	53.8-59.1	105.0	103.7-106.3	106.1	104.5-107.6	Prosaro/ 0.75 L/ha
HORVS	6	58.3	54.1-66.2	101.7	99.6-108.5	102.6	99.6-108.9	All
HORVW*	4	56.4	54.1-60.5	102.4	99.6-108.5	102.1	99.6-108.9	Proline*
HORVW**	2	62.2	58.2-66.2	100.4	99.6-101.1	103.7	103.3-104.0	Prosaro/ 0.75 L/ha

*Direct comparison to Proline applied at 200 g prothioconazole/ha **Direct comparison with Prosaro at 0.75 L/ha

Results – EPPO South-East climatic zone

Of the ~~six~~ 14 EPPO South-East climatic zone effectiveness trials on winter barley and ~~four~~ five trials on spring barley generated between 2017-2020~~2021~~, the impact on grain yield after a single dose of GF-3307 was assessed in ~~seven~~ 16 trials (~~five~~ 13 winter barley and ~~two~~ 3 spring barley). Three trials (one winter barley and two spring barley trials) only have results after two applications. The results from these trials have not been included, however, for completeness they can be found in Appendix 5 of the BAD and show comparable yield increases.

In these ~~seven~~ 16 trials there were no significant negative effects noted in any trial. A single application of GF-3307 at 1.5 L/ha, in the presence of disease, had a positive impact on grain yield across all trials, with a mean yield increase of ~~21.0~~ 15.7% on winter barley and ~~9.0~~ 8.8% on spring barley, relative to the untreated. These trials also achieved an ~~1.5%~~ a 2.9% increase in thousand grain weight (TGWT), relative to the untreated on winter barley and ~~2.5~~ 2.0% increase on spring barley. A ~~1.2%~~ increase in hectolitre weight (HLW) for spring barley was also found. A 1.3% increase in hectolitre weight (HLW) for winter barley and 0.5% on spring barley were also found. The ~~1.2 L/ha~~ 1.2/1.25 L/ha dose achieved a mean yield increase of ~~17.5~~ 13.3% on winter barley and ~~14.2~~ 11.7% on spring barley, relative to the untreated. These trials also achieved an ~~0.3%~~ increase in thousand grain weight (TGWT) and a 1.7% increase in hectolitre weight (HLW) for spring barley. These trials also achieved a 2.4% increase in thousand grain weight (TGWT) and a 0.8% increase in hectolitre weight (HLW) for winter barley and a 0.2% increase in thousand grain weight (TGWT) for spring barley. The 1.0 L/ha dose achieved a mean yield increase of ~~13.2~~ 10.4% on winter barley and ~~10.5~~ 8.9% on spring barley, relative to the untreated. These trials also achieved an ~~2.8~~ 3.8% increase in thousand grain weight (TGWT), relative to the untreated on winter barley and ~~0.6~~ 1.4% increase on spring barley. A ~~0.9~~ 0.5% increase in hectolitre weight (HLW) for ~~spring~~ winter barley was also found. Results for the standards were comparable. **Note:** Some EPPO Maritime and North-East climatic zone trials were used to support some claims. Results in the EPPO Maritime and North-East climatic zone above show comparable increases in yield and quality for ~~both the 1.2 and 1.5 L/ha doses~~ all doses.

A summary of the yield and quality data from efficacy trials is presented in Table 3.2-32032 to Table 3.2-32234. The individual trial results are detailed in Appendix 5 of the BAD.

Table 3.2-320: Impact of GF-3307 on grain yield when applied at 1.0-1.5 L/ha on barley in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)							
				GF-3307		GF-3307		GF-3307		Proline 250	
				150 g as/ha		180 g as/ha		225 g as/ha		200 g as/ha	
				1.0 L/ha		1.2 L/ha		1.5 L/ha		0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
HORVW	5	6.4	4.5-10.5	113.2	101.0-121.0	117.5	109.0-124.3	121.0	107.6-132.1	116.5	107.6-121.3
HORVS	2	5.5	4.9-6.1	110.5	96.2-124.8	114.2	104.6-123.8	109.4	99.8-119.1	108.5*	97.5-119.5

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-321: Impact of GF-3307 on grain quality (TGW) when applied at 1.0-1.5 L/ha on barley in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)							
				GF-3307		GF-3307		GF-3307		Proline 250	
				150 g as/ha		180 g as/ha		225 g as/ha		200 g as/ha	
				1.0 L/ha		1.2 L/ha		1.5 L/ha		0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
HORVW	5	49.1	45.6-52.1	102.8	98.8-110.6	99.7	92.4-104.5	101.5	99.5-103.4	99.9	93.4-105.8
HORVS	2	44.3	43.9-44.7	100.6	96.5-104.7	100.3	100.2-100.5	102.2	102.1-102.3	101.6*	100.7-102.5

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-322: Impact of GF-3307 on grain quality (HLW) when applied at 1.0-1.5 L/ha on barley in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)							
				GF-3307		GF-3307		GF-3307		Proline 250	
				150 g as/ha		180 g as/ha		225 g as/ha		200 g as/ha	
				1.0 L/ha		1.2 L/ha		1.5 L/ha		0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
HORVW	4	61.8	-	98.3	97.7-99.4	98.6	97.5-100.0	99.7	97.9-102.2	99.7	98.1-102.0
HORVS	1	49.9	-	100.9	-	101.7	-	101.2	-	101.5	-

*Direct comparison to Proline applied at 150-200 g prothioconazole/ha

Table 3.2-323: Impact of GF-3307 on grain yield when applied at 0.9-1.5 L/ha on barley in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	Yield (t/ha) untreated control		Relative yield (Untreated = 100%)							
				GF-3307		GF-3307		GF-3307		Proline 250	
				135-150 g as/ha		180-187.5 g as/ha		225 g as/ha		150-200 g as/ha	
				0.9-1.0 L/ha		1.2-1.25 L/ha		1.5 L/ha		0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
HORVW	13	6.1	3.1-10.5	110.4	101.0-121.4	113.3	104.4-124.3	115.7	105.0-132.1	113.1	102.4-125.5
HORVS	3	5.4	4.9-6.1	108.9	96.2-124.8	111.7	104.6-123.8	108.8	99.8-119.1	108.1	97.5-119.5

Table 3.2-324: Impact of GF-3307 on grain quality (TGW) when applied at 0.9-1.5 L/ha on barley in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	TGW (g) untreated control		Relative TGW (Untreated = 100%)							
				GF-3307		GF-3307		GF-3307		Proline 250	
				135-150 g as/ha		180-187.5 g as/ha		225 g as/ha		150-200 g as/ha	
				0.9-1.0 L/ha		1.2-1.25 L/ha		1.5 L/ha		0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
HORVW	13	44.8	34.9-52.1	103.8	98.8-110.6	102.4	92.4-109.9	102.9	96.3-109.9	102.8	93.4-111.2
HORVS	3	44.1	43.6-44.7	101.4	96.5-104.7	100.2	100.0-100.5	102.0	101.5-102.3	102.9	101.5-104.7

Table 3.2-325: Impact of GF-3307 on grain quality (HLW) when applied at 0.9-1.5 L/ha on barley in EPPO South-East climatic zone efficacy trials

Crop	Number of trials	HLW (kg) untreated control		Relative HLW (Untreated = 100%)							
				GF-3307		GF-3307		GF-3307		Proline 250	
				135-150 g as/ha		180-187.5 g as/ha		225 g as/ha		150-200 g as/ha	
				0.9-1.0 L/ha		1.2-1.25 L/ha		1.5 L/ha		0.6-0.8 L/ha	
		Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
HORVW	12	62.4	51.7-75.0	100.5	97.7-103.7	100.8	97.5-104.6	101.3	97.8-106.4	101.1	98.1-105.9
HORVS	1	66.8	-	99.5	-	99.6	-	100.5	-	101.7	-

Summary and conclusion

GF-3307 at the proposed label rates of 1.5 L/ha in the EPPO Maritime climatic zone, 1.2-1.5 L/ha in the EPPO North-East climatic zone or 1.0-1.5 L/ha in the EPPO South-East climatic zone had an overall positive effect on grain yield and quality of barley crops treated in the presence of disease.

zRMS comments:

As the yield data from efficacy trials make part of *Efficacy tests* chapter, the zRMS comments to it is part of the comments following the applicant's summary of this chapter, starting in the page 479.

Summary and conclusions on effectiveness (all crops and disease claims)

zRMS comments:

The present chapter: “**Summary and conclusions on effectiveness (all crops and disease claims)**” has been amended profoundly by the applicant in the course of the dRR updating, and as the result it represented originally a patchwork of the altered and unaltered text and table fragments marked by two different font colours. Considering the importance of the summary, in order to make the chapter more reader-friendly the zRMS decided to mark it with the black font uniformly, i.e. including also the updated parts and items. For completeness, the struck through text parts left under grey font below this commenting box represent the version of the chapter before updating, while the updated chapter starts in the page 462.

~~Data have been presented across a range of disease in wheat.~~

~~The summary tables below are split by EPPO climatic zone and the following colour coding has been used to illustrate both the effectiveness of GF-3307 and the comparability between GF-3307 and the reference standards used.~~

Level of Effectiveness
≥80% control
70-79.9% control
<69.9% control

EPPO Maritime zone

~~Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)~~

~~The proposed use is for a single application applied at 1.5 L/ha, at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, Puccrt, Puccst, FUSASP, PYRNTR and ERYSGT.~~

Summary of effectiveness data for GF-3307 for EPPO Maritime zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3307 1.5 L/ha		Reference standard#	
					Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	MAR	11	31-51	36.7	5.0-87.5	92.2	84.8-100	86.9 [§]	62.0-100
Puccrt	TRZAW	MAR	13	37-61	19.0	5.0-74.8	87.8	70.2-100	85.3 [§]	27.7-100
Puccst	TRZAW	MAR	11	31-45	24.9	6.1-65.0	93.6	87.5-100	90.0 ^{§§}	71.7-100
FUSASP	TRZAW	MAR	10	61-65	31.2	5.7-93.8	80.6	71.0-92.0	74.8	47.4-83.0
PYRNTR	TRZAW	MAR	7	31-51	23.8	7.8-50.8	82.0	75.2-92.4	74.7 [*]	48.0-94.3
		PL	3	35-51	17.6	5.0-26.3	86.4	79.0-92.3	67.5	31.5-88.0
		All	10	31-51	21.9	5.0-50.8	83.3	75.2-92.4	72.6 [*]	21.5-94.3
ERYSGT	TRZAW	MAR	7	32-49	11.5	7.9-17.0	88.9	64.7-100	84.4 ^Δ	46.9-100
		PL	3	39-49	8.8	7.0-11.5	87.3	85.5-88.3	87.0	79.4-91.9

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Applicati on-timing (BBCH)	Untreated % infection		% control			
							GF-3307 1.5 L/ha		Reference standard#	
					Mean	min-max	Mean	min-max	Mean	min-max
		All	10	32-49	10.7	7.0-17.0	88.4	64.7-100	85.2 ^Δ	46.9-100

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

*Reference standards include prothioconazole applied at 180-198 g as/ha and two trials using Aviator Xpro at 1.25 L/ha.

^bReference standards include prothioconazole applied at 180-198 g as/ha, 5 trials using Aviator Xpro at 1.25 L/ha and one trial using Librax at 2.0 L/ha

^{ss}Reference standards include prothioconazole applied at 180-198 g as/ha, one trial using Aviator Xpro at 1.25 L/ha and one trial using Librax at 2.0 L/ha

^{*}Reference standards include prothioconazole applied at 180-198 g as/ha, one trial using Aviator Xpro at 1.25 L/ha and one trial using Librax at 2.0 L/ha

^ΔReference standards include prothioconazole applied at 180-198 g as/ha and one trial using Librax at 2.0 L/ha

GF 3307 applied at 1.5 L/ha at BBCH 31-65 achieved 92.2% control of SEPTTR (mean of 11 trials), 87.8% control of PUCCRT (mean of 13 trials), 93.6% control of PUCCRT (mean of 11 trials), 80.6% control of FUSASP (mean of 10 trials), 83.3% control of PYRNTR (mean of 10 trials – a combination of EPPO Maritime climatic zone trials and Polish trials) and 88.4% control of ERYSGT (mean of 10 trials – a combination of EPPO Maritime climatic zone trials and Polish trials).

Across all data sets the control achieved by the GF 3307 was comparable to or higher than the reference standards and not statistically different in the majority of cases.

Data are only available on winter wheat (TRZAW). However, spring wheat (TRZAS) is generally a minor crop in the EPPO Maritime climatic zone. The area of spring wheat in Austria in 2020 was minor at 2,650 ha (Eurostats). In the Czech Republic 46,000 ha of spring wheat were grown in 2020 compared to 774,000 ha of winter wheat (Eurostats), indicating that the area of spring wheat in the Czech Republic is relatively minor, at just 6% of the winter crop area. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF 3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter wheat is equally applicable to spring wheat.

Similarly, it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar wheat crops, the disease pressures are more challenging in winter wheat and the areas of durum wheat in these countries are relatively minor (Eurostat/2020): Austria: 16,500 ha, the Czech Republic: no significant area).

GF 3307 at the proposed label rate of 1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO Maritime climatic zone of the Central EU Authorisation zone is fully supported.

Winter and spring rye (SECCW and SECCS) and winter and spring triticale (TTLWI and TTLSO)

The proposed uses are for a single application at 1.5 L/ha applied at BBCH 30-69 to winter and spring rye (SECCW and SECCS) for the control of PUCCRE and RHYNSE and to winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP, ERYSGT and PUCCT.

Summary of effectiveness data for GF-3307 for EPPO Maritime zone (rye and triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3307 1.5 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max
PUCCRE	SECCW	MAR	12	32-59	19.6	5.0-74.0	80.5	82.5-100	88.4*	78.7-100

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3307 1.5 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max
RHYNSE	SECCW	MAR	10	32-59	15.7	6.8-27.0	90.7	75.0-100	85.9 [*]	52.0-100
SEPTSP	TTLWI	MAR	7	33-51	21.7	5.8-47.5	91.5	82.3-100	81.8 ^s	63.4-100
		PL	6	33-52	15.3	7.0-33.8	85.9	76.0-100	80.6 ^{ss}	58.3-100
		All	13	33-52	18.8	5.8-47.5	88.9	76.0-100	81.2 ^{sss}	58.3-100
ERYSGT	TTLWI	MAR	5	33-49	19.3	5.0-36.3	86.7	63.5-100	82.1 ⁺	40.4-100
		PL	5	33-49	14.9	7.8-29.4	91.4	65.5-99.3	91.7 ⁺⁺	70.3-100
		All	10	33-49	17.1	5.0-36.3	89.1	63.5-100	86.9 ⁺⁺⁺	40.4-100
PUCST	TTLWI	MAR	10	33-51	37.0	6.0-96.5	90.0	81.8-100	89.7 ⁺	73.9-100

*Mean of 10 trials using Proline at 0.72 L/ha and 2 trials using Aviator Xpro at 1.25 L/ha.

^sMean of 5 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

^{ss}Mean of 4 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

^{sss}Mean of 9 trials using Proline at 0.72 L/ha and 4 trials using Prosaro at 1.0 L/ha.

⁺Mean of 2 trials using Proline at 0.72 L/ha and 3 trials using Prosaro at 1.0 L/ha.

⁺⁺Mean of 4 trials using Proline at 0.72 L/ha and one trial using Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha.

⁺⁺⁺Mean of 6 trials using Proline at 0.72 L/ha, 3 trial using Prosaro at 1.0 L/ha and one trial using Wirtuoz 520 EC in sequence with Artea.

⁺Mean of 9 trials using Proline at 0.72 L/ha and one trial using Prosaro at 1.0 L/ha.

On winter rye (SECCW) a single dose of 1.5 L/ha of GF 3307 applied between BBCH 32-59 achieved 89.5% control of PUCCRE (mean of 12 trials) and 90.7% control of RHYNSE (mean of 10 trials).

On winter triticale (TTLWI) a single dose of 1.5 L/ha of GF 3307 applied between BBCH 33-52 achieved 88.9% control of SEPTSP (mean of 13 trials), 89.1% control of ERYSGT (mean of 10 trials) and 90.0% control of PUCST (mean of 10 trials) from a combination of EPPO Maritime climatic zone trials (DE) and trials in neighbouring countries (PL).

Across all data sets the control achieved by the GF 3307 was comparable to or higher than the reference standards and not statistically different in the majority of cases.

Data are only available on winter crops. However, spring varieties of these crops are generally minor crops in the EPPO Maritime climatic zone. Spring rye (SECCS) and spring triticale (TTLWO) are listed as minor crops in AT. It is also considered that spring rye (SECCS) and spring triticale (TTLWO) are minor crops in CZ. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF 3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter crops are equally applicable to spring crops.

GF 3307 at the proposed label rate of 1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO Maritime climatic zone of the Central EU Authorisation zone is fully supported.

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at 1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH.

Across all diseases, results from both winter and spring crops demonstrated comparable levels of control of these target diseases and have been combined to give an overall result to support the claims on both crops in the following table. For PYRNTE only data from winter barley are available, however it is considered that the data also support use on spring barley.

Summary of effectiveness data for GF 3307 for EPPO Maritime zone (barley data)

Target	Crop	EPPO	Number	Application	Untreated	% control
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							GF-3307 1.5 L/ha		Reference standard#	
					Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	MAR	5	35-49	55.0	7.1-99.0	83.8	65.5-97.9	83.1***	63.0-95.1
	HORVS	MAR	5	31-51	37.7	5.0-74.5	85.4	76.3-93.7	67.8	45.0-86.3
	Both	MAR	10	31-51	46.3	5.0-99.0	84.6	65.8-97.9	75.5*	45.0-95.1
RHYNSE	HORVW	MAR	9	31-37	12.7	5.0-39.8	89.1	76.7-100	81.4	43.1-100
	HORVS	MAR	4	37-51	17.2	5.0-32.5	85.8	75.1-95.8	83.8	80.0-88.2
	Both	MAR	13	31-51	14.1	5.0-39.8	88.1	75.1-100	82.2	43.1-100
PYRNTE	HORVW	MAR	10	32-49	39.3	5.4-99.0	84.7	72.0-100	83.0*	71.0-95.9
PUCCHD	HORVW	MAR	7	32-59	15.5	7.7-23.8	95.7	78.9-100	95.4	83.4-100
	HORVS	MAR	4	37-49	42.0	12.3-76.7	90.8	83.7-99.2	91.3	81.3-100
	Both	MAR	11	32-59	25.2	7.7-76.7	93.9	78.9-100	93.9	81.3-100
ERYSGH	HORVW	MAR	7	30-55	16.7	5.8-60.0	95.4	80.0-100	95.2	69.1-100
	HORVS	MAR	3	30-55	14.0	5.8-30.0	98.6	95.7-100	98.6	95.7-100
	Both	MAR	10	30-55	15.9	5.8-60.0	96.3	80.0-100	96.2	69.1-100

#Proline applied at 0.8 L/ha used a reference standard, unless specified

*Mean of 8 trials using Proline at 0.8 L/ha and 2 trials using Aviator Xpro at 1.0 L/ha.

***Mean of 3 trials using Proline at 0.8 L/ha and 2 trials using Aviator Xpro at 1.0 L/ha.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.5 L/ha of GF 3307 applied between BBCH 30-59 achieved over 80% control of all target diseases: RAMUCC (84.6%), RHYNSE (88.1%), PYRNTE (84.7%), PUCCHD (93.9%) and ERYSGH (96.3%) from 10-13 trials.

Across all data sets the control achieved by the GF 3307 was comparable to, or higher than, the reference standards and not statistically different in the majority of cases. GF 3307 at the proposed label rate of 1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO Maritime climatic zone of the Central EU Authorisation zone is fully supported.

EPPO North-East zone

~~Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)~~

The proposed use is for a single application applied at a dose range of 1.2-1.5 L/ha, at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, Puccrt, Puccst, Fusasp, Pyrntr and Erysgt.

The lower dose of 1.2 L/ha is recommended for application where SEPTTR, Puccrt, Puccst or Erysgt are the major diseases requiring control and where there is lower pressure from Pyrntr and/or Fusasp. Where Pyrntr and/or Fusasp are also present or expected to be a concern and in high disease situations, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.

Summary of effectiveness data for GF-3307 for EPPO North-East Zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard#	
					Mean	min- max	Mean	min- max	Mean	min- max	Mean	min-max
SEPTTR	TRZAW	N-E	12	31-51	18.5	5.8- 49.1	86.2*	71.2- 100	92.6	80.4- 100	83.8	58.5-97.1
	TRZAS	N-E	1	39-41	5.0	-	74.9	-	83.3	-	88.3	-
Puccrt	TRZAW	N-E	8	39-61	27.0	6.0- 43.1	89.5**	84.2- 98.4	90.1	81.1- 97.7	83.3^	62.0-95.0
		DE	5	37-61	24.3	5.0- 74.8	84.9	77.8- 94.4	86.8	77.8- 94.3	92.4*	77.8-98.7
		All	13	37-61	26.0	5.0- 74.8	87.4**	77.8- 98.4	88.8	77.8- 97.7	86.8*	62.0-98.7
Puccst	TRZAW	N-E	6	37-56	22.2	6.4- 40.6	90.2*	69.6- 100	92.1	81.1- 100	78.8*	32.8-100
		DE	3	31-45	28.6	20.0- 37.5	90.0	84.0- 100	91.8	87.5- 100	87.6	81.9-98.0
		All	9	31-45	24.3	6.4- 40.6	90.1*	69.6- 100	92.0	81.1- 100	82.4*	32.8-100
	TRZAS	N-E	1	39-41	8.7	-	90.8	-	93.3	-	95.8	-
Fusasp	TRZAW	N-E	1	61-65	13.7	-	68.3	-	83.6	-	79.1	-
		DE	4	61-65	47.8	8.5- 93.8	69.9	57.0- 83.7	80.3	71.0- 92.0	71.6	47.1-80.6
		All	5	61-65	41.0	8.5- 93.8	69.6	57.0- 83.7	80.9	71.0- 92.0	73.4	47.1-80.6
Pyrntr	TRZAW	N-E	5	35-49	16.7	10.6- 26.3	78.4	68.1- 84.4	86.4	79.0- 93.3	73.8	31.5-82.1
		DE	5	31-49	28.2	7.8- 50.8	78.6	64.0- 86.2	83.8	75.2- 92.4	76.9	48.0-94.5
		All	10	31-49	22.4	7.8- 50.8	78.5**	64.0- 86.2	85.1	75.2- 93.3	74.9*	31.5-94.5
	TRZAS	N-E	1	39-49	13.1	-	72.9	-	78.6	-	67.6	-
Erysgt	TRZAW	N-E	2	37-49	7.5	7.0-8.0	88.4	87.1- 89.7	88.2	88.0- 88.3	90.8	89.6-91.9
		CZ+ DE	4	32-49	13.9	11.9- 17.0	78.5	64.7- 88.7	84.0	64.7- 94.6	73.3*	46.9-100
		All	6	32-49	11.8	7.0- 17.0	80.6***	64.7- 89.7	85.4	64.7- 94.6	78.1*	46.9-100

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated %infection		% control					
							GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard#	
					Mean	min- max	Mean	min- max	Mean	min- max	Mean	min-max
	TRZAS	N-E	1	47-49	11.5	-	69.7	-	85.5	-	70.4	-

*Results for 1.2 L/ha dose for SEPTTR from 11 EPPO North-East trials

**Results for 1.2 L/ha dose for PUCST from 6 EPPO North-East and 5 DE trials

§Results for 1.2 L/ha dose for PUCST from 4 EPPO North-East and 3 DE trials

**Results for 1.2 L/ha dose for PYRNTR from 3 EPPO North-East and 5 DE trials

***Results for 1.2 L/ha dose for ERYSGT from 2 EPPO North-East and 3 DE trials

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha.

^Reference standard results are based on prothioconazole applied at 180-198 g as/ha, 3 trials using Aviator Xpro applied at 1.25 L/ha and one using Vertisan at 1.0 L/ha

*Reference standard results are based on prothioconazole applied at 180-198 g as/ha, 3 trials using Aviator Xpro applied at 1.25 L/ha and one using Librax at 2.0 L/ha.

**Reference standard results are based on prothioconazole applied at 180-198 g as/ha, 6 trials using Aviator Xpro applied at 1.25 L/ha, one trial using Librax at 2.0 L/ha and one trial using Vertisan at 1.0 L/ha.

§Reference standard results are based on prothioconazole applied at 180-198 g as/ha and one trial using Vertisan at 1.0 L/ha.

*Reference standard results are based on prothioconazole applied at 180-198 g as/ha and one trial using Librax at 2.0 L/ha

For SEPTTR, PUCST, PUCST and ERYSGT the results demonstrate that the proposed minimum dose of 1.2 L/ha of GF 3307 applied at BBCH 31-65 is sufficient to achieve a claim of ‘good control’ of these target diseases on winter wheat. The data demonstrate 86.2% control of SEPTTR (mean of 11 trials), 87.4% control of PUCST (mean of six EPPO North East and five DE trials), 90.1% control of PUCST (mean of four EPPO North East and three DE trials) and 80.6% control of ERYSGT (mean of two EPPO North East and three CZ/DE trials). In high disease situations the 1.5 L/ha dose is recommended and this dose demonstrates 92.6% control of SEPTTR (mean of 12 trials), 88.8% control of PUCST (mean of eight EPPO North East and five DE trials), 92.0% control of PUCST (mean of six EPPO North East and three DE trials) and 85.4% control of ERYSGT (mean of two EPPO North East and four CZ/DE trials). Control on spring wheat was comparable for the 1.2 and 1.5 L/ha doses at 74.9% and 83.3% respectively for SEPTTR, 90.8% and 93.3% respectively for PUCST and 69.7% and 85.5% respectively for ERYSGT.

For PYRNTR, the results demonstrate that the proposed maximum 1.5 L/ha dose is the most effective dose required to achieve a claim of ‘very good control’ of PYRNTR, with 85.1% control of (mean of five EPPO North East and five DE trials). The 1.2 L/ha dose offered good control of this disease (78.5% control across three EPPO North East and five DE trials), but did not always provide consistently high levels of control, as control was more variable in some trials. It is considered that the 1.2 L/ha dose will be sufficient in situations where PYRNTR is a secondary disease and not the main target.

For FUSASP, the maximum dose of 1.5 L/ha is required (80.9% control from one EPPO North East and four DE trials), as the 1.2 L/ha dose did not give sufficient control of this disease (>70%).

Note: Additional EPPO North East trials are being generated on FUSASP and ERYSGT in 2021 and can be submitted to support these claims if the current data is not considered sufficient.

Across all data sets the control achieved by both the 1.2 L/ha and 1.5 L/ha doses of GF 3307 was comparable to the reference standards and not statistically different in the majority of cases.

The majority of data are only available on winter wheat (TRZAW). Spring wheat (TRZAS) is major crop in Poland (400,000 ha were grown in Poland in 2020). Three trials on spring wheat are included in the dossier and demonstrate comparable control to that achieved on winter wheat on both SEPTTR, PUCST, PYRNTR and ERYSGT. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF 3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter wheat is equally applicable to spring wheat.

Similarly it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar wheat crops, the disease pressures are more challenging in winter wheat and the area of durum wheat is minor (Eurostat (2020): Poland: no significant area).

GF 3307 at the proposed label rate dose range of 1.2-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) is fully supported.

~~Winter and spring rye (SECCW and SECCS) and winter and spring triticale (TTLWI and TTLSO)~~

The proposed uses are for a single application at 1.2-1.5 L/ha applied at BBCH 30-69 to winter and spring rye (SECCW and SECCS) for the control of Puccinia and RHYNSE and to winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP, ERYSGT and Puccinia.

On rye, the lower dose of 1.2 L/ha is recommended for application where RHYNSE is the major disease requiring control and where there is lower pressure from Puccinia. Where Puccinia is also present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.

On triticale, the lower dose of 1.2 L/ha is recommended for application where ERYSGT or Puccinia are the major disease requiring control and where there is lower pressure from SEPTSP. Where SEPTSP is also present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.

Summary of effectiveness data for GF-3307 for EPPO North-East Zone (rye and triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard*	
					Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Puccinia	SECCW	N-E	3	37-59	32.8	18.1- 49.1	67.4	54.7- 77.8	77.1	69.1- 84.7	73.8	66.2- 86.3
		DE	10	32-51	15.5	5.0- 41.2	83.3	71.4- 95.0	89.6	82.5- 100	88.1	78.7-100
		All	13	32-59	19.5	5.0- 49.1	79.6	54.7- 95.0	86.7	69.0- 100	84.8	66.2-100
RHYNSE	SECCW	N-E	5	37-59	13.1	5.0- 28.4	76.0	64.3- 92.2	81.5	68.1- 97.6	68.6	56.0- 77.3
		DE	8	32-51	15.3	6.8- 27.0	84.5	68.2- 100	89.9	75.0- 100	83.2	59.3-100
		All	13	32-59	14.8	5.0- 28.4	81.2	62.5- 100	87.6	68.1- 100	80.1	56.0-100
SEPTSP	TTLWI	N-E	6	33-52	15.3	7.0- 33.8	72.3 [§]	68.6- 74.6	85.9	76.0- 100	80.6 [§]	58.3-100
		DE	7	33-51	21.7	5.8- 47.5	75.1 [§]	69.2- 90.3	91.5	82.3- 100	81.8 ^{§§}	63.4-100
		All	13	33-52	18.8	5.8- 47.5	73.0 [§]	68.6- 90.3	88.9	76.0- 100	81.2 ^{§§§}	58.3-100
ERYSGT	TTLWI	N-E	5	33-49	14.9	7.8- 29.4	83.7	59.1- 96.1	91.4	65.5- 99.3	91.7 [±]	70.3-100
		DE	4	33-49	22.1	5.0- 36.3	86.2 [§]	-	89.1	63.5- 100	86.9 ^{±±}	40.4-100

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard*	
					Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
		All	9	33-49	18.1	5.0- 36.3	84.2 ^s	59.1- 96.1	87.8	63.5- 100	85.5 ^{***}	40.4-100
Puccst	TTLWI	NE	8	33-52	26.1	7.1- 50.0	76.4 ^s	73.9- 90.0	89.5	82.4- 96.0	63.0 ^Δ	36.6- 87.4
		DE	8	37-51	38.1	6.0- 96.5	85.0	75.0- 100	88.5	81.8- 100	88.8	73.9-100
		All	16	33-52	32.1	6.0- 96.5	82.6 ^s	73.9- 100	89.0	81.8- 100	75.9 ^{ΔΔ}	36.6-100

#Results for 1.2 L/ha dose for SEPTSP from 3 EPPO North-East and 4 DE trials

^sResults for 1.2 L/ha dose for ERYSGT from 5 EPPO North-East and 1 DE trial

^tResults for 1.2 L/ha dose for Puccst from 3 EPPO North-East and 8 DE trials

*Proline applied at 0.72 L/ha used a reference standard, unless specified

^sMean of 4 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

^{ss}Mean of 5 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha

^{sss}Mean of 9 trials using Proline at 0.72 L/ha and 4 trials using Prosaro at 1.0 L/ha.

^tMean of 4 trials using Proline at 0.72 L/ha and one trial using Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

^{tt}Mean of 2 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

^{ttt}Mean of 6 trials using Proline at 0.72 L/ha, 2 trial using Prosaro at 1.0 L/ha and one trial using Wirtuoz 520 EC in sequence with Artea

^ΔMean of 6 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

^{ΔΔ}Mean of 14 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

On winter rye (SECCW), a single dose of 1.5 L/ha of GF 3307 applied between BBCH 32-59 achieved 86.7% control of Puccst (mean of 13 trials, from a combination of EPPO North-East climatic zone and DE trials). These data also demonstrate that the 1.2 L/ha dose achieved 79.6% of Puccst confirming that the 1.2 L/ha dose recommended for control of RHYNSE on rye should deliver good control of Puccst, where Puccst is not the main target. A single dose of 1.2 L/ha of GF 3307 applied between BBCH 32-59 achieved 81.2% control of RHYNSE (over 13 trials, from a combination of EPPO North-East climatic zone and DE trials). Where Puccst also needs to be controlled, a dose of 1.5 L/ha is recommended and GF 3307 achieved 87.6% control of RHYNSE in these trials.

On winter triticale (TTLWI), a single dose of 1.5 L/ha of GF 3307 applied between BBCH 33-52 achieved 88.9% control of SEPTSP (mean of 13 trials, from a combination of EPPO North-East climatic zone and DE trials). Data from three Polish and four German trials demonstrate that the 1.2 L/ha dose achieved 73.9% of SEPTSP. Although this is a more limited dataset, it does confirm that the 1.2 L/ha dose recommended for control of other diseases on triticale (ERYSGT and Puccst) should deliver good control of SEPTSP, where SEPTSP is not the main target.

For ERYSGT on triticale, A single dose of 1.2 L/ha of GF 3307 applied between BBCH 33-49 achieved 84.2% control of ERYSGT (over 6 trials, from a combination of EPPO North-East climatic zone and DE trials). It is considered that this use/claim can also be supported by the data on winter wheat which demonstrated comparable control of 88.4% of ERYSGT for the 1.2 L/ha dose across two EPPO North-East climatic zone trials on winter wheat. Where SEPTSP also needs to be controlled, a dose of 1.5 L/ha is recommended and GF 3307 at 1.5 L/ha achieved 87.8% control of ERYSGT (over 9 trials EPPO North-East climatic zone and DE trials).

For Puccst on triticale, a single dose of 1.2 L/ha of GF 3307 applied between BBCH 33-52 achieved 82.6% control of Puccst (over 11 trials, from a combination of EPPO North-East climatic zone and DE trials). Where SEPTSP also needs to be controlled, a dose of 1.5 L/ha is recommended and GF 3307 at 1.5 L/ha achieved 89.0% control of Puccst (over 16 trials EPPO North-East climatic zone and DE trials).

Across all data sets the control achieved by both the 1.2 L/ha and 1.5 L/ha doses of GF 3307 was comparable to the reference standards and not statistically different in the majority of cases.

The majority of data are only available on winter crops, however spring varieties of most of these

crops are generally minor crops in PL. Spring rye (SECCS) is listed as a minor crop in PL. For spring triticale (TTLSO), 100,000 ha grown in PL in 2020, compared to 1,200,000 ha of winter triticale (Main Statistical Office), indicating that the area of spring triticale in PL is 8.3% of the winter crop area.

Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF 3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter crops are equally applicable to spring crops.

GF 3307 at the proposed label rate dose range of 1.2-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) is fully supported.

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at 1.2-1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH. The lower dose of 1.2 L/ha is recommended for application where RHYNSE, PUCCHD or ERYSGH are the major disease requiring control and where there is lower pressure from PYRNTE and RAMUCC. Where PYRNTE and/or RAMUCC are also present and expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.

In the following tables, where there are less than 8 trial results for either winter and/or spring barley, results from both winter and spring crops have been combined to give an overall result to support the proposed use across both crops, as in all situations control demonstrated by GF 3307 across both winter and spring crops is comparable.

Summary of effectiveness data for GF 3307 for EPPO North-East Zone (barley data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF 3307 1.2 L/ha		GF 3307 1.5 L/ha		Reference standard#	
					Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
RAMUCC	HORVW	DE	5	35-49	55.0	7.1- 99.0	-	-	83.8	65.5- 97.9	83.1*	62.0- 95.1
	HORVS	DE	3	31-39	34.8	5.0- 51.8	-	-	83.7	76.3- 90.0	64.7	45.0- 74.7
	Both	DE	8	31-49	47.4	5.0- 99.0	-	-	83.8	65.5- 97.9	73.4**	45.0- 95.1
RHYNSE	HORVW	N-E	6	31-52	16.7	5.6- 35.0	92.1	80.0- 100	95.6	88.7- 100	83.7	48.5- 100
		NE+ DE	8	31-52	14.4	5.6- 35.0	91.4	80.0- 100	94.7	88.7- 100	84.2	48.5- 100
	HORVS	N-E	4	37-49	10.1	5.6- 17.8	96.3	87.5- 100	97.9	92.1- 100	90.4	80.2- 100
	Both	N-E	10	31-52	13.9	5.6- 35.0	92.1	80.0- 100	95.6	88.7- 100	83.7	48.5- 100
PYRNTE	HORVW	N-E	5	32-52	16.4	5.0- 29.4	80.7	72.1- 87.3	85.2	80.0- 91.4	66.0	48.4- 85.4
		NE+ DE	8	32-52	37.2	5.0- 99.0	81.1*	72.1- 87.3	88.4	80.0- 100	74.6	48.4- 95.0
	HORVS	NE	7	32-52	18.1	5.5- 30.6	83.0	67.9- 95.7	89.2	79.6- 100	76.6	42.4- 95.2

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard#	
					Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
	Both	NE	12	32-52	17.4	5.0- 30.6	82.0	67.9- 95.7	87.2	79.6- 100	72.4	42.4- 95.7
PUCCHD	HORVW	NE	4	47-51	47.5	-	96.0	-	98.1	-	84.8	-
	HORVS	NE	6	37-52	12.4	5.5- 31.9	92.0	79.6- 100	96.7	89.9- 100	89.5	71.4- 100
	Both	NE+ DE	8	37-52	18.1	5.5- 47.5	93.5	79.6- 100	97.1	89.9- 100	89.9	71.4- 100
ERYSGH	HORVW	NE	5	31-52	10.5	5.6- 21.6	88.4	76.8- 98.8	91.1	84.5- 96.7	87.5	68.2- 100
		NE+ DE	8	31-52	10.5	5.6- 21.6	90.0 ^Δ	76.8- 98.8	92.9	84.5- 100	91.9	68.2- 100
	HORVS	NE	5	37-52	12.4	5.9- 23.3	84.2	63.6- 100	88.5	75.8- 100	80.8	48.8- 100
		NE+ DE	8	31-52	13.0	5.8- 30.0	88.7	63.6- 100	92.3	75.8- 100	87.5	48.8- 100
	Both	NE	10	31-52	11.5	5.6- 23.3	86.3	63.6- 100	89.8	75.8- 100	84.2	48.8- 100

^ΔResult from 6 trials

#Proline applied at 0.6-0.8 L/ha used a reference standard, unless specified

*Mean of 3 trials using Proline at 0.8 L/ha and 2 trials using Aviator Xpro at 1.0 L/ha:

**Mean of 6 trials using Proline at 0.8 L/ha and 2 trials using Aviator Xpro at 1.0 L/ha.

On winter barley (HORVW) a single dose of 1.5 L/ha of GF 3307 achieved 88.4% control of PYRNTE across eight trials (five EPPO North East climatic zone and three German trials). On spring barley (HORVS) a single dose of 1.5 L/ha of GF 3307 achieved 89.2% control of PYRNTE across seven EPPO North East climatic zone trials. The 1.2 L/ha dose demonstrated slightly lower control of 81.1% winter barley (six HORVW trials) and 83.0% spring barley (eight HORVS trials) and is recommended for lower disease situations only. 12 trials in both HORVW and HORVS from the North East achieved 82.0% from 1.2 L/ha and 87.2% from the 1.5 L/ha dose which was superior to Proline delivering 72.2% control. It is considered that these data full support claims for control of PYRNTE on both crops in Poland.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.5 L/ha of GF 3307 achieved 83.8% control of RAMUCC across 8 German trials. It is considered that these data from a neighbouring country full support claims for control of RAMUCC on both crops in Poland.

On winter barley (HORVW) a single dose of 1.2 L/ha of GF 3307 achieved 91.4% control of RHYNSE across 8 trials (six EPPO North East climatic zone and two German trials). On spring barley (HORVS) a single dose of 1.2 L/ha of GF 3307 achieved 96.3% control of RHYNSE across four EPPO North East climatic zone trials. The proposed maximum dose rate of 1.5 L/ha demonstrated 94.7% and 97.9% control respectively, in the same trials. 10 trials in both HORVW and HORVS from the North East achieved 92.1% from 1.2 L/ha and 95.6% from the 1.5 L/ha dose which was superior to Proline delivering 83.7% control. It is considered that these data full support claims for control of RHYNSE on both crops in Poland.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.2 L/ha of GF 3307 achieved 93.5% control of PUCCHD across 8 trials (seven EPPO North East climatic zone and one German trial). The proposed maximum dose rate of 1.5 L/ha demonstrated 97.5% control, in the same trials. 8 trials in both HORVW and HORVS from the North East and Germany achieved 93.5% from 1.2 L/ha and 97.1% from the 1.5 L/ha dose which was superior to Proline delivering 89.9% control. It is considered that these data full support claims for control of PUCCHD on both crops in Poland.

~~On winter barley (HORVW) a single dose of 1.2 L/ha of GF 3307 achieved 90.0% control of ERYSGH across five EPPO North East climatic zone and one German trial. On spring barley (HORVS) a single dose of 1.2 L/ha of GF 3307 achieved 88.7% control of ERYSGH across 8 trials (five EPPO North East climatic zone and three German trials). The proposed maximum dose rate of 1.5 L/ha demonstrated 92.9% and 92.3% control respectively across the five EPPO North East climatic zone and three German trials. 10 trials in both HORVW and HORVS from the North East achieved 86.3% from 1.2 L/ha and 89.8% from the 1.5 L/ha dose which was superior to Proline delivering 84.2% control. It is considered that these data full support claims for control of ERYSGH on both crops in Poland.~~

~~Across all data sets the control achieved by the GF 3307 was comparable to, or higher than, the reference standards and not statistically different in the majority of cases.~~

~~GF 3307 at the proposed label rate dose range of 1.2-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.~~

~~It is considered that the proposed GAP for Poland (EPPO North East climatic zone of the Central EU Authorisation zone) is fully supported.~~

EPPO South-East zone

Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)

The proposed use is for a single application at a dose range of 1.0–1.5 L/ha applied at BBCH 30–69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, PUCCRT, PUC CST, FUSASP, PYRNTR and ERYSGT.

The lower dose of 1.0 L/ha is recommended for application where disease pressure is low and only SEPTTR is present or forecast to be a concern. In moderate disease situations a dose of 1.2 L/ha is recommended. Where disease pressure is high, particularly for FUSASP, a higher dose rate of 1.5 L/ha is recommended.

Summary of effectiveness data for GF-3307 for EPPO South-East Zone (1.0–1.5 L/ha dose range)

Target (EPPO code)	Crop (EPPO)	Dose rate	Number of trials	EPPO Zone/ Country	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min- max	Mean	min- max	Mean	min-max
SEPTTR	TRZAW	1.5 L/ha	10	S-E	32–47	22.8	6.0–51.3	90.1	77.7– 100	85.6	75.1–100
		1.2 L/ha	14	S-E	30–47	21.4	6.0–51.3	86.4	71.2– 100	85.4 ^Δ	70.3–100
		1.0 L/ha	7	S-E	32–47	20.0	6.0–51.3	81.5	64.2– 100	86.5	75.9–100
PUCCRT	TRZAW	1.5 L/ha	13	S-E	37–51	40.3	8.4–72.5	91.9	69.4– 100	83.5 ⁺	59.1–100
		1.2 L/ha	9	S-E	37–51	41.7	10.5– 72.5	81.4	62.5– 95.2	74.8	59.1–92.0
PUC CST	TRZAW	1.5 L/ha	7	S-E	39–47	38.4	11.3– 63.8	90.7	82.3– 100	88.3 ⁺⁺	73.7–100
		1.2 L/ha	5	S-E	39–47	37.8	11.3– 63.8	84.6	72.6– 99.0	91.5	73.7–100
FUSASP	TRZAW	1.5 L/ha	4	AT+PL	61–65	17.3	5.7–29.3	81.7	79.0– 83.6	80.4	78.9–83.0
PYRNTR	TRZAW	1.5 L/ha	3	S-E	39–51	7.2	5.2–10.0	92.0	88.6– 97.3	86.4	80.0–94.3
			4	AT+CZ+ PL	35–51	18.3	10.3– 26.3	83.7	77.5– 92.3	67.5 ^S	31.5–86.6
			7	All	35–51	13.5	5.2–26.3	87.3	77.5– 97.3	75.6 ^S	31.5–94.3
		1.2 L/ha	6	S-E	31–51	6.7	5.2–10.0	87.1	74.2– 96.8	88.5 ^Δ	80.0–96.3
			4	AT+CZ+ PL	35–51	18.3	10.3– 26.3	67.5	31.5– 86.6	67.5 ^S	31.5–86.6
			10	All	31–51	11.3	5.2–26.3	83.4	68.1– 96.8	80.1 ^{SS}	31.5–96.3
ERYSGT	TRZAW	1.5 L/ha	6	S-E	37–49	17.2	12.0– 25.0	89.2	83.9– 92.7	93.6 ⁺	87.7–98.0
			3	CZ	32–49	12.9	11.9– 14.9	90.4	86.3– 94.6	74.6	46.9–100
			9	All	32–49	15.7	11.9– 25.0	89.6	83.9– 94.6	86.9 ⁺	46.9–100
		1.2 L/ha	5	S-E	32–49	19.2	12.0– 27.5	86.5	78.9– 91.5	92.6 ⁺⁺	87.7–96.5

Target (EPPO code)	Crop (EPPO)	Dose rate	Number of trials	EPPO Zone/ Country	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min- max	Mean	min- max	Mean	min-max
			2	CZ	43-49	13.4	11.9- 14.9	80.9	73.0- 88.7	60.4	46.9-73.8
			7	All	32-49	17.5	11.9- 27.5	84.9	73.0- 91.5	83.4 ⁺⁺	46.9-96.5

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

ΔReference standard results are based on prothioconazole applied at 180-198 g as/ha, one trial using Aviator Xpro at 1.25 L/ha and 3 trials using Input at 1.0 L/ha

*Reference standard results are based on prothioconazole applied at 180-198 g as/ha, one trial using Vertisan at 1.0 L/ha and one trial using Zantara at 1.0 L/ha

⁺⁺⁺Reference standard results are based on prothioconazole applied at 180-198 g as/ha and one trial using Vertisan at 1.0 L/ha

[§]Reference standard results are based on prothioconazole applied at 180-198 g as/ha and one trial using Aviator Xpro applied at 1.25 L/ha

^{§§}Reference standard results are based on prothioconazole applied at 180-198 g as/ha, three trials using Aviator Xpro at 1.25 L/ha and one trial using Input at 1.0 L/ha

*Reference standard results are based on prothioconazole applied at 180-198 g as/ha and two trials using Zantara at 1.0 L/ha

⁺⁺Reference standard results are based on prothioconazole applied at 180-198 g as/ha and one trial using Input at 1.0 L/ha

Based on 10 EPPO South East climatic zone trials, demonstrating mean overall control of SEPTTR in winter wheat of 90.1% from a single application of GF 3307 at 1.5 L/ha, it is considered that the proposed claim for control of SEPTTR is fully supported. The 1.5 L/ha is considered to be appropriate for situation, where the wheat variety has low resistance to SEPTTR or fungicide resistance for SEPTTR is a concern and season long control is required. In situation where fungicide resistance is not a concern, the lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated 86.4% control across 14 trials. For situations where the wheat variety has inherent resistance to SEPTTR and fungicide resistance is not a concern, the low dose in the proposed range of 1.0 L/ha is considered appropriate, as this has demonstrated 81.5% control across seven trials.

For Puccrt, Puccst, Pyrntr and Erysgt the results demonstrate that the proposed minimum dose of 1.2 L/ha of GF 3307 is sufficient to achieve a claim of 'good control' of these target diseases on winter wheat. The data demonstrate 81.4% control of Puccrt (mean of nine EPPO South East trials), 84.6% control of Puccst (mean of five EPPO South East trials), 83.4% control of Pyrntr (mean of six EPPO South East and four CZ/DE/PL trials) and 84.9% control of Erysgt (mean of five EPPO South East and two CZ trials). In high disease situations the 1.5 L/ha dose is recommended and this dose demonstrates 91.9% control of Puccrt (mean of 13 EPPO South East trials), 90.7% control of Puccst (mean of seven EPPO South East trials), 87.3% control of Pyrntr (mean of three EPPO South East and four CZ/DE/PL trials) and 89.6% control of Erysgt (mean of six EPPO South East and three CZ trials).

For Fusasp, the maximum dose of 1.5 L/ha is required (81.7% from four AT/PL trials), as the 1.2 L/ha dose did not give sufficient control of this disease (>70%).

Note: Many EU Member State regulatory authorities in the EPPO South East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

Across all data sets the control achieved by the GF 3307 at the various doses was comparable to the reference standards and not statistically different in the majority of cases.

Data are only available on winter wheat (TRZAW), however spring wheat (TRZAS) is a minor crop in the EPPO South East zone (Eurostats/2020): Hungary: 9,000 ha, Romania 7,000 ha, Slovenia: no significant area, Slovakia: 13,000 ha). Winter wheat is a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF 3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter wheat are equally applicable to spring wheat. Similarly, it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar and the disease pressures are more challenging in winter wheat.

~~GF 3307 at the proposed label rates of 1.0-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.~~

~~It is considered that the proposed GAP for countries of the EPPO South-East climatic zone of the Central EU Authorisation zone is fully supported.~~

~~Winter and spring barley (HORVW and HORVS)~~

~~The proposed use is for a single application at 1.0-1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH. The lower dose of 1.0 L/ha is recommended for application where disease pressure is low and only PUCCHD is present or forecast to be a concern. In moderate disease situations a dose of 1.2 L/ha is recommended. Where disease pressure is high, particularly for PYRNTE, a higher dose rate of 1.5 L/ha is recommended.~~

~~Across all diseases, results from both winter and spring crops demonstrated comparable levels of control of these target diseases and have been combined to give an overall result to support the claims on both crops in the following table.~~

Summary of effectiveness data for GF-3307 for EPPO South-East Zone (barley data)

Target (EPPO code)	Crop (EPPO)	Dose rate	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min- max	Mean	min- max	Mean	min-max
RAMUCC	HORVW	1.5 L/ha	DE	5	35-39	55.0	7.1-99.0	83.8	65.5- 97.9	83.1	63.0-95.1
	HORVS	1.5 L/ha	DE	3	31-39	34.8	5.0-51.8	83.7	76.3- 90.0	61.7	45.0-71.1
	Both	1.5 L/ha	DE	8	31-49	47.4	5.0-99.0	83.8	65.5- 97.9	75.1	45.0-95.1
	HORVW	1.2 L/ha	DE	2	35-37	78.0	7.1-88.8	83.5	77.0- 96.3	77.9	63.0-92.7
	HORVS	1.2 L/ha	DE	3	31-39	34.8	5.0-51.8	80.1	74.9- 90.0	61.7	45.0-71.1
	Both	1.2 L/ha	DE	5	31-39	40.0	5.0-88.8	81.4	74.9- 90.0	68.2	45.0-92.7
RHYNSE	HORVW	1.5 L/ha	PL	5	32-52	18.3	5.6-35.0	92.9	88.7- 97.2	75.0	48.5-100
	HORVS	1.5 L/ha	PL	4	37-49	10.1	5.6-17.8	97.9	92.1- 100	90.4	80.2-100
	Both	1.5 L/ha	PL	9	32-52	14.7	5.6-35.0	95.1	88.7- 100	81.9	48.5-100
	HORVW	1.2 L/ha	PL	5	32-52	18.3	5.6-35.0	87.4	80.0- 96.6	75.0	48.5-100
	HORVS	1.2 L/ha	PL	4	37-49	10.1	5.6-17.8	96.3	87.5- 100	90.4	80.2-100
	Both	1.2 L/ha	PL	9	32-52	14.7	5.6-35.0	91.4	80.0- 100	81.9	48.5-100
PYRNTE	HORVW	1.5 L/ha	S-E	5	37-49	25.8	10.0- 40.0	87.2	81.1- 96.9	83.4	74.1-92.9
	HORVS	1.5 L/ha	S-E	2	39-49	28.8	21.3- 36.3	87.3	87.0- 87.6	78.1	71.3-84.8
	Both	1.5 L/ha	S-E	7	37-49	26.6	10.0- 40.0	87.2	81.1- 96.9	81.9	71.3-92.9
	HORVW	1.2 L/ha	S-E	5	37-49	25.8	10.0- 40.0	75.5	70.0- 81.8	83.4	74.1-92.9
	HORVS	1.2 L/ha	S-E	2	39-49	28.8	21.3- 36.3	81.6	79.9- 83.2	78.1	71.3-84.8
	Both	1.2 L/ha	S-E	7	37-49	26.6	10.0- 40.0	77.3	70.0- 81.8	81.9	71.3-92.9
PUCCHD	Both	1.5 L/ha	S-E	3	31-49	13.0	7.6-16.9	92.4	89.5- 95.3	93.7*	84.2-98.8
			PL	5	37-52	22.0	5.5-47.5	95.9	89.9- 100	86.0	71.4-92.9
	Both	1.2 L/ha	S-E	2	31-49	12.3	7.6-16.9	90.9	88.2- 93.5	91.5	84.2-98.8
			PL	5	37-52	22.0	5.5-47.5	93.7	87.2- 98.4	86.0	71.4-92.9

Target (EPPO code)	Crop (EPPO)	Dose rate	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
								GF 3307		Reference standard#	
						Mean	min- max	Mean	min- max	Mean	min-max
	Both	1.0 L/ha	S-E	2	31-49	12.3	7.6-16.9	84.9	76.3- 92.5	91.5	84.2-98.8
			PL	5	37-52	22.0	5.5-47.5	86.9	77.6- 97.1	86.0	71.4-92.9
ERYSGH	HORVS	1.5 L/ha	S-E	2	31-33	32.1	20.8- 43.3	87.3	81.9- 92.8	87.3	86.3-88.3
	Both		PL	5	32-52	15.3	8.3-23.3	86.5	75.8- 93.9	71.5	48.8-88.8
	HORVS	1.2 L/ha	S-E	2	31-33	32.1	20.8- 43.3	86.2	81.0- 91.5	87.3	86.3-88.3
	Both		PL	5	32-52	15.3	8.3-23.3	83.6	63.6- 93.5	71.5	48.8-88.8

#Proline applied at 0.6-0.8 L/ha used a reference standard, unless specified

*Mean of 2 trials using Proline at 0.8 L/ha and one trial using Delaro at 0.75 L/ha.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.2 L/ha of GF 3307 achieved 81.4% control of RAMUCC across 5 German trials. The proposed maximum dose rate of 1.5 L/ha demonstrated 83.8% control of RAMUCC across 8 German trials. It is considered that data from this region are a robust (and worst case) test of the product. In the EPPO South East climatic zone, the climatic conditions are less conducive to the development of RAMUCC and this is a relatively minor disease in this region. It is considered that these data full support claims for control of RAMUCC on both crops in the EPPO South East climatic zone, with the maximum dose used in high disease pressure situations.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.2 L/ha of GF 3307 achieved 91.4% control of RHYNSE across 9 Polish trials. The proposed maximum dose rate of 1.5 L/ha demonstrated 95.1% control across the same trials. The climate in Poland, as a neighbouring country, is similar to the EPPO South East climatic zone (i.e., hot summers), but is slightly wetter than in the EPPO South East climatic zone. It is therefore considered that trials from Poland represent a more robust test of the product against RHYNSE, so these data can be used to support use in the EPPO South East climatic zone. It is considered that these data full support claims for control of RHYNSE on both crops in the EPPO South East climatic zone, with the maximum dose used in high disease pressure situations.

On winter barley (HORVW) and spring barley (HORVS) a single dose at the proposed maximum dose of 1.5 L/ha of GF 3307 achieved 87.2% control of PYRNTE across 7 EPPO South East climatic zone trials. Where disease levels are low, the 1.2 L/ha dose could be used, as this provided effective control of PYRNTE in this situation (77.3%). It is considered that these data full support claims for control of PYRNTE on both crops in the EPPO South East climatic zone.

Based on three EPPO South East climatic zone trial results, demonstrating mean overall control of PUCCHD in barley of 92.4% from a single application of GF 3307 at 1.5 L/ha, it is considered that the proposed claim for control of PUCCHD is fully supported. The 1.5 L/ha dose is considered to be appropriate for situations where other diseases such as PYRNTE are present/expected or where season long control is required. In other situations, a lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated 90.9% control. For low disease risk situations, the lowest dose in the proposed range of 1.0 L/ha is considered appropriate, as this demonstrated 84.9% control. Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the later stages of the crop/summer that encourage the development of PUCCHD (hot and dry weather). Data from these trials (a mix of HORVS and HORVW trials) demonstrate

comparable levels of control: 95.9% for the 1.5 L/ha dose, 93.7% for the 1.2 L/ha dose and 86.9% for the 1.0 L/ha dose.

Two EPPO South East climatic zone trials achieved mean overall control of ERYSGH in spring barley of 86.2–87.3% from a single application of GF-3307 at 1.2–1.5 L/ha, which is comparable to the levels of control achieved by the prothioconazole standard (87.3%). Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of ERYSGH (warm and humid weather). Data from these trials (a mix of HORVS and HORVW trials) demonstrate comparable levels of control: 86.5% for the 1.5 L/ha dose and 83.6% for the 1.2 L/ha dose.

Across all data sets the control achieved by the GF-3307 was comparable to, or higher than, the reference standards and not statistically different in the majority of cases.

GF-3307 at the proposed label rate dose range of 1.0–1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO South East climatic zone of the Central EU Authorisation zone is fully supported.

3.2.3.18 Summary and conclusions on effectiveness (all crops and disease claims)

Data have been presented across a range of disease in wheat.

The summary tables below are split by EPPO climatic zone and the following colour coding has been used to illustrate both the effectiveness of GF-3307 and the comparability between GF-3307 and the reference standards used.

Level of Effectiveness
>80% control
70-79.9% control
<69.9% control

EPPO Maritime zone

Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)

The proposed use is for a single application applied at 1.5 L/ha, at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, PUCCRT, PUCGST, FUSASP, PYRNTR and ERYSGT.

Summary of effectiveness data for GF-3307 for EPPO Maritime zone (winter wheat data only*)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3307 1.5 L/ha		Reference standards#	
					Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	MAR	13	31-59	35.8	5.0-87.5	92.7	84.8-100	87.9 ⁺	62.3-100
PUCCRT	TRZAW	MAR	15	37-61	22.0	5.0-74.8	88.0	70.2-100	91.4 ^s	67.2-100
PUCGST	TRZAW	MAR	11	31-45	24.9	6.1-65.0	93.6	87.5-100	90.0 ^s	71.7-100
FUSASP	TRZAW	MAR	10	61-65	31.2	5.7-93.8	80.6	71.0-92.0	74.8	47.1-83.0
PYRNTR	TRZAW	MAR	7	31-51	24.0	7.8-50.8	83.9	75.2-92.4	84.5 ^s	73.6-94.5
		PL	3	35-51	19.7	11.3-26.3	90.4	79.0-100	77.7 ⁺	59.4-84.2
		All	10	31-51	22.7	7.8-50.8	85.9	75.2-100	82.4 ^s	59.4-94.5
ERYSGT	TRZAW	MAR	7	32-49	11.5	7.9-17.0	88.9	64.7-100	92.2 ^s	72.1-100
		PL	6	37-55	10.8	6.0-17.5	94.0	87.5-100	90.4	73.8-100
		All	13	32-55	11.2	6.0-17.5	91.2	64.7-100	91.4 ^s	72.1-100
		All*	10	32-55	12.0	6.0-17.5	90.0	64.7-100	89.0 ^s	72.1-100

*Results for ERYSGT based on only single application trials

#Reference standard results are based on prothioconazole applied at 198 g as/ha, unless specified

*Reference standards include prothioconazole applied at 198 g as/ha and Aviator Xpro at 1.0-1.25 L/ha.

^sReference standards include prothioconazole applied at 198 g as/ha, Aviator Xpro at 1.0-1.25 L/ha and Librax at 2.0 L/ha

GF-3307 applied as a single application at 1.5 L/ha at BBCH 31-65 achieved 92.7% control of SEPTTR (mean of 13 trials), 88.0% control of PUCCRT (mean of 15 trials), 93.6% control of PUCGST (mean of 11 trials), 80.6% control of FUSASP (mean of 10 trials), 85.9% control of PYRNTR (mean of 10 trials - a combination of EPPO Maritime climatic zone trials and Polish trials) and 91.2% control of ERYSGT (mean of 13 trials- a combination of EPPO Maritime climatic zone trials and Polish trials). Results on ERYSGT included three EPPO Maritime climatic zone trials based on two applications (with no disease present until after the second application). Ten trials are available based on a single application (Four EPPO Maritime climatic zone trials and six Polish trials) and these demonstrate 90.0% control of ERYSGT.

Across all data-sets the control achieved by the GF-3307 was comparable to or higher than the reference standards and not statistically different in the majority of cases.

Data are only available on winter wheat (TRZAW). However, spring wheat (TRZAS) is generally a minor crop in the EPPO Maritime climatic zone. In the Czech Republic 46,000 ha of spring wheat were grown in 2020 compared to 774,000 ha of winter wheat (Eurostats), indicating that the area of

spring wheat in the Czech Republic is relatively minor, at just 6% of the winter crop area. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter wheat is equally applicable to spring wheat.

Similarly, it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar wheat crops, the disease pressures are more challenging in winter wheat and the areas of durum wheat in these countries are relatively minor (Eurostat/2020): the Czech Republic: no significant area).

GF-3307 at the proposed label rate of 1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO Maritime climatic zone of the Central EU Authorisation zone is fully supported.

***zRMS comments:**

Data from **spring wheat** are scanty across the entire dossier: include 4 trials overall from the North-Eastern EPPO zone alone: 1 trial in LV (2014) and 3 - in PL (2016, 2020, 2021). To the opinion of zRMS the spring wheat data can support, by extrapolation from winter wheat, the uses in spring wheat against ERYSGR, PUCCST, PYRNTR and SEPTTR, in the North-Eastern EPPO zone, whereas the authorities of the concerned member state Czech Republic are kindly invited to consider whether they can accept these uses despite the absence of specific data from the spring wheat, in their EPPO zone.

No data from **durum wheat** or **spelt wheat** have been submitted, from any location of the Central zone but uses in these crops may be approved based on the art. 51, in the MSs in which these crops are considered as minor crops.

Winter and spring rye (SECCW and SECCS) and winter and spring triticale (TTLWI and TTLSO)

The proposed uses are for a single application at 1.5 L/ha applied at BBCH 30-69 to winter and spring rye (SECCW and SECCS) for the control of PUCCRE and RHYNSE and to winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP, ERYSGT and PUCST.

Summary of effectiveness data for GF-3307 for EPPO Maritime zone (winter rye and winter triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3307 1.5 L/ha		Reference standard	
					Mean	min-max	Mean	min-max	Mean	min-max
PUCCRE	SECCW	MAR	12	32-59	19.6	5.0-74.0	89.5	82.5-100	88.4*	78.7-100
RHYNSE	SECCW	MAR	10	32-59	15.7	6.8-27.0	90.7	75.0-100	85.9*	52.0-100
SEPTSP	TTLWI	MAR	7	33-51	21.7	5.8-47.5	91.5	82.3-100	81.8 ^s	63.4-100
		PL	6	33-52	15.3	7.0-33.8	85.9	76.0-100	80.6 ^s	58.3-100
		All	13	33-52	18.8	5.8-47.5	88.9	76.0-100	81.2 ^s	58.3-100
ERYSGT	TTLWI	MAR	4	33-49	22.1	5.0-36.3	83.4	63.5-100	77.7 ^s	40.4-100
		PL	6	33-49	14.9	7.8-31.9	91.8	65.5-99.3	90.6 ^{±±}	70.3-100
		All	10	33-49	19.5	5.0-36.3	88.4	63.5-100	85.4 ^{±±}	40.4-100
PUCST	TTLWI	MAR	10	33-51	37.0	6.0-96.5	90.0	81.8-100	89.7 ^s	73.9-100

*Reference standard results are based on prothioconazole applied at 198 g as/ha and Aviator Xpro at 1.25 L/ha.

^sReference standard results are based on prothioconazole applied at 198 g as/ha and Prosaro at 1.0 L/ha.

^{±±}Reference standard results are based on prothioconazole applied at 180-198 and Prosaro at 1.0 L/ha.

^{±±}Reference standard results are based on prothioconazole applied at 198 g as/ha and Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

On winter rye (SECCW) a single dose of 1.5 L/ha of GF-3307 applied between BBCH 32-59 achieved 89.5% control of PUCCRE (mean of 12 trials) and 90.7% control of RHYNSE (mean of 10 trials).

On winter triticale (TTLWI) a single dose of 1.5 L/ha of GF-3307 applied between BBCH 33-52 achieved 88.9% control of SEPTSP (mean of 13 trials), 88.4% control of ERYSGT (mean of 10 trials) and 90.0% control of PUCST (mean of 10 trials) from a combination of EPPO Maritime climatic zone trials (DE) and trials in neighbouring countries (PL).

Across all data-sets the control achieved by the GF-3307 was comparable to or higher than the reference standards and not statistically different in the majority of cases.

Data are only available on winter crops. However, spring varieties of these crops are generally minor crops in the EPPO Maritime climatic zone. Spring rye (SECCS) and spring triticale (TTLSO) are listed as minor crops in CZ. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter crops are equally applicable to spring crops.

GF-3307 at the proposed label rate of 1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO Maritime climatic zone of the Central EU Authorisation zone is fully supported.

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at 1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH.

Across all diseases, results from both winter and spring crops demonstrated comparable levels of control of these target diseases and have been combined to give an overall result to support the claims on both crops in the following table. For PYRNTE only data from winter barley are available, however it is considered that the data also support use on spring barley.

Summary of effectiveness data for GF-3307 for EPPO Maritime zone (barley data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
							GF-3307 1.5 L/ha		Reference standard#	
					Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	MAR	5	35-49	55.0	7.1-99.0	83.8	65.5-97.9	83.1*	63.0-95.1
	HORVS	MAR	5	31-51	37.7	5.0-74.5	85.4	76.3-93.7	67.8	45.0-86.3
	Both	MAR	10	31-51	46.3	5.0-99.0	84.6	65.8-97.9	75.5*	45.0-95.1
RHYNSE	HORVW	MAR	9	31-37	12.7	5.0-39.8	89.1	76.7-100	81.4	43.1-100
	HORVS	MAR	4	37-51	17.2	5.0-32.5	85.8	75.1-95.8	83.8	80.0-88.2
	Both	MAR	13	31-51	14.1	5.0-39.8	88.1	75.1-100	82.2	43.1-100
PYRNTE	HORVW	MAR	10	32-49	39.3	5.4-99.0	84.7	72.0-100	83.0*	71.0-95.9
PUCCHD	HORVW	MAR	7	32-59	15.5	7.7-23.8	95.7	78.9-100	95.4	83.4-100
		MAR + PL	7^	32-59	19.8	7.7-47.5	95.5	78.9-100	93.2*	83.4-100
	HORVS	MAR	4	37-49	42.0	12.3-76.7	90.8	83.7-99.2	91.3	81.3-100
		MAR + PL	5^	37-52	15.0	5.5-31.9	93.0	83.7-100	88.2*	80.3-98.4
	Both	MAR	11	32-59	25.2	7.7-76.7	93.9	78.9-100	93.9	81.3-100
	Both	MAR + PL	12^	32-59	17.8	5.5-47.5	94.4	78.9-100	91.1*	80.3-100
ERYSGH	HORVW	MAR	6	30-55	16.7	5.8-60.0	95.4	80.0-100	95.2	69.1-100
		MAR + PL	8	30-55	17.5	5.8-60.0	93.4	80.0-100	91.8*	69.1-100
	HORVS	MAR	3	30-55	14.0	5.8-30.0	98.6	95.7-100	98.6	95.7-100
		MAR + PL	6	30-55	14.6	5.8-30.0	91.4	75.8-100	90.4*	73.5-100
	Both	MAR	10	30-55	15.9	5.8-60.0	96.3	80.0-100	96.2	69.1-100
	Both	MAR + PL	14	30-55	16.2	5.8-60.0	92.6	75.8-100	91.2*	69.1-100

^Results from only single application trials

#Proline applied at 0.8 L/ha used a reference standard, unless specified

*Reference standard results are based on prothioconazole applied at 200 g as/ha and Aviator Xpro at 1.0 L/ha.

**Mean of 3 trials using Proline at 0.8 L/ha and 2 trials using Aviator Xpro at 1.0 L/ha.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.5 L/ha of GF-3307 applied between BBCH 30-59 achieved over 80% control of all target diseases: RAMUCC (84.6%), RHYNSE (88.1%), PYRNTE (84.7%), PUCCHD (94.4%) and ERYSGH (92.6%) from 10-13 trials.

Across all data-sets the control achieved by the GF-3307 was comparable to, or higher than, the reference standards and not statistically different in the majority of cases. GF-3307 at the proposed label rate of 1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO Maritime climatic zone of the Central EU Authorisation zone is fully supported.

EPPO North-East zone

Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)

The proposed use is for a single application applied at a dose range of 1.0-1.5 L/ha, at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, Puccrt, Puccst, Fusasp, Pyrntr and Erysgt.

The lower dose of 1.0 L/ha (supported by data at 0.9 and 1.0 L/ha) is recommended for application where disease levels are low early in the season and SEPTTR or ERYSGT are the only diseases requiring control. For SEPTTR and ERYSGT the results demonstrate that the proposed minimum dose of 1.0 L/ha of GF-3307 at BBCH 31-65 can be sufficient to achieve a claim of 'good control' of these target diseases on winter wheat. The data demonstrate 82.2% control of SEPTTR (mean of 9 trials) and 80.9% control of ERYSGT (mean of six EPPO North-East and three CZ trials). In mixed disease situations the results demonstrate that the 1.2 L/ha dose of GF-3307 is sufficient to achieve a claim of 'good control' of these target diseases on winter wheat. The data demonstrate 86.2% control of SEPTTR (mean of 11 trials), 89.6% control of Puccrt (mean of eight EPPO North-East), 91.2% control of Puccst (mean of six EPPO North-East and three DE trials) and 84.8% control of ERYSGT (mean of six EPPO North-East and three CZ/DE trials). In high disease situations the 1.5 L/ha dose is recommended and this dose demonstrates 92.6% control of SEPTTR (mean of 12 trials), 90.8% control of Puccrt (mean of 10 EPPO North-East), 93.0% control of Puccst (mean of eight EPPO North-East and three DE trials) and 90.0% control of ERYSGT (mean of six EPPO North-East and four CZ/DE trials). Control on spring wheat was comparable for the 1.2 and 1.5 L/ha doses at 74.9% and 83.3% respectively for SEPTTR, 90.8% and 93.3% respectively for Puccst and 69.7% and 85.5% respectively for ERYSGT.

For PYRNTR, the results demonstrate that the proposed maximum 1.5 L/ha dose is the most effective dose required to achieve a claim of 'very good control' of PYRNTR, with 86.8% control of (mean of six EPPO North-East and six DE trials). The 1.2 L/ha dose offered good control of this disease (80.3% control across four EPPO North-East and six DE trials), but did not always provide consistently high levels of control, as control was more variable in some trials. It is considered that the 1.2 L/ha dose will be sufficient in situations where PYRNTR is a secondary disease and not the main target.

For FUSASP, the maximum dose of 1.5 L/ha is required (82.3% control from seven EPPO North-East and four DE trials), as the 1.2 L/ha dose did not give sufficient control of this disease (<75%).

Across all data-sets the control achieved by both the 0.9/1.0 L/ha, 1.2 L/ha and 1.5 L/ha doses of GF-3307 was comparable to the reference standards and not statistically different in the majority of cases.

The majority of data are only available on winter wheat (TRZAW). Spring wheat (TRZAS) is major crop in Poland (400,000 ha were grown in Poland in 2020). Three trials on spring wheat are included in the dossier and demonstrate comparable control to that achieved on winter wheat on both SEPTTR, Puccst, PYRNTR and ERYSGT. The approval for control of Puccrt in spring wheat is supported by the extensive data on winter wheat. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter wheat is equally applicable to spring wheat.

Similarly it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar wheat crops, the disease pressures are more challenging in winter wheat and the area of durum wheat is minor (Eurostat (2020): Poland: no significant area).

GF-3307 at the proposed label rate dose range of 1.0-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease. It is considered that the proposed GAP for Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) is fully supported.

Summary of effectiveness data for GF-3307 for EPPO North-East Zone (wheat data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 0.9-1.0 L/ha		GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	N-E	12	31-51	18.5	5.8-49.1	82.2*	68.3-100	86.2*	71.2-100	92.6	80.4-100	83.8	58.5-97.1
	TRZAS	N-E	1	39-41	5.0	-	-	-	74.9	-	83.3	-	88.3	-
PUCCRT	TRZAW	NE	10	39-61	28.2	6.0-50.0	-	-	89.6**	84.2-98.4	90.8	81.1-97.7	80.8 ⁺	57.7-95.0
PUC CST	TRZAW	N-E	8	37-56	23.2	6.4-45.0	-	-	91.9***	69.6-100	93.3	81.1-100	88.9 [^]	72.9-100
		DE	3	31-45	28.6	20.0-37.5	-	-	90.0	84.0-100	91.8	87.5-100	87.6	81.9-98.0
		All	11	31-56	24.7	6.4-45.0	-	-	91.2***	69.6-100	93.0	81.1-100	88.6 [^]	72.9-100
	TRZAS	N-E	1	39-41	8.7	-	-	-	90.8	-	93.3	-	95.8	-
FUSASP	TRZAW	N-E	7	61-69	48.1	13.7-91.3	-	-	78.8 [§]	66.1-97.6	83.4	50.1-100	82.4 [§]	53.4-96.7
		DE	4	61-65	47.8	8.5-93.8	-	-	69.9	57.0-83.7	80.3	71.0-92.0	83.8 [§]	75.9-90.1
		All	11	61-69	48.0	8.5-93.8	-	-	74.9 [§]	57.0-97.6	82.3	50.1-100	82.9 [§]	53.4-96.7
PYRNTR	TRZAW	N-E	6	35-51	15.8	10.6-26.3	-	-	79.8 ^{§§}	68.1-84.2	88.7	79.0-100	81.3 ⁺	59.4-90.8
		DE (4), CZ (2)	6	31-49	26.2	7.8-50.8	-	-	80.6	64.0-90.6	85.0	75.2-92.4	84.1 ⁺	73.6-94.5
		All	12	31-51	21.0	7.8-50.8	-	-	80.3 ^{§§}	64.0-90.6	86.8	75.2-100	82.7 ⁺	59.4-94.5
	TRZAS	N-E	2	39-49	16.7	13.1-20.3	-	-	80.5	72.9-88.0	88.3	78.6-98.0	75.3	67.6-83.0
ERYSGT	TRZAW	N-E	6	37-55	10.8	6.0-17.5	82.6	57.5-100	89.4	72.5-100	94.0	87.5-100	90.4	73.8-100
		CZ + DE	4	32-49	13.9	11.9-17.0	77.6	71.6-88.8	75.5 ^{§§§}	64.7-88.7	84.0	64.7-94.6	86.9 ^{^^}	72.1-100
		All	10	32-55	12.0	6.0-17.5	80.9 ^{§§§}	57.5-100	84.8 ^{§§§}	64.7-100	90.0	64.7-100	89.0 ⁺	72.0-100
	TRZAS	N-E	1	47-49	11.5	-	58.0	-	69.7	-	85.5	-	79.4	-

*Results for 1.2 L/ha dose for SEPTTR from 11 EPPO North-East trials and 1.0 L/ha from 9 EPPO North-East trials, **Results for 1.2 L/ha dose for PUC CST from 8 EPPO North-East trials

***Results for 1.2 L/ha dose for PUC CST from 6 EPPO North-East and 3 DE trials, §Results for 1.2 L/ha dose for FUSASP from 5 EPPO North-East and 4 DE trials

§§Results for 1.2 L/ha dose for PYRNTR from 4 EPPO North-East and 6 DE trials, §§§Results for 1.2 L/ha dose for ERYSGT from 6 EPPO North-East and 3 CZ/PL trials

#Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified otherwise.

*Reference standard results are based on prothioconazole applied at 198 g as/ha, Aviator Xpro applied at 1.25 L/ha and Vertisan at 1.0 L/ha.

[^]Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro applied at 1.0 L/ha and Vertisan at 1.0 L/ha

^{^^}Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro applied at 1.0 L/ha

^sReference standard results are based on Prosaro applied at 1.0 L/ha. ⁺Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro applied at 1.0 L/ha and Librax at 2.0 L/ha

Winter and spring rye (SECCW and SECCS) and winter and spring triticale (TTLWI and TTLSO)

The proposed uses are for a single application at 1.2-1.5 L/ha applied at BBCH 30-69 to winter and spring rye (SECCW and SECCS) for the control of Puccre and RHYNSE and to winter and spring triticale (TTLWI and TTLSO) for the control of SEPTSP, ERYSGT and Puccst.

On rye, the lower dose of 1.2 L/ha is recommended for application where RHYNSE is the major disease requiring control and where there is lower pressure from Puccre. Where Puccre is also present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.

On triticale, the lower dose of 1.2 L/ha is recommended for application where ERYSGT or Puccst are the major disease requiring control and where there is lower pressure from SEPTSP. Where SEPTSP is also present or expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.2-1.5 L/ha is proposed, to offer growers the greatest flexibility.

Summary of effectiveness data for GF-3307 for EPPO North-East Zone (rye and triticale data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control					
							GF-3307 1.2 L/ha		GF-3307 1.5 L/ha		Reference standard*	
					Mean	min- max	Mean	min- max	Mean	min- max	Mean	min- max
Puccre	SECCW	N-E	5	37-59	26.2	8.8- 49.1	77.4	54.7- 100	84.7	69.0- 100	83.3	66.2-100
		DE	10	32-51	15.5	5.0- 41.2	83.3	71.4- 95.0	89.6	82.5- 100	88.1	78.7-100
		All	15	32-59	19.0	5.0- 49.1	81.3	54.7- 100	88.0	69.0- 100	86.5	66.2-100
RHYNSE	SECCW	N-E	6	37-59	17.6	5.0- 40.0	75.7	63.5- 93.8	81.1	68.1- 97.6	70.7	56.0- 81.3
		DE	8	32-51	15.3	6.8- 27.0	84.5	68.2- 100	89.9	75.0- 100	83.2	59.3-100
		All	14	32-59	16.3	5.0- 40.0	80.7	63.5- 100	86.1	68.1- 100	77.9	56.0-100
SEPTSP	TTLWI	N-E	6	33-52	15.3	7.0- 33.8	72.3#	68.6- 74.5	85.9	76.0- 100	80.6\$	58.3-100
		DE	7	33-51	21.7	5.8- 47.5	75.1#	69.2- 90.3	91.5	82.3- 100	81.8\$\$	63.4-100
		All	13	33-52	18.8	5.8- 47.5	73.9#	68.6- 90.3	88.9	76.0- 100	81.2\$\$\$	58.3-100
ERYSGT	TTLWI	N-E	6	33-49	14.9	7.8- 31.9	84.2	59.1- 96.1	91.8	65.5- 99.3	90.6+	70.3-100
		DE	4	33-49	22.1	5.0- 36.3	86.2\$	-	89.1	63.5- 100	86.9++	40.4-100
		All	10	33-49	19.5	5.0- 36.3	84.5\$	59.1- 96.1	88.4	63.5- 100	85.4+++	40.4-100
Puccst	TTLWI	N-E	8	33-52	26.1	7.1- 50.0	76.4+	73.9- 79.0	89.5	82.4- 96.0	63.0^	36.6- 87.4
		DE	8	37-51	38.1	6.0- 96.5	85.0	75.0- 100	88.5	81.8- 100	88.8	73.9-100
		All	16	33-52	32.1	6.0- 96.5	82.6+	73.9- 100	89.0	81.8- 100	75.9^^	36.6-100

#Results for 1.2 L/ha dose for SEPTSP from 3 EPPO North-East and 4 DE trials

\$Results for 1.2 L/ha dose for ERYSGT from 6 EPPO North-East and 1 DE trial

+Results for 1.2 L/ha dose for Puccst from 3 EPPO North-East and 8 DE trials

*Proline 275 or Proline 250 applied at 0.72 L/ha (180-198 g as/ha) used a reference standard, unless specified

^sMean of 4 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

^{ss}Mean of 5 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha

^{sss}Mean of 9 trials using Proline at 0.72 L/ha and 4 trials using Prosaro at 1.0 L/ha.

[#]Mean of 4 trials using Proline 275 at 0.72 L/ha, one using Proline 250 at 0.72 L/ha and one trial using Wirtuoz 520 EC at 1.0 L/ha in sequence with Artea at 0.5 L/ha

^{##}Mean of 2 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

⁺⁺⁺Mean of 6 trials using Proline 275 at 0.72 L/ha, one using Proline 250 at 0.72 L/ha, 2 trial using Prosaro at 1.0 L/ha and one trial using Wirtuoz 520 EC in sequence with Artea

[^]Mean of 6 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

^{^^}Mean of 14 trials using Proline at 0.72 L/ha and 2 trials using Prosaro at 1.0 L/ha.

On winter rye (SECCW), a single dose of 1.5 L/ha of GF-3307 applied between BBCH 32-59 achieved 88.0% control of PUCCRE (mean of 15 trials, from a combination of EPPO North-East climatic zone and DE trials). These data also demonstrate that the 1.2 L/ha dose achieved 81.3% of PUCCRE confirming that the 1.2 L/ha dose recommended for control of RHYNSE on rye should deliver good control of PUCCRE, where PUCCRE is not the main target. A single dose of 1.2 L/ha of GF-3307 applied between BBCH 32-59 achieved 80.7% control of RHYNSE (over 14 trials, from a combination of EPPO North-East climatic zone and DE trials). Where PUCCRE also needs to be controlled, a dose of 1.5 L/ha is recommended and GF-3307 achieved 86.1% control of RHYNSE in these trials.

On winter triticale (TTLWI), a single dose of 1.5 L/ha of GF-3307 applied between BBCH 33-52 achieved 88.9% control of SEPTSP (mean of 13 trials, from a combination of EPPO North-East climatic zone and DE trials). Data from three Polish and four German trials demonstrate that the 1.2 L/ha dose achieved 73.9% of SEPTSP. Although this is a more limited dataset, it does confirm that the 1.2 L/ha dose recommended for control of other diseases on triticale (ERYSGT and PUCGST) should deliver good control of SEPTSP, where SEPTSP is not the main target.

In addition, data on wheat in section 3.2.3.1 also demonstrate effective control of SEPTTR (92.6% control for the 1.5 L/ha dose and 86.2% control for the 1.2 L/ha dose) across 12/11 EPPO North-East climatic zone trials and are considered to support this proposed claim/use on triticale.

For ERYSGT on triticale, A single dose of 1.2 L/ha of GF-3307 applied between BBCH 33-49 achieved 84.5% control of ERYSGT (over 7 trials, from a combination of EPPO North-East climatic zone and DE trials). It is considered that this use/claim can also be supported by the data on winter wheat which demonstrated comparable control of 88.4% of ERYSGT for the 1.2 L/ha dose across two EPPO North-East climatic zone trials on winter wheat. Where SEPTSP also needs to be controlled, a dose of 1.5 L/ha is recommended and GF-3307 at 1.5 L/ha achieved 88.4% control of ERYSGT (over 10 trials, from a combination of EPPO North-East climatic zone and DE trials).

In addition, data on wheat in section 3.2.3.6 also demonstrate effective control of ERYSGT (94.0% control for the 1.5 L/ha dose and 89.4% control for the 1.2 L/ha dose) across six EPPO North-East climatic zone trials and are considered to support this proposed claim/use on triticale.

For PUCGST on triticale, a single dose of 1.2 L/ha of GF-3307 applied between BBCH 33-52 achieved 82.6% control of PUCGST (over 11 trials, from a combination of EPPO North-East climatic zone and DE trials). Where SEPTSP also needs to be controlled, a dose of 1.5 L/ha is recommended and GF-3307 at 1.5 L/ha achieved 89.0% control of PUCGST (over 16 trials EPPO North-East climatic zone and DE trials).

In addition, data on wheat in section 3.2.3.3 also demonstrate effective control of PUCGST (93.3% control for the 1.5 L/ha dose across eight EPPO North-East climatic zone trials and 86.6% control for the 1.2 L/ha dose across three EPPO North-East climatic zone trials) and are considered to support this proposed claim/use on triticale.

Across all data-sets the control achieved by both the 1.2 L/ha and 1.5 L/ha doses of GF-3307 was comparable to the reference standards and not statistically different in the majority of cases.

The majority of data are only available on winter crops, however spring varieties of most of these crops are generally minor crops in PL. Spring rye (SECCS) is listed as a minor crop in PL. For spring triticale (TTLSO), 100,000 ha grown in PL in 2020, compared to 1,200,000 ha of winter triticale (Main Statistical Office), indicating that the area of spring triticale in PL is 8.3% of the winter crop area. Winter crops are a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter crops are equally applicable to spring crops.

GF-3307 at the proposed label rate dose range of 1.2-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) is fully supported.

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at 1.0-1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH. The lower dose of 1.0 L/ha is recommended for application where disease levels are low and RHYNSE or PUCCHD are the only diseases requiring control. The 1.2 L/ha dose (supported by data at 1.2/1.25 ha) is recommended for application where ERYSGH is the major diseases requiring control and where there is lower pressure from PYRNTE and/or RAMUCC. Where PYRNTE and/or RAMUCC are also present and expected to be a concern, a higher dose rate of 1.5 L/ha is recommended, hence a label dose range of 1.0-1.5 L/ha is proposed, to offer growers the greatest flexibility.

On winter barley (HORVW) a single dose of 1.5 L/ha of GF-3307 achieved 85.9% control of PYRNTE across 10 trials (seven EPPO North-East climatic zone and three German trials). On spring barley (HORVS) a single dose of 1.5 L/ha of GF-3307 achieved 89.2% control of PYRNTE across seven EPPO North-East climatic zone trials. The 1.2/1.25 ha dose demonstrated slightly lower control of 78.8% winter barley (eight HORVW trials) and 83.0% spring barley (seven HORVS trials) and is recommended for lower disease situations only. Fourteen trials in both HORVW and HORVS from the North-East achieved 80.6% from 1.2/1.25 ha and 85.8% from the 1.5 L/ha dose which was comparable to the Proline and Prosaro reference standards, delivering 85.5% control. It is considered that these data full support claims for control of PYRNTE on both crops in Poland.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.5 L/ha of GF-3307 achieved 83.8% control of RAMUCC across 8 German trials. It is considered that these data from a neighbouring country full support claims for control of RAMUCC on both crops in Poland.

On winter barley (HORVW) the lower dose of 1.0 L/ha of GF-3307 achieved 89.6% control of RHYNSE across eight trials (six EPPO North-East climatic zone and two German trials). On spring barley (HORVS) a single dose of 1.0 L/ha of GF-3307 achieved 80.4% control of RHYNSE across four EPPO North-East climatic zone trials. The 1.2/1.25 ha dose achieved 92.3% control of RHYNSE across nine trials (seven EPPO North-East climatic zone and two German trials). On spring barley (HORVS) a single dose of 1.2/1.25 ha of GF-3307 achieved 96.3% control of RHYNSE across four EPPO North-East climatic zone trials. The proposed maximum dose rate of 1.5 L/ha demonstrated 95.3% and 97.9% control respectively, in the same trials. Eleven trials in both HORVW and HORVS from the North-East achieved 92.9% from 1.2/1.25 ha, 96.0% from the 1.5 L/ha dose and 84.4% for the 1.0 L/ha dose across 10 trials. Results were comparable to the Proline and Aviator Xpro reference standards, delivering 92.6% control. It is considered that these data full support claims for control of RHYNSE on both crops in Poland.

On winter barley (HORVW) and spring barley (HORVS) the lower dose of 1.0 L/ha of GF-3307 achieved 86.2% control of PUCCHD across seven EPPO North-East climatic zone trials. The 1.2/1.25 ha dose achieved 94.2% control of PUCCHD across nine trials (eight EPPO North-East climatic zone and one German trial). The proposed maximum dose rate of 1.5 L/ha demonstrated 97.4% control, in the same trials, which was superior to Proline, delivering 90.6% control. Results were comparable to the Proline and Prosaro reference standards, delivering 92.6% control. It is considered that these data full support claims for control of PUCCHD on both crops in Poland.

On winter barley (HORVW) a single dose of 1.2/1.25 ha of GF-3307 achieved 90.0% control of ERYSGH across five EPPO North-East climatic zone and one German trial. On spring barley (HORVS) a single dose of 1.2/1.25 ha of GF-3307 achieved 88.7% control of ERYSGH across 8 trials (five EPPO North-East climatic zone and three German trials). The proposed maximum dose rate of 1.5 L/ha demonstrated 92.9% and 92.3% control respectively across the five EPPO North-East climatic zone and three German trials. 10 trials in both HORVW and HORVS from the North-East achieved 86.3% from 1.2/1.25 ha and 89.8% from the 1.5 L/ha dose. Results were comparable to the Proline and Prosaro reference standards, delivering 89.9% control. It is considered that these data full support claims for control of ERYSGH on both crops in Poland.

Across all data-sets the control achieved by the GF-3307 was comparable to, or higher than, the reference standards and not statistically different in the majority of cases. GF-3307 at the proposed label rate dose range of 1.0-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease. It is considered that the proposed GAP for Poland (EPPO North-East climatic zone of the Central EU Authorisation zone) is fully supported.

Summary of effectiveness data for GF-3307 for EPPO North-East Zone (barley data)

Target (EPPO code)	Crop (EPPO)	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control							
							GF-3307 1.0 L/ha		GF-3307 1.2-1.25 L/ha		GF-3307 1.5 L/ha		Reference standard#	
					Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max	Mean	min-max
RAMUCC	HORVW	DE	5	35-49	55.0	7.1-99.0	-	-	-	-	83.8	65.5-97.9	83.1*	63.0-95.1
	HORVS	DE	3	31-39	34.8	5.0-51.8	-	-	-	-	83.7	76.3-90.0	61.7	45.0-71.7
	Both	DE	8	31-49	47.4	5.0-99.0	-	-	-	-	83.8	65.5-97.9	75.1**	45.0-95.1
RHYNSE	HORVW	N-E	7	31-52	17.0	5.6-35.0	87.0+	78.0-99.1	90.9	80.0-100	94.9	88.7-100	91.7^	80.0-100
		NE + DE	9	31-52	15.1	5.6-35.0	89.6+	78.0-100	92.3	80.0-100	95.3	88.7-100	93.3^	80.0-100
	HORVS	N-E	4	37-49	10.1	5.6-17.8	80.4	59.2-99.2	96.3	87.5-100	97.9	92.1-100	94.1^	78.7-100
	Both	N-E	11	31-52	14.5	5.6-35.0	84.4+	59.2-99.2	92.9	80.0-100	96.0	88.7-100	92.6^	78.7-100
PYRNTE	HORVW	N-E	7	32-52	20.9	5.0-36.4	-	-	78.2	61.8-87.3	82.5	67.6-91.4	85.8^	66.7-97.5
		N-E + DE	10	32-52	36.2	5.0-99.0	-	-	78.8++	61.8-87.3	85.9	67.6-100	88.3^	66.7-97.5
	HORVS	NE	7	32-52	18.1	5.5-30.6	-	-	83.0	67.9-95.7	89.2	79.6-100	85.2^	69.6-100
	Both	NE	14	32-52	19.5	5.0-36.4	-	-	80.6	61.8-95.7	85.8	67.6-100	85.5^	66.7-100
PUCCHD	HORVW	N-E	2	37-51	34.2	20.8-47.5	88.3	82.5-94.1	98.0	96.0-100	99.1	98.1-100	92.4^^	84.8-100
	HORVS	N-E	6	37-52	12.4	5.5-31.9	85.3	77.6-97.1	92.0	79.6-100	96.7	89.9-100	91.9^^	80.3-100
	Both	N-E + DE	9	37-52	18.0	5.5-47.5	86.2++++	77.6-97.1	94.2	79.6-100	97.4	89.9-100	92.6^^	80.3-100
ERYSGH	HORVW	N-E	5	31-52	10.5	5.6-21.6	-	-	88.4	76.8-98.8	91.1	84.5-96.7	91.8^^	78.3-100
		N-E + DE	8	31-52	10.5	5.6-21.6	-	-	90.0+++	76.8-98.8	92.9	84.5-100	94.5^^	78.3-100
	HORVS	N-E	5	37-52	12.4	5.9-23.3	-	-	84.2	63.6-100	88.5	75.8-100	87.9^^	73.5-100
		N-E + DE	8	31-52	13.0	5.8-30.0	-	-	88.7	63.6-100	92.3	75.8-100	91.9^^	73.5-100
	Both	N-E	10	31-52	11.5	5.6-23.3	-	-	86.3	63.6-100	89.8	75.8-100	89.9^^	73.5-100

+Results for RHYNSE at 1.0 L/ha on HORVW from 6 trials NE trials and 2 DE trials and 10 NE trials across both HORVS and HORVW.

++Result for PYRNTE at 1.2 L/ha from 8 trials +++Results for ERYSGH at 1.2 L/ha from 6 trials, ++++Results for PUCCHD at 1.0 L/ha from 7 trials NE trials

#Proline applied at 0.6-0.8 L/ha used a reference standard, unless specified, *Mean of 3 trials using Proline at 0.8 L/ha and 2 trials using Aviator Xpro at 1.0 L/ha.

**Mean of 6 trials using Proline at 0.8 L/ha and 2 trials using Aviator Xpro at 1.0 L/ha., ^Aviator Xpro at 0.8-1.0 L/ha applied as the reference standard

^^Reference standards used based on Proline 250 (P) applied at 0.72-0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

EPPO South-East zone

Winter and spring wheat (TRZAW and TRZAS), spelt (TRZSP) and durum wheat (TRZDU)

The proposed use is for a single application at a dose range of 1.0-1.5 L/ha applied at BBCH 30-69 to winter and spring wheat (TRZAW and TRZAS), spelt wheat (TRZSP) and durum wheat (TRZDU) for control of SEPTTR, PUCCRT, PUC CST, FUSASP, PYRNTR and ERYSGT.

The lower dose of 1.0 L/ha is recommended for application where disease pressure is low and only SEPTTR is present or forecast to be a concern. In moderate disease situations a dose of 1.2 L/ha is recommended. Where disease pressure is high, particularly for FUSASP, a higher dose rate of 1.5 L/ha is recommended.

Summary of effectiveness data for GF-3307 for EPPO South-East Zone (1.0-1.5 L/ha dose range) (winter wheat data only*)

Target (EPPO code)	Crop (EPPO)	Dose rate	Number of trials	EPPO Zone/ Country	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min-max	Mean	min-max	Mean	min-max
SEPTTR	TRZAW	1.5 L/ha	11	S-E	32-49	21.7	6.0-51.3	90.1	77.7-100	86.0	75.1-100
		1.2 L/ha	15	S-E	30-49	20.6	6.0-51.3	86.5	71.2-100	85.7 [^]	70.3-100
		1.0 L/ha	8	S-E	32-49	18.9	6.0-51.3	81.9	64.2-100	86.5	75.9-100
PUC CRT	TRZAW	1.5 L/ha	15	S-E	37-55	36.9	7.0-72.5	92.5	69.4-100	85.7 [±]	59.1-100
			10*	S-E	37-55	30.7	7.0-72.5	91.6	69.4-100	87.3 [±]	63.9-100
		1.2 L/ha	11	S-E	37-53	36.8	7.0-72.5	82.9	62.5-95.2	82.6	59.1-100
			8*	S-E	37-53	31.0	7.0-72.5	84.0	62.5-95.2	84.2	63.9-100
PUC CST	TRZAW	1.5 L/ha	8	S-E	39-49	34.5	6.8-63.8	91.4	82.3-100	89.1 ^{±±}	73.7-100
		1.2 L/ha	6	S-E	39-49	32.6	6.8-63.8	86.2	72.6-99.0	92.0	73.7-100
FUSASP	TRZAW	1.5 L/ha	3	S-E	61-65	39.0	15.0-79.5	70.9	54.1-86.0	81.8 [§]	67.9-89.1
			8	AT + PL	61-69	36.4	5.7-91.3	87.1	79.0-100	86.4 [§]	75.9-96.7
			11	All	61-69	37.1	5.7-91.3	82.6	54.1-100	85.1 [§]	67.9-96.7
PYRNTR	TRZAW	1.5 L/ha	3	S-E	39-51	7.2	5.2-10.0	92.0	88.6-97.3	86.4	80.0-94.3
			6	AT + CZ + PL	35-51	16.9	10.3-26.3	87.6	77.5-100	79.0 [§]	59.4-86.6
			9	All	35-51	13.6	5.2-26.3	89.1	77.5-100	81.5 ^{§§}	59.4-94.3
		1.2 L/ha	6	S-E	31-51	6.7	5.2-10.0	87.1	74.2-96.8	88.5 ^{§§}	80.0-96.3
			6	AT + CZ + PL	35-51	16.9	10.3-26.3	81.1	68.1-90.6	79.0 [§]	59.4-86.6
			12	All	31-51	11.8	5.2-26.3	84.1	68.1-96.8	83.1 ^{§§}	59.4-96.3
ERYSGT	TRZAW	1.5 L/ha	7	S-E	37-49	16.2	10.5-25.0	86.9	73.1-92.7	89.3 [±]	63.3-98.0
			3	CZ	32-49	12.9	11.9-14.9	90.4	86.3-94.6	91.8 [§]	80.2-100
			10	All	32-49	15.2	10.5-25.0	88.0	73.1-94.6	90.0 ^{±±}	63.3-100
		1.2 L/ha	6	S-E	32-49	17.8	10.5-27.5	83.6	69.3-91.5	87.7 ⁺⁺⁺	63.3-96.5
			2	CZ	43-49	13.4	11.9-14.9	80.9	73.0-	87.8 ^{§§}	80.2-95.3

Target (EPPO code)	Crop (EPPO)	Dose rate	Number of trials	EPPO Zone/ Country	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min-max	Mean	min- max	Mean	min-max
									88.7		
			8	All	32-49	16.7	10.5-27.5	82.9	69.3- 91.5	87.7 ^{ss}	63.3-96.5

*Results for Puccrt based on single application only trials, #Reference standard results are based on prothioconazole applied at 180-198 g as/ha, unless specified

[^]Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro at 1.0 L/ha and Input at 1.0 L/ha

^{*}Reference standard results are based on prothioconazole applied at 180-198 g as/ha, one trial using Vertisan at 1.0 L/ha and one trial using Zantara at 1.0 L/ha.

⁺⁺Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Vertisan at 1.0 L/ha

[§]Reference standard results are based on Prosaro applied at 1.0 L/ha, ^{§§}Reference standard results are based on Aviator Xpro applied at 1.0 L/ha

[§]Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Aviator Xpro applied at 1.0-1.25 L/ha

^{ss}Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro at 1.0-1.25 L/ha and Input at 1.0 L/ha

[†]Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Zantara at 1.0 L/ha

⁺⁺Reference standard results are based on prothioconazole applied at 180-198 g as/ha, Aviator Xpro at 1.0 L/ha and Zantara at 1.0 L/ha

⁺⁺⁺Reference standard results are based on prothioconazole applied at 180-198 g as/ha and Input at 1.0 L/ha

Based on 11 EPPO South-East climatic zone trials, demonstrating mean overall control of SEPTTR in winter wheat of 90.1% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of SEPTTR is fully supported. The 1.5 L/ha is considered to be appropriate for situation, where the wheat variety has low resistance to SEPTTR or fungicide resistance for SEPTTR is a concern and season long control is required. In situation where fungicide resistance is not a concern, the lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated 86.5% control across 15 trials. For situations where the wheat variety has inherent resistance to SEPTTR and fungicide resistance is not a concern, the low dose in the proposed range of 1.0 L/ha is considered appropriate, as this has demonstrated 81.9% control across eight trials.

For Puccrt, Puccst, Pyrntr and Erysgt the results demonstrate that the proposed minimum dose of 1.2 L/ha of GF-3307 is sufficient to achieve a claim of ‘good control’ of these target diseases on winter wheat. The data demonstrate 82.9% control of Puccrt (mean of 11 EPPO South-East trials), 86.2% control of Puccst (mean of six EPPO South-East trials), 87.6% control of Pyrntr (mean of six EPPO South-East) and 82.9% control of Erysgt (mean of six EPPO South-East and two CZ trials). In high disease situations the 1.5 L/ha dose is recommended and this dose demonstrates 92.5% control of Puccrt (mean of 15 EPPO South-East trials), 91.4% control of Puccst (mean of eight EPPO South-East trials), 89.1% control of Pyrntr (mean of three EPPO South-East and six trials) and 88.0% control of Erysgt (mean of seven EPPO South-East and three CZ trials).

Note: Results on Puccrt included five EPPO South-East climatic zone trials based on two applications (with no disease present until after the second application). Ten trials at the 1.5 L/ha dose are available based on a single application and these demonstrate 91.6% control of Puccrt and eight trials at 1.2 L/ha demonstrated 84.0% control.

For Fusasp, the maximum dose of 1.5 L/ha is required (82.6% from three EPPO South-East trials and eight AT/PL trials), as the 1.2 L/ha dose did not give sufficient control of this disease (<80%).

Note: Many EU Member State regulatory authorities in the EPPO South-East climatic zone, prefer to see dose ranges for Plant Protection Products, as this allows some level of flexibility for the user, which would otherwise not be permitted by law.

Across all data-sets the control achieved by the GF-3307 at the various doses was comparable to the reference standards and not statistically different in the majority of cases.

Data are only available on winter wheat (TRZAW), however spring wheat (TRZAS) is a minor crop in the EPPO South-East zone (Eurostats/2020): Hungary: 9,000 ha, Romania 7,000 ha, Slovenia: no significant area, Slovakia: 13,000 ha). Winter wheat is a more challenging situation for control of these diseases, as the disease has time to establish in the crop over winter before GF-3307 is applied from BBCH 30. All target diseases equally infect both winter and spring crops and it is considered that the conclusions on effectiveness for winter wheat are equally applicable to spring wheat. Similarly, it is considered that uses on spelt wheat (TRZSP) and durum wheat (TRZDU) can be extrapolated from the data on winter wheat as these crops are very similar and the disease pressures are more challenging in winter wheat.

GF-3307 at the proposed label rates of 1.0-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO South-East climatic zone of the Central EU Authorisation zone is fully supported.

***zRMS comments:**

No single trial in TRZAS is available from the South-Eastern EPPO zone, except HU15E7B072AB01 (2015). The status of this trial is “submitted but not relied on”, as data from it were not used by the applicant in any summaries (the trial only covers PUCCRT and PUCST). No data from durum wheat or spelt wheat are available across the entire dossier either. The approval of the uses in TRZAS, TRZDU or TRZSP is possible only through the individual decision of the Member States of the South-Eastern EPPO zone, supported by extrapolation from winter wheat, or based on the art. 51, for crops of the minor status.

Winter and spring barley (HORVW and HORVS)

The proposed use is for a single application at 1.0-1.5 L/ha applied at BBCH 30-69 to winter and spring barley (HORVW and HORVS) for the control of RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH. The lower dose of 1.0 L/ha is recommended for application where disease pressure is low and only RHYNSE or PUCCHD is present or forecast to be a concern. In moderate disease situations a dose of 1.2 L/ha (supported by data at 1.2/1.25 L/ha) is recommended. Where disease pressure is high, particularly for PYRNTE, a higher dose rate of 1.5 L/ha is recommended. Across all diseases, results from both winter and spring crops demonstrated comparable levels of control of these target diseases and have been combined to give an overall result to support the claims on both crops in the following table.

Summary of effectiveness data for GF-3307 for EPPO South-East Zone (barley data)

Target (EPPO code)	Crop (EPPO)	Dose rate	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min- max	Mean	min- max	Mean	min-max
RAMUCC	HORVW	1.5 L/ha	DE	5	35-39	55.0	7.1- 99.0	83.8	65.5- 97.9	83.1	63.0-95.1
	HORVS	1.5 L/ha	DE	3	31-39	34.8	5.0- 51.8	83.7	76.3- 90.0	61.7	45.0-71.1
	Both	1.5 L/ha	DE	8	31-49	47.4	5.0- 99.0	83.8	65.5- 97.9	75.1	45.0-95.1
	HORVW	1.25 L/ha	DE	2	35-37	78.0	7.1- 88.8	83.5	77.0- 96.3	77.9	63.0-92.7
	HORVS	1.25 L/ha	DE	3	31-39	34.8	5.0- 51.8	80.1	74.9- 90.0	61.7	45.0-71.1
	Both	1.25 L/ha	DE	5	31-39	40.0	5.0- 88.8	81.4	74.9- 90.0	68.2	45.0-92.7
RHYNSE	HORVW	1.5 L/ha	PL	6	32-52	18.7	5.6- 35.0	94.1	88.7- 100	90.3^	80.0-100
	HORVS	1.5 L/ha	PL	4	37-49	10.1	5.6- 17.8	97.9	92.1- 100	94.1^	78.7-100
	Both	1.5 L/ha	PL	10	32-52	15.3	5.6- 35.0	95.6	88.7- 100	91.8^	78.7-100
	HORVW	1.2-1.25 L/ha	PL	6	32-52	18.7	5.6- 35.0	89.5	80.0- 100	90.3^	80.0-100
	HORVS	1.2-1.25 L/ha	PL	4	37-49	10.1	5.6- 17.8	96.3	87.5- 100	94.1^	78.7-100

Target (EPPO code)	Crop (EPPO)	Dose rate	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min- max	Mean	min- max	Mean	min-max
	Both	1.2-1.25 L/ha	PL	10	32-52	15.3	5.6- 35.0	92.2	80.0- 100	91.8^	78.7-100
	HORVW	1.0 L/ha	PL	5	32-52	13.1	5.6- 22.5	82.7	59.2- 99.2	90.9^	78.7-100
	HORVS	1.0 L/ha	PL	4	37-49	15.5	5.6- 22.5	84.6	78.0- 98.5	88.4^	80.0-93.7
	Both	1.0 L/ha	PL	9	32-52	10.1	5.6- 17.8	80.4	59.2- 99.2	94.1^	78.7-100
PYRNTE	HORVW	1.5 L/ha	S-E	11	37-49	21.3	5.0- 42.5	86.1	80.1- 96.9	79.9	69.1-92.9
	HORVS	1.5 L/ha	S-E	3	39-49	22.4	9.5- 36.3	87.8	87.0- 88.9	78.6	71.3-84.8
	Both	1.5 L/ha	S-E	14	37-49	21.5	5.0- 42.5	86.4	80.1- 96.9	79.6	69.1-92.9
	HORVW	1.2-1.25 L/ha	S-E	11	37-49	21.3	5.0- 42.5	75.9	69.5- 87.8	78.6	71.3-84.8
	HORVS	1.2-1.25 L/ha	S-E	3	39-49	22.4	9.5- 36.3	83.7	79.9- 88.1	78.6	71.3-84.8
	Both	1.2-1.25 L/ha	S-E	14	37-49	21.5	5.0- 42.5	77.5	69.5- 88.1	79.9	69.1-92.9
PUCCHD	Both	1.5 L/ha	S-E	6	31-49	10.8	5.3- 16.9	92.0	89.0- 95.9	92.4^^	84.2-98.8
			PL	6	37-52	21.2	5.5- 47.5	96.6	89.9- 100	92.8^^^	84.8-100
	Both	1.2-1.25 L/ha	S-E	5	31-49	10.1	5.3- 16.9	90.3	88.0- 93.5	91.3^^	84.2-98.8
			PL	6	37-52	21.2	5.5- 47.5	94.8	87.2- 100	92.8^^^	84.8-100
	Both	1.0 L/ha	S-E	5	31-49	10.1	5.3- 16.9	85.3	76.3- 93.5	91.3^^	84.2-98.8
			PL	6	37-52	21.2	5.5- 47.5	86.2	77.6- 97.1	92.8^^^	84.8-100
ERYSGH	HORVW	1.5 L/ha	S-E	2	45-49	9.6	8.0- 11.1	84.4	84.0- 84.8	75.9	69.0-82.8
	HORVS		S-E	2	31-33	32.1	20.8- 43.3	87.3	81.9- 92.8	87.3	86.3-88.3
	Both		S-E	4	31-49	20.8	8.0- 43.3	85.9	81.9- 92.8	81.6	69.0-88.3
	HORVW		PL	2	39-43	15.9	9.5- 21.6	89.8	85.7- 93.9	84.0^^^	78.3-89.6
	HORVS		PL	3	32-52	15.1	8.3- 23.3	84.3	75.8- 90.3	82.1^^^	73.5-90.1
	Both		PL	5	32-52	15.3	8.3- 23.3	86.5	75.8- 93.9	82.9^^^	73.5-90.1
	HORVW	1.2-1.25 L/ha	S-E	2	45-49	9.6	8.0- 11.1	77.3	69.0- 85.5	75.9	69.0-82.8

Target (EPPO code)	Crop (EPPO)	Dose rate	EPPO Zone/ Country	Number of trials	Application timing (BBCH)	Untreated % infection		% control			
								GF-3307		Reference standard#	
						Mean	min- max	Mean	min- max	Mean	min-max
	HORVS		S-E	2	31-33	32.1	20.8- 43.3	86.2	81.0- 91.5	87.3	86.3-88.3
	Both		S-E	4	31-49	20.8	8.0- 43.3	81.8	69.0- 91.5	81.6	69.0-88.3
	HORVW		PL	2	39-43	15.9	9.5- 21.6	88.0	85.2- 90.8	84.0^^^	78.3-89.6
	HORVS		PL	3	32-52	15.1	8.3- 23.3	84.3	75.8- 90.3	82.1^^^	73.5-90.1
	Both		PL	5	32-52	15.3	8.3- 23.3	83.6	63.6- 93.5	82.9^^^	73.5-90.1

#Proline applied at 0.6-0.8 L/ha used a reference standard, unless specified, *Mean of 2 trials using Proline at 0.8 L/ha and one trial using Delaro at 0.75 L/ha.

^Aviator Xpro at 0.8-1.0 L/ha applied as the reference standard, ^^Reference standards used based on Proline 250 (P) applied at 0.72-0.8 L/ha

^^^Reference standards used based on Proline 250 (P) applied at 0.72-0.8 L/ha and Prosaro (PO) applied at 0.75 L/ha.

On winter barley (HORVW) and spring barley (HORVS) a single dose of 1.25 L/ha of GF-3307 achieved 81.4% control of RAMUCC across 5 German trials. The proposed maximum dose rate of 1.5 L/ha demonstrated 83.8% control of RAMUCC across 8 German trials. It is considered that data from this region are a robust (and worst case) test of the product. In the EPPO South-East climatic zone, the climatic conditions are less conducive to the development of RAMUCC and this is a relatively minor disease in this region. It is considered that these data full support claims for control of RAMUCC on both crops in the EPPO South-East climatic zone, with the maximum dose used in high disease pressure situations.

On winter barley (HORVW) and spring barley (HORVS) the lower dose of 1.0 L/ha of GF-3307 achieved 80.4% control of RHYNSE across nine Polish trials. The 1.2/1.25 L/ha dose achieved 92.2% control of RHYNSE across 10 Polish trials. The proposed maximum dose rate of 1.5 L/ha demonstrated 95.6% control across the same trials. The climate in Poland, as a neighbouring country, is similar to the EPPO South-East climatic zone (i.e., hot summers), but is slightly wetter than in the EPPO South-East climatic zone. It is therefore considered that trials from Poland represent a more robust test of the product against RHYNSE, so these data can be used to support use in the EPPO South-East climatic zone. It is considered that these data fully support claims for control of RHYNSE on both crops in the EPPO South-East climatic zone, with the lower dose used where RHYNSE is the only disease and maximum dose used in high disease pressure situations.

On winter barley (HORVW) and spring barley (HORVS) a single dose at the proposed maximum dose of 1.5 L/ha of GF-3307 achieved 86.4% control of PYRNTE across 14 EPPO South-East climatic zone trials (86.1% control across 11 trials on HORVW and 87.8% control across 3 trials on HORVS). Where disease levels are low, the 1.2 L/ha dose could be used, as this provided effective control (77.5%) of PYRNTE in this situation (75.9% control across 11 trials on HORVW and 83.7% control across 3 trials on HORVS at 1.2/1.25/ ha).

Based on six EPPO South-East climatic zone trial results, demonstrating mean overall control of PUCCHD in barley of 92.0% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of PUCCHD is fully supported. The 1.5 L/ha dose is considered to be appropriate for situations where other diseases such as PYRNTE are present/expected or where season long control is required. In other situations, a lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated 90.3% control across five trials at 1.2/1.25 ha. For low disease risk situations, the lowest dose in the proposed range of 1.0 L/ha is considered appropriate, as this demonstrated 85.3% control across five trials. Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the later stages of the crop/summer that encourage the development of PUCCHD (hot and dry weather). Data from these trials (a mix of

HORVS and HORVW trials) demonstrate comparable levels of control: 95.9% for the 1.5 L/ha dose, 93.7% for the 1.2/1.25 L/ha dose and 86.9% for the 1.0 L/ha dose.

Based on four EPPO South-East climatic zone trial results, demonstrating mean overall control of ERYSGH in barley of 85.9% from a single application of GF-3307 at 1.5 L/ha, it is considered that the proposed claim for control of ERYSGH is fully supported. The 1.5 L/ha dose is considered to be appropriate for situations where other diseases such as PYRNTE are present/expected or where season long control is required. In other situations, a lower dose of 1.2 L/ha is considered appropriate, as this has demonstrated 81.8% control across these four trials at 1.2/1.25 ha. Supporting data are available from five Polish trials. Poland is a neighbouring country which has similar climatic conditions in the middle stages of the crop development/early summer that encourage the development of ERYSGH (warm and humid weather). Data from these trials (a mix of HORVS and HORVW trials) demonstrate comparable levels of control: 86.5% for the 1.5 L/ha dose and 83.6% for the 1.2/1.25 ha dose.

Across all diseases, results on both winter and spring crops are comparable and it is therefore considered that all data fully support use on both winter and spring crops.

Across all data-sets the control achieved by the GF-3307 was comparable to, or higher than, the reference standards and not statistically different in the majority of cases.

GF-3307 at the proposed label rate dose range of 1.0-1.5 L/ha had an overall positive effect on grain yield and quality of crops treated in the presence of disease.

It is considered that the proposed GAP for countries of the EPPO South-East climatic zone of the Central EU Authorisation zone is fully supported.

zRMS comments on Efficacy results:

The preceding part, 3.2.3.18 “*Summary and conclusions on effectiveness (all crops and disease claims)*”, provides the review of the efficacy results by the applicant, and the number of trials supporting the uses claimed. The zRMS confirms that the uses listed below, and the respective dose rates or dose ranges, are, with few exceptions for trial location, supported by the sufficient number of trials. Where a situation is ambiguous an explanation is provided, and the decision is left to the respective cMSs. The application interval proposed in the GAP table (BBCH 30-69) reflects, and is supported by, the experimental conditions of the submitted trials. The right-hand column of the GAP table has been marked respectively, according to the zRMS acceptance of the individual uses.

Uses supported in the EPPO Maritime zone

In **winter¹⁾ wheat** in control of SEPTTR, PUCCRT, PUCST, FUSASP, PYRNTR and ERYSGT¹⁾, at 1.5 L/ha,
in **winter rye** in control of PUCCRE and RHYNSE, at 1.5 L/ha,
in **winter triticale** in control of SEPTSP, ERYSGT and PUCST, at 1.5 L/ha,
in winter and spring **barley** in control of RAMUCC, RHYNSE, PUCCHD and ERYSGH, at 1.5 L/ha,
in **winter barley** in control of PYRNTE, at 1.5 L/ha.

Uses supported in the EPPO North-Eastern zone

In winter and spring **wheat** in control of SEPTTR and ERYSGT, at 1.0-1.5 L/ha,
in control of PUCST and PYRNTR, at 1.2-1.5 L/ha,
in **winter wheat** in control of PUCCRT at 1.2 – 1.5 L/ha and in control of FUSASP²⁾, at 1.5 L/ha,
in **winter rye** in control of PUCCRE and RHYNSE at 1.2-1.5 L/ha,
in **winter triticale** in control of SEPTSP, ERYSGT and PUCST, at 1.2 - 1.5 L/ha,
in spring triticale in control of PYRNTR and PUCCRT, at 1.2 - 1.5 L/ha,
in winter and spring **barley** in control of RHYNSE and PUCCHD at 1.0 - 1.5 L/ha, and in control of PYRNTE and ERYSGH at 1.2 – 1.5 L/ha.

Uses supported in the EPPO South-Eastern zone

In **winter wheat** in control of SEPTTR at 1.0-1.5 L/ha,
In **winter wheat** in control of PUCCRT, PUCST, PYRNTR and ERYSGT¹⁾, at 1.2-1.5 L/ha, and in control of FUSASP - at 1.5 L/ha *,
in winter and spring **barley** in control of RAMUCC **, PYRNTE and ERYSGH at 1.2-1.5 L/ha and in control of RHYNSE*** and PUCCHD at 1.0 - 1.5 L/ha.

Data from **spring wheat** are scanty across the entire dossier: they include 4 trials overall from the North-Eastern EPPO zone alone: 1 trial in LV (2014) and 3 - in PL (2016, 2020, 2021). To the opinion of zRMS the spring wheat data can support, by extrapolation from winter wheat, the uses against ERYSGR, PUCCST, PYRNTR and SEPTTR, in the North-Eastern EPPO zone, whereas the concerned member states Czech Republic, Slovakia and Romania are kindly invited to consider whether they can accept these uses based on extrapolation or based on the minor crop status of TRZAS, in their countries.

No data from **durum wheat** or **spelt wheat** have been submitted, neither those from the **spring rye** (SECCS) or **spring triticale** (TTLSO), from any location of the Central zone. Uses in these crops may be approved based on the extrapolation from winter forms, or based on the art. 51, in the member states in which these spring forms are considered as minor crops. The concerned member states are kindly invited to take their respective decisions individually.

No data on control of **powdery mildew on winter rye** have been submitted. Since *B. graminis* f. sp. *secalis* has no ability to infect triticale, whereas *B. graminis* f. sp. *triticales*, defined based on infection tests (Menardo et al. 2016, see at the bottom of this box), has very little potential to infect rye, to the opinion of zRMS there is rather faint grounds to extrapolate ERYSGR data from triticale to rye, as two different strains are indeed considered here and there. Therefore the use is not approved in the zRMS country. The concerned member state Czech Republic may certainly take their own decision on the powdery mildew use in winter rye, bearing in mind that the use is mentioned directly nowhere in the dRR text, except that it is listed in the GAP table. Fungi causing powdery mildew are not the main target of GF-3307 as most of the control is provided by the triazole component and not by fenpicoxamid.

¹⁾ No ERYSGT data from TRZAS are available from the Maritime and from the South-Eastern EPPO zones, therefore the decision on extrapolation to spring wheat is left to the cMSs in these zones.

²⁾ The only NE zone trial in TRZAS showing FUSASP control data is LV14E7B012MN01C, demonstrating PESSEV on the UNCK plots 0.9% and 4.1%, on 34DAA and 50 DAA, respectively.

* The use against FUSASP is supported by 3 trials in HU, and 8 trials from AT and PL altogether. Although the applicant's rationale on the climatic conditions in AT and PL being more favourable for *Fusarium* development is accepted, by the zRMS, not all of the MSs of the EPPO South-Eastern zone may feel equally "neighbouring" Austria or Poland, where the trials in question had been carried out. Therefore, the final decision on the approval of this use in Slovakia and in Romania is kindly left for consideration of these member states, as much as the decision on extrapolation, of this use, to the spring wheat.

** The use against RAMUCC in barley in the SE zone is proposed by the applicant based on Maritime zone data alone, therefore the decision on the approval is left to the cMSs of Romania and Slovakia.

*** The use against RHYNSE in barley in the SE zone is proposed by the applicant based on the 10 PL trials, therefore the decision on the approval is left to the cMSs of Romania and Slovakia.

Menardo F., Praz C.R., Wyder S., Ben-David R., Bourras S., Matsumae H., McNally K.E., Parlange F., Riba A., Roffler S., Schaefer L.K., Shimizu K.K., Valenti L., Zbinden H., Wicker T., Keller B. **2016**. Hybridization of powdery mildew strains gives rise to pathogens on novel agricultural crop species. **Nature Genetics** **48** (2): 201–205.

zRMS comments on Yield results:

The test item GF-3307, when applied at all the proposed label rates of 1.0 - 1.5 L/ha across the EPPO Maritime, North-Eastern and South-Eastern climatic zones, had demonstrated positive effect on yield amount and quality in wheat, barley, triticale and rye crops. The effect on the grain yield was most apparent in wheat, where > 20% increase was observed on average, compared to UNCK. In barley, triticale and rye the yield increase was slightly weaker, but still 2-digit values were harvested. In the two other parameters, TGW and HLWT, the increase by 1-digit values was recorded.

All parameters were respectively lower (down to 1-digit-only grain yield increase) from plots treated with the lower doses of the range requested, in the NE and SE EPPO zones, yet they were, most of the time, still higher compared to the UNCK.

Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

zRMS comments:

The resistance chapter has been re-arranged or – precisely speaking – re-written, by the applicant, in the course of the updating (32 pages following the update *versus* original 11 pages), yet not all of the amended parts have been marked clearly. Therefore the natural solution (and the one most reader-friendly) was to ~~struck through the original text~~ and mark the new chapter's content by the orange font completely.

The struck through and shaded text part below this commenting box represents the version of the chapter before updating, while the updated chapter starts in the page 493.

Summary

~~GF 3307 150 g/L EC is a co-formulation containing 50 g/L of fenpicoxamid (DE 777) and 100 g/L of prothioconazole and is effective against foliar diseases of cereals. This section follows the guidance laid out in EPPO Guideline PP1/213(4) in order to determine the resistance risk associated with the product and the target pathogens.~~

~~Fenpicoxamid is a fungicide with a mode of action belonging to the picolinamide class of chemistry with primary activity on ascomycete and basidiomycete pathogens in cereals. It is a potent inhibitor of fungal respiration acting via binding to the Quinone Inside (Qi) site of the cytochrome bc₁ (ubiquinone reductase) complex (complex III) in the electron transport chain. Fenpicoxamid belongs to the FRAC resistance group 21, Mode of Action group C4.~~

~~Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventative and eradicated action. The biological mode of action of prothioconazole has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi. At the target site level prothioconazole inhibits C-14 demethylase and belongs to the group of compounds collectively termed as Demethylation Inhibitors (DMIs). The molecule is classified by FRAC in group 3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51)).~~

~~Studies indicated that fenpicoxamid is not cross resistant with other fungicide classes, including DMI fungicides. Also, fungicides affecting ergosterol biosynthesis are not cross resistant with fungicides inhibiting other biochemical target sites. On the other hand, for the purposes of effective resistance risk management it is prudent to consider that cross resistance is present between DMI fungicides (including prothioconazole) active against the same target disease.~~

~~Sensitivity baselines have been established for fenpicoxamid on *Zymoseptoria tritici*, *Puccinia recondita tritici*, *Ramularia collo-cygni* and *Pyrenophora teres*, using isolates from different European countries.~~

~~The mode of action of GF 3307 150 g/L EC on target pathogens as well as a recent history of resistance to DMI groups suggest that the risk of development of resistance in high and medium risk pathogens of the unrestricted use is unacceptable and that measures must be taken to prevent or at least delay the risk of resistance developing. A resistance management strategy is proposed which relies on the use of tank mixtures, alternation with other fungicides with a different mode of action and limiting the number of GF 3307 150 g/L EC applications to one per season. Such recommendations are aligned with those published by the Fungicide Resistance Action Committee (FRAC). It is considered that with these modifiers in place the risk is reduced to an acceptable level.~~

Introduction

~~GF 3307 150g/L EC is a co-formulation of 50g/L of fenpicoxamid + 100g/L of prothioconazole and will be registered for use against a range of cereal diseases including: SEPTTR/SEPTSP in wheat and triticale, PUCCSP in wheat, rye, triticale and barley, RHYNSE on rye and barley, ERYSSP in wheat, triticale and barley, PYRNTE and RAMUCC in barley.~~

~~Fenpicoxamid has been combined with prothioconazole in order to broaden spectrum of control and to build in resistance management by combination of two different modes of action (MOAs). This dossier section will mainly concentrate on analysis of resistance risk to fenpicoxamid since this will be a new active substance in barley in Europe whereas prothioconazole and its associated resistance risk~~

is well understood. The applicant also refers the assessing authority to data submitted in support of prothioconazole efficacy and resistance risk management by Bayer Crop Sciences to which Dow AgroSciences has been granted a letter of access.

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide resistant population develops because the sensitive population is suppressed and the rare fungicide resistant individual is allowed to multiply and occupy the biological niche previously filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the nature of the pathogen and its interactions with the crop, environment and fungicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term “resistance” be limited to situations where the conditions in both (a) and (b) below are met:

—— (a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and

—— (b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity.

From a regulatory and product stewardship standpoint it is essential to evaluate the potential resistance risk posed by a product and to ensure that a practical and effective management strategy is put in place in order to mitigate against the potential risk. The resistance risk analysis for GF 3307 presented within this section follows the requirements set out in EPPO Guideline PP1/213(2).

Mode of Action:

Prothioconazole.

The biological mode of action of prothioconazole has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi (Parker et al. 2011). Ergosterol is a unique component of the membrane of fungi, the inhibition of its biosynthesis makes the cell membrane rigid and leaky, so that the pathogen's hyphae cannot grow and infect the plant. At the target site level prothioconazole inhibits C 14 demethylase of ergosterol precursors, which then accumulate at the expense of ergosterol and belongs to the group of compounds collectively termed as De Methylation Inhibitors (DMIs). The molecule is classified by FRAC in group 3 (G1, C 14 demethylase in sterol biosynthesis (erg11/cyp51).

Fenpicoxamid – DE-777.

Fenpicoxamid (XDE-777) is the first and to date only member of a new picolinamides class of fungicides representing a novel mode of action within the cereal fungicide segment. Its target site has been identified as the Quinone Inside (Qi) site of the cytochrome *bc*1 (ubiquinone reductase) complex (complex III) in the electron transport chain.

This target site was confirmed by a combination of previously published literature references, biochemical and molecular genetics studies. Biochemical binding assays were performed on a range of fungi including *Zymoseptoria tritici* (SEPTTR) whilst molecular genetic studies were performed using chemically induced resistant mutants of *Saccharomyces cerevisiae* (SACCCE).

Summary

Aside from the literature publications around UK 2A MOA, additional evidence generated by Dow AgroSciences in support of the likely biological and biochemical (target site) MOA of DE-777 include the following.

(1) — DE 777 / UK 2A were both active in inhibiting mitochondrial respiration in cell free mitochondrial preparations from a wide range of fungi, as well as wheat and bovine heart. Fungal species could be categorized in two groups based on target site sensitivity: a highly sensitive group comprising SEPTTR, LEPTNO, PYRIOR and BOTRCL, and a less sensitive group which included GIBBZE, USTIMA and PLASVI.

(2) — At the cellular level, DE 777 and UK 2A caused a rapid partial depolarization of mitochondria, which is characteristic of complex III inhibition.

(3) — Further evidence for the target site of UK 2A was demonstrated in the model organism SACCCE by isolation of cytochrome *b* mutants with 3 distinct mutations involving amino acids which are highly conserved between species. Clustering of these mutations at the Qi site, and cross resistance to Antimycin A, confirmed binding of UK 2A to the Qi site.

Mechanism of Resistance—Evidence of Resistance

~~Individual active substance components of the combination—GF-3307.~~

~~Prothioconazole~~

As previously mentioned prothioconazole is known to rely on the inhibition of demethylation at the C-14 position in fungal sterol biosynthesis (DMI). In excess of 30 DMI fungicides are currently commercialised although prothioconazole is in relative terms a more recent introduction from this group of inhibitors. Prothioconazole is a triazolinthione as opposed to triazole. Work in yeast has shown prothioconazole only weakly inhibits Cyp51 and it requires metabolism to the triazole form prothioconazole-desthio in order for significant inhibition to occur i.e. the IC₅₀ of prothioconazole is 100 times higher than the desthio form (Parker et al. 2011). Available information on mode of action and resistance risk with this class of inhibitors is probably the most complete of any fungicide group. Numerous publications are available on the mechanisms functioning with respect to DMI resistance. The resistance risk of DMI fungicides including Prothioconazole is classified by FRAC as medium. The applicant also refers the assessing authority to specific data generated by Bayer Crop Sciences supporting the resistance risk and effect of Cyp51 mutations on prothioconazole efficacy and resistance risk management—to which Dow AgroSciences has been granted a letter of access.

Ergosterol is the sterol predominating in fungal membranes serving a similar function to that of cholesterol in animals. The critical presence of ergosterol in fungi and its absence from humans and other mammals make it a useful target for fungicides. Prothioconazole and other demethylase inhibitor (DMI) fungicides block ergosterol biosynthesis in plant pathogenic fungi by inhibiting the cytochrome P 450 sterol 14 α demethylase protein, also called eburiol 14 α demethylase or CYP51, a key enzyme in the sterol biosynthetic pathway (Horne and Holloman 1997).

Reduced sensitivity in plant pathogenic fungi to DMI fungicides has been reported in the field in numerous plant pathogens⁷. Several mechanisms are involved, including alterations in the target site, over expression of the target gene and fungicide export from fungal cells before reaching the target site. A combination of these mechanisms can occur in the same fungal species, for example the combination of over expression and different target site mutations was found in Brazil on *Phakopsora pachyrhizi* of soybeans (Schmitz et al. 2014) and on *Puccinia triticina* in Europe, where the Y134F mutation in the cyp51 gene or cyp51 overexpression was detected (Stammler et al, 2009).

Alterations in the target site. In regard to altered target site, more than 20 mutations, deletions or substitutions in the target CYP51 gene have been reported to affect sensitivity to various DMI fungicides (HGCA, Understanding evolution and selection of azole resistance mechanisms in the United Kingdom population of *Mycosphaerella graminicola*, HGCA website <http://hgca.com>, Cools et al. 2006.) Much of the research on target site mutations affecting DMI sensitivity in fungi has been conducted on the human pathogen *Candida albicans* (Marichal et al. 1999) and the non pathogenic yeast *Saccharomyces cerevisiae* (Sanglard et al. 1998). But reduced sensitivity in plant pathogenic fungi to DMI fungicides due to alterations in the target site has been reported, inter alia, in *Uncinula necator* (Delye et al. 1997), *Blumeria graminis* (Delye et al. 1998, De Waard et al. 1986, Wyand and Brown, 2005), *Oculimacula* spp.(Albertini et al. 2003, Wood et al. 2001, Dyer et al. 2000), and *Mycosphaerella graminicola* (Mavroedi and Shaw, 2005, Fraaije et al. 2007). Combinations of various CYP51 mutations, deletions and often other resistance mechanisms, however, may result in significant

⁷ www.frac.info FRAC List of Plant Pathogenic Organisms Resistant to Disease control agents, 2018

shifts in sensitivity as well as efficacy under practical field conditions (Stergiopoulos et al. 2003). No single mutation conferring high levels of DMI resistance has conclusively been identified and consistently associated with reduced field performance.

Over-expression of the target gene. Evaluation of isolates of *Venturia inaequalis* with variation in sensitivity to myclobutanil indicated that sensitivity differences were not correlated with mutations in the CYP51 gene but were associated with higher levels of gene expression (Schnabel and Jones, 2001). Higher levels of 14 α demethylase in fungal cells presumably would require greater concentrations of fungicide for inhibition. Over expression of the target gene has also been reported for the isolates of the human pathogen *Candida albicans* with reduced sensitivity to fluconazole (White, 1997) and in DMI resistant field isolates of *Sclerotinia homoeocarpa* were induced to express ShCYP51 at significantly higher levels than baseline isolates in the presence of propiconazole (Ma and Tredway, 2014).

Transporter mediated efflux. Simultaneous resistance to many unrelated inhibitors conferred by a single gene, often referred to as multi drug resistance, has been reported in a wide range of organisms against several diverse inhibitor classes. The mechanism of reduced sensitivity is active efflux of the inhibitor from the fungal cell before reaching the target site, mediated by products of either ABC transporter or major superfamily transporter genes. Interestingly, these same genes have been associated with pathogenicity and virulence in plant pathogenic fungi (Roohparvar et al. 2007). Transporter mediated efflux has been implicated in reduced sensitivity to DMI fungicides in several fungi including *Mycosphaerella graminicola* (Zwiers et al. 2002) and *Pyrenophora tritici-repentis* (Reimann and Deising, 2005).

Since the mid 1980's, reports of decreased levels of field efficacy have been attributed to reduced levels of sensitivity in target populations for DMI fungicides (Fletcher and Wolfe, 1981). Several studies have shown that shifts toward reduced sensitivity to DMI fungicides follow a quantitative or progressive pattern typical of changes controlled by several genes (Berg et al. 1990). Unlike benzimidazole and QoI fungicides for which the resistance is qualitative or disruptive (i.e. higher rates may not control resistant strains and field activity is lost), the development of less sensitive strains with DMI fungicides is quantitative or progressive. Higher rates can offset a slight decrease of activity. According to a recent report from FRAC⁷, naturally occurring isolates from the field with reduced sensitivity to DMI fungicides now have been reported for numerous plant pathogenic fungi. For cereals crops in which prothioconazole currently is used, reduced sensitivity to DMI fungicides has been reported for the majority of the target diseases for GF-3307.

***Zymoseptoria tritici* (SEPTTR).** SEPTTR has adapted to a number of different fungicides in recent years such as the Methyl Benzimidazole Carbamates (MBCs) (target site mutations in β tubulin gene); DMIs (reduced sensitivity based on several mechanisms, including target site mutation) (Cools and Fraaije, 2012, Cools et al 2011) and QoIs (G143A and F129L mutation in cytochrome b gene) (Clark, 2005). FRAC designates SEPTTR as a pathogen with a medium risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version)

SEPTTR is also not amongst the pathogens listed in EPPO guidance document PP1/213(2) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance although the closely related *Mycosphaerella fijiensis* is mentioned. SEPTTR is also not mentioned in EPPO guidance document PP1/213(2) in Appendix III Table 2 as a pathogen for which sensitivity data should normally be provided. However as fenpicoxamid will be a new active substance for use in the SEPTTR segment in Europe DAS considers baseline data essential and a full package of data will be submitted in this dossier (see section 3.3.5).

***Puccinia triticina* (PUCCRT).** Reports of resistance development to both PUCCRT and PUCGST are very infrequent in the literature. A review of (Fungicide Resistance Action Committee (FRAC) List of Pathogenic Organisms resistant to Disease Control Agents – 2013 revision) references only one publication reporting a sensitivity shift with PUCGST to DMI fungicides as measured in the laboratory (Bayles et al, 2000). The 2014 report of the FRAC SBI WG (<http://www.frac.info/docs/default-source/sbi-wg/sbi-wg-current/minutes-of-the-2014-meeting-recommendations-for-2015.pdf?sfvrsn=2>) states that “good field performance of DMIs against rust was maintained and sensitivity data from 2014 for brown rust showed that sensitivities were within the range of the previous 10 years”.

FRAC designate both PUCCRT and PUCST as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). PUCCRT and PUCST are also not amongst the pathogens listed in EPPO guidance document PP1/213(2) as an example of pathogens considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated. However as fenpicoxamid will be a new active substance for use in the PUCCRT and PUCST segment in Europe DAS considers baseline data essential and a full package of data will be submitted in this dossier on PUCCRT (see section 3.3.5).

***Pyrenophora tritici-repentis* (PYRNTR).** Reports of resistance development to QoI inhibitors in PYRNTR in the field have been reported from Germany, Sweden and Denmark (Jorgensen and Olson, 2007). Reimann and Deising (2005) have also reported detection of isolates of PYRNTR with reduced sensitivity to both DMIs and QoIs from fields in Germany treated with reduced doses of fungicide. The mechanism underlying this reduced sensitivity is based on an energy dependent active efflux transporter. FRAC designates PYRNTR as pathogen with a medium risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). PYRNTR is also not listed in EPPO guidance document PP1/213(2) as an example of a pathogen considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated.

Fusarium Head Blight. FRAC designates *Fusarium* spp. as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). *Fusarium* spp. in wheat are also not listed in EPPO guidance document PP1/213(2) as being considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated. Resistance of *Fusarium graminearum* to benzimidazoles and DMIs has only been reported from laboratory studies (Chen, *et al.* 2009, Yin *et al.* 2009 respectively) although no details were provided as to the resistance mechanism operating in each case.

Blumeria graminis (De Waard *et al.* 1986; Wyand and Brown, 2005). The primary mechanism of reduced sensitivity in field isolates of *B. graminis* f. sp. *tritici* in wheat and *B. graminis* f. sp. *hordei* in barley are mutations in the target CYP51 gene. The Y136F mutation has been found in both wheat and barley while another mutation K147Q was found only in barley. Y136F alone confers low levels of resistance but may result in higher resistance levels if present in combination with K147Q. Research also indicated that target site mutations were not the only resistance mechanism present in *B. graminis*. FRAC designates ERYSGH as a pathogen with a high risk of developing resistance to fungicides 7. ERYSGH is also amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

Pyrenophora teres (Sheridan *et al.* 1985; Locke, 1996, 2000) . No specific mechanisms of reduced sensitivity have been reported in field populations of *P. teres*, but slight shifts toward reduced sensitivity were reported in the United Kingdom in the late 1990's after prolonged use of DMI fungicides. Later research, however, reported that sensitivity had stabilized, and that field performance generally remained acceptable. FRAC designates PYRNTE as a pathogen with a medium risk of developing resistance to fungicides (FRAC Pathogen Risk List 2019; https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2). PYRNTE is also not amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

Rhynchosporium secalis (Hunter *et al.* 1986; Kendall and Hollomon, 1990; Kendall *et al.* 1993; Cooke *et al.* 2004). Although no specific mechanisms of reduced sensitivity have been reported in *R. secalis*, significant shifts toward reduced sensitivity and field performance in DMI fungicides have been observed in the United Kingdom. Prior to the early 1990's, combinations of DMI fungicides with benzimidazoles like carbendazim were highly effective for both disease control and resistance management. But widespread resistance to benzimidazoles resulted in use of DMI fungicides alone until introduction of new fungicides with different biochemical target sites like the QoI fungicides (e.g. azoxystrobin) and anilinopyrimidines (e.g. cyprodinil). Shifts toward reduced DMI sensitivity were greater when reduced rates were used. Addition of an effective mix partner with a different site of action, however, reduced the selection of DMI resistant strains. FRAC designates RHYNSE as a pathogen with a low risk of developing resistance to fungicides (FRAC Pathogen Risk List 2019; https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2).

2019.pdf?sfvrsn=caf3489a_2). RHYNSE is also not amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

Ramularia collo-cygni. FRAC designates RAMUCC as a pathogen with a high risk of developing resistance to fungicides (FRAC Pathogen Risk List 2019; https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2). RAMUCC is also amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

As shifts toward reduced sensitivity to DMI fungicides have been reported in some economically important diseases, each year the FRAC webpage provides information on the evolution of geographic distribution and frequency of resistance to DMI fungicides across Europe.

Resistance of RAMUCC to DMI fungicides has been reported by FRAC. In 2016, a broad sensitivity range has been identified with very high frequency of highly resistant strains in southern Germany, with moderate frequency in Denmark, Ireland, Belgium, North-western Germany, and low frequency detected in France, Austria, Sweden, and United Kingdom. No detection of resistance in Estonia

The following information on the resistance status of various pathogens (for which control is claimed on the GF 3307 label) is available, from the Sterol Biosynthesis Inhibitor (SBI) Working Group (2018 meeting), FRAC (Fungicide Resistance Action Committee)⁸:

Powdery mildew (*Blumeria graminis* f.sp. *hordei*) – Barley

No monitoring was carried out in 2017, monitoring data presented for 2018. In 2018, disease pressure was low in Europe. Monitoring was carried out in Czech Republic, Denmark (2016), France, Germany, Latvia, Sweden (2016), Ukraine, and United Kingdom. DMI products performed well. The sensitivity of the populations stayed in the range observed for more than 15 years. Reduced sensitivity was reported in barley powdery mildew in western and eastern Australia (ACNFP/Curtin University) in 2014. For latest resistance monitoring data on prothioconazole refer to Bayer Crop Science when Dow AgroSciences has a letter of access.

Leaf blotch (*Rhynchosporium secalis*) – Barley

Disease pressure was extremely low in Europe in 2018. Field performance of DMIs was good. Monitoring was carried out in Denmark, France, Germany, Ireland, Poland, and United Kingdom. The sensitivity of the populations stayed in the range observed in the previous 15 years.

Net blotch (*Pyrenophora teres*) – Barley

Disease pressure was generally low in 2018. Performance of SBI-containing spray programmes was good.

Monitoring was carried out in Belgium, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Poland, Romania, Spain, Switzerland, and United Kingdom.

In 2017 in France significant shifts of sensitivity of populations have been observed. Highest EC50 values were observed in areas of elevated disease pressure, often coupled with a reported reduced variety resistance at significant cultivation areas, and sub-optimal use of azoles in spray programs (e.g. reduction of rates in comparison to the manufacturer's recommended rate and inappropriate use of effective mix partners).

In general, over the past years a significant fluctuation in sensitivity levels between the years was detected. In 2017 in single locations in Germany there have been seen some shifting which needs to be observed in the next season. The monitoring in the other countries showed a stable situation in 2017 within the regular fluctuation.

The monitoring of the last 20 years showed a certain level of fluctuations of the sensitivity level in the regions over the years. In 2018, the situation stabilized again in all countries including France and Germany, thus being comparable to the long term monitoring results.

***Ramularia* leaf spot (*Ramularia collo-cygni*) – Barley**

Disease pressure was low in 2018. Monitoring was carried out in Austria, Belgium, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, Switzerland, and United Kingdom.

⁸—https://www.frac.info/docs/default-source/sbi-wg/sbi-wg-current/minutes-of-the-2018-sbi-telco-meeting-recommendations-for-2019-6th-of-june-20197efe292e512362eb9a1eff00004acf5d.pdf?sfvrsn=d6dd4b9a_2

Field performance can be regionally significantly affected, due to the low disease pressure hard to evaluate in 2018.

Isolates were detected showing significant loss of sensitivity. Relevant CYP51 mutations explaining the effects have been identified (I325T, I328L, Y403C/Y405H).

2016: broad sensitivity range has been identified with very high frequency of high resistant strains in southern Germany, with moderate frequency in Denmark, Ireland, Belgium, North western Germany, and low frequency detected in France, Austria, Sweden, and United Kingdom. No detection of resistance in Estonia.

First data from 2016 showed high frequency of resistant strains in Denmark, Ireland, and United Kingdom, moderate frequency in Estonia, low to moderate frequency in Sweden, and no resistant strains were detected in Finland. In other countries the monitoring is still ongoing, the results will be reported later.

In 2018 the results are:

- no isolates with the above mentioned mutations detected in Switzerland, Spain and Italy, and Sweden.
- no to high frequency in Denmark,
- low to moderate frequency in single samples from Austria, France, Hungary,
- low to high frequency in Germany,
- moderate to high frequency in Belgium, Netherlands, United Kingdom, Ireland, and Latvia.

Given that there already exist populations in Europe resistant to all the main specific modes of action, it is recommended to add as a precaution, a multi site fungicide mode of action, to ensure robust disease control and an effective resistance management.

Leaf rust (*Puccinia hordei*) – Barley

Monitoring was carried out in 2014 and 2018 by Bayer in Denmark, France, Germany, Sweden, and United Kingdom. Very stable situation with a narrow range of sensitivity in this four year interval.

Fenpicoxamid (DE-777)

Since DE 777 will represent the first and only current example of a QiI inhibitor in the barley fungicide segment there is of course no history of selection pressure from this mode of action on European field populations of any of the target diseases

Amisulbrom and Cyazofamid are the only current examples of QiI inhibitors in commercial use although they are relatively narrow spectrum and solely restricted to control of Oomycete pathogens. FRAC classifies both molecules into group 21 target site and code C4 (complex III, cytochrome *bc_L*, (ubiquinone reductase) at Qi site). FRAC currently recommends the following for molecules in group 21: “Resistance risk unknown but assumed to be medium to high (mutations at target site known in model organisms). Resistance management required No spectrum overlap between fenpicoxamid and oomycete fungicides cyazofamid and amisulbrom.”⁹.

In addition, FRAC has also published the specific guidance on resistance risk for fenpicoxamid. (Group 21 (C4) fenpicoxamid (QiI) Recommendations 17th April 2019)¹⁰: “Field resistance not currently known to this molecule. Resistance risk unknown but assumed to be medium to high risk. Resistance management required.

A single publication (Kousik and Keinath, 2008) reported detection of insensitivity to cyazofamid in field isolates of *Phytophthora capsici* in the SE of the US. No details about the likely mechanism for reduced sensitivity were reported.

The literature reports on single point mutations in cyt b conferring resistance to QiI inhibitors (specifically Antimycin A) in SACCCE and bacteria (Brasseur et al 1996 and Di Rago and Colson, 1988). Also as demonstrated in section 3.3.1 we have been able to generate point mutations in SACCCE which result in resistance factors of between 57 and 99.7. In addition, the single point G37V mutation in cytochrome *bc_L* has also been reportedly generated in SEPTTR following repeated exposure to Antimycin A on YGB agar plates (Fehr et al. 2015). This isolate was not cross resistant to either the QoI inhibitors pyraclostrobin or azoxystrobin or the QoSI inhibitor stigmatellin. It did

⁹ FRAC Code List, 2019 version https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2019.pdf?sfvrsn=98ff4b9a_2

¹⁰ [https://www.frac.info/docs/default-source/other-fungicide-recommendations/group-21-\(c4\)-fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=aad54b9a_2](https://www.frac.info/docs/default-source/other-fungicide-recommendations/group-21-(c4)-fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=aad54b9a_2)

however show reduced sensitivity to Antimycin A (RF=176). No information was reported as to the fitness of this mutant and hence its significance if any to a field population situation is unclear. In addition Dow AgroSciences is continuing to undertake additional lab studies exploring potential resistance mechanisms to fenpicoxamid using SEPTTR as a test organism. Pressurization studies involving continuous selection in amended growth media yielded lab mutants with resistance factors of around 60 vs fenpicoxamid. (Fouche, 2019). *Cytb* gene sequences displayed no polymorphism except for one single point mutation that led to the substitution of glycine in position 37 by valine. This amino acid is located at the ubiquinone inner binding site (Qi site) and the G37V change was the only one found in all resistant strains selected by experimental evolution. Whether or not this mutation can also occur in barley pathogens remains unknown. The likelihood of selection under field conditions also remains unknown. Future work will explore the impact of G37V on strain pathogenicity and fitness at both the organism and enzyme level.

Cross Resistance

What is cross resistance? Assessing patterns of cross resistance both between different fungicide classes as well as among members of the same class is an important element in the understanding of resistance risk and risk management. Cross resistance means a correlation in sensitivity within a group of inhibitors toward specific pest targets, while absence of cross resistance indicates no correlation in sensitivity within the group. In the case of target site mutations that reduce sensitivity to specific inhibitors, if sensitivity to other inhibitors against the same target also is reduced, then those compounds exhibit positive cross resistance (or just “cross resistance”). In the case where reduced sensitivity to one inhibitor results in increased sensitivity to other inhibitors, however, those groups exhibit negative cross resistance. Confirmation of positive or negative cross resistance depends only on the directions of sensitivity shifts and not on their magnitude. Identification of patterns of positive cross resistance is important in resistance risk assessment because use of these fungicides together may represent increased selection pressure and a greater risk of resistance development and spread. Patterns of negative cross resistance, although rarer, also may be important since they may be used to reduce selection pressure and reduce the probability and rate of resistance development

Prothioconazole

Despite sharing a common target site cross resistance patterns between C-14 demethylase inhibitors are not necessarily straight forward due to the multiple mechanisms and polygenic nature of resistance as previously discussed. However, for the purposes of effective resistance risk management it is prudent to consider that cross resistance is present between DMI fungicides (including prothioconazole) active against the same fungal target. In common with other DMIs used in the cereal fungicide segment prothioconazole does not show target site based cross resistance to other key MOAs used in this market space including QoIs, morpholines and Succinate Dehydrogenase Inhibitors (SDHIs).

Fenpicoxamid (DE-777)

Since DE-777 does not have activity against oomycete pathogens whilst amisulbrom and cyazofamid are not active on barley pathogens any potential cross resistance within the Qi inhibitor group is not considered relevant at this stage. Dow AgroSciences has however conducted laboratory testing to look for evidence of cross resistance between DE-777 and other key commercially important MOAs used in the cereal fungicide segment e.g. QoIs, DMIs and SDHIs.

In vitro susceptibility testing of SEPTTR field strains showed no cross resistance between Fenpicoxamid (XDE-777)(X772777) and the five other compounds tested, representing MBC, QoI, azole, SDHI and multi site fungicides, previously or currently being used to control *Septoria* leaf blotch. Fenpicoxamid controlled azole insensitive, MBC resistant and QoI resistant SEPTTR field strains as well as a selection of SDHI resistant lab mutants of SEPTTR. These results indicate that Fenpicoxamid has a different mode of action to fungicides currently used to control SEPTTR and will be a good potential resistance management partner for combinations with these other MOAs. Full details can be found in the BAD.

Although no cross resistance testing was performed with DE-777 outside of SEPTTR it is argued that these results can be extrapolated to other pathogens i.e. with the assumption that DE-777 has a different mode of action to fungicides currently used to control RAMUCC, ERYSGH, RHYNSE,

PUCCHD and PYRNT and will be a good potential resistance management partner for combinations with these other MOAs.

Sensitivity data – baseline information on Fenpicoxamid (DE-777)
Full details of baseline sensitivity data can be found in the BAD.

Use pattern and Resistance risk associated with unrestricted use pattern

In order to assess the risk of practical resistance in the target pests, it is necessary to evaluate the different factors contributing to the risk. The inherent risk depends on various factors, some of which are associated with the pest and others with the product. These factors do not necessarily operate in isolation and do not apply in all cases. Local growing conditions also can play an important role and should be considered. These are usually referred to as the agronomic risk. The actual risk of evolution of resistance to a fungicide depends on three main parameters.

Mechanism of resistance against the compound (intrinsic fungicide risk)

Fenpicoxamid DE-777

Fenpicoxamid (DE-777) is a single site inhibitor at the Qil site.

FRAC has published the following specific guidance on resistance risk for fenpicoxamid in wheat (Group 21 (C4) fenpicoxamid (Qil) Recommendations 17th April 2019¹¹) and will be amended in the future to include barley.

“Field resistance not currently known to this molecule. Resistance risk unknown but assumed to be medium to high risk. Resistance management required.”

There are to date no reports of field resistance to Qil inhibitors in cereal pathogens as would be expected since this MOA is not currently commercialised in this segment and no other current MOA used in cereals would be expected to have target site based cross resistance to Fenpicoxamid (DE-777). It is not known if the mutations generated in yeast and *SEPTTR in vitro* which confer reduced sensitivity to Qil inhibitors will also occur in other target diseases and furthermore if they would appear and persist in the field population. Based on our knowledge today we must assume that the intrinsic fungicide risk for Fenpicoxamid's biochemical MOA at the Qil target site is medium to high.

Prothioconazole

Available information on mode of action and resistance risk with the triazole class of inhibitors is probably the most complete of any fungicide group. Numerous publications are available on the mechanisms functioning with respect to DMI resistance. The most significant of these mechanisms is based on the accumulation of different mutations within the Cyp51 locus. Multiple different Cyp51 mutations have been identified and it is now clear that the different mutations and combinations of mutations have varying impacts on the efficacy of different triazoles.

The resistance risk of DMI fungicides including Prothioconazole is classified by FRAC as high to low depending on the target disease. Resistance management for prothioconazole in cereals is coordinated as for all DMIs by the FRAC SBI working group of which the applicant is an active member.

All the recommendations of the group are applied for prothioconazole and will be covered by the proposed use pattern for GF-3307. The applicant also refers the assessing authority to data previously submitted in support of prothioconazole efficacy and resistance risk management by Bayer Crop Sciences to which Dow AgroSciences has been granted a letter of access.

Biology of the pathogen (pathogen risk)

No scientific criteria are available to accurately determine the risk of a pathogen to develop resistance. Thus, FRAC's classification is based on experience and reported resistance claims over the last 45 years. Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high, sexual recombination is mandatory in the disease cycle and the competitive ability of resistant individual is at least as high as that of the wild type (in the absence of selection pressure). Pathogens with shorter life cycles generally require more

¹¹—[https://www.frac.info/docs/default-source/other-fungicide-recommendations/group-21-\(c4\)—fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=aad54b9a_2](https://www.frac.info/docs/default-source/other-fungicide-recommendations/group-21-(c4)—fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=aad54b9a_2)

frequent fungicide application resulting in greater selection pressure and more rapid resistance development. Pathogens producing more spores have higher potential for resistance development due to more genetic diversity available for selection as well as more rapid and extensive dispersal of resistant isolates. Pathogens with sexual stages will have a different resistance risk compared to strictly asexual organisms. Finally, pathogens in isolated populations will have higher resistance risk due to limited genetic variability.

SEPTTR has a high potential to cause serious epidemics and an ability to produce large numbers of spores both asexual and sexual. More important the degree of sexual recombination in SEPTTR is significant. Septoria leaf blotch is currently, in the absence of host resistance, controlled by programmed application of azoles (triazoles and imidazoles), succinate dehydrogenase inhibitors (SDHIs) and multi-site inhibitors. Methyl benzimidazole carbamates (MBC) (e.g. carbendazim) and quinone outside inhibitors (QoIs) (e.g. azoxystrobin) no longer control the disease in some major cereal producing regions of Western Europe due to development of mutations resulting in amino acid substitutions in the target proteins β tubulin (E198A) and cytochrome *b* (F129L and G143A), respectively (Fraaije *et al.*, 2005; Lucas and Fraaije, 2008). SEPTTR is classified by FRAC as a medium risk pathogen in regards to potential to develop fungicide resistance. (FRAC Pathogen Risk List, 2013 version <http://www.frac.info/docs/default-source/publications/pathogen-risk/pathogen-risk-list.pdf?sfvrsn=8>). Reports of resistance development to both Puccinia striiformis (PuccRT) and Puccinia striiformis (PuccST) are very infrequent in the literature. A review of (Fungicide Resistance Action Committee (FRAC) List of Pathogenic Organisms resistant to Disease Control Agents—2013 revision) references only one publication reporting a sensitivity shift with PuccST to DMI fungicides as measured in the laboratory (Bayles *et al.*, 2000). FRAC designate both PuccRT and PuccST as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). PuccRT and PuccST are also not amongst the pathogens listed in EPPO guidance document PP1/213(2) as an example of pathogens considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated.

PYRNTR has a high potential for causing serious epidemics with an ability to produce large numbers of airborne spores. The degree of sexual recombination within PYRNTR is also significant. Reports of resistance development to QoI inhibitors in PYRNTR in the field have been reported from Germany, Sweden and Denmark (Jorgensen and Olson, 2007). Sensitivity of PYRNTR to DMI fungicides appears to remain good with no published reports of resistance issues. FRAC designates PYRNTR as a pathogen with a medium risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). PYRNTR is also not listed in EPPO guidance document PP1/213(2) as an example of a pathogen considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated.

FRAC designates *Fusarium spp.* as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). *Fusarium spp.* in wheat are also not listed in EPPO guidance document PP1/213(2) as being considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated. Resistance of *Fusarium graminearum* to benzimidazoles and DMIs has only been reported from laboratory studies (Chen, *et al.* 2009, Yin *et al.* 2009 respectively) although no details were provided as to the resistance mechanism operating in each case.

Historical data suggests that *Blumeria graminis* is as a high risk pathogen with regard to resistance (Brent and Holloman, 2007) due to a short life cycle and abundant sporulation. The pathogen has developed resistance to benzimidazoles soon after their introduction (Holloman and Wheeler, 2002). Resistance developed also to 2 aminopyrimidines (ethirimol) in the 1970's and later to triazoles (SBI Class I) and morpholines (SBI Class II). Then, were reported: resistance to QoIs at the end of 90s (Sierotzki *et al.* 2000), reduced sensitivity to quinoxifen in early 2000s and to metrafenone in 2009 (Felsenstein, *et al.* 2010). *Blumeria graminis* baseline was not established in wheat or barley because fenpicoxamid has minimal activity on this disease when applied alone and regular testing is conducted by Bayer Crop Science for prothioconazole and reported to FRAC.

In addition, among the fungal diseases targeted by GF 3307 *Ramularia collo-cygni* on barley is considered at high risk with regard to resistance development. This emerging pathogen, having only been recognized as important in Europe in the last 30 years, was capable of relatively rapid build-up of resistance to QoI fungicides.

Other pathogenic fungi on barley such as net blotch (*Pyrenophora teres*) are viewed by FRAC as medium risk, as some resistance to certain fungicides has been confirmed. On the other hand, various cereal rusts (*Puccinia* spp.), barley scald (*Rhynchosporium secalis*) have low risk of resistance development, even if resistance of some of these pathogens to certain groups of fungicides was reported.

Agronomical factors (agronomic risk)

Agronomic factors comprising effects of locally variable factors such as disease pressure, climate, or complexity of cultivars are most important in assessing the risk (Kuck, 2005). Resistance is more likely to develop first in areas of intensive cropping and fungicide use that are, as a result, areas of severe disease outbreaks because environmental conditions favoured the development and spread of the disease. Use of cultural practices such as stubble burial, crop rotation, and varietal resistance can play a role in lowering primary inoculum pressure and slowing rate of epidemic development with cereal diseases however fungicides remain the key component of strategies to manage this disease effectively. In the most intensive cereal growing regions of Europe and particularly in seasons where weather conditions are favourable for build-up of high pressure up to 4 foliar sprays per crop may be applied. Considering the above parameters, the overall resistance risk for GF 3307 used alone within an unrestricted use pattern scenario should be considered as medium to high in relation to the SEPTTR wheat pathosystem and the RAMUCC barley pathosystems but medium to low in relation to the other target pathosystems. With respect to the high risk pathogen ERYSSP, Fenpicoxamid has only moderate intrinsic activity on this pathogen and the majority of the mildew control seen with GF 3307 is provided by the prothioconazole component in the product. Out of the target pathogens applied for on the GF-3307 label SEPTTR, RAMUCC and ERYSSP are considered likely to be the pathogens at most risk of potential resistance development. As such a risk management strategy will be necessary and driven by SEPTTR on wheat and RAMUCC on barley although the risk modifiers which will be proposed in section 3.3.7 will also directly help to manage risk in other target diseases.

Management Strategy for GF 3307

GF 3307 150 g/L EC will provide crop growers with a valuable new resistance management option for disease control in cereals. Because fenpicoxamid and prothioconazole do not share the same mode of action, the mixture represents a valid resistance management practice for the control of high resistance risk pathogens. However, given the nature of the other target pests and the history of resistance associated with these pests and DMI fungicides, we propose that the following modifiers be applied to the product use pattern in order to reduce the potential risk of resistance. The following risk modifiers are proposed:

- GF 3307 EC should be applied preventively i.e. at the early stages of disease development and in any case before the disease is established in the crop.
- The number of foliar applications of GF 3307 within a total disease management program must be limited to **one per season**.
- Tank mixtures and / or sequential applications with a fungicide from a different cross resistance group to picolinamides and DMI fungicides can be recommended and will contribute to reducing the development of resistance to both mode of actions.
- Strongly reduced rate programs including multiple 'split' applications must not be used.
- Always follow product specific label recommendations for resistance management.

Resistance management of Fenpicoxamid, prothioconazole and the mixtures of both should align with that of the picolinamide and DMI fungicides as specified by the Fungicide Resistance Action Committee (FRAC).

The above recommendations are based on the combinations of different strategies i.e. mixtures, alternation, restricted number of applications, preventive use and chemical diversity. This integrated approach is supported by FRAC as described in the FRAC Monograph No. 1. The FRAC guidelines are available on the internet (<http://www.frac.info>) and are available to plant protection advisors in European countries. The GF 3307 EC label includes a statement reflecting the above guidelines for the control of cereal diseases.

The applicant also undertakes to actively promote the resistance management plan, via product literature and during product technical presentations with customers and growers.

Implementation of the Management Strategy

There are a number of steps in the implementation of the resistance management strategy, ultimately based on methods of communication with the grower, either directly or indirectly. Proposals are outlined below:

1. — An internal training program of sales and development representatives prior to and during the launch of GF 3307 150 g/L EC will be organized with emphasis on resistance management. Educational material on resistance and resistance management will be presented at launch meetings with customers.
2. — The principles of good plant protection practice will be promoted both during training sessions and within commercial advisory literature. These include the use of both cultural and chemical control measures and recommendations to ensure that fungicide application is made under favourable environmental conditions.
3. — The use of GF 3307 150 g/L EC with differing modes of action either in tank mix or in sequence will be promoted within training meetings and on all commercial support literature.
4. — The statements / modifiers relating to resistance management presented in the preceding sections will appear on the label. Study of the label is recommended prior to the use of the product.
5. — One application per season of GF 3307 in all crops.

The applicant will also undertake to actively promote the resistance management plan, via product literature and during product technical presentations with customers and growers. The fenpicoxamid and prothioconazole resistance management strategies are communicated on the FRAC website (Working Group #21 “QiIs” and Working Group #3 “SBI Fungicides”, respectively) and in the form of technical publications in appropriate journals or conferences.

Monitoring, reporting and reaction to the changes in performance

The applicant is an active member of FRAC and would anticipate joining the FRAC QiI cereals task force group once Fenpicoxamid DE 777 is commercialised. Annual monitoring of the sensitivity of the EU SEPTTR, RAMUCC and PYRNTE populations to Fenpicoxamid (DE 777) and prothioconazole will continue post launch in order to detect any signs of a shift away from the pre-launch baseline which has been presented in this dossier section. This will be supplemented by continuous observation of field performance. Any significant change in sensitivity will be reported through FRAC and the relevant country resistance management and regulatory agencies. This will allow the applicant to rapidly adapt the resistance management strategy should the need arise.

Conclusion:

The active substances of GF 3307 150 g/L EC: fenpicoxamid (50 g/L) and prothioconazole (100 g/L), are a pre-mixture of non-cross resistant fungicides effective against foliar pathogens on cereals.

The applicant is conducting a resistance monitoring programme on a regular basis in order to detect the potential development of fungicide resistance in fungi in Europe and help farmers and advisors to make a better diagnosis after a control failure with any of its products.

If this should occur, the applicant will be able to provide sound recommendations in terms of chemical control and agronomic practices to come back to a manageable situation.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

Summary

GF-3307 150 g/L is a co-formulation containing 50 g/L of fenpicoxamid (DE-777) and 100 g/L of prothioconazole and is effective against foliar diseases of cereals. This section follows the guidance laid out in EPPO Guideline PP1/213(4) in order to determine the resistance risk associated with the product and the target pathogens.

Fenpicoxamid is a fungicide with a mode of action belonging to the picolinamide class of chemistry with primary activity on ascomycete and basidiomycete pathogens in cereals. It is a potent inhibitor of fungal respiration acting via binding to the Quinone Inside (Qi) site of the cytochrome bc₁ (ubiquinone reductase) complex (complex III) in the electron transport chain. Fenpicoxamid belongs to the FRAC resistance group 21, Mode of Action group C4.

Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventative and eradication action. The biological mode of action of prothioconazole has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi. At the target site level prothioconazole inhibits C-14 demethylase and belongs to the group of compounds collectively termed as De-Methylation Inhibitors (DMIs). The molecule is classified by FRAC in group 3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51)).

Studies indicated that fenpicoxamid is not cross-resistant with other fungicide classes, including DMI fungicides. Also, fungicides affecting ergosterol biosynthesis are not cross-resistant with fungicides inhibiting other biochemical target sites. On the other hand, for the purposes of effective resistance risk management it is prudent to consider that cross-resistance is present between DMI fungicides (including prothioconazole) active against the same target disease.

Sensitivity baselines have been established for fenpicoxamid on *Zymoseptoria tritici*, *Puccinia recondita tritici*, *Ramularia collo-cygni* and *Pyrenophora teres*, using isolates from different European countries.

The mode of action of GF-3307 on target pathogens as well as a recent history of resistance to DMI groups suggest that the risk of development of resistance in high and medium-risk pathogens of the unrestricted use is unacceptable and that measures must be taken to prevent or at least delay the risk of resistance developing. A resistance management strategy is proposed which relies on the use of tank mixtures, alternation with other fungicides with a different mode of action and limiting the number of GF-3307 applications to one per season. Such recommendations are aligned with those published by the Fungicide Resistance Action Committee (FRAC). It is considered that with these modifiers in place the risk is reduced to an acceptable level.

Introduction

GF-3307 is a co-formulation of 50g/L of fenpicoxamid + 100g/L of prothioconazole and will be registered for use against a range of cereal diseases including: SEPTTR/SEPTSP in wheat and triticale, PUCCSP in wheat, rye, triticale and barley, RHYNSE on rye and barley, ERYSSP in wheat, triticale and barley, PYRNTE and RAMUCC in barley.

Fenpicoxamid has been combined with prothioconazole in order to broaden spectrum of control and to build in resistance management by combination of two different modes of action (MOAs). This dossier section will mainly concentrate on analysis of resistance risk to fenpicoxamid since this will be a new active substance in barley in Europe whereas prothioconazole and its associated resistance risk is well understood. The applicant also refers the assessing authority to data submitted in support of prothioconazole efficacy and resistance risk management by Bayer Crop Sciences to which Dow AgroSciences has been granted a letter of access.

Resistance to crop protection chemicals is a natural biological phenomenon that occurs in insects, weeds and fungi. It usually becomes evident after the repeated use of a particular pesticide selects the naturally-occurring resistant strains within the wild population and allows them to multiply over several seasons until they become dominant in the population and pose a control problem.

The fungicide-resistant population develops because the sensitive population is suppressed and the rare fungicide-resistant individual is allowed to multiply and occupy the biological niche previously

filled by the sensitive population. An increase in the frequency of such resistant strains may result in loss of disease control. As a general principle, resistance develops at different rates depending on the nature of the pathogen and its interactions with the crop, environment and fungicide.

Reports of the appearance of resistant strains in laboratory studies do not necessarily imply that any loss of control is expected in the field. Likewise, the appearance of less-sensitive strains in the field does not always result in failure of disease control. When the frequency of resistant individuals is low and/or the level of resistance is moderate, fungicide applications in most cases will provide satisfactory control.

To avoid the misinterpretation of potential resistance cases, the Fungicide Resistance Action Committee (FRAC) states that the term “resistance” be limited to situations where the conditions in both (a) and (b) below are met:

(a) the development of resistance leads to failure of disease control under practical field conditions following application of a fungicide correctly and according to the label and

(b) a demonstration that a loss of control is due to the presence of pathogenic strains with reduced fungicide sensitivity.

From a regulatory and product stewardship standpoint it is essential to evaluate the potential resistance risk posed by a product and to ensure that a practical and effective management strategy is put in place in order to mitigate against the potential risk. The resistance risk analysis for GF-3307 presented within this section follows the requirements set out in EPPO Guideline PP1/213(2).

3.3.1 Mode of Action.

Prothioconazole.

The biological mode of action of prothioconazole has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi (Parker et al. 2011). Ergosterol is a unique component of the membrane of fungi, the inhibition of its biosynthesis makes the cell membrane rigid and leaky, so that the pathogen's hyphae cannot grow and infect the plant. At the target site level prothioconazole inhibits C-14 demethylase of ergosterol precursors, which then accumulate at the expense of ergosterol and belongs to the group of compounds collectively termed as De-Methylation Inhibitors (DMIs). The molecule is classified by FRAC in group 3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51).

Fenpicoxamid - DE-777.

Fenpicoxamid (XDE-777) is the first and to date only member of a new picolinamides class of fungicides representing a novel mode of action within the cereal fungicide segment. Its target site has been identified as the Quinone Inside (Qi) site of the cytochrome *bc1* (ubiquinone reductase) complex (complex III) in the electron transport chain.

This target site was confirmed by a combination of previously published literature references, biochemical and molecular genetics studies. Biochemical binding assays were performed on a range of fungi including *Zymoseptoria tritici* (SEPTTR) whilst molecular genetic studies were performed using chemically induced resistant mutants of *Saccharomyces cerevisiae* (SACCCE).

Summary

Aside from the literature publications around UK-2A MOA, additional evidence generated by Dow AgroSciences in support of the likely biological and biochemical (target site) MOA of DE-777 include the following .

(4) DE-777 / UK-2A were both active in inhibiting mitochondrial respiration in cell free mitochondrial preparations from a wide range of fungi, as well as wheat and bovine heart. Fungal species could be categorized in two groups based on target site sensitivity: a highly sensitive group comprising SEPTTR, LEPTNO, PYRIOR and BOTRCI, and a less sensitive group which included GIBBZE, USTIMA and PLASVI.

(5) At the cellular level, DE-777 and UK-2A caused a rapid partial depolarization of mitochondria, which is characteristic of complex III inhibition.

(6) Further evidence for the target site of UK-2A was demonstrated in the model organism SACCCE by isolation of cytochrome *b* mutants with 3 distinct mutations involving amino acids which

are highly conserved between species. Clustering of these mutations at the Qi site, and cross-resistance to Antimycin A, confirmed binding of UK-2A to the Qi site.

(7) As RAMUCC, RHYNSE, PYRNTE, PUCCHD and ERYSGH on barley are in the same class of fungi as SACCCE and SEPTTR (ascomycetes), it is considered they will also be highly sensitive to DE-777 and UK-2A.

3.3.2 Mechanism of Resistance – Evidence of Resistance

Individual active substance components of the combination - GF-3307.

Prothioconazole

As previously mentioned prothioconazole is known to rely on the inhibition of demethylation at the C-14 position in fungal sterol biosynthesis (DMI). In excess of 30 DMI fungicides are currently commercialised although prothioconazole is in relative terms a more recent introduction from this group of inhibitors. Prothioconazole is a triazolinthione as opposed to triazole. Work in yeast has shown prothioconazole only weakly inhibits Cyp51 and it requires metabolism to the triazole form prothioconazole-desthio in order for significant inhibition to occur i.e. the IC₅₀ of prothioconazole is 100 times higher than the desthio form (Parker et al. 2011). Available information on mode of action and resistance risk with this class of inhibitors is probably the most complete of any fungicide group. Numerous publications are available on the mechanisms functioning with respect to DMI resistance. The resistance risk of DMI fungicides including Prothioconazole is classified by FRAC as medium. The applicant also refers the assessing authority to specific data generated by Bayer Crop Sciences supporting the resistance risk and effect of Cyp51 mutations on prothioconazole efficacy and resistance risk management - to which Corteva Agrisciences has been granted a letter of access.

Ergosterol is the sterol predominating in fungal membranes serving a similar function to that of cholesterol in animals. The critical presence of ergosterol in fungi and its absence from humans and other mammals make it a useful target for fungicides. Prothioconazole and other demethylase inhibitor (DMI) fungicides block ergosterol biosynthesis in plant pathogenic fungi by inhibiting the cytochrome P-450 sterol 14 α -demethylase protein, also called eburicol 14 α -demethylase or CYP51, a key enzyme in the sterol biosynthetic pathway (Horne and Holloman 1997).

Reduced sensitivity in plant pathogenic fungi to DMI fungicides has been reported in the field in numerous plant pathogens¹². Several mechanisms are involved, including alterations in the target site, over-expression of the target gene and fungicide export from fungal cells before reaching the target site. A combination of these mechanisms can occur in the same fungal species, for example the combination of over-expression and different target site mutations was found in Brazil on *Phakopsora pachyrhizi* of soybeans (Schmitz et al. 2014) and on *Puccinia triticina* in Europe, where the Y134F mutation in the cyp51 gene or cyp51 overexpression was detected (Stammler et al. 2009).

Alterations in the target site. In regard to altered target site, more than 20 mutations, deletions or substitutions in the target CYP51 gene have been reported to affect sensitivity to various DMI fungicides (HGCA, Understanding evolution and selection of azole resistance mechanisms in the United Kingdom population of *Mycosphaerella graminicola*, HGCA website <http://hgca.com>, Cools et al. 2006.) Much of the research on target site mutations affecting DMI sensitivity in fungi has been conducted on the human pathogen *Candida albicans* (Marichal et al. 1999) and the non-pathogenic yeast *Saccharomyces cerevisiae* (Sanglard et al. 1998). But reduced sensitivity in plant pathogenic fungi to DMI fungicides due to alterations in the target site has been reported, inter alia, in *Uncinula necator* (Delye et al. 1997), *Blumeria graminis* (Delye et al. 1998, De Waard et al. 1986, Wyand and Brown, 2005), *Oculimacula* spp. (Albertini et al. 2003, Wood et al. 2001, Dyer et al. 2000), and *Mycosphaerella graminicola* (Mavroedi and Shaw, 2005, Fraaije et al. 2007). Combinations of various CYP51 mutations, deletions and often other resistance mechanisms, however, may result in significant shifts in sensitivity as well as efficacy under practical field conditions (Stergiopoulos et al. 2003). No single mutation conferring high levels of DMI resistance has conclusively been identified and consistently associated with reduced field performance.

Over-expression of the target gene. Evaluation of isolates of *Venturia inaequalis* with variation in sensitivity to myclobutanil indicated that sensitivity differences were not correlated with mutations in

¹² www.frac.info FRAC List of Plant Pathogenic Organisms Resistant to Disease control agents, 2018

the CYP51 gene but were associated with higher levels of gene expression (Schnabel and Jones, 2001). Higher levels of 14 α -demethylase in fungal cells presumably would require greater concentrations of fungicide for inhibition. Over-expression of the target gene has also been reported for the isolates of the human pathogen *Candida albicans* with reduced sensitivity to fluconazole (White, 1997) and in DMI-resistant field isolates of *Sclerotinia homoeocarpa* were induced to express ShCYP51 at significantly higher levels than baseline isolates in the presence of propiconazole (Ma and Tredway, 2014).

Transporter-mediated efflux. Simultaneous resistance to many unrelated inhibitors conferred by a single gene, often referred to as multi-drug resistance, has been reported in a wide range of organisms against several diverse inhibitor classes. The mechanism of reduced sensitivity is active efflux of the inhibitor from the fungal cell before reaching the target site, mediated by products of either ABC transporter or major superfamily transporter genes. Interestingly, these same genes have been associated with pathogenicity and virulence in plant pathogenic fungi (Roohparvar et al. 2007). Transporter-mediated efflux has been implicated in reduced sensitivity to DMI fungicides in several fungi including *Mycosphaerella graminicola* (Zwiers et al. 2002) and *Pyrenophora tritici-repentis* (Reimann and Deising, 2005).

Fenpicoxamid (DE-777)

Since DE-777 will represent the first and only current example of a QII inhibitor in the barley fungicide segment there is of course no history of selection pressure from this mode of action on European field populations of any of the target diseases.

3.3.3 Evidence of Resistance

Individual active substance components of the combination - GF-3307.

Prothioconazole

Since the mid-1980's, reports of decreased levels of field efficacy have been attributed to reduced levels of sensitivity in target populations for DMI fungicides (Fletcher and Wolfe, 1981). Several studies have shown that shifts toward reduced sensitivity to DMI fungicides follow a quantitative or progressive pattern typical of changes controlled by several genes (Berg et al. 1990). Unlike benzimidazole and QoI fungicides for which the resistance is qualitative or disruptive (i.e. higher rates may not control resistant strains and field activity is lost), the development of less sensitive strains with DMI fungicides is quantitative or progressive. Higher rates can offset a slight decrease of activity. According to a recent report from FRAC⁷, naturally occurring isolates from the field with reduced sensitivity to DMI fungicides now have been reported for numerous plant pathogenic fungi. For cereals crops in which prothioconazole currently is used, reduced sensitivity to DMI fungicides has been reported for the majority of the target diseases for GF-3307.

***Zymoseptoria tritici* (SEPTTR).** SEPTTR has adapted to a number of different fungicides in recent years such as the Methyl Benzimidazole Carbamates (MBCs) (target site mutations in β tubulin gene), DMIs (reduced sensitivity based on several mechanisms, including target site mutation) (Cools and Fraaije, 2012, Cools et al 2011) and QoIs (G143A and F129L mutation in cytochrome b gene) (Clark, 2005). FRAC designates SEPTTR as a pathogen with a medium risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version)

SEPTTR is also not amongst the pathogens listed in EPPO guidance document PP1/213(2) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance although the closely related *Mycosphaerella fijiensis* is mentioned. SEPTTR is also not mentioned in EPPO guidance document PP1/213(2) in Appendix III Table 2 as a pathogen for which sensitivity data should normally be provided. However as fenpicoxamid will be a new active substance for use in the SEPTTR segment in Europe DAS considers baseline data essential and a full package of data will be submitted in this dossier (see section 3.3.5).

***Puccinia triticina* (PUCCRT).** Reports of resistance development to both PUCCRT and PUCCST are very infrequent in the literature. A review of (Fungicide Resistance Action Committee (FRAC) List of Pathogenic Organisms resistant to Disease Control Agents - 2013 revision) references only one

publication reporting a sensitivity shift with Puccst to DMI fungicides as measured in the laboratory (Bayles et al, 2000). The 2014 report of the FRAC SBI WG (<http://www.frac.info/docs/default-source/sbi-wg/sbi-wg---current/minutes-of-the-2014-meeting-recommendations-for-2015.pdf?sfvrsn=2>) states that “good field performance of DMIs against rust was maintained and sensitivity data from 2014 for brown rust showed that sensitivities were within the range of the previous 10 years”.

FRAC designate both Puccrt and Puccst as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). Puccrt and Puccst are also not amongst the pathogens listed in EPPO guidance document PP1/213(2) as an example of pathogens considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated. However as fenpicoxamid will be a new active substance for use in the Puccrt and Puccst segment in Europe DAS considers baseline data essential and a full package of data will be submitted in this dossier on Puccrt (see section 3.3.5).

***Pyrenophora tritici-repentis* (PYRNTR).** Reports of resistance development to QoI inhibitors in PYRNTR in the field have been reported from Germany, Sweden and Denmark (Jorgensen and Olson, 2007). Reimann and Deising (2005) have also reported detection of isolates of PYRNTR with reduced sensitivity to both DMIs and QoIs from fields in Germany treated with reduced doses of fungicide. The mechanism underlying this reduced sensitivity is based on an energy dependent active efflux transporter. FRAC designates PYRNTR as pathogen with a medium risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). PYRNTR is also not listed in EPPO guidance document PP1/213(2) as an example of a pathogen considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated.

Fusarium Head Blight. FRAC designates *Fusarium spp.* as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). *Fusarium spp.* in wheat are also not listed in EPPO guidance document PP1/213(2) as being considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated. Resistance of *Fusarium graminearum* to benzimidazoles and DMIs has only been reported from laboratory studies (Chen, et al. 2009, Yin et al. 2009 respectively) although no details were provided as to the resistance mechanism operating in each case.

Blumeria graminis (De Waard et al. 1986; Wyand and Brown, 2005). The primary mechanism of reduced sensitivity in field isolates of *B. graminis* f. sp. *tritici* in wheat and *B. graminis* f. sp. *hordei* in barley are mutations in the target CYP51 gene. The Y136F mutation has been found in both wheat and barley while another mutation K147Q was found only in barley. Y136F alone confers low levels of resistance but may result in higher resistance levels if present in combination with K147Q. Research also indicated that target site mutations were not the only resistance mechanism present in *B. graminis*. FRAC designates ERYSGH as a pathogen with a high risk of developing resistance to fungicides 7. ERYSGH is also amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

Pyrenophora teres (Sheridan et al. 1985; Locke, 1996, 2000) . No specific mechanisms of reduced sensitivity have been reported in field populations of *P. teres*, but slight shifts toward reduced sensitivity were reported in the United Kingdom in the late 1990's after prolonged use of DMI fungicides. Later research, however, reported that sensitivity had stabilized, and that field performance generally remained acceptable. FRAC designates PYRNTE as a pathogen with a medium risk of developing resistance to fungicides (FRAC Pathogen Risk List 2019; https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2). PYRNTE is also not amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

Rhynchosporium secalis (Hunter et al. 1986; Kendall and Hollomon, 1990; Kendall et al. 1993; Cooke et al. 2004). Although no specific mechanisms of reduced sensitivity have been reported in *R. secalis*, significant shifts toward reduced sensitivity and field performance in DMI fungicides have been observed in the United Kingdom. Prior to the early 1990's, combinations of DMI fungicides with benzimidazoles like carbendazim were highly effective for both disease control and resistance management. But widespread resistance to benzimidazoles resulted in use of DMI fungicides alone until introduction of new fungicides with different biochemical target sites like the QoI fungicides (e.g. azoxystrobin) and anilinopyrimidines (e.g. cyprodinil). Shifts toward reduced DMI sensitivity were greater when reduced rates were used. Addition of an effective mix partner with a different site of action, however, reduced the selection of DMI-resistant strains. FRAC designates RHYNSE as a pathogen with a low risk of developing resistance to fungicides (FRAC Pathogen Risk List 2019; https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2). RHYNSE is also not amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

Ramularia collo-cygni. FRAC designates RAMUCC as a pathogen with a high risk of developing resistance to fungicides (FRAC Pathogen Risk List 2019; https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf?sfvrsn=caf3489a_2). RAMUCC is also amongst the pathogens listed in EPPO guidance document PP1/213(4) in Appendix II Table 1 as an example of a pathogen considered to be at high risk of developing resistance.

As shifts toward reduced sensitivity to DMI fungicides have been reported in some economically important diseases, each year the FRAC webpage provides information on the evolution of geographic distribution and frequency of resistance to DMI fungicides across Europe.

Resistance of RAMUCC to DMI fungicides has been reported by FRAC. In 2016, a broad sensitivity range has been identified with very high frequency of highly resistant strains in southern Germany, with moderate frequency in Denmark, Ireland, Belgium, Northwestern Germany, and low frequency detected in France, Austria, Sweden, and United Kingdom. No detection of resistance in Estonia.

The following information on the resistance status of various pathogens (for which control is claimed on the GF-3307 label) is available, from the Sterol Biosynthesis Inhibitor (SBI) Working Group (2018 meeting and later information), FRAC (Fungicide Resistance Action Committee)¹³.

Powdery mildew (*Blumeria graminis* f.sp. *hordei*) - Barley

No monitoring was carried out in 2017, monitoring data presented for 2018. In 2018, disease pressure was low in Europe. Monitoring was carried out in Czech Republic, Denmark (2016), France, Germany, Latvia, Sweden (2016), Ukraine, and United Kingdom. DMI products performed well. The sensitivity of the populations stayed in the range observed for more than 15 years. Reduced sensitivity was reported in barley powdery mildew in western and eastern Australia (ACNFP/Curtin University) in 2014. For latest resistance monitoring data on prothioconazole refer to Bayer Crop Science when Corteva Agrisciences has a letter of access.

Leaf blotch (*Rhynchosporium secalis*) - Barley

Disease pressure was extremely low in Europe in 2018. Field performance of DMIs was good. Monitoring was carried out in Denmark, France, Germany, Ireland, Poland, and United Kingdom. The sensitivity of the populations stayed in the range observed in the previous 15 years.

Net blotch (*Pyrenophora teres*) – Barley

Overall, the sensitivity of populations monitored in 2020 stayed in the range observed in previous years, without any major geographical differences across Europe.

¹³ https://www.frac.info/docs/default-source/sbi-wg/sbi-wg---current/minutes-of-the-2018-sbi-telco-meeting-recommendations-for-2019-6th-of-june-2019?sfvrsn=caf3489a_2

In 2020, monitoring was carried out in Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Ukraine, and United Kingdom.

In 2019, like 2017 lower sensitivities have been frequently detected in major French regions and in a single location in North-Eastern Germany. In the other European regions monitored sensitivity ranges were stable.

In 2017 in France significant shifts of sensitivity of populations have been observed. Highest EC50 values were observed in areas of elevated disease pressure, often coupled with a reported reduced variety-resistance at significant cultivation areas, and sub-optimal use of azoles in spray programs (e.g. reduction of rates in comparison to the manufacturer's recommended rate and inappropriate use of effective mix-partners).

In general, over the past years a significant fluctuation in sensitivity levels between the years was detected. In 2017 in single locations in Germany there have been seen some shifting which needs to be observed in the next season. The monitoring in the other countries showed a stable situation in 2017 within the regular fluctuation.

The monitoring of the last 20 years showed a certain level of fluctuations of the sensitivity level in the regions over the years. In 2018, the situation stabilized again in all countries including France and Germany, thus being comparable to the long-term monitoring results.

Ramularia leaf spot (*Ramularia collo-cygni*) - Barley

In 2020, monitoring was carried out in Denmark France, Germany, Hungary, Ireland, Italy, Lithuania, Poland, Slovakia, Spain, Sweden, Switzerland, and United Kingdom.

Isolates were detected showing significant loss of sensitivity. Relevant CYP51- mutations explaining the effects have been identified (I325T, I328L, Y403C/Y405H).

In 2016, a broad sensitivity range has been identified with very high frequency of high resistant strains in southern Germany, with moderate frequency in Denmark, Ireland, Belgium, Northwestern Germany, and low frequency detected in France, Austria, Sweden, and United Kingdom. No detection of resistance in Estonia

Data from 2017 showed high frequency of resistant strains in Denmark, Ireland, and United Kingdom, moderate frequency in Estonia, low to moderate frequency in Sweden, and no resistant strains were detected in Finland.

In 2018 the results are:

- no isolates with the above-mentioned mutations detected in Switzerland, Spain and Italy, and Sweden.
- no to high frequency in Denmark,
- low to moderate frequency in single samples from Austria, France, Hungary,
- low to high frequency in Germany,
- moderate to high frequency in Belgium, Netherlands, United Kingdom, Ireland, and Latvia.

In 2019 the results are:

- no isolates/samples with the above-mentioned mutations were detected in Spain & Italy
- no to low frequencies in Slovenia and Croatia • low frequencies of DMI resistance allele were detected in Switzerland and Slovakia
- in Austria, low to moderate frequencies were observed
- moderate to high frequencies in Belgium, Germany and Sweden
- high frequencies in Ireland, United Kingdom and France

In 2020, the results from bioassay and molecular analysis focusing on the most relevant mutations are:

- no to low frequencies of resistance in Italy, Switzerland, and Spain
 - no to high frequencies of resistance in France
 - moderate to high frequencies of resistance in Germany and Sweden
- high frequencies of resistance in Czech Republic, Denmark, France, Hungary, Ireland, Lithuania, Slovakia, and United Kingdom

Leaf rust (*Puccinia hordei*) - Barley

Monitoring was carried out in 2014 and 2018 by Bayer in Denmark, France, Germany, Sweden, and United Kingdom. Very stable situation with a narrow range of sensitivity in this four-year interval.

Fenpicoxamid (DE-777)

Since DE-777 will represent the first and only current example of a QiI inhibitor in the barley fungicide segment there is of course no history of selection pressure from this mode of action on European field populations of any of the target diseases.

3.3.4 Cross Resistance

What is cross-resistance? Assessing patterns of cross resistance both between different fungicide classes as well as among members of the same class is an important element in the understanding of resistance risk and risk management. Cross resistance means a correlation in sensitivity within a group of inhibitors toward specific pest targets, while absence of cross-resistance indicates no correlation in sensitivity within the group. In the case of target site mutations that reduce sensitivity to specific inhibitors, if sensitivity to other inhibitors against the same target also is reduced, then those compounds exhibit positive cross resistance (or just “cross resistance”). In the case where reduced sensitivity to one inhibitor results in increased sensitivity to other inhibitors, however, those groups exhibit negative cross resistance. Confirmation of positive or negative cross-resistance depends only on the directions of sensitivity shifts and not on their magnitude. Identification of patterns of positive cross-resistance is important in resistance risk assessment because use of these fungicides together may represent increased selection pressure and a greater risk of resistance development and spread. Patterns of negative cross resistance, although rarer, also may be important since they may be used to reduce selection pressure and reduce the probability and rate of resistance development.

Prothioconazole

Despite sharing a common target site cross resistance patterns between C-14 demethylase inhibitors are not necessarily straight forward due to the multiple mechanisms and polygenic nature of resistance as previously discussed. However, for the purposes of effective resistance risk management it is prudent to consider that cross resistance is present between DMI fungicides (including prothioconazole) active against the same fungal target. In common with other DMIs used in the cereal fungicide segment prothioconazole does not show target site based cross resistance to other key MOAs used in this market space - including QoIs, morpholines and Succinate Dehydrogenase Inhibitors (SDHIs).

Fenpicoxamid (DE-777)

Since DE-777 does not have activity against oomycete pathogens whilst amisulbrom and cyazofamid are not active on barley pathogens any potential cross resistance within the Qi inhibitor group is not considered relevant at this stage. Dow AgroSciences has however conducted laboratory testing to look for evidence of cross resistance between DE-777 and other key commercially important MOAs used in the cereal fungicide segment e.g. QoIs, DMIs and SDHIs. This work has been conducted in *Mycosphaerella graminicola* and is described below.

In vitro susceptibility testing of SEPTTR field strains showed no cross-resistance between fenpicoxamid/ DE-777(X772777) and the five other compounds tested, representing MBC, QoI, azole, SDHI and multi-site fungicides, previously or currently being used to control Septoria leaf blotch. DE-777 controlled azole-insensitive, MBC-resistant and QoI-resistant SEPTTR field strains as well as a selection of SDHI-resistant lab mutants of SEPTTR. These results indicate that DE-777 has a different mode of action to fungicides currently used to control SEPTTR and will be a good potential resistance management partner for combinations with these other MOAs.

Although no cross resistance testing was performed with DE-777 outside of SEPTTR it is argued that these results can be extrapolated to key barley pathogens i.e. with the assumption that DE-777 has a different mode of action to fungicides currently used to control PYRNTR, PUCCHD, RHYNSE and

RAMUCC and will be a potential resistance management partner for combinations with these other MOAs.

3.3.5 Sensitivity data –baseline information on Fenpicoxamid (DE-777)

Full details of baseline sensitivity data for fenpicoxamid can be found in the BAD. A brief summary of cross years results is presented in the dRR.

A Pan European baseline for fenpicoxamid against SEPTTR and PUCCRT in wheat and PYRNTE and RAMCUU RAMUCC in barley has been established pre-launch. Baseline data for SEPTTR has been established from 2011-2014, PUCCRT 2015, PYRNTE 2018-2021 and RAMCUU from 2018-2020. These are the major pathogens of these crops where fenpicoxamid will be used and present the highest risk where resistance risk may occur.

SEPTTR in wheat

Summary and Conclusions

Looking at MEC₅₀ values across the 4 years of sampling on a pooled EU wide scale the MEC₅₀ value for SEPTTR sensitivity to Fenpicoxamid in the EU population sits within the range of 0.026 to 0.044 mg/L. (Tables 3.3-16,17). This is based upon a substantial sample size of 1876 isolates. No shift in sensitivity across the 4 sample years has been observed (Figs 3.3-9, and 3.3-11). Looking at the cumulative frequency plots (Fig. 3.3-11) it appears that the sensitivity of the population moved slightly to the right when comparing 2012 with 2011 (MEC₅₀ of 0.044mg/L vs 0.26 mg/L but then back to the left in 2013 and 2014 (MEC₅₀s of 0.03 mg/L in both 2013 and 14). This lack of a discernible shift is as anticipated for a compound which has not yet been launched commercially and hence exerted no significant selection pressure on the field population. In addition since no QiI inhibitors are currently registered in wheat the SEPTTR populations have not been exposed to selection pressure from this specific MOA. The above trend also holds true when MEC₅₀ values are examined at individual country level with no significant differences between countries or across years (Figs. 3.3-12 and 3.3-13) suggesting the sensitivity of the wild type EU SEPTTR population to Fenpicoxamid /UK-2A is relatively homogeneous across the EU. Fenpicoxamid was first launched in UK and France in 2021. SEPTTR population in Europe have not been exposed to fenpicoxamid before this time and so the isolate data from 2011 -2014 is valid as a comprehensive baseline to monitoring isolates post launch.

It is also profitable to look at the data set with respect to the spread of individual sensitivity values across countries and years (Figs 3.3-12, 3.3-13 and Table 3.3-17). The countries with the largest range between min and max EC₅₀ are France, UK and Germany which is likely a reflection of the significantly larger samples sizes in these 3 countries versus other areas sampled as opposed to any inherent difference in sensitivity range. A simple way to assign a numerical value to the size of the range between min and max EC₅₀ values is to calculate the diversity factor for a sample (Max EC₅₀/Min EC₅₀) (Table 3.3-17). It can be seen from Table 3.3-17 that the diversity factors calculated are relatively homogeneous across years and countries.

Looking for appearance of individual isolates with abnormally high EC₅₀s (i.e. outside baseline range) is an important component of active monitoring programs. These isolates are typically at very low frequencies initially but will increase in frequency if a true sensitivity shift is occurring. The lowest EC₅₀ for Fenpicoxamid detected to date across 1875 isolates assayed is 0.003 mg/L from Italy and Spain in 2014 whilst the highest was 0.496 mg/L from Poland in 2011 which was very much higher than other samples from Poland in subsequent years and likely may be experimental error.

If the data set is grouped according to the frequency classes shown in Table 3.3-18 and Fig. 3.3-14 then looking across the distribution of EC₅₀ values for the 1875 isolates bio assayed between 2011 and 2014 it is evident that 1864 out of 1875 isolates (99.7%) fall within the range of <0.01 - to 0.19 mg/L. It is suggested that this range is used to set the upper limits of the baseline distribution with careful analysis of future post launch monitoring program data to track any appearance of a significant frequency of isolates with EC₅₀ values >0.2 mg/L.

The data set generated across 2011 thru 2014 forms a comprehensive picture of the baseline sensitivity of EU SEPTTR populations and will be invaluable as reference point for future post launch monitoring programs for Fenpicoxamid.

3.3.5.1 Data on SEPTTR – summary of data from 2011-2014

Figure 3.3-1: Box and whisker plot of EU wide EC₅₀ values 2011 – 2014

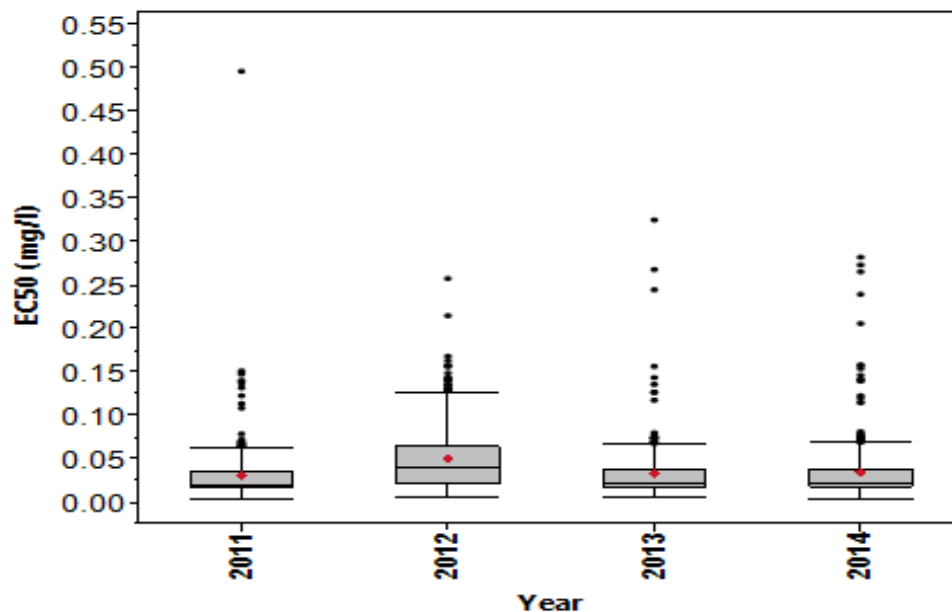


Figure 3.3-2: Fig 3.3-10 . Data distribution plot of EU wide EC₅₀ values 2011 – 2014

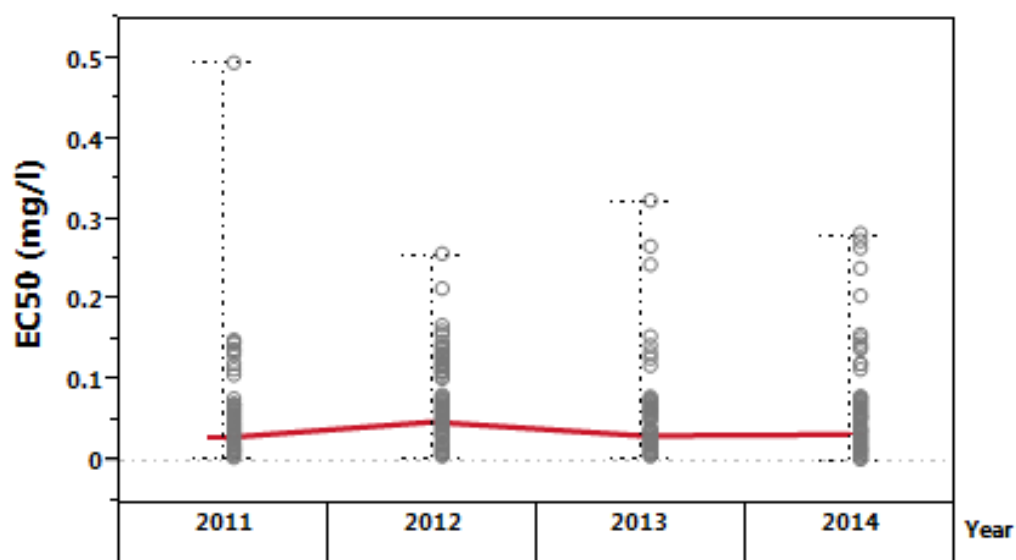


Figure 3.3-3: Cumulative frequency plot of EU wide MEC₅₀ values 2011 through 2014

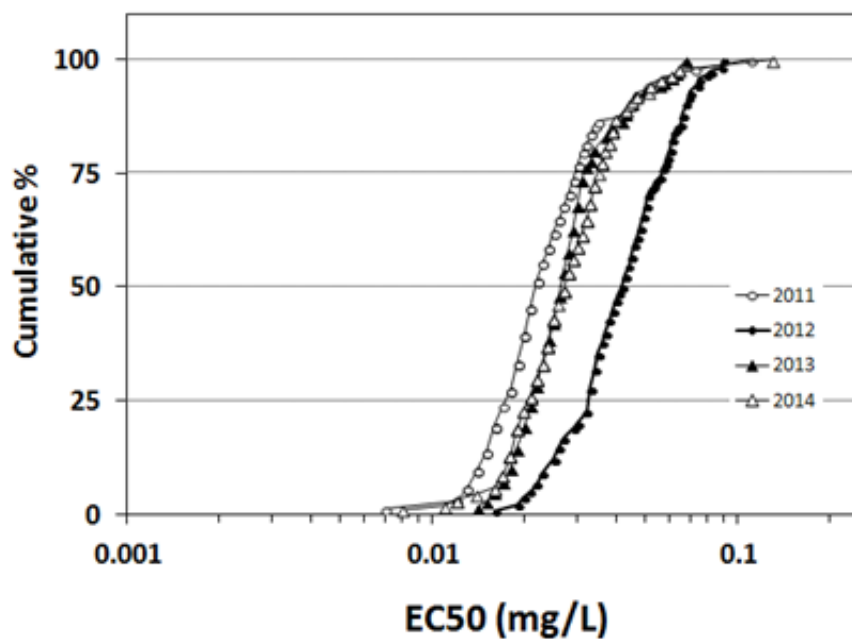


Figure 3.3-4: EC₅₀ values - country view by year - box and whisker plot summary

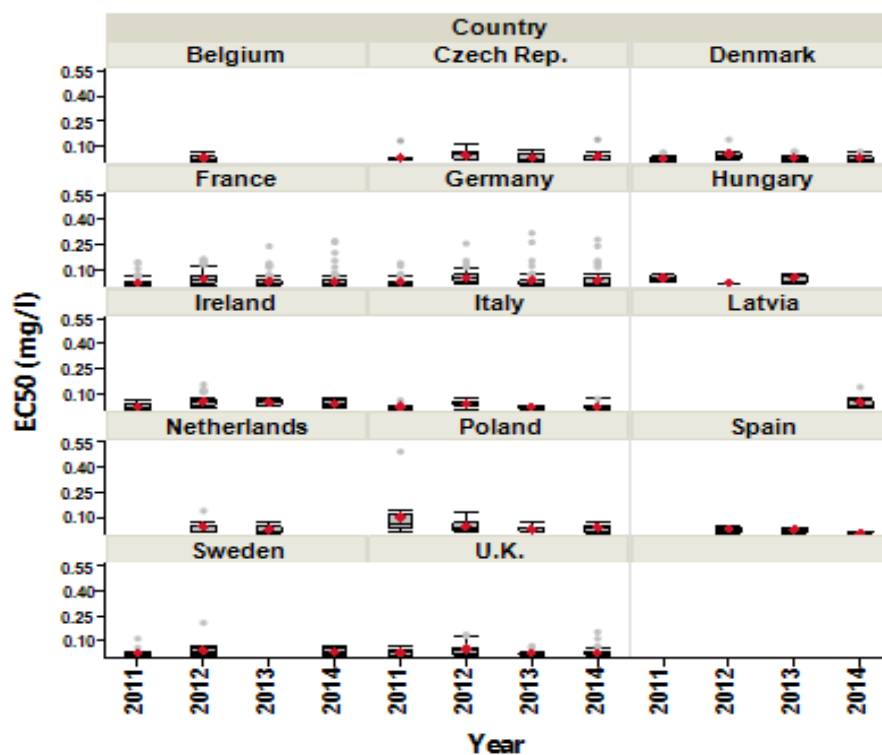
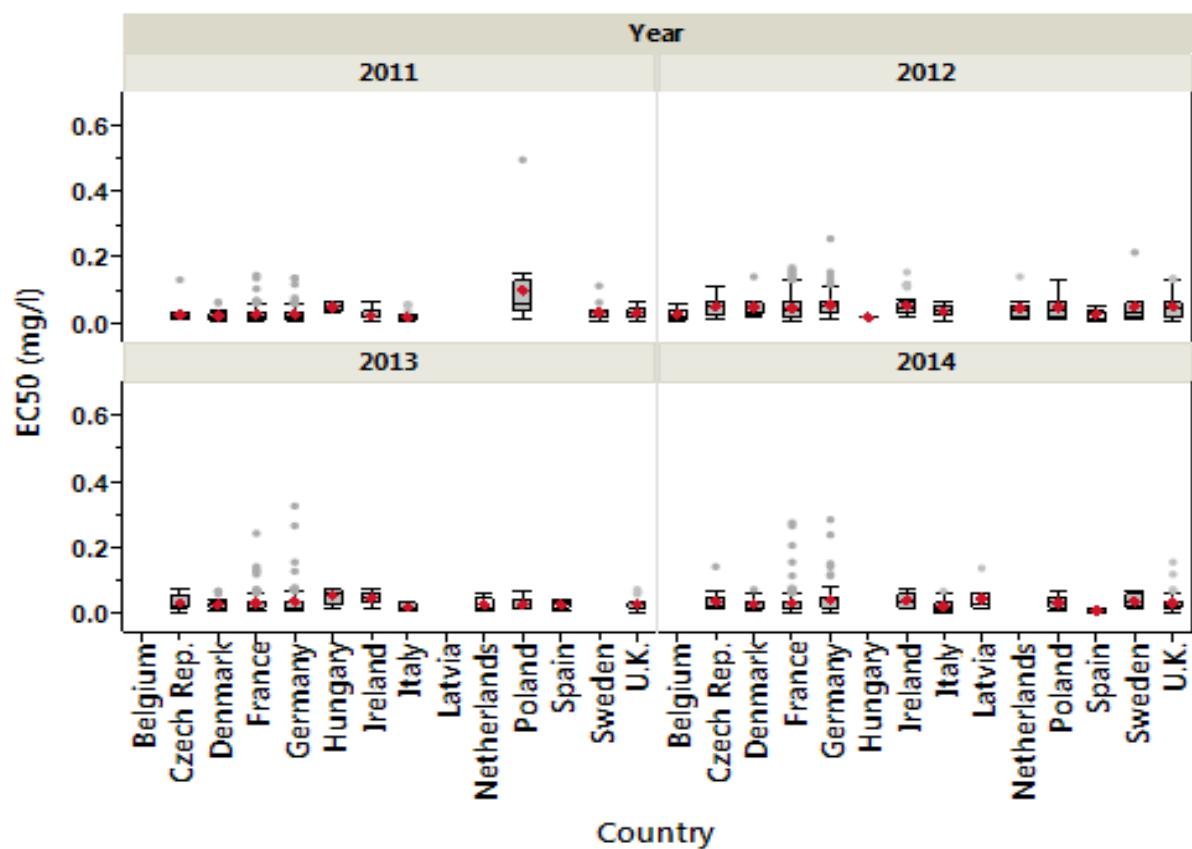


Figure 3.3-5: EC₅₀ values - yearly view by country - box and whisker plot summary



**Table 3.3-1: Minimum and maximum EC₅₀ values measured within countries over period of sampling
(Diversity factor - Max EC₅₀/Min EC₅₀)**

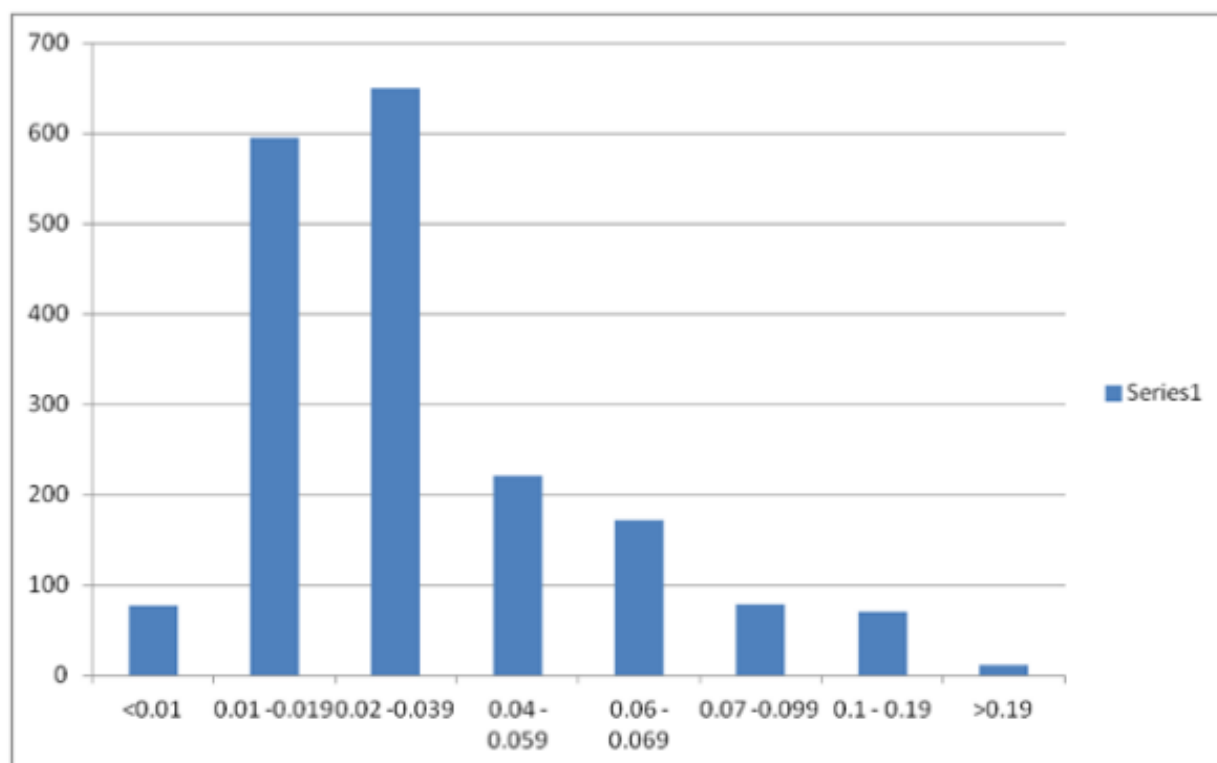
Country	Year	Number of samples	Min EC ₅₀	Max EC ₅₀	Diversity factor
Ireland	2011	15	0.008	0.064	8
Ireland	2012	47	0.018	0.156	8.6
Ireland	2013	10	0.021	0.075	3.6
Ireland	2014	18	0.013	0.076	5.8
UK	2011	50	0.006	0.067	11.2
UK	2012	67	0.011	0.139	12.6
UK	2013	47	0.006	0.074	12.3
UK	2014	77	0.004	0.157	39.2
France	2011	130	0.005	0.147	29.4
France	2012	169	0.006	0.168	28
France	2013	157	0.009	0.244	27
France	2014	171	0.008	0.265	33
Sweden	2011	20	0.01	0.114	11.4
Sweden	2012	16	0.016	0.215	13.4
Sweden	2014	10	0.016	0.072	4.5
Denmark	2011	34	0.004	0.063	15.8
Denmark	2012	10	0.018	0.142	7.9
Denmark	2013	35	0.01	0.071	7.1
Denmark	2014	30	0.01	0.074	7.4
Germany	2011	102	0.005	0.137	27.4
Germany	2012	119	0.015	0.257	17.1
Germany	2013	135	0.009	0.324	36
Germany	2014	85	0.007	0.282	40
Poland	2011	12	0.017	0.496	29.2
Poland	2012	20	0.015	0.134	8.9
Poland	2013	30	0.015	0.068	4.5
Poland	2014	21	0.011	0.069	6.3
Czech	2011	12	0.014	0.132	9.4
Czech	2012	17	0.017	0.111	6.5
Czech	2013	18	0.008	0.75	9.4
Czech	2014	20	0.014	0.141	10
Italy	2011	27	0.004	0.059	14.8
Italy	2012	20	0.011	0.069	6.3
Italy	2013	5	0.01	0.032	3.2
Italy	2014	31	0.003	0.067	22
Hungary	2011	5	0.034	0.069	2
Hungary	2012	2	0.02	0.02	1
Hungary	2013	4	0.018	0.074	4.1
Netherlands	2012	12	0.015	0.143	9.5
Netherlands	2013	17	0.009	0.067	7.4
Belgium	2012	10	0.017	0.059	3.5
Latvia	2014	10	0.015	0.139	9.3

Spain	2012	10	0.011	0.056	5
Spain	2013	9	0.011	0.041	3.7
Spain	2014	10	0.003	0.017	5.7
EU wide	2011	407	0.004	0.496	124
EU wide	2012	519	0.006	0.257	42.8
EU wide	2013	467	0.006	0.324	54
EU wide	2014	483	0.003	0.282	94
EU wide	2011-14	1876	0.003	0.496	165

Table 3.3-2: Grouping of EC₅₀ values into frequency classes

Range of EC ₅₀	No. of isolates 2011 -2014 combined	2011	2012	2013	2014
<0.01	77	43	4	9	21
0.01 -0.019	595	160	77	195	163
0.02 -0.039	650	125	171	163	191
0.04 - 0.059	221	39	95	41	46
0.06 - 0.069	172	23	90	31	28
0.07 -0.099	79	5	37	19	18
0.1 - 0.19	70	10	43	6	11
>0.19	11	1	2	3	5
	1875	406	519	467	483

Figure 3.3-6: Histogram representation of distribution of isolates across frequency groupings (2011 -2014 data combined)



3.3.5.2 PUCCRT in Wheat – summary of data from 2015

Results and Conclusions

The bioassay results for all isolates obtained from the samples are expressed as calculated mean EC50 (geometric mean) values in Table 3.3-21. i.e. the mean value of the 10 isolates isolated from each sampled region. The individual inhibition values across the complete dose response for each isolate are recorded in DAS report (2032179 -Kemmitt- 2015) . The test series produced consistent results within and between the single runs / tests / bioassays - indicating good performance of the in vitro testing system for Fenpicoxamid. The bioassay produced a clear dose response at the EC50 sensitivity level - leading to a typical and expected sensitive reaction in all cases and allowing clear EC50 calculations.

The EC50 min max values and a diversity factor (EC50max/EC50min) for the samples are presented in Table 3.3-22. This figure is a useful measure of the range of sensitivity within the population and any increase in the size of the value can be an indicator that there is a possible shift to lower sensitivity. Figure 3.3-15 shows the cumulative frequency distribution for all 260 isolates. This is a classical way of visualising sensitivity data and any shift of the curve towards the right in future years of testing will provide early warning of possible reduction of sensitivity in the population.

For evaluation and assessment of the sensitivity level of the pathogen, for monitoring and resistance risk analysis as well as for investigations of population dynamics under selection pressure, it appears that using the EC50 values will be more accurate. Overall mean EC50 values at an individual country and a pan European level for 2015 are summarised in Table 3.3-3 (all figures rounded up or down to nearest 2 decimal places). Additional monitoring of PUCCRT sensitivity will be carried out in 2016 in order to add additional data to this initial pre-launch baseline. This will also allow the data to be grouped into frequency classes as has been done for SEPTTR and hence derive an upper sensitivity limit for the wild type population. It is envisaged that post launch of Fenpicoxamid monitoring of sensitivity of the PUCCRT population will be continued.

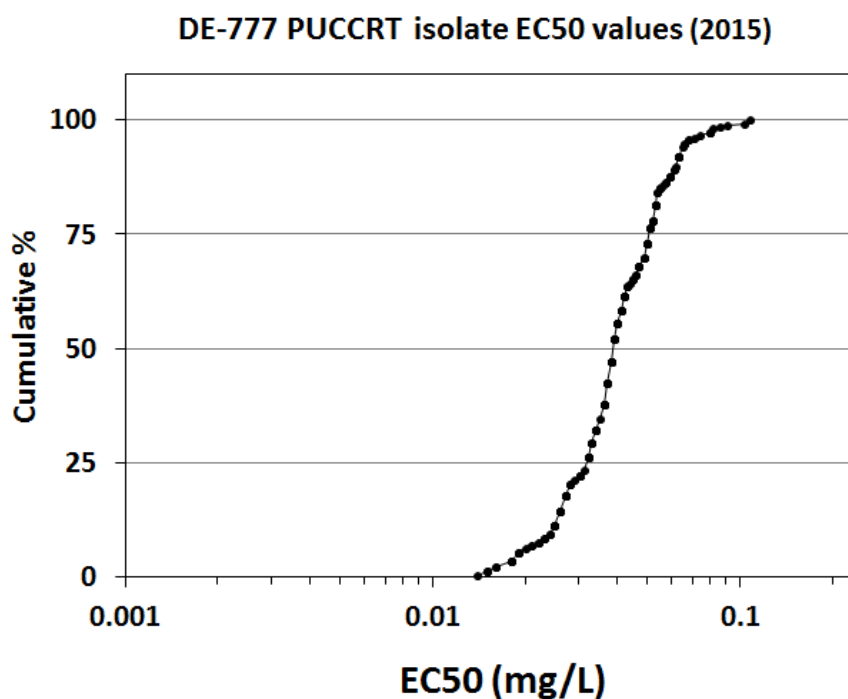
Table 3.3-3: Summary of PUCCRT Mean EC₅₀ (MEC₅₀) by country for sample year 2015

	mean EC50 mg/L	no of isolates
United Kingdom	0.04	20
France	0.04	90
Belgium	0.06	10
Germany	0.04	80
Denmark	0.02	10
Italy	0.04	20
Poland	0.04	10
Hungary	0.05	10
Austria	0.04	10
EU wide	0.04	260

Table 3.3-4: Diversity factor (EC_{50max} / EC_{50min}) of a) all isolates and b) all samples of brown rust of wheat (*Puccinia triticina*) bioassayed for sensitivity to GF-3308 / Fenpicoxamid (XDE-777), 2015

a) Isolates:				
Year	n (Isolates)	EC_{50min}	EC_{50max}	Diversity factor
2015	260	0.014	0.108	7.7
b) Samples:				
Year	n (Regions)	MEC_{50min}	MEC_{50max}	Diversity factor
2015	26	0.020	0.062	3,1

Figure 3.3-7: Cumulative frequency plot of MEC_{50} values for all 260 isolates of *Puccinia triticina* (PUCCRT) tested in 2015.



3.3.5.3 Data on PYRNTE- summary of data from 2018-2021

Summary and Conclusions - PYRNTE Fenpicoxamid (DE-777) baseline

Looking at MEC₅₀ values across 2018-2021 on a pooled EU wide scale the MEC₅₀ value for PYRNTE sensitivity to DE-777 in the EU population sits within the range of 0.52 to 0.849 mg/L (Table 3.3-5).

This is based upon a sample size of 993 isolates, suggesting the sensitivity of the wild type EU PYRNTE population to DE-777 is relatively homogeneous across the EU.

It is also useful to look at the data set with respect to the spread of individual sensitivity values across countries and years (Table 3.3-5). The countries with consistently the largest range between min and max EC₅₀ are France, UK, Germany and Denmark. A simple way to assign a numerical value to the size of the range between min and max EC₅₀ values is to calculate the diversity factor for a sample (Max EC₅₀/Min EC₅₀), see Table 3.3-5. It can be seen from Table 3.3-5 that the diversity factors calculated are relatively homogeneous across all countries.

Looking for appearance of individual isolates with abnormally high EC₅₀s (i.e. outside baseline range) is an important component of active monitoring programs. These isolates are typically at very low frequencies initially but will increase in frequency if a true sensitivity shift is occurring. The lowest EC₅₀ for fenpicoxamid (DE-777) detected to date across 301 isolates assayed is 0.013 mg/L from Czech Republic whilst the highest was 1.88 mg/L from Germany.

If the data set is grouped according to the frequency classes shown in and

Figure 3.3 - 8, then looking across the distribution of EC₅₀ values for the 993 isolates bio assayed, it is evident that 884 out of 993 isolates (89%) fall within the range of 0.3 to 1.65 mg/L. It is suggested that this range is used to set the upper limits of the baseline distribution with careful analysis of future post launch monitoring program data to track any appearance of a significant frequency of isolates with EC₅₀ values >2mg/L.

The data set generated from 2018-2021 forms a comprehensive picture of the baseline sensitivity of EU PYRNTE populations and will be invaluable as reference point for future post launch monitoring programs for DE-777.

Table 3.3-5: Minimum and maximum EC50 values measured within countries over period of sampling (Diversity factor - Max EC50/Min EC50)

Country	Year	n (Isolates)	EC50min	EC50max	Diversity factor
United Kingdom	2018	50	0.3	1.85	6.2
United Kingdom	2019	50	0.27	2	7.3
United Kingdom	2020	36	0.35	1.78	5.1
United Kingdom	2021	48	0.26	1.56	6
France	2018	60	0.19	1.16	6.1
France	2019	67	0.28	1.9	6.6
France	2020	48	0.15	1.56	10.4
France	2021	50	0.26	1.69	6.5
Germany	2018	100	0.27	1.88	7
Germany	2019	73	0.32	2	6.3
Germany	2020	34	0.27	0.96	3.6
Germany	2021	44	0.17	1.69	9.9
Austria	2018	10	0.32	0.94	2.9
Austria	2019	10	1.08	1.9	1.8
Austria	2021	5	0.37	0.57	1.5
Belgium	2018	3	0.46	0.64	1.4
Belgium	2019	8	0.46	0.8	1.7
Belgium	2020	10	0.26	1.54	5.9
Denmark	2018	25	0.41	1.08	2.6
Denmark	2019	20	0.38	2.6	6.9
Denmark	2020	10	0.17	1.67	9.8
Sweden	2018	3	0.33	0.76	2.3
Sweden	2019	10	0.34	2.3	6.8
Sweden	2020	9	0.82	2.88	3.5
Italy	2018	10	0.38	1.11	2.9
Italy	2020	8	0.39	0.96	2.5
Italy	2021	10	0.2	0.84	4.2
Czech Republic	2018	10	0.13	1.71	13.1
Czech Republic	2019	10	0.33	1.8	5.3
Czech Republic	2020	3	0.65	0.88	1.4
Czech Republic	2021	10	0.6	1.78	3
Hungary	2018	10	0.39	1.25	3.2
Hungary	2019	9	0.41	1.4	3.3
Hungary	2020	4	0.3	0.86	2.9
Hungary	2021	20	0.23	1.95	8.5
Poland	2018	20	0.36	1.77	4.9
Poland	2019	30	0.35	2.1	5.9
Poland	2020	20	0.17	1.93	11.4
Ireland	2020	18	0.25	1.81	7.2
Ireland	2021	15	0.33	1.51	4.6
Slovakia	2020	3	0.93	1.51	1.6
EU wide	2018	301	0.13	1.88	4.78
EU wide	2019	287	0.422	1.9	5.2
EU wide	2020	203	0.4	1.5	5.4
EU wide	2021	202	0.3025	1.44875	5.5

Table 3.3-6: Grouping of EC50 values into frequency classes (PYRNTE) - fenpicoxamid

EC50 ranges mg/L	Number isolates
0 -0.29	51
0.3 - 0.39	107
0.4 -0.49	123
0.5 - 0.849	332
0.85 - 0.99	168
1 - 1.64	155
>1.65	57

Figure 3.3 - 8 Sensitivity classes of EU *P. teres* isolates: distribution of EC50 values (across years) fenpicoxamid

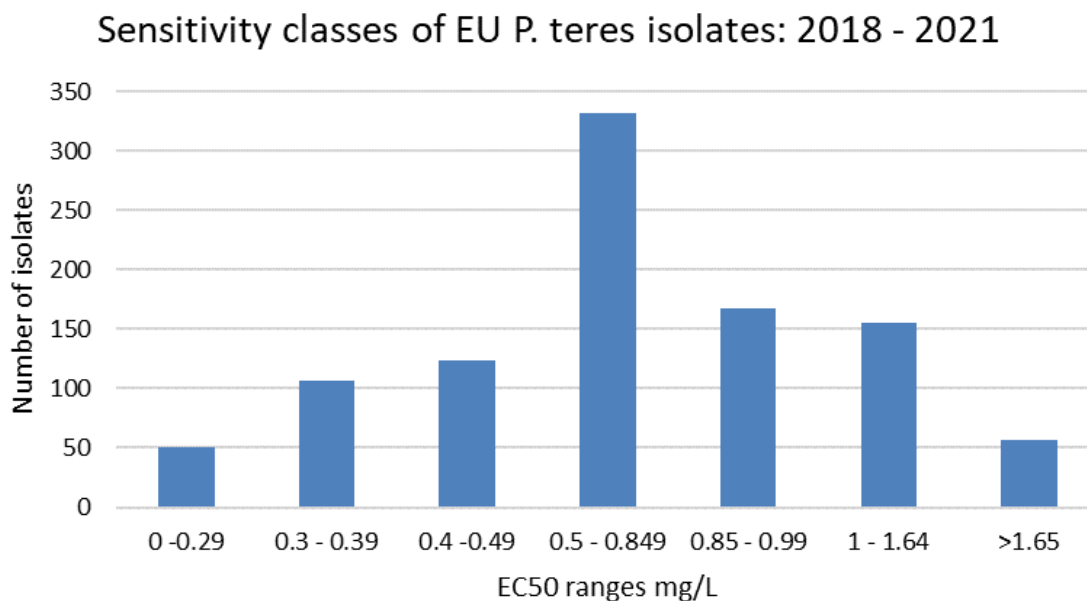


Figure 3.3 - 9 Evolution of sensitivity to fenpicoxamid over years

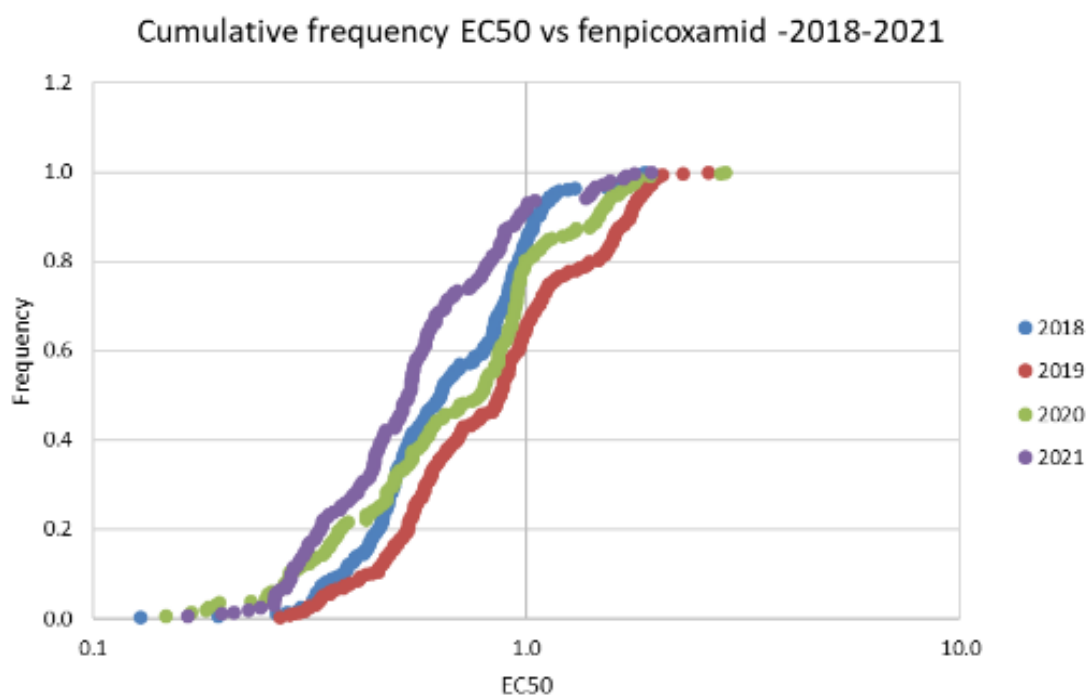
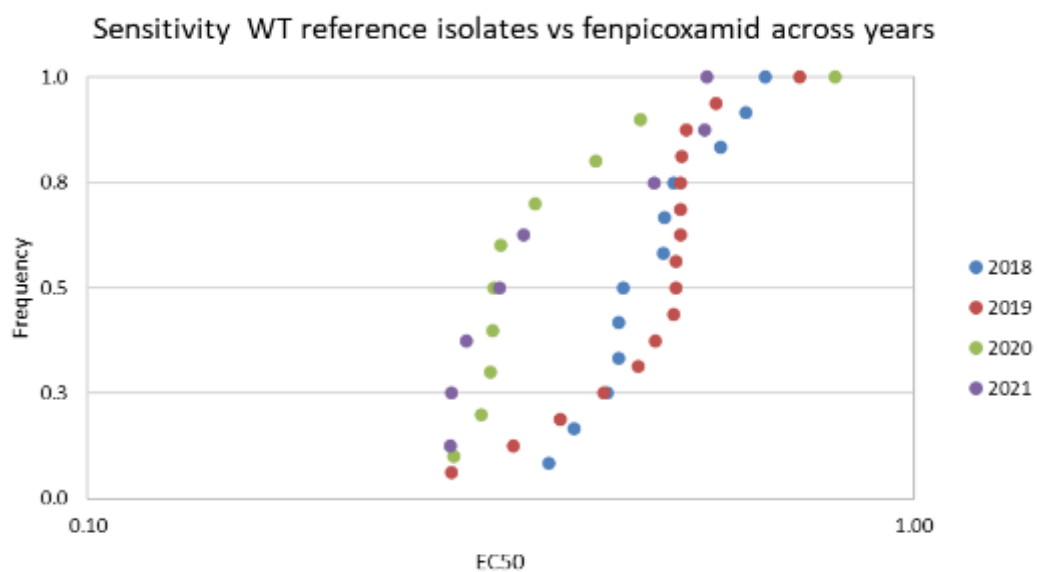


Figure 3.3 - 10 Evolution of sensitivity to fenpicoxamid over years



Variability observed for sensitive wild type strains is identical to the one observed for the baseline.

Sensitivity baseline for European *Pyrenophora teres* population versus Prothioconazole Conclusions **2021**

A bioassay was conducted for 252 isolates collected from 36 European regions of 12 countries (Table 3.3-7). The test series produced consistent results within and between the single runs / tests / bioassays - indicating good performance of the *in vitro* testing system for prothioconazole. At the European Level, the mean EC50 was found to be 7.11 mg/L and mean EC50min and mean EC50max were 3.29 and 12.96 respectively. The distribution of the EC50s shows that most isolates have an EC50 in between 4 and 8.99 (Figure 3.3 - 11).

The distribution of the EC50s and sensitivity classes can be considered as a useful reference for setting the baseline of EU populations of PYRNTE to prothioconazole prior commercialisation.

Table 3.3-7: Summary of Mean EC50s (prothioconazole) by country for PYRNTE samples -2021 prothioconazole

Country	Arithmetic mean MEC50* mg/L	no of isolates
United Kingdom	7.91	48
France	6.06	50
Germany	6.5	44
Austria	5.28	5
Ireland	8.53	15
Czech Republic	4.63	10
Italy	2.5	10
Sweden	10.83	15
Denmark	10.11	20
Hungary	5.67	20
Finland	7.9	5
Latvia	9.43	10
EU wide	7.11	252

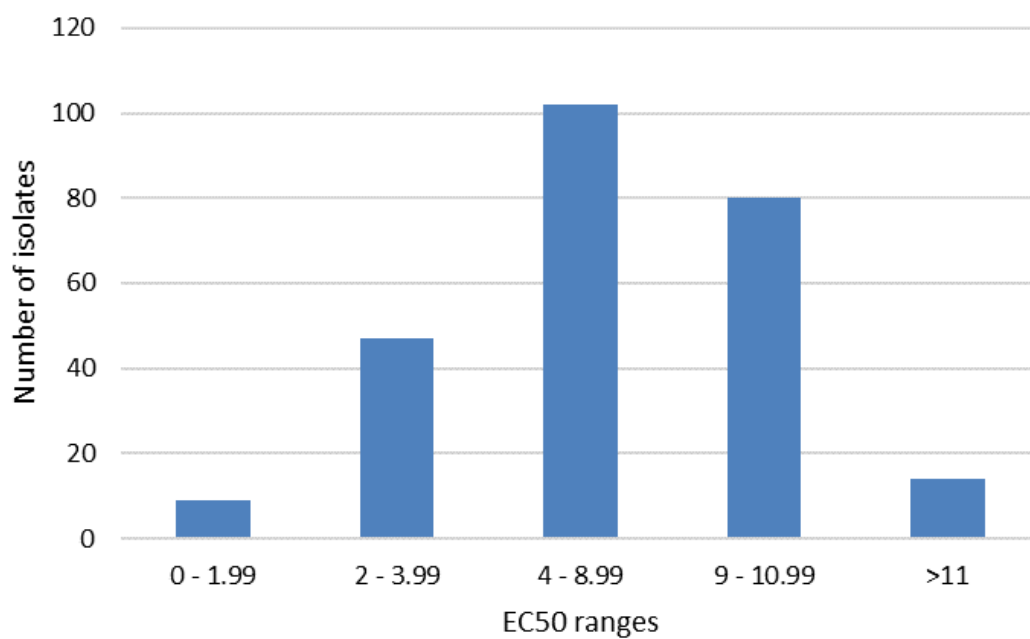
Table 3.3-8: Minimum and maximum EC50 values measured within countries for PYRNTE samples (Diversity factor - Max EC50/Min EC50) – 2021 prothioconazole

Country	n (Isolates)	EC50min	EC50max	Diversity factor
United Kingdom	48	3.13	17.32	5.53
France	50	1.34	17.32	12.93
Germany	44	0.87	17.32	19.91
Austria	5	2.15	8.75	4.07
Ireland	15	3.6	10.91	3.03
Czech Republic	10	2.04	6.63	3.25
Italy	10	1.23	3.39	2.76
Sweden	15	8.82	17.32	1.96
Denmark	20	7.08	17.32	2.45
Hungary	20	0.77	11.28	14.65
Finland	5	3.33	10.58	3.18
Latvia	10	5.17	17.32	3.35
EU wide	252	3.29	12.96	6.42

Table 3.3-9: Sensitivity classes of EU *P. teres* isolates: distribution of EC50 values - 2021 prothioconazole

EC50 ranges (mg/L)	n° isolates
0 - 1.99	9
2 - 3.99	47
4 - 8.99	102
9 - 10.99	80
>11	14

Figure 3.3 - 11 Histogram representation of distribution of PYRNTE isolates across frequency groupings - 2021 prothioconazole



Data on RAMUCC – summary of data from 2018-2020

Summary and Conclusions RAMUCC fenpicoxamid (DE-777) baseline.

Looking at MEC₅₀ values across 2018-2020 on a pooled EU wide scale the MEC₅₀ value for RAMUCC sensitivity to fenpicoxamid (DE-777) in the EU population sits within the range of 0.24 to 1.1 mg/L). This is based upon a sample size of 613 isolates between 2018-2020.

It is useful to look at the data set with respect to the spread of individual sensitivity values across countries and years (Table 3.3-10). The country with the largest range between min and max EC₅₀ is Germany (0.05-9.93) which reflects the significantly higher sample size taken from this country (45% of all samples of 3 years are from Germany). A simple way to assign a numerical value to the size of the range between min and max EC₅₀ values is to calculate the diversity factor (DF) for a sample (Max EC₅₀/Min EC₅₀) (Table 3.3-10). It can be seen from Table 3.3-10 that the diversity factors calculated are relatively homogeneous across countries, although once again Germany has a higher DF due to the large sample size analysed. However it should be noted that the UK also has large min/max range from 40 samples (0.08-8.9 Max EC₅₀/Min EC₅₀) and the second highest DF behind Germany.

Looking for appearance of individual isolates with abnormally high EC₅₀s (i.e. outside baseline range) is an important component of active monitoring programs. These isolates are typically at very low frequencies initially but will increase in frequency if a true sensitivity shift is occurring. The lowest EC₅₀ for fenpicoxamid (DE-777) detected to date across 617 isolates assayed is 0.05 mg/L from Germany whilst the highest was 9.93 mg/L also from Germany in 2019 and 8.9 mg/L from the UK in 2020.

If the data set is grouped according to the frequency classes shown in

Table 3.3-11 and

Figure 3.3 - 12, then looking across the distribution of EC₅₀ values for the 617 isolates bioassayed it is evident that 555 out of 613 isolates (73%) fall within the range of 0.1 to 1.49 mg/L. The majority of the population is between 0.2-0.49 mg/L. It is suggested that this range is used to set the upper limits of the baseline distribution with careful analysis of future post launch monitoring program data to track any appearance of a significant frequency of isolates with EC₅₀ values >5.0 mg/L.

Table 3.3-10: Minimum and maximum EC50 values measured within countries over period of sampling (Diversity factor - Max EC50/Min EC50)

Country	Year	n (Isolates)	EC50min	EC50max	Diversity factor
France	2018	12	0.17	1.4	8.2
France	2019	82	0.05	2.19	43.8
France	2020	30	0.1	0.93	9.3
Germany	2018	103	0.05	3.69	74
Germany	2019	59	0.1	9.93	99.3
Germany	2020	120	0.08	2.89	36.1
United Kingdom	2018	21	0.11	4.08	37
United Kingdom	2019	9	0.08	1.87	23.38
United Kingdom	2020	10	0.11	8.9	80.9
Ireland	2018	30	0.11	3.06	27.8
Ireland	2020	10	0.11	0.6	5.5
Czech Republic	2018	10	0.15	0.49	3.3
Czech Republic	2020	28	0.17	1.29	7.6
Italy	2018	10	0.09	1.28	14.2
Danemark	2019	36	0.1	1.76	17.6
Slovakia	2019	5	0.15	2.65	17.67
Switzerland	2019	9	0.1	2.92	29.2
Hungary	2020	29	0.09	1.63	18.1
EU wide	2018	186	0,05	4,08	27.41
EU wide	2019	200	0.1	3.55	38.49
EU wide	2020	227	0.11	2.71	26.2

Table 3.3-11: Grouping of EC50 values into frequency classes (RAMUCC)

EC50 ranges mg/L	Number Isolates
0 - 0.099	28
0.1 - 19	155
0.2- 0.49	281
0.5-0.99	94
1 -1.49	25
>1.5	30

Figure 3.3 - 12 Sensitivity classes of EU RAMUCC isolates: distribution of EC50 values (across years)

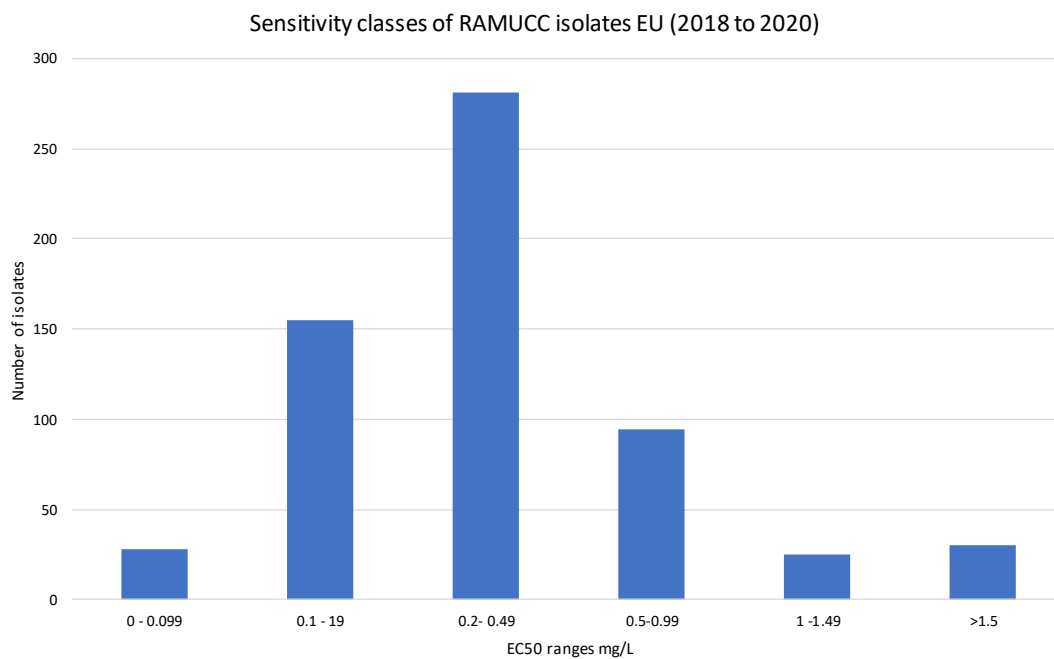
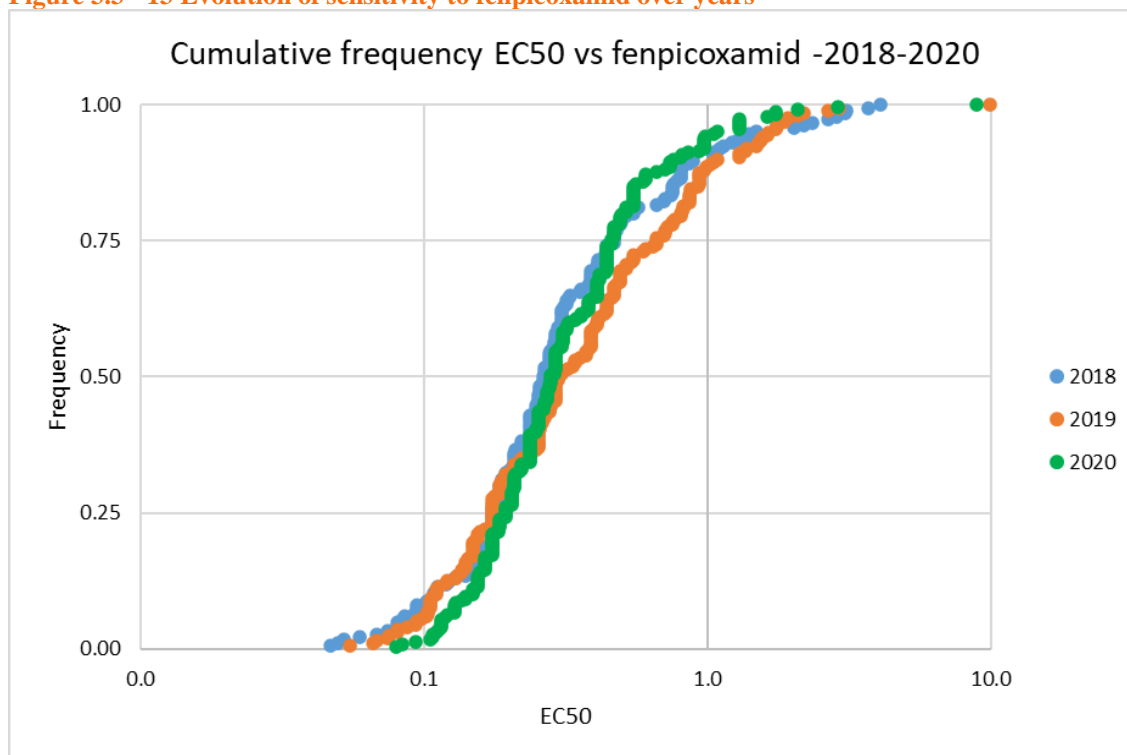


Figure 3.3 - 13 Evolution of sensitivity to fenpicoxamid over years



3.3.6 Use pattern and Resistance risk associated with unrestricted use pattern

The proposed use of GF-3307 on wheat is for one application at 1.0-1.5 L/ha (50-75 g fenpicoxamid/ha + 100-150 g prothioconazole/ha), applied between BBCH 30-69 of the crop.

The proposed use of GF-3307 on rye is for one application at 1.2-1.5 L/ha (60-75 g fenpicoxamid/ha + 120-150 g prothioconazole/ha), applied between BBCH 30-69 of the crop.

The proposed use of GF-3307 on triticale is for one application at 1.2-1.5 L/ha (60-75 g fenpicoxamid/ha + 120-150 g prothioconazole/ha), applied between BBCH 30-69 of the crop.

The proposed use of GF-3307 on barley is for one application at 1.0-1.5 L/ha (50-75 g fenpicoxamid/ha + 100-150 g prothioconazole/ha), applied between BBCH 30-69 of the crop.

3.3.7 Mechanism of resistance against the compound (intrinsic fungicide risk)

In order to assess the risk of practical resistance in the target pests, it is necessary to evaluate the different factors contributing to the risk. The inherent risk depends on various factors, some of which are associated with the pest and others with the product. These factors do not necessarily operate in isolation and do not apply in all cases. Local growing conditions also can play an important role and should be considered. These are usually referred to as the agronomic risk. The actual risk of evolution of resistance to a fungicide depends on three main parameters.

Fenpicoxamid DE-777

Fenpicoxamid (DE-777) is a single site inhibitor at the Qil site. FRAC has published the following specific guidance on resistance risk for fenpicoxamid in wheat (Group 21 (C4) fenpicoxamid (Qil) Recommendations 17th April 2019¹⁴) and will be amended in the future to include barley. “Field resistance not currently known to this molecule. Resistance risk unknown but assumed to be medium to high risk. Resistance management required.”

There are to date no reports of field resistance to Qil inhibitors in cereal pathogens as would be expected since this MOA is not currently commercialised in this segment and no other current MOA used in cereals would be expected to have target site based cross resistance to Fenpicoxamid (DE-777). It is not known if the mutations generated in yeast and SEPTTR *in vitro* which confer reduced sensitivity to Qil inhibitors will also occur in other target diseases and furthermore if they would appear and persist in the field population. Based on our knowledge today we must assume that the intrinsic fungicide risk for Fenpicoxamid’s biochemical MOA at the Qil target site is medium to high.

Prothioconazole

Available information on mode of action and resistance risk with the triazole class of inhibitors is probably the most complete of any fungicide group. Numerous publications are available on the mechanisms functioning with respect to DMI resistance. The most significant of these mechanisms is based on the accumulation of different mutations within the Cyp51 locus. Multiple different Cyp51 mutations have been identified and it is now clear that the different mutations and combinations of mutations have varying impacts on the efficacy of different triazoles.

The resistance risk of DMI fungicides including Prothioconazole is classified by FRAC as high to low depending on the target disease. Resistance management for prothioconazole in cereals is coordinated as for all DMIs by the FRAC SBI working group of which the applicant is an active member.

All the recommendations of the group are applied for prothioconazole and will be covered by the proposed use pattern for GF-3307. The applicant also refers the assessing authority to data previously submitted in support of prothioconazole efficacy and resistance risk management by Bayer Crop Sciences to which Corteva Agrisciences has been granted a letter of access .

¹⁴ [https://www.frac.info/docs/default-source/other-fungicide-recommendations/group-21-\(c4\)---fenpicoxamid-\(qii\)-recommendations-17th-of-april-2019.pdf?sfvrsn=aad54b9a_2](https://www.frac.info/docs/default-source/other-fungicide-recommendations/group-21-(c4)---fenpicoxamid-(qii)-recommendations-17th-of-april-2019.pdf?sfvrsn=aad54b9a_2)

3.3.7.1 Biology of the pathogen (pathogen risk)

No scientific criteria are available to accurately determine the risk of a pathogen to develop resistance. Thus, FRAC's classification is based on experience and reported resistance claims over the last 45 years. Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high, sexual recombination is mandatory in the disease cycle and the competitive ability of resistant individual is at least as high as that of the wild type (in the absence of selection pressure). Pathogens with shorter life cycles generally require more frequent fungicide application resulting in greater selection pressure and more rapid resistance development. Pathogens producing more spores have higher potential for resistance development due to more genetic diversity available for selection as well as more rapid and extensive dispersal of resistant isolates. Pathogens with sexual stages will have a different resistance risk compared to strictly asexual organisms. Finally, pathogens in isolated populations will have higher resistance risk due to limited genetic variability.

SEPTTR has a high potential to cause serious epidemics and an ability to produce large numbers of spores both asexual and sexual. More important the degree of sexual recombination in **SEPTTR** is significant. Septoria leaf blotch is currently, in the absence of host resistance, controlled by programmed application of azoles (triazoles and imidazoles), succinate dehydrogenase inhibitors (SDHIs) and multi-site inhibitors. Methyl benzimidazole carbamates (MBC) (e.g. carbendazim) and quinone outside inhibitors (QoIs) (e.g. azoxystrobin) no longer control the disease in some major cereal producing regions of Western Europe due to development of mutations resulting in amino acid substitutions in the target proteins β -tubulin (E198A) and cytochrome *b* (F129L and G143A), respectively (Fraaije *et al.*, 2005; Lucas and Fraaije, 2008). **SEPTTR** is classified by FRAC as a medium risk pathogen in regards to potential to develop fungicide resistance. (FRAC Pathogen Risk List, 2013 version <http://www.frac.info/docs/default-source/publications/pathogen-risk/pathogen-risk-list.pdf?sfvrsn=8>).

Reports of resistance development to both Puccin (Puccin) and Puccin (Puccin) are very infrequent in the literature. A review of (Fungicide Resistance Action Committee (FRAC) List of Pathogenic Organisms resistant to Disease Control Agents - 2013 revision) references only one publication reporting a sensitivity shift with Puccin to DMI fungicides as measured in the laboratory (Bayles *et al.*, 2000). FRAC designate both Puccin and Puccin as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). Puccin and Puccin are also not amongst the pathogens listed in EPPO guidance document PP1/213(2) as an example of pathogens considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated.

PYRNTR has a high potential for causing serious epidemics with an ability to produce large numbers of airborne spores. The degree of sexual recombination within **PYRNTR** is also significant. Reports of resistance development to QoI inhibitors in **PYRNTR** in the field have been reported from Germany, Sweden and Denmark (Jorgensen and Olson, 2007). Sensitivity of **PYRNTR** to DMI fungicides appears to remain good with no published reports of resistance issues. FRAC designates **PYRNTR** as a pathogen with a medium risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). **PYRNTR** is also not listed in EPPO guidance document PP1/213(2) as an example of a pathogen considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated.

FRAC designates *Fusarium spp.* as pathogens with a low risk of developing resistance to fungicides. (FRAC Pathogen Risk List, 2013 version). *Fusarium spp.* in wheat are also not listed in EPPO guidance document PP1/213(2) as being considered to be at high risk of developing resistance and requiring that sensitivity baseline data be generated. Resistance of *Fusarium graminearum* to benzimidazoles and DMIs has only been reported from laboratory studies (Chen, *et al.* 2009, Yin *et al.* 2009 respectively) although no details were provided as to the resistance mechanism operating in each case.

Historical data suggests that *Blumeria graminis* is as a high-risk pathogen with regard to resistance (Brent and Holloman, 2007) due to a short life-cycle and abundant sporulation. The pathogen has developed resistance to benzimidazoles soon after their introduction (Holloman and Wheeler, 2002).

Resistance developed also to 2-aminopyrimidines (ethirimol) in the 1970's and later to triazoles (SBI Class I) and morpholines (SBI Class II). Then, were reported: resistance to QoIs at the end of 90s (Sierotzki et al. 2000), reduced sensitivity to quinoxifen in early 2000s and to metrafenone in 2009 (Felsenstein, et al. 2010). *Blumeria graminis* baseline was not established in wheat or barley because fenpicoxamid has minimal activity on this disease when applied alone and regular testing is conducted by Bayer Crop Science for prothioconazole and reported to FRAC.

In addition, among the fungal diseases targeted by GF-3307 *Ramularia collo-cygni* on barley is considered at high risk with regard to resistance development. This emerging pathogen, having only been recognized as important in Europe in the last 30 years, was capable of relatively rapid build-up of resistance to QoI fungicides.

Other pathogenic fungi on barley such as net blotch (*Pyrenophora teres*) are viewed by FRAC as medium risk, as some resistance to certain fungicides has been confirmed. On the other hand, various cereal rusts (*Puccinia* spp.), barley scald (*Rhynchosporium secalis*) have low risk of resistance development, even if resistance of some of these pathogens to certain groups of fungicides was reported.

3.3.7.2 Agronomical factors (agronomic risk)

Agronomic factors comprising effects of locally variable factors such as disease pressure, climate, or complexity of cultivars are most important in assessing the risk (Kuck, 2005). Resistance is more likely to develop first in areas of intensive cropping and fungicide use that are, as a result, areas of severe disease outbreaks because environmental conditions favoured the development and spread of the disease. Use of cultural practices such as stubble burial, crop rotation, and varietal resistance can play a role in lowering primary inoculum pressure and slowing rate of epidemic development with cereal diseases however fungicides remain the key component of strategies to manage this disease effectively. In the most intensive cereal growing regions of Europe and particularly in seasons where weather conditions are favourable for build-up of high pressure up to 4 foliar sprays per crop may be applied. Considering the above parameters, the overall resistance risk for GF-3307 used alone within an unrestricted use pattern scenario should be considered as medium to high in relation to the SEPTTR wheat pathosystem and the RAMUCC barley pathosystems but medium to low in relation to the other target pathosystems. With respect to the high risk pathogen ERYSSP, Fenpicoxamid has only moderate intrinsic activity on this pathogen and the majority of the mildew control seen with GF-3307 is provided by the prothioconazole component in the product. Out of the target pathogens applied for on the GF-3307 label SEPTTR, RAMUCC and ERYSSP are considered likely to be the pathogens at most risk of potential resistance development. As such a risk management strategy will be necessary and driven by SEPTTR on wheat and RAMUCC on barley although the risk modifiers which will be proposed in section 3.3.7 will also directly help to manage risk in other target diseases.

3.3.8 Test methods.

See 'Sensitivity data' section (3.3.5).

3.3.9 Acceptability of the resistance risk

The risk of development of resistance in cereal pathogens from unrestricted use is considered low to high depending on the target pathogen. As there is a potential of resistance developing over time, it is considered that unmodified use is not recommended and a management strategy is required to ensure the risk from use of GF-3307 is acceptable.

3.3.10 Management Strategy for GF-3307

GF-3307 150 g/L EC will provide crop growers with a valuable new resistance management option for disease control in cereals. Because fenpicoxamid and prothioconazole do not share the same mode of action, the mixture represents a valid resistance management practice for the control of high resistance risk pathogens. However, given the nature of the other target pests and the history of resistance associated with these pests and DMI fungicides, we propose that the following modifiers be applied to the

product use pattern in order to reduce the potential risk of resistance. The following risk modifiers are proposed:

- GF-3307 EC best practice (as recommended by FRAC for all cereal fungicides) is to apply preventively i.e. at the early stages of disease development and in any case before the disease is firmly established in the crop.
- The number of foliar applications of GF-3307 within a total disease management program must be limited to **one per season**.
- Tank-mixtures and / or sequential applications with a fungicide from a different cross resistance group to picolinamides and DMI fungicides can be recommended and will contribute to reducing the development of resistance to both mode of actions.
- Strongly reduced rate programs including multiple ‘split’ applications must not be used.
- Always follow product specific label recommendations for resistance management.

Resistance management of Fenpicoxamid, prothioconazole and the mixtures of both should align with that of the picolinamide and DMI fungicides as specified by the Fungicide Resistance Action Committee (FRAC).

The above recommendations are based on the combinations of different strategies i.e. mixtures, alternation, restricted number of applications, preventive use and chemical diversity. This integrated approach is supported by FRAC as described in the FRAC Monograph No. 1. The FRAC guidelines are available on the internet (<http://www.frac.info>) and are available to plant protection advisors in European countries. The GF-3307 EC label includes a statement reflecting the above guidelines for the control of cereals diseases.

The applicant also undertakes to actively promote the resistance management plan, via product literature and during product technical presentations with customers and growers.

3.3.11 Implementation of the Management Strategy

There are a number of steps in the implementation of the resistance management strategy, ultimately based on methods of communication with the grower, either directly or indirectly. Proposals are outlined below:

1. An internal training program of sales and development representatives prior to and during the launch of GF-3307 150 g/L EC will be organized with emphasis on resistance management. Educational material on resistance and resistance management will be presented at launch meetings with customers.
2. The principles of good plant protection practice will be promoted both during training sessions and within commercial advisory literature. These include the use of both cultural and chemical control measures and recommendations to ensure that fungicide application is made under favourable environmental conditions.
3. The use of GF-3307 150 g/L EC with differing modes of action either in tank-mix or in sequence will be promoted within training meetings and on all commercial support literature.
4. The statements / modifiers relating to resistance management presented in the preceding sections will appear on the label. Study of the label is recommended prior to the use of the product.
5. One application per season of GF-3307 in all crops.

The applicant will also undertake to actively promote the resistance management plan, via product literature and during product technical presentations with customers and growers. The fenpicoxamid and prothioconazole resistance management strategies are communicated on the FRAC website (Working Group #21 “QiIs” and Working Group #3 “SBI-Fungicides”, respectively) and in the form of technical publications in appropriate journals or conferences.

3.3.12 Monitoring, reporting and reaction to the changes in performance

The applicant is an active member of FRAC and would anticipate joining the FRAC QiI cereals task force group once Fenpicoxamid DE-777 is commercialised. Annual monitoring of the sensitivity of the EU SEPTTR, RAMUCC and PYRNTE populations to Fenpicoxamid (DE-777) and prothioconazole will continue post launch in order to detect any signs of a shift away from the pre-launch baseline which has been presented in this dossier section. This will be supplemented by continuous observation of field performance. Any significant change in sensitivity will be reported through FRAC and the

relevant country resistance management and regulatory agencies. This will allow the applicant to rapidly adapt the resistance management strategy should the need arise.

3.3.13 Conclusion.

The active substances of GF-3307: fenpicoxamid (50 g/L) and prothioconazole (100 g/L), are a pre-mixture of non-cross resistant fungicides effective against foliar pathogens on cereals.

The applicant is conducting a resistance monitoring programme on a regular basis in order to detect the potential development of fungicide resistance in fungi in Europe and help farmers and advisors to make a better diagnosis after a control failure with any of its products.

If this should occur, the applicant will be able to provide sound recommendations in terms of chemical control and agronomic practices to come back to a manageable situation.

zRMS comments on the risk of resistance:

1. Prothioconazole represents well known SBI Class I (DMI), FRAC group 3 (G1), while fenpicoxamid is relatively novel a compound, representing FRAC group 21 (C4), with the mode of action based on binding to the quinone **inside** site of mitochondrial electron transport complex III. Both prothioconazole and fenpicoxamid represent **single-site** mode of action, whereas some of the pathogens targeted by GF-3307, as ERYSGH and RAMUCC, are considered as **pathogens of high risk** of resistance development.
2. Following the scheme outlined in the EPPO guidance PP1 / 213 (4), the applicant characterized: 1) the resistance risk intrinsic in the key target pathogens (SEPTTR, PUCCRT, PYRNTE and RAMUCC) and 2) the one intrinsic in the actives – components of the GF-3307:

The applicant has presented brief characteristics of the pathogen targets of GF-3307, and in some cases, short info on monitoring of their **sensitivity** to **prothioconazole**, in the years of 2017-2020, along with new data on **baseline sensitivity to fenpicoxamid**, in key pathogens targeted by GF-3307: SEPTTR and PUCCRT in wheat, and in PYRNTE and RAMUCC in barley. Of all the pathogens monitored for **prothioconazole** sensitivity, only the situation with RAMUCC seems complex, with locally high frequency of isolates highly resistant to prothioconazole. As for the baseline sensitivity to **fenpicoxamid**, the data submitted show stable situation in SEPTTR (2011-2014) and in PYRNTE (2018-2021) and a uniform sensitivity across the sampled area in PUCCRT (although PUCCRT data cover one year only – 2015). The data for RAMUCC (2018-2020) are also quite “clustered”, showing no excessive frequency of insensitive or very sensitive isolates, and seem to be more stable in consecutive years compared to PYRNTE, in spite of the isolate count being two-fold higher for RAMUCC compared to PYRNTE. As concluded from preliminary studies on GF-3307, although the pathogen of high risk of resistance development, powdery mildew (ERYSGR) is not primary target for the new active fenpicoxamid. Consequently, no data on baseline sensitivity of ERYSGR are presented for this active.

To the knowledge of zRMS the 2021 might have been the first year of the use of fenpicoxamid in cereals in Europe.

3. The applicant has concluded that the **unmodified** risk of resistance resulting from the unrestricted use is medium to high for SEPTTR and RAMUCC, and low to medium for PUCCRT and PYRNTE.
4. **Cross-resistance**
to other MoAs, including DMI, was addressed experimentally on SEPTTR alone, during the preliminary trial phase. No resistance was found to fenpicoxamid in *Septoria* strains not sensitive or resistant to azole, MBC, QoI or SDHI fungicides. The applicant assumes that in the other target pathogens the situation would be similar.

For prothioconazole, the short statement is presented, to the sense that no cross-resistance in the main groups of fungicides, potentially applicable as partner-actives, has been observed.

Both statements have been accepted by zRMS. The absence of data for other targets in case of fenpicoxamid possibly results from the short period of use of this substance in other MSs in Europe. On the other hand, the screening in SEPTTR is not the field data, but a laboratory experiment by the applicant and it might have been expected that at least one other target pathogen could be tested for cross resistance. Yet, since the active emerged relatively recently and shows MoA different from the other main groups of contemporary fungicides, there is no reason to anticipate high frequency of resistance to it in targets so far non-exposed, even those possibly resistant to other MsoA. Therefore the lack of data other than those on SEPTTR can be accepted.

The FRAC recommendations for DMI fungicides on the other hand, including prothioconazole, remain unaltered since 2018: the cross-resistance **within** DMI subgroups I-III is prudently taken for granted, while no new cross-resistance cases **between** DMI and other main fungicide groups have been reported.

5. As for the new active, fenpicoxamid, the FRAC website is not really outgoing about the uses in cereals: “*resistance unknown, resistance management required*”. Indeed, the resistance in fenpicoxamid may be claimed unknown, and both actives require resistance management strategy, but, as they are **applied as manufacturer’s mixture**, then at least initially no reduced sensitivity, to the new product as a whole, should be expected.

The risk modifiers proposed by the applicant:

- The test item itself may be considered a resistance management tool, working both ways to preserve the

efficacy / usefulness of both actives at the same time.

- GF-3307 is recommended for preventive application, and the use pattern includes a single application per growth season, preventing repeated exposure in the same year.
 - The applicant recommends using GF-3307 in a sequence or in tank mixtures with still other (not named) products. The recommendation is already included in the project label and should be retained and followed, provided that no restrictions are expressed by the manufacturers of potential partner products.
 - Indirectly, the applicant refers a number of times to a rather acknowledged concept of varietal resistance that “*can play a role in lowering primary inoculum pressure and slowing rate of epidemic development...*”. To the opinion of zRMS the varietal resistance should be clearly included, as a standard entry, in the resistance management section of any fungicide label, since it works in unison with chemical fungicides.
6. As the GF-3307 is a new product with only initial a history of usage, it deserves attention and vigilance of the applicant as much as that of farmers. Once the monitoring claimed by the applicant starts and reports on field performance appear, any necessary amendments to the “resistance management strategy” will be easier to identify and more applicable. At the moment, however, there is no reason to make a fuss. One application per growth season is claimed and accepted; it is just impossible to be more cautious than that.

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4: Adverse effects on treated crops)

The efficacy trials reported no phytotoxicity or adverse effects to treated crops at dose rates of GF-3307 up to 1.5 L/ha, on all crops (see section 3.4.1.) and yield results from these trials demonstrated no adverse effects in the presence of disease (see section 3.2.3).

EPPO PP 1/135(4) '*Phytotoxicity Assessment*' states that no specific crop safety/selectivity trials to assess adverse effects on treated crops (yield and quality) are required, where no adverse effects have been reported in the effectiveness trials. However, some selectivity data are available and these have been included in this dossier for completeness and are detailed in Table 3.4-1.

Table 3.4-1: Presentation of trials (selectivity trials, transformation trials)

Crop*	Country	Type of trial**	Number of trials			Years	GEP, non-GEP, official***	Comments (any other relevant information)
			Maritime zone	North-East zone	South-East zone			
TRZAW	France	S + Y + Q + P	1	-	-	2014	GEP	
	France	P	1	-	-	2014	GEP	Germination test
	France	TF	4	-	-	2015	GEP	Bread baking
	UK	S + Y + Q + P	2	-	-	2014	GEP	
	UK	P	2	-	-	2014	GEP	Germination test
	Latvia	S + Y + Q + P	-	1	-	2014	GEP	
	Latvia	P	-	1	-	2014	GEP	Germination test
	Hungary	S + Y + Q + P	-		1	2014	GEP	
	Hungary	P	-		1	2014	GEP	Germination test
	Poland	P	-	1	-	2014	GEP	Germination test
	Germany	TF	2	-	-	2015	GEP	Beer brewing studies with grain from 2 field trials
	Germany	P	1		-	2014		Germination test
TRZAS	Germany	S + Y + Q	1		-	2014	GEP	
	Poland	S + Y + Q	-	1	-	2014	GEP	
TTLWI, SECCW, HORVW	UK	S	1	-	-	2014	GEP	Crop screening trial
HORVW	France	TF	2	-	-	2017	GEP	Brewing
HORVS	France	TF	2	-	-	2017	GEP	Brewing
TOTAL	-	-	19	4	2	-	-	

* According to the GAP table

** S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

*** Official: carried out by a national official organisation

Table 3.4-2: Presentation of reference standards used in trials (selectivity trials, transformation trials)

Crop(s)	Reference standards	Country(ies) where the product is registered ⁽¹⁾	Authorization number	Active substance(s) (a.s)	Formulation		Registered application rate ⁽³⁾	Application rate in trials (per treatment)	Remark ⁽⁴⁾
					Type ⁽²⁾	Concentration of a.s.			
TRZAW	Proline 275	(see Table 3.2-29)		prothioconazole	EC	275 g/L	0.72 L/ha	0.72 L/ha	
	Aviator XPRO 225 EC	(see Table 3.2-29)		Bixafen + prothioconazole	EC	75+150 g/L	1.25 L/ha	1.25 L/ha	
	Artea	(see Table 3.2-29)		cyproconazole + propiconazole	EC	80+250 g/L	0.5 L/ha	0.4-0.6 L/ha	
TRZAS	Proline 275	(see Table 3.2-29)		prothioconazole	EC	275 g/L	0.72 L/ha	0.72 L/ha	
	Aviator XPRO 225 EC	(see Table 3.2-29)		bixafen + prothioconazole	EC	75+150 g/L	1.25 L/ha	1.25 L/ha	
TRZAW	Ignite	As the active is generic many products and brands are registered across the EU countries.		epoxiconazole	EC	83 g/L	1.5 L/ha	1.5 L/ha	Only used in bread baking study as azole reference
HORVW, HORVS	Opus	Previously registered in France (until 2019)		epoxiconazole	SC	125 g/L	1.0 L/ha when authorised	1.0 L/ha	Brewing studies

(1) only on use(s) applied for (with the test product)

(2) e.g. WP (wetable powder), EC (emulsifiable concentrate), etc.

(3) Dose / dose range authorized in the country

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application...)

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Introduction

Data presented in this section cover phytotoxicity data from ~~232~~ 267 efficacy trials with GF-3307 applied at the proposed label dose for the countries in this dossier. Data is also presented from specific selectivity trials conducted to evaluate potential phytotoxicity of GF-3307 at up to 2.0 L/ha (maximum label dose in Europe) and at dose rates up to 4.0 L/ha as the 2 N dose rates. The crops involved in the testing were winter wheat, spring wheat, winter rye, winter triticale, winter barley and spring barley. An overview of the evaluation of the crop tolerance of GF-3307 is presented in Table 3.4-3.

Table 3.4-3: Overview on the cereal crop tolerance of GF-3307 observed in the efficacy and selectivity trials

Trial type	Crop	GF-3307 1N/2N rate	Number of GEP trials	Number of GEP trials	Maximum phytotoxicity (%) recorded during the trials
Efficacy	TRZAW	1N	107	129	0
Efficacy	TRZAS	1N	3	4	0
Efficacy	SECCW	1N	17	19	0
Efficacy	TTLWI	1N	32	32	0
Efficacy	HORVW	1N	45	54	0
Efficacy	HORVS	1N	28	29	0
Selectivity	TRZAW	1N/2N	5	5	0
Selectivity	TRZAS	1N/2N	2	2	0
Selectivity variety screening*	TTLWI, SECCW, HORVW	1N/2N	1	1	0

*A non-replicated trial.

3.4.1.1 Phytotoxicity in efficacy trials

Introduction

In total, 107 effectiveness trials were carried out on winter wheat (TRZAW), three on spring wheat (TRZAS), 17 trials in winter rye (SECCW), 32 trials on winter triticale (TTLWI), 45 trials on winter barley (HORVW) and 28 trials in spring barley (HORVS) to evaluate the efficacy of GF 3378, applied at a dose rate of up to 1.5 L/ha against various diseases. All 232 trials included assessments of crop phytotoxicity and the majority were taken to harvest. All trials were conducted according to GEP and were of an RCB plot design with 4 replicates on a wide range of commercially grown varieties, across a range of climatic and agronomic conditions. Crops were treated between growth stages BBCH 30–65.

The trials were conducted in Austria, Belgium Czech Republic, Denmark, France, Germany, UK, Latvia, Poland, Bulgaria, Hungary, Romania and Slovakia between 2014 and 2020. The trials covering countries in the Maritime, North East and South East EPPO climatic zones, as described in EPPO Standard PP 1/241, and are representative of the proposed GAP.

Material and methods

For information on testing organisations used, as well as for trials site and experimental details refer to section 3.2 and Appendix 3 and Appendix 4 of the BAD. A summary of the varieties used is as follows:

Table 3.4.4: Phytotoxicity assessments of GF 3307 – Varieties tested in efficacy trials

Crop (EPPO)	No-of trials	No-of varieties	Variety names (No-of trials)
Winter wheat (TRZAW)	Total: 107 EPPO Maritime: 47 EPPO North East: 25 EPPO South East: 35	Total: 68 EPPO Maritime: 33 EPPO North East: 15 EPPO South East: 20	EPPO Maritime: Altamira, Artist, Akteur (5), Ambition, Bernstein, Bohemia, Bussard, Colonia, Cordiale, Crusoe (2), Dagmar, Desamo, Element, Etana, Grafton, Hereford, Hermann, Ilona, JB Asano (6), Judita, Muza (2), Nakskov, Patras (2), Pionier, Princeps, Ritmo, Santiago, Smaragd, Socrates, Solstice, Substance (2), Tobak (6), Toras. EPPO North East: Arkadia (2), Artis, Bogatka (3), Emil, Fidelius, Fredis, Hondia, Muszelka, Sailor (3), Sukees, Tobak, Turnia, Wydma, Zentos (4), Zyta (3). EPPO South East: Antonius (2), Ariesan (2), Balaton (1), Babilio, MV Buzogány, Cellule, GK Csillag, Enova (2), Genius (2), GK Élet (4), Glosa (2), Glossa (2), Iridium (3), Lupus, Marshall, Miranda (3), Rubisko (3), MV Suba, MV Toldi, Sadovo 772.
Spring wheat (TRZAS)	Total: 3 EPPO North East: 3	Total: 3 EPPO North East: 3	EPPO North East: Tybalt, Zebra, Harenda
Winter rye (SECCW)	Total: 17 EPPO Maritime: 12 EPPO North East: 5	Total: 8 EPPO Maritime: 4 EPPO North East: 4	EPPO Maritime: Minello, Palazzo (8), Reerut, Visello (2). EPPO North East: Bono, Dankowskie Diament (2), Kier, Palazzo.
Winter triticale (TTLWI)	Total: 32 EPPO Maritime: 17 EPPO North East: 15	Total: 17 EPPO Maritime: 10 EPPO North East: 7	EPPO Maritime: Adverda, Agostino (2), KWS Avea, Aveo, Cedrico, Grenado, (2), SU Agendus (2), Talendro (2), Talento (2), Tender (4). EPPO North East: Grenado (3), Magnat (4), Remiko (2), Trismart, Tulus, Twingo, Witen.
Winter barley (HORVW)	Total: 45 EPPO Maritime: 30 EPPO North East: 9 EPPO South East: 6	Total: 31 EPPO Maritime: 20 EPPO North East: 7 EPPO South East: 4	EPPO Maritime: Arcanda, California (2), Casino, KWS Cassia, Cervoise, Etincel (5), Frigg, KWS Glacier, Hannelore, Henriette, Infinity, Lomerit (2), Maltesse, Maris Otter, KWS Meridian (3), Sandra (2), KWS Tonic (2), SU Vireni, Wootan, Yatsy. EPPO North East: Bartosz, Carola (3), Kobuz, Kosmos, Meridian, Padura, Zenek. EPPO South East: Antonella, Obzor (2), SU Ellen, Vanessa.
Spring barley (HORVS)	Total: 28 EPPO Maritime: 14 EPPO North East: 10 EPPO South East: 4	Total: 23 EPPO Maritime: 11 EPPO North East: 8 EPPO South East: 4	EPPO Maritime: Avalon, Concerto, Grace (3), Laurikka, Milford, Odyssey, Oviation (2), Propino, Sebastian, Salome, Vendela. EPPO North East: Blask, Iron (2), Nokia, Propino, Ringo,

			Stratus, Tocada (2), KWS Vermont. EPPO South-East: Conchita, Kangoo, Tango, Xanadu.
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Results

No phytotoxicity symptoms were seen at any point in the season, using GF 3307 at dose rates up to 1.5 L/ha or using the commercial standards, in any of the 107 trials were carried out on winter wheat (TRZAW), three on spring wheat (TRZAS), 17 trials in winter rye (SECCW), 32 trials on winter triticale (TTLWI), 45 trials on winter barley (HORVW) and 28 trials in spring barley (HORVS), across a wide range of varieties (150). The individual results from the trials are detailed in Appendix 6 of the BAD.

Introduction

In total, 129 effectiveness trials were carried out on winter wheat (TRZAW), 4 on spring wheat (TRZAS), 19 trials in winter rye (SECCW), 32 trials on winter triticale (TTLWI), 54 trials on winter barley (HORVW) and 29 trials in spring barley (HORVS) to evaluate the efficacy of GF-3378, applied at a dose rate of up to 1.5 L/ha against various diseases. All 267 trials included assessments of crop phytotoxicity and the majority were taken to harvest. All trials were conducted according to GEP and were of an RCB plot design with 4 replicates on a wide range of commercially grown varieties, across a range of climatic and agronomic conditions. Crops were treated between growth stages BBCH 30-65.

The trials were conducted in Austria, Belgium Czech Republic, Denmark, France, Germany, UK, Latvia, Poland, Bulgaria, Hungary, Romania and Slovakia between 2014 and 2021. The trials covering countries in the Maritime, North-East and South-East EPPO climatic zones, as described in EPPO Standard PP 1/241, and are representative of the proposed GAP.

Material and methods

For information on testing organisations used, as well as for trials site and experimental details refer to section 3.2 and Appendix 3 and Appendix 4 in the BAD. A summary of the varieties used is as follows:

Table 3.4-5: Phytotoxicity assessments of GF-3307 - Varieties tested in efficacy trials

Crop (EPPO)	No of trials	No of varieties	Variety names (No of trials)
Winter wheat (TRZAW)	Total: 129 EPPO Maritime: 49 EPPO North-East: 38 EPPO South-East 42	Total: 79 EPPO Maritime: 34 EPPO North-East: 23 EPPO South-East 22	EPPO Maritime: Altamira, Artist, Akteur (5), Ambition, Bernstein, Bohemia, Bussard, Colonia, Cordiale, Crusoe (2), Dagmar, Desamo, Element, Etana, Federer, Grafton, Hereford, Hermann, Ilona, JB Asano (6), Judita (2), Muza (2), Nakskov, Patras (3), Pionier, Princeps, Ritmo, Santiago, Smaragd, Socrates, Solstice, Substance (2), Tobak (6), Toras. EPPO North-East: Arkadia (3), Artis, Artist (2), Bilanz, Bogatka (3), Emil, Euforia (2), Fidelius, Fredis, Hondia, Joker, Julius, Muszelka, Patras, Princeps, Sailor (3), Sukces, Tobak, Tonacja, Turnia, Wydma, Zentos (4), Zyta (5). EPPO South-East: Altigo, Antonius (2), Ariesan (2), Balaton (3), Basilio, MV Buzogány, Cellule, GK Csillag, Dagmar, Enova (2), Genius (3), GK Élet (4), Glosa (4), Glossa (2), Iridium (3), Lupus, Marshall, Miranda (3), MV Nador, Rubisko (4), MV Suba, MV-Toldi, Sadovo 772.
Spring wheat (TRZAS)	Total: 4 EPPO North-East: 4	Total: 4 EPPO North-East: 4	EPPO North-East: Goplana, Tybalt, Zebra, Harenda
Winter rye (SECCW)	Total: 19 EPPO Maritime: 12 EPPO North-East: 7	Total: 10 EPPO Maritime: 4 EPPO North-East: 6	EPPO Maritime: Minello, Palazzo (8), Recrut, Visello (2), EPPO North-East: Bono, Brasetto, Dankowskie Diament (2), Kier, Palazzo, Brasetto, Dankowskie Diament, Kier, SU Performer.
Winter triticale (TTLWI)	Total: 32 EPPO Maritime: 16 EPPO North-East: 16	Total: 16 EPPO Maritime: 9 EPPO North-East: 7	EPPO Maritime: Adverda, Agostino (2), KWS Avea, Aveo, Grenado, (2), SU Agendus (2), Talendro (2), Talento (2), Tender (4). EPPO North-East: Grenado (4), Magnat (4), Remiko (2), Trismart, Tulus, Twingo, Witon.

Winter barley (HORVW)	Total: 54 EPPO Maritime: 29 EPPO North-East: 11 EPPO South-East 14	Total: 37 EPPO Maritime: 19 EPPO North-East: 9 EPPO South-East 9	EPPO Maritime: Arcanda, California (2), Casino, KWS Cassia, Cervoise, Etincel (5), Frigg, KWS Glacier, Hannelore, Henriette, Lomerit (2), Maltesse, Maris Otter, KWS Meridian (3), Sandra (2), KWS Tonic (2), SU Vireni, Wootan. Yatsy. EPPO North-East: Bartosz, Bazant, Carola (3), Kobuz, Kosmos, SU Jule, KWS Meridian, Padura, Zenek. EPPO South-East: Antonella, Astaire, Calypso, Cardinal (2), Casanova (2), Obzor (2), Planet, SU Ellen (2), Vanessa.
Spring barley (HORVS)	Total: 29 EPPO Maritime: 14 EPPO North-East: 10 EPPO South-East 5	Total: 24 EPPO Maritime: 11 EPPO North-East: 8 EPPO South-East 5	EPPO Maritime: Avalon, Concerto, Grace (3), Laurikka, Milford, Odyssey, Ovation (2), Propino, Sebastian, Salome, Vendela. EPPO North-East: Blask, Iron (2), Nokia, Propino, Ringo, Stratus, Tocada (2), KWS Vermont. EPPO South-East: Bojo, Conchita, Kangoo, Tango, Xanadu.

Table 3.4-6: Maximum phytotoxicity on winter and spring wheat recorded for the duration of the effectiveness trials in treatments with GF-3307 and the reference standards.

Number of trials with...		TRZAW Efficacy trials (129 trials)		TRZAS Efficacy trials (4 trials)	
		GF-3307	Standards#	GF-3307	Standards#
		N	N	N	N
Maximum of phytotoxicity recorded during the trials	0%	129	129	4	4
	>0% to 10%	0	0	0	0
	>10 %	0	0	0	0
Level of symptoms at the last assessments	0%	129	129	4	4
	>0% to 10%	0	0	0	0
	>10 %	0	0	0	0

#For standards used, see relevant sections

Table 3.4-7: Maximum phytotoxicity on winter rye and winter triticale recorded for the duration of the effectiveness trials in treatments with GF-3307 and the reference standards.

Number of trials with...		SECCW Efficacy trials (19 trials)		TTLWI Efficacy trials (32 trials)	
		GF-3307	Standards#	GF-3307	Standards#
		N	N	N	N
Maximum of phytotoxicity recorded during the trials	0%	19	19	32	32
	>0% to 10%	0	0	0	0
	>10 %	0	0	0	0
Level of symptoms at the last assessments	0%	19	19	32	32
	>0% to 10%	0	0	0	0
	>10 %	0	0	0	0

#For standards used, see relevant sections

Table 3.4-8: Maximum phytotoxicity on winter and spring barley recorded for the duration of the effectiveness trials in treatments with GF-3307 and the reference standards.

Number of trials with...		HORVW Efficacy trials (54 trials)		HORVS Efficacy trials (29 trials)	
		GF-3307	Standards#	GF-3307	Standards#
		N	N	N	N
Maximum of phytotoxicity recorded during the trials	0%	54	54	29	29
	>0% to 10%	0	0	0	0
	>10 %	0	0	0	0

Number of trials with...		HORVW Efficacy trials (54 trials)		HORVS Efficacy trials (29 trials)	
		GF-3307	Standards#	GF-3307	Standards#
		N	N	N	N
Level of symptoms at the last assessments	0%	54	54	29	29
	>0% to 10%	0	0	0	0
	>10 %	0	0	0	0

#For standards used, see relevant sections

Results

No phytotoxicity symptoms were seen at any point in the season, using GF-3307 at dose rates up to 1.5 L/ha or using the commercial standards, in any of the 129 trials were carried out on winter wheat (TRZAW), 4 on spring wheat (TRZAS), 19 trials in winter rye (SECCW), 32 trials on winter triticale (TTLWI), 54 trials on winter barley (HORVW) and 29 trials in spring barley (HORVS), across a wide range of varieties (170). The individual results from the trials are detailed in Appendix 6 in the BAD.

zRMS comments:

Based on the complete inspection of all the efficacy trial reports submitted by the applicant the zRMS confirms that phytotoxicity symptoms were reported by none of the testing units in none of the trials, which makes the submission of the dedicated selectivity trials unnecessary, according to the PP 1/135(4) EPPO guidance.

3.4.1.2 Phytotoxicity to winter wheat in selectivity trials

Introduction

In total five phytotoxicity trials were established to demonstrate the selectivity of GF-3307 applied in winter wheat. The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were placed in France (1), the United Kingdom (2), Hungary (1) and Latvia (1) in 2014 in areas where winter wheat is commercially grown. The trial from France was within the Maritime EPPO zone part of the country.

On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The EU Central Regulatory Zone covers countries in EPPO climatic zones Maritime, North-East and South-East as described in EPPO standard PP 1/241. This chapter comprises data from the Maritime, North-East and South-East EPPO zones which are representative of the proposed GAP.

Material and methods

Testing facilities or organisations

The selectivity trials were carried out by the testing facilities in the countries listed in Table 3.4-9 below

Table 3.4-9: Testing facilities involved by EPPO Zone

Table 3.4-8: Testing facilities involved by EPPO Zone

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	EPPO Guideline	Trial Status
Southern	Maritime	France	2014	FR14E7B016MC01C	Biotek Agriculture, FR	PP1/135	GEP
Central	Maritime	UK	2014	GB14E7B016EB01C	Armstrong Fisher LTD, UK	PP1/135	GEP
Central	Maritime	UK	2014	GB14E7B016EB02C	Oxford Ag. Trials, UK	PP1/135	GEP

Northern	North-East	Latvia	2014	LV14E7B016MN02C	Latvian Plant Protection Research Centre	PP1/135	GEP
Central	South-East	Hungary	2014	HU14E7B016AB01C	Agrofil, HU	PP1/135	GEP

Trial sites were selected on the basis of favourable agronomical and environmental factors, in areas representative of those where the crop is grown. For further trial site details see the BAD.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	fenpicoxamid + Prothioconazole (50 + 100 g as/L)	2.0, 4.0	300, 600
Proline 275	EC	Prothioconazole (275 g as/L)	0.72	198

Experimental details

The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 24 and 36 m². The treatments in all trials were applied using self-propelled, or bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 100 and 300 L/ha.

To support the label claims GF-3307 was applied at the maximum European proposed label rate of 2.0 L/ha (300 g as/ha) and 2X dose of 4.0 L/ha (600 g as/ha) in accordance with the EPPO standard PP 1/135 (*Phytotoxicity assessment*) as leading guideline. The reference product included was Proline 275 applied at 0.72 L/ha (198 g as/ha prothioconazole). GF-3307 and Proline each were applied at 2 timings between BBCH 37-43 and BBCH 65-69, respectively to maximise any selectivity issue and to cover the maximum growth stage of BBCH 69 (although the GAP is 1 application/year for GF-3307 at 1.5 L/ha for countries in this dossier, this presents the worst case situation with 2 application at 4.0 L/ha).

Assessments for crop selectivity were performed at 1 and 2 weeks after each application. Crop injury was assessed as % crop injury; phytotoxic effects such as chlorosis, necrosis, stunting, or thinning were specified if present.

Statistical analysis

The tabulated selectivity data presented in this section of the biological dossier are showing the treatment means of the percentage of crop injury found relative to the untreated. Instead of statistical tests across trials the minimum and maximum means of the individual trial means are presented in the summary tables.

Results

GF-3307 at 2.0 L/ha and 4.0 L/ha applied at two timings at proposed label rate and 2N rate proved to be fully selective to the crop in all trials.

Table 3.4-10:

Table 3.4-9: Maximum phytotoxicity on winter wheat recorded for the duration of the selectivity trials in treatments with GF-3307 and the reference Proline.

EPPO Zone	Trial number	Winter wheat variety	1st Application		2nd Application		Maximum Phytotoxicity(%)		
			Crop BBC H	Date	Crop BBC H	Date	GF-3307	GF-3307	Proline
							2 x 2.0 L/ha	2 x 4.0 L/ha	2 x 0.72 L/ha
Maritime	FR14E7B016MC01C	Oregrain	41-43	23-Apr-14	65-65	14-May-14	0	0	0
Maritime	GB14E7B016EB01C	Revelation	39-39	14-May-14	65-69	03-Jun-14	0	0	0
Maritime	GB14E7B016EB02C	Claire	43-43	30-May-14	69-69	30-Jun-14	0	0	0
North-East	LV14E7B016MN02C	Skagen	37-41	22-May-14	69-69	19-Jun-14	0	0	0
South-East	HU14E7B016AB01C	Genius	37-39	07-May-14	65-69	11-Jun-14	0	0	0

zRMS comments:

Five trials listed in Table 3.4-9 are double application trials. The only case of considerable injury observed but not listed in the table is in the LV14E7B016MN02C trial, 7 days after the **second** application of the test item GF-3307 **at 4.0L/ha** (>5 week application interval).

The 4.0 L/ha dose rate used exceeds the 2N value claimed in the present submission where 3.0 L/ha should be considered as 2N, and moreover the application was doubled. Therefore the record of this particular injury should be considered as non relevant for the use pattern applied for in the present dossier.

3.4.1.3 Phytotoxicity to spring wheat in selectivity trials

Introduction

In total two phytotoxicity trials were established to demonstrate the selectivity of GF-3307 applied in spring wheat. The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

The trials were placed in Germany and the United Kingdom in areas where spring wheat is typically grown.

On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The EU Central Regulatory Zone covers countries in EPPO climatic zones Maritime, North-East and South-East as described in EPPO standard PP 1/241. This chapter comprises data from the Maritime and North-East EPPO zones which are representative of the proposed GAP.

Material and methods

Testing facilities or organisations

The selectivity trials were carried out by the testing facilities in the countries listed in Table 3.4-11 below.

Table 3.4-11: Testing facilities involved by EPPO Zone

Table 3.4-10: Testing facilities involved by EPPO Zone

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	EPPO Guideline	Trial Status
Central	Maritime	Germany	2014	DE14E7B016UB01C	BioChem Agrar GmbH	PP1/135	GEP
Central	North-East	Poland	2014	PL14E7B016AS01C	Ior Sosnicowice, PL	PP1/135	GEP

Trial sites were selected on the basis of favourable agronomical and environmental factors, in areas representative of those where the crop is grown. For further trial site details see 3.4-17 to 3.4-18 below.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	fenpicoxamid + Prothioconazole (50 + 100 g as/L)	2.0, 4.0	300, 600
Proline 275	EC	Prothioconazole (275 g as/L)	0.72	198

Experimental details

The trials were of a randomized complete block design with 4 replicates and a plot size ranging between 15 and 20.02 m². The treatments in all trials were applied using self-propelled, or bicycle or knapsack precision small plot sprayers equipped with conventional or low drift flat fan nozzles delivering water volumes between 100 and 300 L/ha.

To support the label claims GF-3307 was applied at the proposed label rate of 2.0 L/ha (300 g as/ha) and 4.0 L/ha (600 g as/ha) in accordance with the EPPO standard PP 1/135 (*Phytotoxicity assessment*) as leading guideline. The reference product included was Proline 275 applied at 0.72 L/ha (198 g as/ha prothioconazole). To support the suggested GAP suggested GF-3307 and Proline each were applied at 2 timings between BBCH 39-41 and BBCH 65-69, respectively.

Assessments for crop selectivity were performed at 1 and 2 weeks after each application. Crop injury was assessed as % crop injury; phytotoxic effects such as chlorosis, necrosis, stunting or thinning were specified if present.

Statistical analysis

The tabulated selectivity data presented in this section of the biological dossier are showing the treatment means of the percentage of crop injury found relative to the untreated. Instead of statistical tests across trials the minimum and maximum means of the individual trial means are presented in the summary table.

Results

GF-3307 at 2.0 L/ha and 4.0 L/ha applied at sequential timings between BBCH 39-41 and BBCH 65-69 proved to be fully selective to the crop in both trials. No injury effects were observed on the spring wheat varieties caused due to treatments with GF-3307 or the reference Proline for the duration of the trials (see. Table 3.4-12).

Table 3.4- below).

Table 3.4-12:

Table 3.4-11: Maximum phytotoxicity on spring wheat recorded for the duration of the selectivity trials in treatments with GF-3307 and the reference Proline.

EPPO Zone	Trial number	Spring wheat variety	1st Application		2nd Application		Maximum Phytotoxicity(%)		
			Crop BBCH	Date	Crop BBCH	Date	GF-3307	GF-3307	Proline
							2 x 2.0 L/ha	2 x 4.0 L/ha	2 x 0.72 L/ha
Maritime	DE14E7B016UB01C	Triso	39-41	31-May-14	65-65	12-Jun-14	0	0	0
North-East	PL14E7B016AS01C	Å»ura	39-39	20-May-14	69-69	16-Jun-14	0	0	0

zRMS comments:

Confirmed based on inspection of trial reports DE14E7B016UB01C and PL14E7B016AS01C.

3.4.1.4 Phytotoxicity to varieties of winter triticale, winter rye and winter barley in a cereal crop screening trial

To evaluate the crop selectivity of GF-3307 at the proposed label rate to cereal crops other than wheat, commercial varieties of TTLWI, SECCW and HORVW were included in a non-replicated cereal crop screening trial carried out in the UK in 2014. GF-3307 was applied at two application timings (BBCH 32-39 and BBCH 55-65) at the maximum European dose of 2.0 L/ha to three varieties of TTLWI and two varieties each of SECCW and HORVW. No reference product was included. Further trial details are presented below. Although two applications are applied in these trials and the dose rate is higher than proposed in this dossier, this presents the worst case scenario to cover the maximum growth stages in the GAP.

Table 3.4-13:

Table 3.4-12: Material and methods for cereal crop screening trial

Trial details	Trial number	GB14E7B042MF01
	EPPO Zone	Maritime
	Trial status	GEP
	Testing organisation	Dow AgroSciences UK
	Country	United Kingdom
	Trial location/Zip Code State/Region	Wellesbourne, CV35 9EF Warwickshire
Guidelines	Guidelines	EPPO PP 1/135, 1/152, 1/181, 1/225 and guidelines referred therein
Experimental	Plot design	Non-randomized

design	Plot size	2 m x 22 m
	Number of replications	1
Crop	Trials per crop	1 trial comprising TTLWI (winter triticale), SECCW (winter rye) and HORVW (winter barley)
	Varieties per crop	TTLWI cv Agostine, Benetto, Grenado, Twingo SECCW cv Agronom, Askari HORVW cv Matros, Volume
	Drilling date	20-Oct-13
Application	Application timings, at crop BBCH	1 st Application 22-April-14 , BBCH 32-39 2 nd Application 15-May-14, BBCH 55-65
	Spray interval days	23
	Spray volume L/ha	Timing A: 150 L/ha, Timing B 100 L/ha
	Nozzle	Flat fan, Lurmark F110-02
	Air temperature °C	11/21
	Relative humidity	90/63
Assessment	Assessment types	Phytotoxic effects as % injury to crop
	Assessment dates*	8 DAAA, 14 DAAA, 8 DAAB, 15 DAAB*

* DAAA=days after timing A, DAAB=days after timing B

Results

Applied in sequence with a 23 days interval, GF-3307 at the maximum European dose rate of 2.0 L/ha, proved to be fully selective to all varieties. Although the treatments were sprayed using low water volumes (100 L/ha and 150 L/ha) across the two application timings, no phytotoxic effects, such as chlorosis, necrosis, growth inhibition, lodging or other adverse effects, were observed at the 2.0 L/ha rate of GF-3307 (which is ~~25% greater~~ **33% higher** than the highest dose of GF-3307 proposed – **1.5 L/ha**).

~~Table 3.4-14:~~

Table 3.4-153: Maximum phytotoxicity of GF-3307 applied at 2 x 2.0 L/ha to varieties of winter triticale, winter rye and winter barley in a cereal crop screen

Crop	Varieties	Maximum level of crop injury (%) observed for the duration of the trial
		GF-3307
		2 x 2.0 L/ha
TTLWI	Agostine, Benetto, Grenado, Twingo	0
SECCW	Agronom, Askari	0
HORVW	Matros, Volume	0

zRMS comments:

Confirmed based on inspection of GB14E7B042MF01 trial report.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Introduction

In total five phytotoxicity trials in winter wheat and two trials in spring wheat were established to demonstrate the selectivity and yield impact of GF-3307. The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). All trials were placed in areas where winter wheat and spring wheat are typically grown

The five trials for winter wheat were placed in France (1), the United Kingdom (2), Hungary (1) and Latvia (1) in 2014 in areas where winter wheat is commercially grown. The trial from France was within the Maritime EPPO zone part of the country. The trials with spring wheat were placed in Germany and Poland in 2014. The trials were placed within the EPPO climatic zones Maritime, North-East and South-East as described in EPPO standard PP 1/241 and therefore are representative of the EU Central Regulatory Zone and of the proposed GAP.

Material and methods

For information on testing organisations involved, for trials site and experimental details refer to sections 3.4.1.2 (winter wheat) and 3.4.1.3 (spring wheat).

Results

A summary of the yield data from five selectivity trials in winter wheat is presented in [Table 3.4-16](#). GF-3307 across the trials yielded 9.1 t/ha (102.6%) at 2.0 L/ha relative to the control plots which yielded 8.4 t/ha (100%). The reference Proline 275 applied at 0.72 L/ha yielded 105.2% relative to untreated. The yield increase observed in treatments with GF-3307 and Proline 275 can be ascribed to a certain level of diseases which were present in the trials and which cannot be fully eliminated using other fungicides for trial maintenance measures.

The yield data obtained from two selectivity trials in spring wheat are presented in [Table 3.4-18](#); [Table 3.4-19](#). Across the trials GF-3307 applied in sequence at 2.0 L/ha yielded 5.1 t/ha (105.2%) and at 4.0 L/ha (2N) 106.8% relative to the control plots which yielded 4.9 t/ha (100%). The reference Proline 275 applied at 0.72 L/ha yielded 115.1% relative to untreated. The yield increase observed in treatments with GF-3307 and Proline 275 can be ascribed to a certain level of diseases present in the trials.

GF-3307 and the reference products included did not exhibit positive or negative effects of the 1000 grain weight of winter wheat or spring wheat varieties tested in the trials.

Table 3.4-16:

Table 3.4-174: Impact of GF-3307 on yield amount (t/ha) and thousand grain weight (g) applied at the proposed label rate in phytotoxicity trials. Summary of data from 5 phytotoxicity trials conducted in winter wheat in the absence of disease or at low disease pressure.

EPPO Zone	Country	Trial number	Yield (corrected to 86% dry matter)										Thousand grain weight (g)											
					GF-3307			GF-3307			Proline					GF-3307			GF-3307			Proline		
			Untr.		2 x 2.0 L/ha			2 x 4.0 L/ha			2 x 0.72 L/ha			Untr.		2 x 2.0 L/ha			2 x 4.0 L/ha			2 x 0.72 L/ha		
			t/ha		t/ha		rel%	t/ha		rel%	t/ha		rel%	g		g		g		g				
Maritime		Mean	8.7		9.1		104.7	9.3		108.2	9.2		107.0	45.5		49.4		49.1		47.7				
		min	6.3		6.8		97.7	7.1		101.0	7.1		98.6	40.2		45.2		43.3		42.0				
		max	10.3		11.3		109.3	11.4		113.5	11.2		114.2	50.8		53.7		54.8		53.4				
		n trials	3		3		3	3		3	3		3	2		2		2		2				
North-East			7.47	b	8.23	a	110.2	8.17	a	109.3	8.14	a	109.0	44.7	b	47.10	a	47.3	a	45.80	ab			
South-East			8.34	a	7.40	a	88.7	9.25	a	110.9	7.99	a	95.8	45.88	a	45.50	a	46.73	a	45.98	a			
All trials	All trials	Mean	8.4		8.6		102.6	9.1		109.0	8.7		105.2	45.4		47.9		48.0		46.8				
		min	6.3		6.8		88.7	7.1		101.0	7.1		95.8	40.2		45.2		43.3		42.0				
		max	10.3		11.3		110.2	11.4		113.5	11.2		114.2	50.8		53.7		54.8		53.4				
		n trials	5		5		5	5		5	5		5	4		4		4		4				

* trial means followed by the same letter do not significantly differ, Tukey mean separation test, p=0.05

~~Table 3.4-18:~~

Table 3.4-19: Impact of GF-3307 on yield amount (t/ha) and thousand grain weight (g) applied at the proposed label rate in phytotoxicity trials. Summary of data from 2 phytotoxicity trials conducted in spring wheat in the absence of disease or at low disease pressure.

EPPO Zone	Country	Trial number	Yield (corrected to 86% dry matter)											Thousand grain weight (g)							
					GF-3307			GF-3307			Proline					GF-3307		GF-3307		Proline	
			Untr.		2 x 2.0 L/ha			2 x 4.0 L/ha			2 x 0.72 L/ha			Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha	
			t/ha		t/ha		rel%	t/ha		rel%	t/ha		rel%	g		g		g		g	
Maritime			5.62	a	5.71	a	102.4	5.69	a	101.7	5.65	a	100.7	34.7	a	34.63	a	33.8	a	34.25	a
North-East			4.15	a	4.46	a	107.9	4.63	a	111.9	5.35	a	129.4	36.67	a	38.82	a	38.87	a	41.74	a
All trials		Mean	4.9		5.1		105.2	5.2		106.8	5.5		115.1	35.7		36.7		36.3		38.0	
		min	4.2		4.5		102.4	4.6		101.7	5.4		100.7	34.7		34.6		33.8		34.3	
		max	5.6		5.7		107.9	5.7		111.9	5.7		129.4	36.7		38.8		38.9		41.7	
		n trials	2		2		2				2		2	2		2		2		2	

zRMS comments:

Confirmed based on inspection of trial reports FR14E7B016MC01C, GB14E7B016EB01C, GB14E7B016EB02C, HU14E7B016AB01C and LV14E7B016MN02C.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

All None of the ~~232~~ 267 efficacy trials reported no phytotoxicity or adverse effects to treated crops at dose rates up to 1.5 L/ha of GF-3307 (see section 3.4.1.1) and quality results (TGW and HLW) from these trials demonstrated no adverse effects on grain quality, in the presence of disease (see section 3.2.3).

The following chapters demonstrate the effect of GF-3307 yield quality parameters such as protein content, thousand grain weight, hectolitre weight, Hagberg falling number or the viability of seeds harvested from selectivity trials.

3.4.3.1 Effect on yield quality in phytotoxicity trials – winter wheat Introduction

In total five phytotoxicity trials were established to demonstrate the selectivity of GF-3307 applied in winter wheat. The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were placed in France (1), the United Kingdom (2), Hungary (1) and Latvia (1) in 2014 in areas where winter wheat is commercially grown. The trial from France was within the Maritime EPPO zone part of the country.

On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The EU Central Regulatory Zone covers countries in EPPO climatic zones Maritime, North-East and South-East as described in EPPO standard PP 1/241. This chapter comprises data from the Maritime, North-East and South-East EPPO zones which are representative of the proposed GAP.

Material and methods

For information on testing organisations involved, for trials site and experimental details refer to section 3.4.1.2 (*Phytotoxicity to winter wheat in selectivity trials*).

Results

In five trials conducted in 2014 in France (1), the United Kingdom (2), Hungary (1) and Latvia (1) in winter wheat treatments with GF-3307 applied twice in sequence at 2.0 L/ha (proposed label rate) and 4.0 L/ha 2N rate revealed no negative impact on yield quality parameters grain moisture at the timing of harvest, the specific weight, the protein content of the grain or Hagberg falling number of the winter wheat. Results are summarized in ~~Table 3.4-20 and Table 3.4-22~~ Table 3.4-206 and Table 3.4-227 below.

Table 3.4-20:

Table 3.4-216: Impact of GF-3307 on yield quality parameters of winter wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Specific weight (kg/HL)								Protein content %							
					GF-3307		GF-3307		Proline				GF-3307		GF-3307		Proline	
			Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha		Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha	
			kg		kg		kg		kg		%		%		%		%	
Maritime		Mean	75.2		75.1		75.2		74.7		10.0		10.1		10.2		10.2	
		min	74.2		75.1		75.1		74.5		9.7		9.8		9.9		9.6	
		max	76.1		75.1		75.2		74.9		10.3		10.6		10.5		11.1	
		n trials	2		2		2		2		3		3		3		3	
North-East											11.7	a	12.5	a	12.7	a	11.9	a
South-East			78.8	a	78.7	a	80.1	a	79.9	a	12.3	a	11.6	a	14.7	a	12.1	a
All trials		Mean	76.4		76.3		76.8		76.4		10.8		10.9		11.6		10.9	
		min	74.2		75.1		75.1		74.5		9.7		9.8		9.9		9.6	
		max	78.8		78.7		80.1		79.9		12.3		12.5		14.7		12.1	
		n trials	3		3		3		3		5		5		5		5	

Table 3.4-22:

Table 3.4-237: Impact of GF-3307 on yield quality parameters of winter wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Hagberg falling number (seconds)								Grain moisture content %							
					GF-3307		GF-3307		Proline				GF-3307		GF-3307		Proline	
			Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha		Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha	
			s		s		s		s		%		%		%		%	
Maritime		Mean	337.8		334.0		337.1		339.1		16.8		16.9		16.8		16.8	
		min	320.5		305.3		312.3		308.8		16.8		16.9		16.8		16.8	
		max	355.0		362.6		361.9		369.4		16.8		16.9		16.8		16.8	
		n trials	2		2		2		2		1		1		1		1	
North-East										12.1	a	12.3	a	12.7	a	12.2	a	
South-East			322	a	298.3	a	324	a	326.8	a	11.8	a	12.1	a	12.2	a	11.9	a
All trials		Mean	332.5		322.1		332.7		335.0		13.6		13.8		13.9		13.6	
		min	320.5		298.3		312.3		308.8		11.8		12.1		12.2		11.9	
		max	355.0		362.6		361.9		369.4		16.8		16.9		16.8		16.8	
		n trials	3		3		3		3		3		3		3		3	

zRMS comments:

Confirmed based on inspection of trial reports FR14E7B016MC01C, GB14E7B016EB01C, GB14E7B016EB02C, HU14E7B016AB01C and LV14E7B016MN02C.

3.4.3.2 Effect on yield quality in phytotoxicity trials – spring wheat

Introduction

In total two phytotoxicity trials were established to demonstrate the selectivity of GF-3307 applied in spring wheat. The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

The trials were placed in Germany and Poland in 2014 in areas where spring wheat is typically grown. On the basis of the EPPO standard 1/241 '*Guidance on comparable climates*', the trials included in the BAD have been grouped and summarized by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region. The EU Central Regulatory Zone covers countries in EPPO climatic zones Maritime, North-East and South-East as described in EPPO standard PP 1/241. This chapter comprises data from the Maritime and North-East EPPO zones which are representative of the proposed GAP.

Material and methods

For information on testing organisations involved, for trials site and experimental details refer to section 3.4.1.3 (*Phytotoxicity to spring wheat in selectivity trials*).

Results

In two phytotoxicity trials conducted in 2014 in Germany and Poland in spring wheat treatments with GF-3307 applied in sequence at the maximum European dose of 2.0 L/ha or 4.0 L/ha (2 N rate) between crop growth stage BBCH 39 and BBCH 69 revealed no negative impact on yield quality parameters grain moisture content measured at the time of harvest, the specific weight, the protein content and Hagberg falling number of the spring wheat varieties tested. Although two applications are applied in these trials and the dose rate is higher than proposed in this dossier, this presents the worst-case scenario to cover the growth stages in the GAP. The results from the trials are summarized in ~~Table 3.4-245:~~

~~Table 3.4-25 and~~

~~Table 3.4-26:~~

~~Table 3.4-27 Table 3.4-245:~~

~~Table 3.4-258 and~~

~~Table 3.4-26:~~

~~Table 3.4-279~~ below.

~~Table 3.4-245:~~

Table 3.4-258: Impact of GF-3307 at on yield quality of spring wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Specific weight (kg/HL)								Protein content %							
					GF-3307		GF-3307		Proline				GF-3307		GF-3307		Proline	
			Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha		Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha	
			kg		kg		kg		kg		%		%		%		%	
Maritime			74	a	74	a	73.7	a	73.7	a	12.7	a	12.4	a	12.8	a	12.7	a
North-East											13.7	ab	13.2	ab	13.5	ab	13.4	ab
All trials		Mean	74		74		73.7		73.7		13.2		12.8		13.2		13.1	
		min	74		74		73.7		73.7		12.7		12.4		12.8		12.7	
		max	74		74		73.7		73.7		13.7		13.2		13.5		13.4	
		n trials	1		1		1		1		2		2		2		2	

~~Table 3.4-26:~~

Table 3.4-279: Impact of GF-3307 at on yield quality of spring wheat in phytotoxicity trials

EPPO Zone	Country	Trial number	Hagberg falling number (seconds)							Grain moisture content %								
					GF-3307		GF-3307		Proline				GF-3307		GF-3307		Proline	
			Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha		Untr.		2 x 2.0 L/ha		2 x 4.0 L/ha		2 x 0.72 L/ha	
			s		s		s		s		%		%		%		%	
Maritime											11.8	a-d	11.4	cde	11.3	de	11.3	e
North-East											15.2	a	15.3	a	14.9	a	15.3	a
All trials		Mean									13.5		13.4		13.1		13.3	
		min									11.8		11.4		11.3		11.3	
		max									15.2		15.3		14.9		15.3	
		n trials									2		2		2		2	

zRMS comments:

Confirmed based on inspection of trial reports DE14E7B016UB01C and PL14E7B016AS01C.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Plant protection products such as fungicides may affect processes performed for the transformation of harvested crops. For the use of GF-3307 all crops concerned in this dossier may be subjected to transformation processes such as brewing or baking. The following chapter reports on the impact of fenpicoxamid (DE-777, XDE-777) straight on the growth of yeast (*Saccharomyces cerevisiae*) cultures under laboratory conditions and the effect of GF-3307 on brewing and bread baking.

3.4.4.1 Effect of Fenpicoxamid and UK-2A on the growth of yeast

Introduction

Preliminary biological spectrum characterization with UK-2A and Fenpicoxamid *in-vitro* indicated strong growth inhibition of fungi such as SEPTTR, LEPTNO, USTIMA, PYRIOR and a wild type strain of the yeast *S. cerevisiae* growing on a medium with glycerol as sole carbon source. However, since yeasts such as *S. cerevisiae* are capable of fermentative growth, which bypasses terminal mitochondrial respiration involving the *bcl* complex, it would be expected that growth under conditions supporting fermentation, i.e. media containing a fermentable carbon source, would not be inhibited by either UK-2A or Fenpicoxamid.

Testing facilities involved

A non GEP/non GLP laboratory study (report # DAI 1399) was carried out by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN., 46268, USA to evaluate Fenpicoxamid and UK-2A for antifungal activity against *S. cerevisiae*.

Material and methods

The yeast culture with yeast strain X2180-1A was initiated by transfer onto petri dishes containing YPD agar and maintained in the dark for 24h in an incubator set at 30 °C. Assay inoculums were subsequently prepared by spore transfer into two separate broths, YPD broth (1% yeast extract, 2% peptone and 2% dextrose) and YPG broth (1% yeast extract, 2% peptone and 3% glycerol) and spore densities adjusted to 1.0 x 10 spores/mL. Assays conducted with yeast growing in each of the two media were initiated by addition of 200 µl inoculum into wells of 96-well plates containing 2 µL of a 5-fold dilution series of Fenpicoxamid or UK-2A prepared using stock solutions in DMSO, to deliver a total of 7 test concentrations ranging from 0.000128 ppm to 2 ppm. Test plates were placed on a tray with moistened paper towels, covered to reduce evaporation, and incubated in the dark without shaking for 96 h at 30 °C. Initial and final cell density readings were determined using a NepheloStar nephelometer (BMG LABTECH GmbH, D-77799 Ortenberg, Germany). Six replicates were assayed and percentage growth inhibition was calculated by reference to control wells containing only growth media, amended with 2 µL DMSO, and inoculum.

Results

~~Table 3.4-28:~~

~~Table 3.4-~~

~~Table 3.4-28:~~

Table 3.4-20 below presents the data obtained on the effect of both UK-2A and Fenpicoxamid on *S. cerevisiae* when growing on either a fermentable (dextrose, medium YPD) or non-fermentable (glycerol, medium YPG) carbon source. The data clearly demonstrates very strong growth inhibition of *S. cerevisiae* by Fenpicoxamid and UK-2A when grown aerobically on the non-fermentable glycerol as sole carbon source. However, neither compound is inhibitory to growth when *S. cerevisiae* is presented with a fermentable sugar (dextrose) which supports anaerobic fermentation.

Table 3.4-28:

Table 3.4-20: Effects of UK-2A & Fenpicoxamid on growth of *S. cerevisiae* on a fermentable vs. non-fermentable carbon source

Rate (as, mg/L)	Growth inhibition [%]			
	YPG Medium (glycerol, non-fermentable)		YPD Medium (dextrose, fermentable)	
	Fenpicoxamid	UK-2A	Fenpicoxamid	UK-2A
2.0	100	91	3	0
0.4	87	93	3	0
0.08	81	85	1	0
0.016	100	94	2	1
0.0032	89	85	0	0
0.00064	98	94	0	0
0.000128	61	68	0	0

Summary and conclusions

When growing on a fermentable carbon source such as dextrose the growth of *S. cerevisiae* is not inhibited by either UK-2A or Fenpicoxamid. From this data it can be concluded that it is unlikely that Fenpicoxamid or UK-2A residues in the grain have a negative effect on the growth of *S. cerevisiae* during fermentation in the beer production process.

Reference report: Owen, W. J; Slanec, T; Impact of Carbon Source on Growth Inhibition of *Saccharomyces cerevisiae* by XDE-777 and UK-2A. Dow AgroSciences, unpublished report number DAI 1399, 12. February 2015.

zRMS comments:

Results confirmed based on inspection of trial report DAI 1399 (KCP 6.4/14).

3.4.4.2 Effect of GF-3307 on brewing (wheat)

Wheat beer or in German Weizenbier, in the southern parts of Germany is called Weißbier (literally 'white beer'). Weißbier is a beer in which a significant proportion of malted barley is replaced with malted wheat. By law Weißbier brewed in Germany must be top-fermented. Specialized strains of yeast are used which produce certain overtones and clove as by-products of fermentation. Weißbier is so called because at the time of its inception it was paler in colour than Munich brown beer. The terms 'Hefeweizen' or 'Hefeweißbier' refer to wheat beer in its traditional, unfiltered form which has a cloudy appearance due to the yeast content. The term 'Kristallweizen' refers to a wheat beer that is filtered to remove the yeast from suspension and has a 'crystal clear' appearance. Weißbier is available in a number of other forms including Dunkelweizen (dark wheat) and Weizenstarkbier (strong wheat beer), commonly referred to as Weizenbock. The dark wheat varieties are made with darker, more highly kilned malts, of both, wheat and barley. The Weizenbock typically have a much higher alcohol content than their lighter cousins.

To evaluate the effect of GF-3307 on beer making and the gustatory qualities of the resulting Weißbier, two processing studies DE15E7B005UB01C (KCP 6.4/13)* and DE15E7B005UB01C DE15E7B005UB02C (KCP 6.4/13)* each comprising grain samples collected from the field sites were initiated in Germany in 2015. The studies fell into a field part to provide the grain for malting and a laboratory part to evaluate possible effects of GF-3307 on the processing phase. The reference product included was Proline 275.

The trials were carried out on behalf of Dow AgroSciences by BioChem located in Kupferstraße 6 in 04827 Gerichshain, Germany which is a qualified contractor following the EPPO standards and is

officially recognized by the competent authorities to carry out registration efficacy field trials in accordance with the principles of Good Experimental Practice (GEP). The leading EPPO standards followed were PP 1/242 (*Taint Tests*) and PP 1/243 (*Effects of plant protection products on transformation processes*). For the laboratory processing parts of the studies GLP compliance is not claimed but procedural GLP aspects were included within the QA programme of both studies.

***zRMS comments:**

The applicant had listed the study twice based on the field phase trials and their different IDs. However, both these trials are reported in the same document listed under KCP 6.4/13, as both trials provide material for the taint test.

Material and methods

Testing facilities or organisations

The trials were carried out as detailed in the subsequent Table.

Table 3.4-29:

Table 3.4-21: Testing facilities involved

Admin. Zone	EPPO Zone	Country	Year	BioChem Study Code	Trial number	Testing Organisation	EPPO Guideline	Trial Status
Central	Maritime	GERMANY	2015	15 1047 2114	DE15E7B005UB01C	BioChem agrar	PP 1/242 PP 1/243	GEP
					DE15E7B005UB02C	BioChem agrar	PP 1/242 PP 1/243	GEP

Field trial sites

Trial sites were selected on the basis of favourable agronomical and environmental factors, in areas representative of those where the crop is grown commercially. For further trial site details (field phase) ~~see the BAD~~ see Table 3.4-30 below. The following map provides an overview of the geographical distribution of the field trials in Germany.

Figure 3.4-1: Distribution of 2 field trials sites conducted to obtain the wheat grain samples for the beer processing (field phase)



Formulations applied and rates

Test products	Formulation type	Active substance	Rate product L/ha	Rate gas/ha
GF-3307	EC	Fenpicoxamid + prothioconazole (50 +100 g/L)	2.0	300
Proline 275	EC	Prothioconazole	0.72	198

Treatment and application timings

Treatment	Appl. timing	Formulation	Rate L/ha	Appl. crop growth stage aimed at in protocol
1	AB	GF-3307	2.0	Timing A at BBCH 39/45 and timing B at BBCH 65/69
2	AB	Proline 275	0.72	Timing A at BBCH 39/45 and timing B at BBCH 65/69

All treatments were applied in accordance with the requirements of the test protocol EA15E7B005. Although two applications are applied in these trials and the dose rate is the maximum in Europe (2.0 L/ha) is , that is: higher than proposed in this dossier (1.5 L/ha), this presents the worst case scenario to cover the growth stages in the GAP.

Experimental details

To obtain the grain for malting 2 field trials were carried out in Germany in 2015. The trials were conducted to GEP and followed the appropriate EPPO standards by officially recognized testing organisations. The trials were of a randomized complete block design with 4 replicates and a plot size of 30 m² in either trial. The treatments in both trials were applied using precision small plot sprayers equipped with flat fan nozzles delivering water volumes of 200 and 250 L/ha.

GF-3307 and the reference product Proline in both field trials were applied in sequence at wheat growth stage BBCH 39-41 and BBCH 65. The late application timing of the test products is considered worst case in terms of testing the impact on brewing beer. Further application details are shown in the BAD Table 3.4-303 below.

The 2 field trials were conducted under almost pest free conditions through the use of appropriate plant protection products such as herbicides, insecticides and fungicides. Before malting, seed viability test was conducted. The grain specimens were cleaned and sieved prior to malting. After sieving, wet steeping was conducted. After steeping a germination procedure followed. Kiln-drying was conducted in a dry chamber or drying oven. After drying the germs were removed mechanically using a trimmer. Until brewing the malt was stored at room temperature (malt rest).

The processing phase was performed between January and March 2016 at laboratory scale which fully compared to the industrial beer brewing process. After fermentation and maturation all specimens were filled into suitable glass bottles which were clearly and uniquely identified. The specimens were then stored at cooled conditions until the triangle taint test was carried out.

Table 3.4-30: Trial site details - field phase

EPPO Zone	Trial number	Country	Trial location	Zip Code	State/Region	Crop (EPPO Code)	Crop variety	Plot Size m ²	#reps/ trial layout
Maritime	DE15E7B005UB01C	Germany	Grimma	04668	Saxony	TRZAW	Matrix	30	4/RCB
Maritime	DE15E7B005UB02C	Germany	Tützpatz	17091	Mecklenburg-Vorpommern	TRZAW	Akteur	30	4/RCB

Table 3.4-31: Application details – field phase

Trial number	Application timing	Application BBCH min	Application BBCH max	Application date	Water volume L/ha
DE15E7B005UB01C	A	39	41	29-May-2015	250
	B	65	65	16-June-2015	250
DE15E7B005UB01C	A	39	41	29-May-2015	200
	B	65	69	16-June-2015	200

Table 3.4-32: Processing schedule

Processing steps	Grain Specimen			
	Trial DE15E7B005UB01C		Trial DE15E7B005UB02C	
	GF-3307	Proline	GF-3307	Proline
Receipt of field specimens	05.08.2015	05.08.2015	01.09.2016	01.09.2016
Germination rest	05.08.2015	05.08.2015	26.08.2015	26.08.2015
	– 20.01.2016	– 20.01.2016	– 20.01.2016	– 20.01.2016
Malting	20.01.2016	20.01.2016	20.01.2016	20.01.2016
	– 26.01.2016	– 26.01.2016	– 26.01.2016	– 26.01.2016
Malt rest	26.01.2016	26.01.2016	26.01.2016	26.01.2016
	– 08.02.2016	– 10.02.2016	– 11.02.2016	– 15.02.2016
Brewing	08.02.2016	10.02.2016	11.02.2016	15.02.2016
	– 01.03.2016	– 03.03.2016	– 07.03.2016	– 09.03.2016
Triangle taint testing	14.03.2016	14.03.2016	14.03.2016	14.03.2016

Determination of quality parameters.

The following parameters were evaluated prior, during or after finishing the processing:

Grain protein content (%)

Protein content of the grain sampled in the field parts of the studies.

Alcohol content (v/v)

Ethanol content by volume of the beer produced

Carbon dioxide content (g/L)

Carbon dioxide (CO₂) content of the beer produced

Oxygen content (mg/L)

Oxygen (O₂) content of the beer produced

Original Extract (°Plato or °P)

The Original Gravity is the specific gravity measured before fermentation. From it the analyst can compute the Original Extract (Stammwürze) which is the mass (grams) of sugar in 100 grams of wort. Real or true extract (°Plato or °P).

It is the amount of extract which was not converted to yeast biomass, carbon dioxide or ethanol during fermentation. It can be estimated by removing the alcohol from beer which has been degassed and clarified by filtration or other means. This is the number of grams of extract remaining in 100 grams of beer at the completion of fermentation.

Colour (EBC)

The Standard Reference Method is used by the European Brewery Convention (EBC) to measure colour intensity, roughly darkness of a beer or wort. The method involves the use of a spectrophotometer or photometer to measure the attenuation of light of a particular wavelength as it passes through a sample contained in a cuvette located in the light path of the instrument. The EBC convention also measures beer and wort colour, as well as quantifying turbidity (also known as haze) in beer.

Density (g/mL)

Density of the beer produced

Foam stability (s)

Lasting of foam in seconds

Taint testing of beer

After completion of fermentation a triangle test and a descriptive taint testing (odour or flavour of samples) was carried out with the beer specimens obtained. The taint testing was conducted with 18 assessors to ensure statistical confidence. In the triangle test each assessor was presented with 3 coded samples whereby two of them were the same and one was different. The results were statistically interpreted with a significance level of $\alpha = 0.05$ as shown below:

$$x = \frac{n}{3} + z \sqrt{\frac{2n}{9}}$$

x = minimum number of correctly determined differences

n = number of test persons

z = 1.64 at $\alpha = 0.05$

Results

To evaluate the effect of GF-3307 on beer making and the gustatory qualities of the resulting Weißbier a processing study comprising grain samples collected from 2 field sites was initiated in Germany in 2015. The studies fell into a field part to provide the grain for malting and a laboratory part to evaluate possible effects of GF-3307 on the processing phase. The reference product included was Proline 275 (275 g /L prothioconazole).

GF-3307 and Proline in both field trials were applied in sequence at wheat growth stage BBCH 39-41 and BBCH 65. The late application timing of the test products is considered worst case in terms of testing the impact on brewing beer.

No adverse effects due to the application of GF-3307 on fermentation were apparent in both studies. Quality parameters such as seed viability, protein, alcohol, carbon dioxide, oxygen and extract contents, colour or foam stability were all in normal range and presented no distinct differences.

No significant ($\alpha=0.05$) differences were found in the taint test between GF-3307 and Proline and none of the testers attributed a bad or negative taste profile to either GF-3307 or Proline treated specimen samples.

~~Table 3.4-33:~~

Table 3.4-25: Impact of GF-3307 on grain quality and quality parameters of the produced Weißbier

Trial number	Treatment	Appli- cation timing	Seed viability germination [%]	Protein grain [%]	Original extract [°P]	Real extract [°P]	Alcohol v/v [%]	Protein beer [%]	Carbon dioxide g/L	Oxygen mg/L	Colour [EBC]	Density g/mL	Foam stability [s]
DE15E7B005UB01C	GF-3307 at 2.0 L/ha	AB	95.3	12.4	12.7	4.37	4.42	0.73	6.61	n.d.	7.8	1.0075	188
	Proline at 0.72 L/ha	AB	95.5	12.3	12.7	4.31	4.43	0.67	6.58	n.d.	7.9	1.0073	193
DE15E7B005UB02C	GF-3307 at 2.0 L/ha	AB	92.5	10.1	12.5	4.35	4.31	0.48	6.97	n.d.	6.4	1.0076	188
	Proline at 0.72 L/ha	AB	91.8	10.5	12.8	4.74	4.30	0.52	6.48	n.d.	7.2	1.0092	208

n.d. = not detectable

~~Table 3.4-34:~~

Table 3.4-356: Results of the triangle taint test

Trial number	Treatment/specimen	Number of testers	Number of correctly determined differences	Percent of correctly determined differences	Significance ($\alpha = 0.05$)
DE15E7B005 UB01C	GF-3307	18	9	50	no
	Proline				
DE15E7B005 UB02C	GF-3307	18	7	39	no
	Proline				

No difference in taste could be observed between treatment GF-3307 vs Proline in both trials.

~~Table 3.4-36:~~

Table 3.4-377: Results of preferences within the triangle taint test

Trial number	Treatment/specimen	Number of tests with correct determined differences	Preferred specimen GF-3307	Preferred specimen Proline	Significance ($\alpha = 0.05$)
DE15E7B005 UB01C	GF-3307	9	5	3	no
	Proline				
DE15E7B005 UB02C	GF-3307	7	2	4	no
	Proline				

~~Table 3.4-38:~~

Table 3.4-398: Description of taste descriptors attributed to the specimen beer

Specimen source trial	Treatment/specimen	Description of the preferred specimen
DE15E7B005UB01C	GF-3307	long lasting taste, sweeter, more distinct banana tone, fresh, fruity, pleasant
	Proline	clove* tone, dryer, fruity
DE15E7B005UB02C	GF-3307	clove tone, malty, fresh, fruity
	Proline	sweeter, quaffable, clove tone, intensive, aromatic

* Cloves (English) = Gewürznelke (German) = *Syzygium aromaticum*

Summary and conclusions

GF-3307 applied at the proposed label rate of 2.0 L/ha does not have a negative impact on the course of fermentation nor does the product negatively affect the quality parameters and gustatory qualities of the resulting Weißbier.

Reference report: Kästner, K; Processing phase report. Field study to generate specimen of beer from RAC wheat treated with GF-3307 or GF-3309 for subsequent triangle taint testing and determination of quality parameters, 2 Sites in Germany 2015. BioChem agrar, unpublished report number 15 1047 2114 (KCP 6.4/13)

zRMS comments:

Results confirmed based on inspection of the study by Kästner (KCP 6.4/13).

3.4.4.3 Effect of GF-3307 on brewing (barley)

Introduction

One study was carried out in France by the French Institute of Beverages, Brewing and Malting (IFBM) to demonstrate that GF-3307 does not affect the brewery and malting processes. The study included a field phase and a laboratory phase. The study complied with CEB n°185 guideline, established to check the unintentional effects of fungicide products on the brewery process and the quality of barley, malt and beer.

Four trials were conducted in 2017, two on winter barley and two on spring barley. The varieties were chosen as varieties inscribed on malting and brewing list of varieties.

Material and methods

Testing facilities or organisations

The trials were carried out in France by officially recognized testing facilities following to the EPPO and CEB guidelines indicated in Table 3.4-40:

Table 3.4-41 Table 3.4-40:

Table 3.4-419 below and in accordance with the principles of Good Experimental Practice (GEP).

Table 3.4-40:

Table 3.4-419: Testing facilities involved

EPPO Zone	Country	Year	IFBM Internal identification code (Laboratory phase)	Trial number (Field phase)	Official Testing Organizations		Crop (EPPO Code)	Guidelines
					Field phase	Laboratory phase		
Maritime	FR	2017	RAF-1025	FR17E7B044MC02C	Biotek agriculture	IFBM*	HORVW	EPPO PP 1/243 CEB n° 185
				FR17E7B044MC04C	Biotek agriculture	IFBM*		
				FR17E7B044MC05C	Biotek agriculture	IFBM*	HORVS	
				FR17E7B044MC08C	Biotek agriculture	IFBM*		

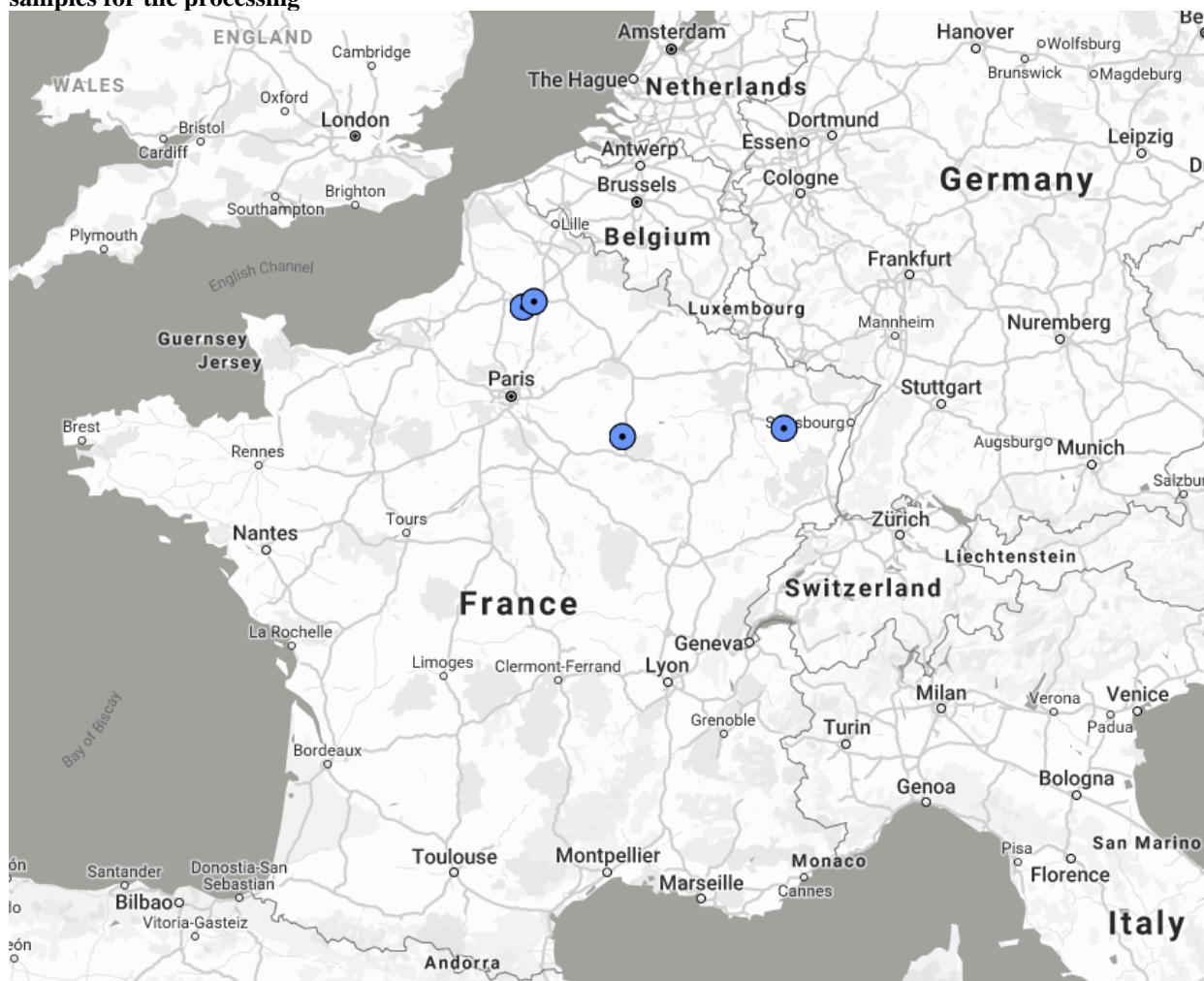
*Institut Français des Boissons, de la brasserie et de la Malterie in Vandœuvre Les Nancy (54)

Sites and experimental details

The trials were conducted in North and East of France, in areas with favourable agronomic and environmental conditions for malting barley production and known as areas where barley is grown commercially.

The following map provides an overview of the geographical distribution of the field trials across France.

Figure 3.4-2: Geographical distribution of the 4 field trials sites conducted to obtain the barley grain samples for the processing



Full trial site details during field phase are presented in the BAD.

The experimental design was a randomized complete block with 3 replicates and a minimum plot size of 48 m², to allow the harvest of 50 kg per plot. The applications were performed with precision small plot sprayers equipped with flat fan nozzles delivering water volume of 200 L/ha. The trials were yielded using a small plot combined harvester.

Formulations applied and applications details

Test products	Formulation type	Active substance	Rate product L/ha	Rate g as/ha	Appl. crop growth stage aimed at in the test protocol
GF-3307	EC	fenpicoxamid + prothioconazole	2.0	300	BBCH 31/33 & 39/59
OPUS	SC	epoxiconazole	1.0	125	BBCH 31/33 & 39/59

GF-3307 was applied twice at the maximum European dose of 2.0 L/ha at BBCH 31-33 followed by BBCH 39-59. OPUS was applied twice at 1.0 L/ha at the same application timings. The late application timing of the test products is considered worst case in terms of testing the impact on brewing beer. Further application details are shown in the BAD. Although two applications are applied in these trials and the dose rate is higher than proposed in this dossier, this presents the worst case scenario to cover the typical growth stages in the GAP.

OPUS was chosen as standard as it is included on the list of products recommended for the malting barley and known to have no effects on brewery process.

was carried out on a bulk of the 3 replicates

Results

The data generated from these brewing studies are presented below step by step for winter barley and then for spring barley. The tolerance is mentioned for each criteria.

Impact of GF-3307 applied on winter barley (HORVW)

GF-3307 was applied twice at 2.0 L/ha and compared to the standard OPUS applied twice at 1.0 L/ha at the same application timings. The data presented in the tables are the averages of the 2 trials results. The following table presents the results of the barley analyses done on grain.

Table 3.4-42:

Table 3.4-30: Impact of GF-3307 on barley analyses (grain)

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Proteins (% dry matter)	10.6	10.4	-0.2	1
Germination index	9.8	9.8	0.0	1
Kernel size (% > 2.5 mm)	85.0	87.9	2.9	15
Deoxynivalenol (µg/kg)	15	15	0	50
T2 + HT2 (µg/kg)	0.0	0.0	0.0	-
Ergosterol (mg/kg)	6.4	7.6	1.2	2.0
Enniatins (µg/kg)	3	3	0	-

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.
The following table presents the results of the malt analyses.

Table 3.4-43:

Table 3.4-31: Impact of GF-3307 on malt analyses

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Extract fine grind (% dry matter)	78.8	79.1	0.3	1
Viscosity (mPa.s)	1.627	1.643	0.016	0.1
Soluble proteins (% dry matter)	3.71	3.76	0.05	0.2
α-amylases (D.U)	57	54	-3	7
β-glucans (mg/L)	329	345	16	50
Friability (% flour)	84	85	1	10
Calcofluor (% modification)	91	91	0	10
Calcofluor (% homogeneity)	82	80	-2	10

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.
The following tables present functional analyses of malts.

Table 3.4-44:

Table 3.4-32: Impact of GF-3307 on filtration test

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Quantity of wort (g)	381	382	1	10
Filtration rate (g/min)	30	30	0	15
Washing rate (g/min)	40	42	2	15

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

Table 3.4-45:

Table 3.4-33: Impact of GF-3307 on fermentation test

Criteria	OPUS (standard)	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and	Tolerance
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	2 x 1.0 L/ha		OPUS	
Attenuation limit (%)	77.6	77.3	-0.3	1.5
Apparent gravity, 8th day (°Plato)	6.0	6.0	0.0	1

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.
The following tables present the results of the brewing study.

~~Table 3.4-46:~~

Table 3.4-34: Impact of GF-3307 on wort filtration

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	<i>Tolerance</i>
Duration of wort filtration (min)	76	75	-1	10

~~Table 3.4-47:~~

Table 3.4-35: Impact of GF-3307 on wort analyses

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	<i>Tolerance</i>
Attenuation limit (%)	82.3	82.8	0.5	1.5
Free amino nitrogen (mg/L)	179	175	-4	20

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

zRMS comments:

Trials FR17E7B044MC02C and FR17E7B044MC04C are **field trials only**, providing test material (grain), whereas the results of the analyses concerning the brewing process are confirmed based on inspection of the study by Gless (KCP 6.4/12).

Table 3.4-48:

Table 3.4-36: Impact of GF-3307 on beer fermentation

Criteria	OPUS (standard) 2 x 1.0 L/ha		GF-3307 2 x 2.0 L/ha		Difference between GF-3307 and OPUS	Tolerance
	1	2	1	2		
Fermentation						
Time to ferment 5°Plato (hour)	80	74	91	63	0	12
Time to reach 95% of fermentable extract (hour)	140	141	142	120	-9.5	12
% Attenuation at 7th day (%)	100.0	97.9	98.9	99.0	0.0	2
Harvested Yeast viability (108/g)	18	20	17	21	0	5
Apparent extract at the end of maturation (°Plato)	2.4	2.1	2.4	1.9	-0.1	1
Apparent attenuation at the end of maturation (%)	80.0	82.1	79.5	83.6	0.5	1.5

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

Table 3.4-49:

Table 3.4-37: Impact of GF-3307 on beer analyses

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Alcohol (% V/V)	5.08	4.98	-0.10	0.2
Apparent extract (°Plato)	2.11	2.03	-0.08	0.25
Colour (EBC)	5.0	4.7	-0.3	2
Head retention (sec)	197	222	25	15

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS regarding the criteria alcohol, apparent extract and colour. The results of beer analyses revealed higher head retention value for GF-3307 compared to the reference standard OPUS thus causing no negative effect.

Sensory analyses

A ~~significance~~ **significant** difference was noticed between GF-3307 and the reference OPUS only for the beers from the trial FR17E7B044MC04C. The nature of the difference between samples was commented as below:

Table 3.4-50:

Table 3.4-38: Impact of GF-3307 on sensory analyses

Reference beer	Treated beer
More fruity (apple and pear) (3) More almond (2) More bitter (1)	More oxidized (1)

In the second trial, there was no significant difference between the two beers.
Therefore, there was no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

Impact of GF-3307 applied on spring barley (HORVS)

GF-3307 was applied twice at 2.0 L/ha and compared to the standard OPUS applied twice at 1.0 L/ha at the same application timings. The data presented in the tables are the averages of the 2 trials results. The following table presents the results of the barley analyses done on grain.

Table 3.4-51:

Table 3.4-39: Impact of GF-3307 on barley analyses (grain)

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Proteins (% dry matter)	10.6	10.4	-0.2	1
Germination index	9.9	9.9	0.0	1
Kernel size (% > 2.5 mm)	88.8	89.4	0.6	15
Deoxynivalenol (µg/kg)	0	0	0	50
T2 + HT2 (µg/kg)	9.1	49.5	40.4	-
Ergosterol (mg/kg)	8.1	8.1	0.0	2.0
Enniatins (µg/kg)	5	3	-2	-

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS. The following table presents the results of the malt analyses.

Table 3.4-52:

Table 3.4-40: Impact of GF-3307 on malt analyses

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Extract fine grind (% dry matter)	82.0	82.1	0.1	0.5
Viscosity (mPa.s)	1.542	1.530	-0.012	0.05
Soluble proteins (% dry matter)	3.81	3.77	-0.04	0.2
α-amylases (D.U)	55	51	-4	7
β-glucans (mg/L)	221	239	18	30
Friability (% flour)	86	85	-1	10
Calcofluor (% modification)	94	93	-1	10
Calcofluor (% homogeneity)	85	85	0	10

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS. The following tables present functional analyses of malts.

Table 3.4-53:

Table 3.4-41: Impact of GF-3307 on filtration test

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Quantity of wort (g)	394	395	1	10
Filtration rate (g/min)	40	37	-3	10
Washing rate (g/min)	51	53	2	10

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

Table 3.4-54:

Table 3.4-42: Impact of GF-3307 on fermentation test

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Attenuation limit (%)	77.4	77.2	-0.2	1.5
Apparent gravity, 8th day (°Plato)	6.1	6.1	0.0	1

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS. The following tables present the results of the brewing study.

Table 3.4-55:

Table 3.4-43: Impact of GF-3307 on wort filtration

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Duration of wort filtration (min)	73	81	8	10

Table 3.4-56:

Table 3.4-44: Impact of GF-3307 on wort analyses

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Attenuation limit (%)	82.7	82.2	-0.5	1.5
Free amino nitrogen (mg/L)	169	171	2	20

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

Table 3.4-57:

Table 3.4-45: Impact of GF-3307 on beer fermentation

Criteria	OPUS (standard) 2 x 1.0 L/ha		GF-3307 2 x 2.0 L/ha		Difference between GF-3307 and OPUS	Tolerance
Fermentation	1	2	1	2		
Time to ferment 5°Plato (hour)	106	71	96	68	-6.5	12
Time to reach 95% of fermentable extract (hour)	167	136	157	139	-3.5	12
% Attenuation at 7th day (%)	95.3	97.9	98.9	98.0	1.9	2
Harvested Yeast viability (10 ⁸ /g)	17	22	16	22	-0.5	5
Apparent extract at the end of maturation (°Plato)	2.8	2.0	3.0	2.1	0.2	1
Apparent attenuation at the end of maturation (%)	75.4	82.9	75.0	82.6	-0.4	1.5

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

Table 3.4-58:

Table 3.4-46: Impact of GF-3307 on beer analyses

Criteria	OPUS (standard) 2 x 1.0 L/ha	GF-3307 2 x 2.0 L/ha	Difference between GF-3307 and OPUS	Tolerance
Alcohol (% V/V)	4.85	5.05	0.20	0.2
Apparent extract (°Plato)	2.29	2.45	0.16	0.25
Colour (EBC)	4.5	4.5	0.0	2
Head retention (sec)	263	259	-4	15

There is no significant difference between GF-3307 at 2.0 L/ha and the standard OPUS.

Sensory analyses

No significant difference was observed between GF-3307 at 2.0 L/ha and the standard OPUS.

Conclusion

One study was carried out in France by the French Institute of Beverages, Brewing and Malting (IFBM) to test whether two applications of GF-3307 at 2.0 L/ha have any effect on the brewery and malting processes. GF-3307 was compared to the reference product OPUS.

Four trials were conducted in 2017, two on winter barley and two on spring barley. The varieties were chosen as varieties inscribed on malting and brewing list of varieties. The barley samples were converted in the IFBM laboratory as they complied with the four following brewing criteria especially the protein content and the vitality of seeds.

The results demonstrated that when applied twice at 2.0 L/ha at BBCH 31-33 followed by BBCH 39-59 on winter or spring barley, GF-3307 had no impact on the brewery and malting processes. Indeed there was no significant difference between GF-3307 and the standard OPUS on grain analyses, physico-chemical and functional analyses of malt and brewery analyses.

The use of two applications of GF-3307 at 2.0 L/ha on winter and spring barley had no negative effect on the different steps of the brewery and malting processes. Therefore GF-3307 can be applied on spring and winter malting barley as proposed without restriction.

Reference report: 113-RAF-1025 Gless: Study of unintentional effects of phytopharmaceutical products on malt and beer quality and process; IFBM 2017 Study n° 17/105-E1025 (KCP 6.4/12)

zRMS comments:

Trials FR17E7B044MC05C and FR17E7B044MC08C are **field trials only**, providing test material (grain), whereas the results of the analyses concerning the brewing process are confirmed based on inspection of the study by Gless (KCP 6.4/12).

3.4.4.4 Effect of GF-3307 on bread baking

Introduction

Four studies **in winter wheat** were carried out in France in 2015 to show that GF-3307 does not affect the quality of wheat and the baking process. All trials were carried out by officially recognized organizations according to Good Experimental Practice (see list and GEP certificates enclosed). The studies included a field phase and a laboratory phase whereby both were carried out by the same contractor.

Material and methods

Testing facilities or organisations

The trials were carried out in France by the testing facilities listed in the following table below.

Table 3.4-59:

Table 3.4-607: Testing facilities involved

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	Guidelines	Trial Status
Southern	Maritime	France	2015	FR15E7B006MC01C	Biotek agriculture	EPPO PP 1/243 CEB n° 218	GEP
Southern	Mediterranean	France	2015	FR15E7B006MC02C	Biotek agriculture	EPPO PP 1/243 CEB n° 218	GEP
Southern	Maritime	France	2015	FR15E7B006MC03C	Biotek agriculture	EPPO PP 1/243 CEB n° 218	GEP
Southern	Maritime	France	2015	FR15E7B006MC04C	Biotek agriculture	EPPO PP 1/243	GEP

Admin. Zone	EPPO Zone	Country	Year	Trial number	Testing Organisation	Guidelines	Trial Status
						CEB n° 218	

Sites and experimental details

The trials were conducted in central, north and South-West of France which correspond to areas with favourable conditions for the production of milling wheat. The trials were conducted in almost pest-free situations with maintenance sprays carried out as per normal farming practice using only fungicides different to GF-3307 and the reference product.

The following map provides an overview of the geographical distribution of the field trials across France.

Figure 3.4-3: Geographical distribution of the 4 field trials sites conducted to obtain the wheat grain samples for the processing



Full trial site details during field phase are presented in the BAD.

The trials were carried out by officially recognized testing organizations according to GEP and followed the appropriate EPPO standards and the CEB method n°218. The experimental design was a randomized complete block with 3 replicates and plot size of 24 m² minimum. The trials were yielded using a small plot combined harvester.

The applications were performed with compressed air sprayers using flat fans nozzles delivering water volumes of 200-250 L/ha.

Formulations applied and applications details

Test products	Formulation type	Active substance	Rate product L/ha	Rate g ai/ha	Appl. crop growth stage aimed at in the test protocol
GF-3307	EC	fenpicoxamid + prothioconazole	2.0	300	BBCH 39/45 & 65/69
IGNITE	EC	epoxiconazole	1.5	124.5	BBCH 39/45 & 65/69

GF-3307 was applied twice at the maximum European dose of 2.0 L/ha at BBCH 39-45 followed by BBCH 65-69. IGNITE was applied twice at 1.5 L/ha at the same application timings. Further application details are shown in the BAD Table 3.4-61 below. Although two applications are applied in these trials and the dose rate is higher than proposed in this dossier, this presents the worst case

scenario to cover the growth stages in the GAP.

Table 3.4-61: Applications details – Field phase

Trial number	Application timing	Application Date	Crop Growth Stage BBCH min	Crop Growth Stage BBCH max	Spray volume L/ha
FR15E7B006MC01C	A	12/05/2015	37	39	200 L/ha
	B	22/05/2015	65	65	200 L/ha
FR15E7B006MC02C	A	30/04/2015	39	41	200 L/ha
	B	15/05/2015	61	65	200 L/ha
FR15E7B006MC03C	A	29/04/2015	39	39	200 L/ha
	B	21/05/2015	65	65	200 L/ha
FR15E7B006MC04C	A	12/05/2015	41	43	250 L/ha
	B	30/05/2015	61	65	250 L/ha

Results

The data generated from these bread-making studies are presented below step by step. The following table presents yield measured in tonnes/ha.

Table 3.4-62: Impact of GF-3307 on baking process: Yield in tons/ha

Trial	GF-3307		IGNITE		Untreated	
FR15E7B006MC01C	10.1	a	10.1	a	10.2	a
FR15E7B006MC02C	7.5	a	7.4	a	7.5	a
FR15E7B006MC03C	10.7	a	10.9	a	10.8	a
FR15E7B006MC04C	9.2	a	9.4	a	9.3	a

No significant yield difference was observed between GF-3307, the untreated and the reference standard. Therefore, the bread-making tests could be performed. The results of the qualitative analyses and bread-making tests are summarized in the next tables.

Protein content and Hagberg test

According to CEB method n°218, treatments tested should not show any statistical difference to the reference product for protein content and show a Hagberg falling number superior to the minimum threshold of 180.

Table 3.4-63:

Table 3.4-649: Impact of GF-3307 on baking process: % Protein content

Trial	GF-3307		IGNITE		Untreated	
FR15E7B006MC01C	8.6	a	8.7	a	8.6	a
FR15E7B006MC02C	12.8	a	13	a	13.1	a
FR15E7B006MC03C	11.8	a	12	a	12	a
FR15E7B006MC04C	9.8	a	9.8	a	10	a

The results presented in Table 3.4-63 and Table 3.4-65 reveal no statistical difference between GF-3307 at 2 L/ha and the reference product.

Table 3.4-65:

Table 3.4-50: Impact of GF-3307 on baking process: Hagberg falling number in seconds

Trial	GF-3307		IGNITE	
FR15E7B006MC01C	316.8	a	348.8	a
FR15E7B006MC02C	348.5	a	344.7	a
FR15E7B006MC03C	350.2	a	346.2	a
FR15E7B006MC04C	357.2	a	355.7	a

The Hagberg falling number was always higher than 180 and no significant differences were evident between the treatments. When applied twice at 2.0 L/ha on winter wheat, GF-3307 had no impact on the protein content and the amylases activity.

Zeleny test and Chopin alveograph

The Zeleny test and Chopin alveograph were performed on the bulk sample.

Table 3.4-66:

Table 3.4-51: Impact of GF-3307 on baking process: Zeleny volume in mL

Trial	GF-3307	IGNITE
FR15E7B006MC01C	26	24
FR15E7B006MC02C	30	32
FR15E7B006MC03C	30	31
FR15E7B006MC04C	23	24

The Zeleny rating is expressed as a volume in mL. The test checks the capability of flour protein to inflate. Values are considered to differ significantly if the difference is superior to 10 %. In these four trials, the difference between GF-3307 and the reference product never exceeded 10 % (Table 3.4-66 Table 3.4-51). F-3307 applied twice at 2.0 L/ha on winter wheat had no negative impact on the Zeleny index. The results of the Chopin alveograph parameters are presented on the following table.

Table 3.4-67:

Table 3.4-52: Impact of GF-3307 on baking process: Chopin alveograph

Trial	Chopin Type	GF-3307	IGNITE
FR15E7B006MC01C	CHOPIN W	143	119
	CHOPIN G (Swelling)	14.9	13.5
	CHOPIN P (Tenacity)	83	79
	CHOPIN P/L	1.8	2.1
FR15E7B006MC02C	CHOPIN W	214	204
	CHOPIN G (Swelling)	21	17.8
	CHOPIN P (Tenacity)	72	86
	CHOPIN P/L	0.8	1.3
FR15E7B006MC03C	CHOPIN W	190	177
	CHOPIN G (Swelling)	17.5	17.1
	CHOPIN P (Tenacity)	90	85
	CHOPIN P/L	1.5	1.4
FR15E7B006MC04C	CHOPIN W	112	113
	CHOPIN G (Swelling)	12.8	12.2
	CHOPIN P (Tenacity)	79	86
	CHOPIN P/L	2.4	2.9

According to the CEB method n°218, values are considered to differ significantly if the difference is 8 % for W, 8 % for P and 5 % for G.

The results of the Chopin test revealed equivalent or higher W and G values for GF-3307 compared to those of the reference standard IGNITE thus causing no negative effect. The P value for tenacity was lower than that of IGNITE in one trial though being equivalent in the other three studies and the difference may therefore be considered as an experimental artifact.

The results of the Chopin test indicate that two applications of GF-3307 at 2 L/ha on winter wheat have no negative impact on the various parameters (W, G, P and P/L) measured.

Results for baking test

Finally, the studies were completed by a bread-making test followed by a sensory test. The observations were performed on the dough, on the bread, on the soft part of the bread using a scale from 0 - 100 leading to an overall score ranging between 0 and 300. The results illustrate the quality of the flour. If the value obtained by the bread is superior to 250, the grain is classified as superior bread making wheat. If the final score is between 200 and 250, the wheat will need an improving agent to enable use for bread making and if the final score is below 200 the wheat cannot be used for bread making but only for animal feed instead. According to CEB method n°218, the reproducibility limits are governed by the method AFNOR NF V 03-716, which fixes the acceptable difference limits shown in the table below.

The results of the bread-making test are presented in ~~Table 3.4-68~~ **Table 3.4-6853** below.

~~Table 3.4-68:~~

Table 3.4-53: Impact of GF-3307 on baking process: Total bread assessment

Trial	Evaluation Type	Scale	GF-3307	IGNITE	Acceptable difference limit
FR15E7B006MC01C	DOUGH	(0-100)	97	99	24
	BREAD	(0-100)	56	60	16
	SOFT PART/CRUMB	(0-100)	94	94	26
	TOTAL BREAD	(0-300)	247	253	43
FR15E7B006MC02C	DOUGH	(0-100)	87	99	24
	BREAD	(0-100)	57	52	16
	SOFT PART/CRUMB	(0-100)	94	94	26
	TOTAL BREAD	(0-300)	238	245	43
FR15E7B006MC03C	DOUGH	(0-100)	85	85	24
	BREAD	(0-100)	28	28	16
	SOFT PART/CRUMB	(0-100)	94	91	26
	TOTAL BREAD	(0-300)	207	204	43
FR15E7B006MC04C	DOUGH	(0-100)	96	99	24
	BREAD	(0-100)	35	47	16
	SOFT PART/CRUMB	(0-100)	96	94	26
	TOTAL BREAD	(0-300)	227	240	43

According to the reproducibility limits governed by the method AFNOR NF V 03-716, no significant difference were highlighted between GF-3307 and the reference product considering dough, soft part of bread, bread and total bread results. GF-3307 applied twice at 2.0 L/ha on winter wheat at BBCH 39-45 followed by BBCH 65-69 had no impact on the bread-making measures on bread and dough.

Conclusion

Four bread-making studies were performed in 2015 in France within the Maritime and Mediterranean EPPO Zone to test whether two applications of GF-3307 at 2.0 L/ha have any effect on the baking processes. GF-3307 was compared to the untreated control and the reference product IGNITE.

The results demonstrated that when applied twice at 2.0 L/ha at a late application timing (BBCH 39-45 followed by BBCH 65-69), GF-3307 had no negative impact on the quality of grains and baking process. Indeed there was no significant difference of yield, protein content, Zeleny index, the results of the Hagberg test, Chopin alveograph and the bread-making parameters measured.

It can be concluded that GF-3307 applied up to 2.0 L/ha in sequence of two applications early or late has no negative effect on the grain quality and the different steps of the baking process.

zRMS comments:

The results confirmed based on the reports inspection of the trials FR15E7B006MC01C, FR15E7B006MC02C, FR15E7B006MC03C and FR15E7B006MC04C, all of which include the field part and the baking test. The results indicate that grain parameters and flour baking properties as much as the parameters assessed directly in the bread are comparable in material from the plants treated with the test item GF-3307 and with the reference standard.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

3.4.5.1 Impact on wheat, rye and triticale to be used for propagation

The only part of the plant used for propagating wheat, rye or triticale is the seeds that are stored after the harvest to be used for drilling in the next growing season. To evaluate a possible impact of treatments with GF-3307 on the germination ability of wheat, grain samples from 7 selectivity trials were collected and tested according to ISTA¹⁵ testing rules.

Material and methods

Testing facilities or organisations

Table 3.4-69:

Table 3.4-54: Testing facilities involved by EPPO Zone

Admin. Zone	EPPO Zone	Country	Year	Trial#	Testing Organisation	EPPO Guideline	Trial Status
Southern	Maritime	France	2014	FR14E7B016MC01C	BioteK Agriculture, FR	PP1/135	GEP
Central	Maritime	Germany	2014	DE14E7B016UB01C	BioChem Agrar GmbH	PP1/135	GEP
Central	Maritime	United Kingdom	2014	GB14E7B016EB01C	Armstrong Fisher LTD, UK	PP1/135	GEP
Central	Maritime	United Kingdom	2014	GB14E7B016EB02C	Oxford Ag. Trials, UK	PP1/135	GEP
Northern	North-East	Latvia	2014	LV14E7B016MN02C	Latvian Plant Protection Research Centre	PP1/135	GEP
Central	North-East	Poland	2014	PL14E7B016AS01C	Ior Sosnicowice, PL	PP1/135	GEP
Central	South-East	Hungary	2014	HU14E7B016AB01C	Agrofil, HU	PP1/135	GEP

Sites selection, trial site and application details (field trials)

The impact of GF-3307 on the germination of seeds was evaluated with seeds collected in 7 phytotoxicity trials. The trials were carried out by contractor companies and Official Research institutes, all of which follow the EPPO standards and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP). The trials were conducted in France, Germany, the United Kingdom (2), Hungary and Latvia in 2014. For France only trials were considered in this dossier which were carried out in the Maritime EPPO zone part of the country.

On the basis of the EPPO standard 1/241 ‘Guidance on comparable climates’, the trials included in the in this section been grouped and summarized by EPPO zone. EPPO zones have been defined by considering differences between the agro-climatic sub-areas of the EPPO region thus covering data from the Maritime, North-East and South-East EPPO zones which are representative of the proposed GAP.

GF-3307 was applied to winter wheat at the maximum European dose of 2.0 L/ha in a sequence of 2 applications between BBCH 31 and 69 of the crop for the worst case situation. For further information on site selection, trials site and application details see section 3.4.1.1 (phytotoxicity trials).

Formulations applied and rates (field trials)

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	fenpicoxamid + Prothioconazole (50 g as/L + 100 g as/L)	2 x 2.0	300
Proline 275	EC	Prothioconazole (275 g as/L)	2 x 0.72*	200

* Proline was primarily evaluated in the phytotoxicity trials

¹⁵ The International Seed Testing Association, International rules for seed testing.

ISTA germination test rules applying for *Triticum aestivum* (laboratory)

The germination tests were carried out using standardized seed testing methods according to ISTA rules as recommended in EPPO guideline PP 1/135 (*Phytotoxicity assessment*).

Four hundred seeds are usually taken at random from a well-mixed and pure seed sample and spaced uniformly on the moist substrate. Replicates of 100 seeds are recommended. Growing media for germination tests can be paper (seeds on top or between layers) or sand. To break the dormancy of the seeds, prior to the testing the wheat seeds are stored at 30 to 35 °C for 7 days or prechilled at 5-10 °C for a period of 7 days. To break dormancy the pure seed sample alternatively can be treated with gibberellic acid solution.

For testing germination the seeds - arranged in replicates - are tested under favourable moisture conditions at a temperature of 20°C for duration of 8 days. Illumination is recommended but not a requirement. To calculate % germination a first count is made after 4 days, the final count after 8 days. The results of the germination tests are presented in [Table 3.4-70](#) [Table 3.4-55](#). The percent germination values indicate the proportion of seeds which have produced seedlings classified as normal approximately after 8 days under the test conditions given.

Results

To evaluate a possible impact of treatments with GF-3307 on the germination ability of wheat, grain samples from 7 selectivity trials were collected and evaluated according to ISTA testing rules. In these trials GF-3307 was applied to winter wheat at the proposed label rate of 2.0 L/ha in a sequence of 2 applications across trials between BBCH 31 and 69 of the crop. The trials were conducted under GEP in France, Germany, the United Kingdom (2), Hungary and Latvia in 2014. In all 7 trials no reduced germination or an increase of the proportion of abnormal seeds or germlings was apparent in the treatments with GF-3307 relative to the untreated control.

Table 3.4-70:

Table 3.4-55: Impact of treatments with GF-3307 on the germination ability of winter wheat seeds obtained in phytotoxicity trials presented under section 3.4.2

EPPO Zone	Country	Trial number	Germination of seeds (%)					
			Untreated		GF-3307		Proline	
					2 x 2.0 L/ha		2 x 0.72 L/ha	
			%		%		%	
Maritime		Mean	95.5		93.8		96.1	
		min	90.0		82.0		92.0	
		max	99.0		99.0		99.0	
		n trials	4		4		4	
North-East		Mean	92.8		94.0		91.8	
		min	89.0		92.5		85.5	
		max	96.5		95.5		98.0	
		n trials	2		2		2	
All trials			89	m/s	90	m/s	90	m/s
		Mean	93.8		93.3		94.0	
		min	89.0		82.0		85.5	
		max	99.0		99.0		99.0	
		n trials	7		7		7	

* trial means followed by the same letter do not significantly differ, Tukey HSD mean comparison test, p=0.05

**m/s: germination test on composite mixed sample collected from 4 replicates

Summary and conclusion on the effect of germination in wheat, rye and triticale

The only part of the plant used for propagating wheat, rye or triticale is the seeds that are stored after the harvest to be used for drilling in the next season. Germination tests carried out with seeds obtained from 7 selectivity trials clearly demonstrated that GF-3307 applied at the proposed label rate does not negatively affect the germination ability of seeds.

zRMS comments:

Results confirmed, based on inspection of trial reports no. FR14E7B016MC01C, DE14E7B016UB01C, GB14E7B016EB01C, GB14E7B016EB02C, LV14E7B016MN02C, PL14E7B016AS01C and HU14E7B016AB01C. It can be assumed that GF-3307 has no negative effect on propagative ability of the protected cereal crops: wheat, rye and triticale.

3.4.5.2 Impact on barley to be used for propagation

No selectivity trials were carried out to specifically investigate the possible adverse effects of GF-3307 on propagation materials (barley seed). In line with EPPO PP 1/135(3) '*Phytotoxicity Assessment*' (Table 1: 'The circumstances under which data on plant parts for propagation are required'), as no phytotoxicity effects have been reported in the effectiveness trials, it is considered that data on seed germination, using barley grain from crops treated with GF-3307, are not required.

However, germination tests were undertaken in eight effectiveness trials carried out on winter barley and five effectiveness trials carried out in spring barley, to evaluate the safety of GF-3307 applied at dose rates up to 2.0 L/ha. ~~The majority of trials~~ Three of these trials (DE18E7B007UB01C (HORVW), GB17E7B046RH01 (HORVS) and GB17E7B049RH02 (HORVS)) were based on two applications of GF-3307 and compared to the standard Proline (applied at the commercial rate). All trials were conducted according to GEP and were of an RCB plot design with 4 replicates on a wide range of commercially grown varieties and climatic and agronomical conditions. The trials were conducted in Austria, France, Germany, UK, Poland and Latvia between 2017 and 2018.

Material and methods

For information on testing organisations involved, as well as for trials site and experimental details, refer to sections 3.2.3.12 through 3.2.3.16 and Appendix 3 and Appendix 4 of the BAD.

Results

These trials demonstrated that using one or two applications of GF-3307 at 2.0 L/ha, will have no significant negative effects on germination of seed from treated winter barley crops (99.9% of the germination rate in the untreated across 8 trials) and spring barley crops (99.5% of the germination rate in the untreated across 5 trials). The results of the individual trials are detailed in ~~Table 3.4-71~~ **Table 3.4-56**.

~~Table 3.4-71:~~

Table 3.4-56: Impact of GF-3307 applied at 2.0 L/ha on the germination of barley seed. Summary of efficacy trials conducted in the EPPO Maritime and North-East climatic zones (2017-2018).

EPPO Zone	Country	Trial number	Crop (EPPO)	Untreated (%)	% germination and % relative to untreated					
					GF-3307			Proline		
					300 g as/ha			200 g as/ha		
					2.0 L/ha			0.8 L/ha		
					%		rel%	%		rel%
HORVW			Mean	94.4	-		99.9	-		99.6
			min	87.5	-		98.6	-		96.7
			max	98.3	-		103.2	-		102.2
			n trials	8	-		8	-		8
HORVS			Mean	94.0	-		99.5	-		100.9
			min	86.0	-		94.7	-		97.4
			max	98.5	-		102.7	-		103.5
			n trials	5	-		5	-		5

#2 applications of each treatment in these trials

Summary and conclusions ~~on the adverse effects on treated crops~~ on the effect on germination in barley

It considered that the use of GF-3307 as proposed ~~doses of between 1.2 and 1.5 L/ha~~, at the dose rate range of 1.2-1.5 L/ha, in the countries concerned in this dossier will have no adverse effects on seed from winter and spring barley crops treated between growth stages BBCH 30 (beginning of stem elongation) up to and including BBCH 69 (end of heading/inflorescence fully emerged).

zRMS comments:

The results from the 13 data points summarized in the Table 3.4-56 above agreed. Based on these trials it may be assumed that GF-3307 exerts no negative effect on propagative ability of seeds from the protected barley crop.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Introduction

Cereals such as barley are arable crops that are typically part of intensive crop rotations. In this section a risk assessment is made according to EPPO guideline PP 1/207 whether GF-3307 causes a negative effect on crops grown as rotational or replacement crops after a preceding crop was treated with GF-3307.

Winter or spring cereals such as barley in the Central EU Authorisation Zone is typically harvested in July and August. Crops following within rotations are cereals such as barley or wheat, oilseed rape, legumes such as winter field beans (*Vicia* spp.) or ~~breaking~~ ~~breaking~~ crops such as mustard (*Sinapis* spp.) or legume or legume-grass mixtures. To evaluate whether GF-3307 affects the emergence or growth of plants through soil activity an NTP seedling emergence study following OECD Guideline 208 (July 19, 2006) was carried in the laboratory and glasshouses of *agro-check*, Dr. Teresiak & Erdmann GbR in Lentzke, Germany. The study coded AC/DOW/14/03 (KCP 6.5/01) was conducted in compliance with the principles of GLP.

Material and methods

GF-3307 containing 50 g/L DE-777 + 100 g/L prothioconazole was applied to the soil pre-emergence shortly after seeding of the 10 representative test species at rates between 0.2500 L/ha (37.5 g as/ha) and 4.000 L/ha GF-3307 (600 g as/ha). Test products were sprayed by means of a laboratory application chamber 'Spraylab 210/110-SPS', from Schachtner, Ludwigsburg, Germany. The nozzle type used was flat fan EVS 80 01 used at 2.8 bar pressure with water volumes at 188 L/ha.

The 10 representative plant species included were oats (*Avena sativa*), ryegrass (*Lolium perenne*), onion (*Allium cepa*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), carrot (*Daucus carota*), cucumber (*Cucumis sativa*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus*) and tomato (*Lycopersicon esculentum*). The test species were sown in pots containing a natural light silty sand soil taken from the field, sieved to 2 mm with a pH of 7.23 and an organic matter content of 0.64%.

After application of GF-3307 the test species were cultivated in the glasshouse for 21 days (28 days for onion and carrot) at a daily average temperature ranging between 21.3 °C and 26.8 °C. The daily mean relative humidity ranged between 47.8 % and 68.1 %, the day length was ≥ 16 hours.

Assessments for plant injury (phytotoxicity) and plant stand (emergence and mortality) were done 7, 14 and 21 days after treatment (DAT) (onion and carrot 14, 21 and 28 days). The shoot fresh weight was determined at study termination 21 DAT (28 DAT for onion and carrot).

Results

The detailed results for each test species are summarised in Table 3.5-1 below.

Plant emergence and survival

All plant species had reached the 50 % emergence rate 7 days after application of GF-3307 except onion and carrot (14 days). Following the application of GF-3307 no adverse effects on seedling emergence and plant survival were observed on any of the test species. ER_{50} values could not be calculated for any of the test species. Therefore ER_{50} values are estimated to be > 4.000 L/ha, the highest rate of GF-3307 tested.

Phytotoxicity

None of the tested plant species showed phytotoxic symptoms after pre-emergence applications of GF-3307 except ryegrass. In ryegrass slight discolourations were found and deformation of leaves on smaller plants at application rates of ≥ 1.000 L/ha GF-3307 (see Table 3.5-2).

Biomass (fresh weight)

The plant biomass (shoot fresh weight) was determined 21 DAT (28 DAT for onion and carrot). No influence of GF-3307 on plant fresh weight was observed for any of the tested plant species. No dose

response effect was apparent and hence it was not possible to calculate ER₅₀ values. Therefore, ER₅₀ values are estimated to be >4.000 L/ha or >600 g as/ha, the highest rate of GF-3307 tested.

Conclusion

Based on the results of the NTP seedling emergence study conducted under glasshouse conditions it can be concluded that the fungicide GF-3307 did not cause any adverse effects to the seedling emergence, plant survival and biomass of the tested plant species even at the highest rate tested. The ER₅₀ values are considered to be > 4.000 L/ha or > 600 g as/ha which was the highest rate of GF-3307 tested and which is 2.66 N rate of the maximum proposed label rate for countries in this dossier. Ryegrass (*Poaceae*) showed slight phytotoxic effects after application of ≥ 1.000 L/ha GF-3307 but this was not considered significant. GF-3307 applied at practical field rates has no herbicidal potential through residues in the soil and hence does not pose a risk to succeeding crops within a normal rotation or to replacements crops in case of a crop failure.

Label restrictions or risk phrases with regard to following crops after application of GF-3307 are not required.

Table 3.5-1: NTP seedling emergence test. ER₅₀-values (g as/ha) of different test plants to GF-3307

Test species			Variety	GF-3307, ER ₅₀ g as/ha		
				Plant emergence	Plant survival	Biomass reduction
Oat	<i>Avena sativa</i>	Poaceae	Typhon	> 4.000*	> 4.000	> 4.000
Ryegrass	<i>Lolium perenne</i>	Poaceae	Lidelta	> 4.000	> 4.000	> 4.000
Onion	<i>Allium cepa</i>	Liliaceae	Summit	> 4.000	> 4.000	> 4.000
Oilseed rape	<i>Brassica</i>	Brassicaceae	Primus	> 4.000	> 4.000	> 4.000
Soybean	<i>Glycine max</i>	Fabaceae	ES Mentor	> 4.000	> 4.000	> 4.000
Carrot	<i>Daucus carota</i>	Apiaceae	Laguna	> 4.000	> 4.000	> 4.000
Cucumber	<i>Cucumis sativus</i>	Cucurbitaceae	Profi, F1	> 4.000	> 4.000	> 4.000
Sugar beet	<i>Beta vulgaris</i>	Chenopodiaceae	Lukas	> 4.000	> 4.000	> 4.000
Sunflower	<i>Helianthus annuus</i>	Asteraceae	Extrasol	> 4.000	> 4.000	> 4.000
Tomato	<i>Lycopersicon esculentum</i>	Solanaceae	Golden Pearl	> 4.000	> 4.000	> 4.000

* > 4.000 L/ha equals 600 g as/ha of GF-3307 as formulated product, double rate of the proposed label rate

Table 3.5-2: Phytotoxic symptoms 21 days after application of GF-3307 pre emergence

Test species		Rate - GF-3307 L/ha					
		0.000	0.2500	0.5000	1.000	2.000	4.000
Oat	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Ryegrass	Mean	10	10	10	10	9	8
	SD	0	0	0	1	1	1
Onion*	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Oilseed rape	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Soybean	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Carrot*	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Cucumber	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Sugar beet	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Sunflower	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0
Tomato	Mean	10	10	10	10	10	10
	SD	0	0	0	0	0	0

SD-standard deviation

*onion and carrot 28DAT

zRMS comments:

1) OECD 208 guideline

The applicant reports leaf injury in ryegrass on 21 DAA, at the dose rates ≥ 1.0 L/ha, although the Table 3.5-2 may suggest that it is only the ≥ 2.0 L/ha that causes plant damage. Table 25 and Figure 3 in the study report (page 35 and 36) show that the first symptoms were visible already on the day 7 AA and gradually receded (although not completely) until the day 21 AA. The study does not make it clear whether the 1.0 L/ha is equal to LOER, nor does it inform where precisely lies the NOER for ryegrass. The dose rate claimed in the present submission is higher compared to the one causing injury. Since the authors claim “no unusual test conditions affecting the study”, the test item plus ryegrass sensitivity combined seem to be the main reason for the injury observed.

According to the OECD guideline no. 208 followed by the test unit “*The test can be conducted in order to determine the dose-response curve, or at a single concentration/rate as a limit test according to the aim of the study.*” and “*The selected concentrations/rates should encompass the EC_x or ER_x values that are to*

be determined. For example, if an EC50 value is required it would be desirable to test at rates that produce a 20 to 80 % effect. The recommended number of test concentrations/rates to achieve this is at least five in a geometric series plus untreated control, and spaced by a factor not exceeding three.”

The study by Brockmann (KCP 6.5/01) does not include dose rate values high enough to enable determination of ER₅₀, which would be more than welcome while introducing completely new a product. Should the spacing factor assumed be a bit lower, e.g. 1.823, then starting at 0.250 L/ha would make it possible to arrive at 5.034 L/h in six dose rates overall, including the 1.515 L/ha, and would enable both: addressing of the 1.5 L/ha dose rate almost directly from the experimental data, and plotting the regression line, in order to determine ER₅₀, NOER and LOER properly. Regrettably, although the study authors glide safely over the complete dose range up to the highest dose rate per growth season applied for in Europe*, using low-resolution experiment does not allow to focus on the 1.5 L/ha claimed in the present dossier. Moreover, from the presented data the dose response in survival or biomass could not be found either, according to the test report.

2) EPPO PP 1/207 guideline

In the study supporting the 3.5.1 (present) chapter, the test item was “applied pre emergence shortly after seedling” (of the test plants representing potential succeeding crops), which is in disagreement with the crop replacement situation, when the product is already present in soil before the replacement or succeeding crop is planted. The soil concentrations are then far from the initial concentrations resulting from the application rate, and this fact is normally accounted for by using canopy interception rates, PEC values, and measures of decomposition in time. All this is neatly explained in the EPPO guideline PP 1/207, which the applicant refers to, but does not follow.

3) Overall:

Guidelines intended for the use in ecotoxicological research, such as the OECD 208, are not always suitable for efficacy studies which, even though addressing phytotoxic effects, see them through another perspective. Such is the case of the succeeding crops. The approach of the applicant, of adoption of a study carried out for another section, is irrelevant in case of completely new a product, even considered GF-3307 shows no herbicidal activity.

Seemingly, the data submitted by the applicant may represent a slightly worse-case scenario compared to the practical situation of replacing one crop by another, first for the short time elapsing between the application and the start of seed imbibition, and second, for the (probably) negligible contribution of the experimental growth medium to the actives` decomposition. These are, though, just speculations not supported by data, as those submitted by the applicant are irrelevant to the issue considered.

Therefore as the minimum requirement, the label warning must be issued for the ryegrass as replacement crop, concerning possible leaf damage and plant stunting, in case the species is sown less than 3 weeks after the application of GF-3307 followed by failure and termination of the cereal crop protected with it. For the remaining test species used in the study, one could provisionally assume that negative effects on succeeding crops are unlikely, following the application of GF-3307 at the dose rates up to 1.5 L/ha in cereals as the preceding crops.

Nevertheless, to the opinion of zRMS the data provided by the applicant are inadequate in that they address the succeeding crops issue only partially. Therefore the zRMS recommends conducting the proper study of the effect on succeeding crops, following the EPPO PP 1/207(2) guidance, and supplementing the present dossier in the future with the data that would cover the subject in a proper manner.

* 4.0 L/ha in double-application scheme, as in the Southern administrative zone

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

3.5.2.1 Impact on adjacent crops

For GF-3307 a risk assessment was performed based on NTP seedling emergence study AC/DOW/14/03 already quoted in section 3.5-1 (*Impact on succeeding crops*) and a vegetative vigour study which is described below.

With both studies a risk assessment according to EPPO Standard PP 1/256 (*Effects on adjacent crops*) was carried out for crops grown adjacent to a field treated with GF-3307. For adjacent crops the TER-value is calculated by comparing the biological activity of the test product (ER₅₀-value for each plant species) to the estimated drift values in order to predict the likelihood of effects on adjacent crops at different distances from the treated crop. If the TER-value of the most sensitive crop is greater than 1, according to EPPO PP1/256 no higher tier testing is required.

Material and methods: (vegetative vigour study AC/DOW/14/04)

To evaluate whether GF-3307 affects the growth of plants through foliar contact an NTP vegetative vigour study on a range of representative crops was carried in the glasshouses of *agro-check*, Dr. Teresiak & Erdmann GbR in Lentzke, Germany. The study coded AC/DOW/14/04 (KCP 6.5/02) was conducted following OECD Guideline 227, July 19, 2006 and compliance to GLP principles.

The 10 representative plant species included were oats (*Avena sativa*), ryegrass (*Lolium perenne*), onion (*Allium cepa*), oilseed rape (*Brassica napus*), soybean (*Glycine max*), carrot (*Daucus carota*), cucumber (*Cucumis sativa*), sugar beet (*Beta vulgaris*), sunflower (*Helianthus annuus*) and tomato (*Lycopersicon esculentum*).

Applications were made using a laboratory application chamber 'Spraylab 210/110-SPS', from Schachtner, Ludwigsburg, Germany. The nozzle type used was flat fan EVS 8001 used at 2.8 bar pressure with water volumes of 185 L/ha. GF-3307 was applied at BBCH 12 – 14 of the representative plant species included in the bioassay.

After the application of GF-3307 the test plants were cultivated further for 21 days. The test rates of GF-2925 ranged between 0.25 L/ha and (37.5 g as/ha) and 4.0 L/ha (600 g as/ha). The factor between two consecutive rates was 2. During the test period the glasshouse was kept at a daily average temperature between 18.8°C and 25.7°C, a daily mean relative humidity within the trial period ranged from 54.1 % to 83.2 % and a day length of ≥ 16 hours.

Assessments for plant injury (phytotoxicity) and plant survival were done 7, 14 and 21 days after application of GF-3307, shoot fresh weight was determined at study termination 21 days after application.

Results

Plant survival

Following the application of GF-3307 at BBCH stage 12-14 no effects on plant survival were observed on any of the test species. Due to the absence of negative effects ER₅₀ values could not be calculated for any of the test species. Therefore, ER₅₀ values are estimated as > 4.0 L/ha (600 g as/ha), the highest rate of GF-3307 tested.

Phytotoxicity

No phytotoxic effects were found 21 DAT for all tested monocotyledonous species (oat, ryegrass, onion) and for the dicotyledonous species carrot up to the highest tested rate of 4.0 L GF-3307/ha.

Very slight to slight effects were found on leaves, which occurred at application time, for **oilseed rape, soybean, cucumber and tomato** after use of GF-3307 at BBCH 12-14.

Sugar beet and sunflower*, as the most influenced species, showed slight phytotoxic effects also on the new developed plant parts after application of the highest tested rate of 4.0 L GF-3307/ha. See details in Table 3.5-3 and 3.5-4 below. * font bolding by zRMS

Table 3.5-3: Phytotoxic effects (visual assessment) 21 DAT of GF-3307 applied at BBCH stage 12-14 (mean of all replicates)

Plant species		Rate - GF-3307 [L/ha]					
		0.000	0.250	0.500	1.000	2.000	4.000
Oat	Mean	10.0	10.0	10.0	10.0	10.0	10.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0
Ryegrass	Mean	10.0	10.0	10.0	10.0	10.0	10.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0
Onion	Mean	10.0	10.0	10.0	10.0	10.0	10.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0
Oilseed Rape	Mean	10.0	10.0	10.0	10.0	9.0	9.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0
Soybean	Mean	10.0	10.0	10.0	10.0	9.0	8.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0
Carrot	Mean	10.0	10.0	10.0	10.0	10.0	10.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0
Cucumber	Mean	10.0	10.0	10.0	9.0	9.0	8.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0
Sugar beet	Mean	10.0	10.0	9.0	9.0	9.0	7.2
	SD	0.0	0.0	0.0	0.0	0.0	0.4
Sunflower	Mean	10.0	10.0	10.0	9.0	8.6	7.0
	SD	0.0	0.0	0.0	0.0	0.5	0.0
Tomato	Mean	10.0	9.0	9.0	9.0	9.0	9.0
	SD	0.0	0.0	0.0	0.0	0.0	0.0

SD - standard deviation * **BOLDING AND POSITIONING OF THE VALUES BY zRMS**

Table 3.5-4: Phytotoxic symptoms 21 days after application of GF-3307 at BBCH stage 12-14

Species	Symptoms
Oilseed rape	Discolouration of tips of the leaves at ≥ 2.000 L/ha Discolouration and necrosis of edges of the leaves at 4.000 L/ha
Soybean	Discolouration of tips of the leaves at ≥ 2.000 L/ha Necrotic spattered points of the leaves at 4.000 L/ha
Cucumber	Discolouration of tips and necrotic spattered points of the leaves at ≥ 1.000 L/ha Necrotic areas between the veins of the leaves at 4.000 L/ha
Sugar beet	Discolouration of tips of the leaves and paler plants at ≥ 0.500 L/ha Necrotic spattered points and malformation of the leaves at ≥ 2.000 L/ha Smaller plants at ≥ 4.000 L/ha
Sunflower	Discolouration of edges of the leaves at ≥ 1.000 L/ha Necrotic spattered points and malformation of the leaves at ≥ 2.000 L/ha
Tomato	Discolouration of tips of the leaves at ≥ 0.250 L/ha Necrotic spattered points of the leaves at 4.000 L/ha

Biomass (fresh weight)

The plant biomass (shoot fresh weight) was determined 21 days after application. No influence of GF-3307 on plant weight was observed in any of the tested plant species after application of 4.00 L/ha (600 g as/ha). No dose response could be found for the tested plant species and it was not possible to calculate ER₅₀ values. Therefore, the ER₅₀ values are considered to be > 4.00 L/ha, the highest rate of GF-3307 tested. The results are summarised in Table 3.5-5 below.

Table 3.5-5: NTP vegetative vigour study. ER₅₀-values (g ai/ha) of different test plant species to GF-3307

Test species			Variety	GF-3307, ER ₅₀ g ai/ha L f.p./ha	
				Plant survival	Biomass reduction
Oat	<i>Avena sativa</i>	Poaceae	Typhon	> 4.00	> 4.00
Ryegrass	<i>Lolium perenne</i>	Poaceae	Lidelta	> 4.00	> 4.00
Onion	<i>Allium cepa</i>	Liliaceae	Summit	> 4.00	> 4.00
Oilseed rape	<i>Brassica</i>	Brassicaceae	Primus	> 4.00	> 4.00
Soybean	<i>Glycine max</i>	Fabaceae	ES Mentor	> 4.00	> 4.00
Carrot	<i>Daucus carota</i>	Apiaceae	Laguna	> 4.00	> 4.00
Cucumber	<i>Cucumis sativus</i>	Cucurbitaceae	Profi	> 4.00	> 4.00
Sugar beet	<i>Beta vulgaris</i>	Chenopodiaceae	Lukas	> 4.00	> 4.00
Sunflower	<i>Helianthus annuus</i>	Asteraceae	Extrasol	> 4.00	> 4.00
Tomato	<i>Lycopersicon esculentum</i>	Solanaceae	Golden Pearl	> 4.00	> 4.00

* Estimated > 4 L/ha equals > 600 g as/ha of GF-3307 as product

The corresponding TER-values for arable crops are presented in Table 3.5-6 below.

Table 3.5-6: PEC and estimated TER-values (g ai/ha) for drift in arable crops

Vegetative vigour							
species		test material		ER ₅₀ (L f.p./ha)	PER (L fp/ha)	TER (ER ₅₀ /PER)	
(<i>Avena sativa</i> L.) – Poaceae	Oat	GF-3307	>	4	0.08092	49	Pass
(<i>Avena sativa</i> L.) – Poaceae	Oat	GF-3312*	>	3	0.08092	37	Pass

Seedling emergence							
species		Test material		ER ₅₀ (L f.p./ha)	PER (L fp/ha)	TER (ER ₅₀ /PER)	
(<i>Avena sativa</i> L.) – Poaceae	Oat	GF-3307	>	4	0.09044	44	Pass
(<i>Avena sativa</i> L.) – Poaceae	Oat	GF-3312*	>	3	0.09044	33	Pass

*66.7 g as/L fenpicoxamid + 83.33 g as/L Pyraclostrobin

Summary and conclusions

In both NTP studies AC/DOW/14/03 (seedlings emergence test, see section 3.5-1) and study AC/DOW/14/04 (vegetative vigour test) the ER₅₀ values were estimated as >4.0 L/ha. Based on the results of this study, conducted under greenhouse conditions it can be concluded that the fungicide GF-3307 applied at BBCH 12-14 with rates up to 4.0 L/ha did not result in adverse effects on survival or fresh weight of any of the plant species tested.

The NOER for plant mortality and plant weight appeared to be higher than or equal 4.0 L/ha. ER₅₀ values could not be calculated for any of the tested species.

Very slight to slight phytotoxic effects were seen in oilseed rape, soybean, cucumber and tomato. Slight effects were found in sugar beet and sunflower, also in few of the new developed leaves of the plants. But no influence on plant development and biomass could not found.

No negative impact was found for the tested plant species oat, ryegrass, onion and carrot 21 DAT.

zRMS comments:

Much the same as the study previously quoted by the applicant (KCP 6.5/01), the KCP 6.5/02 study by Brockmann and Teresiak, coming from the same laboratory, is based on similar design of too narrow a dose rate range and too low resolution (too high a spacing factor), and the zRMS has similar reservations to using ecotox studies for efficacy purpose (see the preceding commenting box).

Nominally, and according to the EPPO PP 1/256(1) guideline, the TER values calculated by the applicant for AVESA make it unnecessary to carry out further field testing as they exceed 1 many times. One may note, however, that, following the design suggested by the OECD guideline no. 227, and not by EPPO 1/256(1), the study relies on a series of arbitrarily selected dose rates, instead of on doses determined based on assumed drift values, as described in the EPPO PP 1/256(1). Consequently, the origin of the PER values, used to calculate TER quotient (Table 3.5-6 above) is unknown.

The applicant's general conclusion is based on TER calculated for one test species, not even the one most sensitive as can be seen in Table 3.5-3. Then the records of plant injury at 2.0 and even 1.0 L/ha (same table) are mostly dismissed, by the applicant, based on their not affecting plant biomass. Still, all these conclusions are based on raw data points of the range too narrow to produce any reliable regression function, as recommended by the OECD 227 guideline. In this respect the study is essentially in disagreement with OECD guideline to which it refers. It clearly does not follow the EPPO guideline quoted, either.

Since one cannot decline that at least **some** data have been presented and (again) these seemingly represent a worse-case scenario, as the minimum requirement the label warning must be issued, concerning the 4 most sensitive species (according to data submitted): *“particular care should be taken during the application of the GF-3307, to avoid spray drift on adjacent crops if these are Cucumber, Sugar beet, Sunflower or Tomato”*. Notwithstanding this provisional solution, the zRMS recommends conducting the proper study of the effect on adjacent crops, following the EPPO PP 1/256(1) guidance, and supplementing the present dossier in the future with the data that would cover the subject in a proper manner.

3.5.2.2 Tank cleaning procedure for GF-3307

Introduction

An insufficient tank cleaning can cause adverse effects on non-target plants such as rotational crops or crops that are sprayed using the same tank that could contain residues of a phytotoxic product that has been applied previously to a different crop. GF-3307 at practical use rates has no herbicidal properties that would cause phytotoxic effects to succeeding (see section 3.5-1) or to adjacent crops (see 3.5.2.1). A study was conducted to determine how effectively tested fungicide formulations could be cleaned from the internal surfaces of a sprayer using a water only cleaning regime at 10% volume of the spray tank capacity.

The five experimental fungicide formulations that were tested and their application rates were: GF-2925 at 0.5%, GF-3307 at 1% and GF-3309 at 1%, GF-3308 and GF-3312. (KCP 6.5/03)

Methodology

Amega Sciences laboratory methods 157 Fungicide Removal Test and 165 Determination and Analysis of Fungicide Residue using HPLC HP1100 and Agilent 1220 were followed and analysis was carried out alongside advice adopted from UK guideline 305 ‘Cleaning Application equipment – small scale jar test protocol’.

Table 3.5-7: Summary of test treatments

Treatment	Active substance	Formulation type
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GF-3307	fenpicoxamid + prothioconazole	EC
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Table 3.5-8: Summary of test treatments

Treatment	Active substance	Formulation type
GF-2925	fenpicoxamid	SC
GF-3307	fenpicoxamid + prothioconazole	EC
GF-3309	fenpicoxamid + pyraclostrobin	EC
GF-3308	fenpicoxamid	EC
GF-3312	fenpicoxamid + pyraclostrobin	EC

For this work, AmegA Sciences methods 157 and 165 were used.

Method 157 relates to the contamination of bottles with herbicides and fungicides and cleaning/washing with water. A solution of herbicide and the relevant fungicide solution are added to the bottles agitated and stored for 16 hours prior to the solution being discarded and rinsed with water. The bottles are then cleaned using either water or All Clear Extra and samples are retained for analysis. Method 165 is the HPLC method for analysis of herbicide residues. The methodology has been developed by AmegA Sciences and can be summarised as follows:

A sample to be tested was analysed using HPLC to determine the wavelength at which the highest absorbance (tallest peak) is seen, and the retention time of the peaks that are being analysed. This then allowed the correct wavelength for analysis to be set as well as the run time for the method. The samples obtained from the extraction were then analysed following the criteria that were highlighted by testing the individual components, and the results are calculated to give a total area. The area relates to how much residue remains, and as all the bottles followed the same procedure and were subject to the same extraction volume, this allows a comparison of results. The area is calculated in the HPLC software, and shows relatively how much contamination there is in the tank that was being tested.

Analysis by HPLC determines the wavelength at which the highest absorbance (tallest peak) is seen and the retention time of the peaks from the samples being analysed. Analysing the individual products or formulations establishes the correct wavelength and criteria for use in order to test the samples obtained following extraction with acetyl nitrite and the results are expressed as a calculated area for each peak.

The tests have been designed to simulate the “triple rinse” system typically used on UK farms.

Table 3.5-9: Summary treatments/Short test descriptions

Method	Herbicide/Fungicide	Description
155	All	Separate contamination
155	All	Tank mixed contamination
157	GF-3307	Water as cleaner

Table 3.5-10: Summary treatments/Short test descriptions

Method	Herbicide/Fungicide	Description
155	All	Separate contamination
155	All	Tank mixed contamination
157	GF-2925	Water as cleaner
157	GF-3307	Water as cleaner
157	GF-3309	Water as cleaner
157	GF-3308	Water as cleaner
157	GF-3312	Water as cleaner

Results

A calibration curve was made of each of the fungicide formulations at 0ppm, 20ppm, 50ppm, and 100ppm, this was then used to calculate the results and in combination with calculating the use rate, an effective clean out percentage was determined, as well as residual parts per million.

Table 3.5-11: Summary of % tank wash clean out

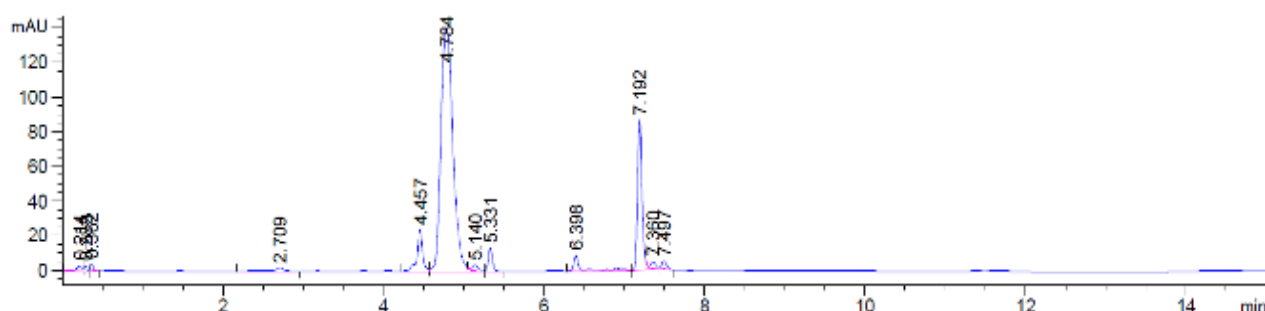
Fungicide Formulation	Active Concentration (total) (ppm)	ppm-retained without washing	%-removed without cleaning	ppm-retained after washing with 10% tank	%-Removed after 10% tank volume
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				volume water	water used to wash
GF-3307	1500	0.0628	99.9958	0.0086	99.9994

Table 3.5-12: Summary of % tank wash clean out

Fungicide Formulation	Active Concentration (total) (ppm)	ppm retained without washing	% removed without cleaning	ppm retained after washing with 10% tank volume water	% Removed after 10% tank volume water used to wash
GF-2925	650	0.1703	99.9738 99.8253	0.0534	99.9918
GF-3307	1500	0.0628	99.9958 99.9720	0.0086	99.9994
GF-3308	500	0.0724	99.9855 99.9903	0.0277	99.9945
GF-3309	1125	0.0596	99.9947 99.9646	0.0134	99.9988
GF-3521	1000	0.0615	99.9939 99.9590	0.0148	99.9985

Figure 3.5-1: chromatographic profile for GF-3307



Conclusion

The results show that there is generally low adhesion of the fungicide formulations to the tank wall, and because of this a significant amount of the active ingredients are removed, with less than 0.1ppm remaining in the spray tank after washing with water in all cases, and less than 0.1ppm remaining in the spray tank without water cleaning except for GF-2925, however this only retains 0.1703ppm of material in the tank.

The active ingredients and fungicide formulations are easily removed from the spray tank using 10% tank volume of water to clean, to below 1ppm in all cases, with there being very low adherence of the fungicide formulations, leading to >99% of removal of the residues in all cases and no label wording, advising of the need for a proprietary tank cleaner, is required for GF-3307.

zRMS comments:

Agreed. No special tank cleaning instruction is necessary in the product label, other than the standard requirement of triple rinsing with water at the volume of 10% total tank capacity.

3.5.3 Effects on beneficial and other non-target organisms (KCP 6.5.3)

No observations on adverse effects to beneficials or other non-target organisms have been reported in the efficacy and selectivity trials presented in this document. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

Summary and conclusions on other undesirable or unintended side-effects

It is considered that the use of GF-3307 as proposed will have no other undesirable or unintended side-effects on succeeding crops, adjacent crops or on beneficial and other non-target organism.

zRMS comments:

Overall, the data submitted by the applicant address the issues of the section 3.5: “Other undesirable or unintended side-effects” sufficiently enough, considered the extent of the submitted claims.

3.6 Other/special studies

3.6.1 Rainfastness of GF-3307

3.6.1.1 Rainfastness of GF-3307 on wheat

Introduction

Application of agricultural pesticides often takes places under marginal conditions. One problem which may impact performance is rainfall. Loss of fungicide from plant surfaces due to exposure in the field to dew or rain can impact fungicide performance. Rain fastness of foliar applied fungicides is influenced by a range of factors including the physiochemical properties of the active ingredient influencing uptake into plant tissue, cuticular waxes and fungicide formulation being used. GF-3307 was developed as a fungicide to control a range of pathogens in cereal crops. The objective of the experiment was to determine the rain fast intervals of GF-3307 and other products not relevant in the context of this dossier.

Material and methods

Testing facilities involved

The rain fastness study (non GEP/non GLP) for GF-3307 (KCP 3.6/01) was carried out in the laboratories and glasshouses of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN., 46268, USA.

Formulations applied and rates

Test product	Formulation type	Active substance	Rate product L/ha	Rate g as/ha
GF-3307	EC	Fenpicoxamid + prothioconazole	1.0-2.0	150-300
Bravo 500	SC	Chlorothalonil	0.75-1.5	375-750
Aviator XPro 235	EC	Prothioconazole + bixafen	0.625-1.25	146.9-293.8
Proline	EC	Prothioconazole	0.375-0.72	99-198

Experimental details

Wheat seedlings cv. Yuma were used as host for SEPTTR and PUCCRT. Seeds were planted in small plastic pots (6.5cm x 6.5 cm) containing artificial potting soil and then placed in a greenhouse. Seedlings were thinned to 10 to 12 per pot and watered and fertilized as needed to sustain plant growth. Plants were kept at 21 to 25°C. The experiments used a randomized complete block design with 4 replicates for each treatment. Treatments consisted of factorial arrangement of the treatments and two rates placed in four blocks.

Fungicide application

GF-3307 was applied with the use of a Generation III Research Sprayer, DeVries Manufacturing at the proposed label rate of 2.0 L/ha (1N) and 1.0 L/ha (0.5N) using a water volume of 150 L/ha. Before spraying activated charcoal was placed on the surface of the soil to prevent compound which was washed off during the application of the rain from being translocated from the roots back up into the plants.

Rain simulation

The rain was applied with the Generation III sprayer using a Teejet 8002 flat fan nozzle. A total of 10 mm of rain was applied in a 25 minute period. Each compound was subdivided into four groups. Each group received rain at a different time post compound application. The timings were 1) no rain, 2) 5 minutes 3) 60 minutes and 4) 120 minutes after application of the test products. Plants were dried for 24 hr after the rain application and the pathogens were applied through artificial inoculation.

Inoculation

Two separate tests were done and, in each test, a different fungal organism used. The test was carried out using SEPTTR and PUCCRT which were inoculated onto the test plants 24 hours after application of the test products to represent a one day protection situation. The seedlings were inoculated with a spore suspension applied with a spray gun powered with compressed air. After inoculation seedlings were placed in a dark dew room for 24 hours, next moved to a lighted dew room for 48 hours, and then transferred to a greenhouse (20° C). For PUCCRT the seedlings were evaluated 8 days after inoculation and the seedlings inoculated with SEPTTR were evaluated for disease 21 days after inoculation. The sprayed leaves on the seedlings were assessed for the total percent leaf area with disease.

Assessments

Percent disease control was calculated by comparing the amount of disease on the treated plants to the untreated diseased plants which were considered to have zero control, [Percent control=(1-disease in treated plants/disease in untreated plants)*100]. The experiments used a randomized complete block design.

Statistical analysis

The experiments used a randomized complete block design. To analyse the data Tukey's HSD means comparison test (p=0.05) was used to assess treatment differences.

Results

The results are summarised in Tables 3.6-6 to 3.6-7. GF-3307 was rain fast after simulated rainfall of 10 mm rain within 25 minutes starting 5 minutes after application at 1.0 L/ha or 2.0 L/ha against PUCCRT and SEPTTR. The reference product Bravo 500 overall showed a lower level of efficacy against PUCCRT and SEPTTR and was significantly less rain fast than GF-3307. The reference Aviator XPro 235 at 1N and 0.5N dose rate maintained high levels of control of PUCCRT and SEPTTR after rainfall with efficacy comparable to that of GF-3307 at 1N and 0.5N rate. Proline wasn't used in the PUCCRT test but showed decreased activity when applied against SEPTTR and was inferior to GF-3307 at 1N and 0.5N.

Table 3.6-1: Rain fastness of GF-3307 in a glasshouse bioassay when applied as a 1 day protectant for the control of PUCCRT

Rain application pattern**	% Control of PUCCRT					
	GF-3307 1.0 L/ha	GF-3307 2.0 L/ha	Bravo 500 0.75 L/ha	Bravo 500 1.5 L/ha	Aviator XPro 235 0.625 L/ha	Aviator XPro 235 1.25 L/ha
No rain	100 a*	100 a	45 a	85 a	100 a	99 a
5 minutes	100 a	100 a	57 a	88 a	99 a	100 a
60 minutes	100 a	100 a	10 b	29 b	99 a	100 a
120 minutes	100 a	100 a	10 b	24 b	100 a	100 a
Prob. >F	n/a	n/a	0.0001	0.0001	0.5	n/a

* Tukey HSD test, p=0.05, means in the same column followed by the same letter are not significantly different

** Rainfall amount, 10 mm of simulated rainfall within a period of 25 minutes.

Table 3.6-2: Rain fastness of GF-3307 in a glasshouse bioassay when applied as a 1 day protectant for the control of SEPTTR

Rain application pattern**	% Control of SEPTTR							
	GF-3307 1.0 L/ha	GF-3307 2.0 L/ha	Bravo 500 0.75 L/ha	Bravo 500 1.5 L/ha	Proline 275 0.36 L/ha	Proline 275 0.72 L/ha	Aviator XPro 235 0.625 L/ha	Aviator XPro 235 1.25 L/ha

No rain	99 a*	99 a	59 a	24 a	88 a	94 a	100 a	98 a
5 minutes	99 a	98 a	17 a	0 a	75 ab	96 a	97 b	98 a
60 minutes	100 a	99 a	20 b	9 b	42 bc	61 b	98 b	99 a
120 minutes	99 a	100 a	24 b	17 b	28 c	64 b	97 b	96 a
Prob. >F	0.4	0.4	0.23	0.3	0.001	0.0045	0.0001	0.4

* Tukey HSD test, $p=0.05$, means in the same column followed by the same letter are not significantly different

** Rainfall amount, 10 mm of simulated rainfall within a period of 25 minutes.

Summary and Conclusions

Exposed to simulated rainfall of 10 mm rain within 25 minutes GF-3307 was rain fast when applied immediately (5 minutes) or 2 hours after application even when applied at the 50% rate of the proposed label rate.

Exposed to simulated rainfall of 10 mm rain within 25 minutes GF-3307 was rain fast when applied immediately (5 minutes) or 1 hour after application even when applied at the 50% rate of the proposed label rate. For label purposes we propose the product is rainfast within 1 hour.

zRMS comments:

Agreed based on the inspection of the study quoted by the applicant. Exposed to rainfall of 10 mm volume within 5 minutes following the application the GF-3307 had shown no loss of efficacy in control of Puccinia or Septoria on wheat.

For larger precipitation volumes it seems reasonable to declare that GF-3307 is rainfast starting 1h after application.

Reference report: Mathieson, T; Rainfast studies to compare the rainfast ability of new Dow AgroSciences fungicide formulations to current market fungicides (KCP 3.6/01)

3.6.1.2 Rainfastness of GF-3307 on barley

Introduction

Application of agricultural pesticides often takes place under marginal conditions. One problem which may impact performance is rainfall. Loss of fungicide from plant surfaces due to exposure in the field to dew or rain can impact fungicide performance. Rain fastness of foliar applied fungicides is influenced by a range of factors including the physiochemical properties of the active ingredient influencing uptake into plant tissue, cuticular waxes and fungicide formulation being used. GF-3307 was developed as a fungicide to control a range of pathogens in cereal crops. The objective of the experiment was to determine the effect of rain fast on the efficacy of GF-3307 for the control of *Rhynchosporium secalis* (RHYNSE).

Material and methods

A greenhouse bioassay¹⁶ (KCP 3.6/03) was conducted to characterize the efficacy and rainfastness of GF-3307 for controlling *Rhynchosporium secalis* (RHYNSE) following a 1-day protectant application and rain simulation 30 minutes or 1 hour after application on 9-day-old barley plants. The efficacy of GF-3307 was compared to Proline and Aviator Xpro.

Fungicides were applied to 9-day-old barley plants using a Generation III Research Track Sprayer (DeVries Manufacturing) using an 8002E TwinJet flat fan nozzle with a spray arm speed of 2.14 km/h and a spray pressure of 220 kPa. Pots of barley plants were placed in the spray chamber such that their mid-canopy was 50 cm below the spray nozzle. Fungicides were delivered to barley seedlings at different rates simulating a spray volume of 150 L/ha. (Table 3.6-3).

Following treatment application plants were allowed to dry at room temperature. Thirty minutes after treatment, an artificial rain of 60 mm/hour was applied on four replicated plants for 30 minutes (total

¹⁶ Vriesman, M, Leader, A, Diehl, C., Wineglass, A., Loeffler, J., 2019; Rainfastness performance of Dow agrosciences™ products GF-3308 and GF-3307, and Proline, and Aviator 235 Xpro for control of barley scald (*Rhynchosporium secalis*) on barley following a preventive application and a simulated 30 mm rain 30 minutes or 1 hour after application - Dow agrosciences internal report (GL19E7B008F-DYC110 and GL19E7B008F-DYC116)

amount of 30 mm rain), using a rain simulator. In another four replicated plants, an artificial rain of 60 mm/hour was applied one hour after treatment for 30 minutes (total amount of 30 mm rain). Four other replicated plants were kept without rain, in order to evaluate the effect of wash-off.

Table 3.6-3: Fungicide products rates used in preventive and rainfastness studies against *Rhynchosporium secalis* (RHYNSE) in barley

Formulation	Active substance	g a.s./L	Rates tested (g a.s./ha)			
GF-3307	fenpicoxamid + prothioconazole	50 + 100	300	262.5	225	180
GF-3308	fenpicoxamid	50	100	75	60	
Proline	prothioconazole	275	200	150	120	
Aviator Xpro	bixafen + prothioconazole	75 + 160	293.75			

Rhynchosporium secalis (RHYNSE) spores were harvested from 10-day-old RHYNSE cultures grown on Yeast Malt Agar (YMA) plates. One day after application (1-day preventive study), barley seedlings were sprayed to run-off with a RHYNSE spore suspension using a compressed air spray gun. The spore suspension was filtered through two layers of cheesecloth and adjusted to 4 10⁶/ml. To the final suspension, 3 drops of Tween 20/100 ml of inoculum were added. Inoculated plants were placed in a dark dew room (100% RH, 22°C) for 48 hours. Inoculated plants were then transferred to a greenhouse with a suitable environment for disease development.

Plants were evaluated for disease approximately two weeks after application (12-14 DAA). Percent disease severity was averaged from ten leaves per pot on a 0-100% scale. The percent disease control was calculated relative to the untreated inoculated control. Pots were arranged in a randomized complete block design with four replications. The experiment was repeated once.

Results

The percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application at four rates and rain simulation in Table 3.6-4.

Table 3.6-4: Percentage control of *Rhynchosporium secalis* (RHYNSE) after 1-day preventive application at four rates and rain simulation. Results of two trials (n=8), except for treatments with rain event one hour after application (n=4) assessed 12-14 DAA.

Formulation	Rate (g a.s./ha)	Percent disease control ^z						P value ^x
		No rain event ^y		Rain event 30 minutes after appl. ^y		Rain event 1 hour after appl. ^y		
GF-3308	100	86.5	a	78.4	a	81.5	a	NS
GF-3308	75	80.0	a	76.4	a	80.8	a	NS
GF-3308	60	78.0	a	71.9	a	81.9	a	NS
GF-3307	300	99.0	b	98.9	b	98.5	b	NS
GF-3307	262.5	99.6	b	97.7	b	98.5	b	NS
GF-3307	225	98.4	b	97.7	b	98.5	b	NS
GF-3307	180	97.9	b	97.1	b	95.4	b	NS
Proline	200	97.8	b	97.7	b	100	b	NS
Proline	150	97.5	b	96.1	b	97.3	b	NS
Proline	120	95.3	b	93.8	b	97.7	b	NS
Aviator Xpro	293.75	100	b	99.6	b	99.2	b	NS
P value ^y		<0.05		<0.05		<0.05		

^z Percentage control values were calculated for each treatment within a rep according to the formula: [(SC – ST)/SC]*100 where SC is the severity on the untreated inoculated control and ST is the severity on the treatment.

^y Values are the means of two independent trials with four replications each; means followed by the same lower-case letter within a column are not significantly different at P value <0.05. Means were separated using Tukey's mean comparison test.

^x Values are the means of two independent trials with four replications each; means followed by the same upper-case letter across a row are not significantly different at P value <0.05. Means were separated using Tukey's mean comparison test.

The reduced efficacy of GF-3308 in this test with and without rain is because of the efficacy of fenpicoxamid against RHYNSE which is below that of Proline and is clearly boosted when fenpicoxamid is combined with prothioconazole in GF-3307. There were no significant differences for

RHYNSE control between non-rained plants, and plants which received a simulated rain 30 minutes or 1 hour after the application (see BAD).

When no rain occurred, a >90% control was observed with GF-3307 and reference products. No significant differences in barley scald control 12-14 DAA were observed between GF-3307, Proline, and Aviator Xpro (see the BAD).

When rain occurred 30 minutes after application, a >90% control was observed with GF-3307 and reference products. No significant differences in barley scald control 12-14 DAA were observed between GF-3307, Proline, and Aviator Xpro (see the BAD).

When rain occurred 1 hour after application, a >90% control was observed with GF-3307 and reference products. No significant differences in barley scald control 12 DAA were observed between GF-3307, Proline, and Aviator Xpro (see the BAD).

Summary and Conclusions

The performance of GF-3307 was not affected when a simulated 30 mm rain event occurred 30 minutes or 1 hour after the application.

Percentage control of *Rhynchosporium secalis* (RHYNSE) was high (>90%) and statistically similar to that of standards Proline and Aviator Xpro, at all rates tested and within each of the rain simulation events. It is considered that these results are equally applicable to the other disease claims for GF-3307 on barley (RAMUCC, PYRNTE, PUCCHD and ERYSGH) and ~~no specific label warnings in relation to rainfastness are required~~ it is proposed for label purposes the product is rainfast within an hour after application.

zRMS comments:

Agreed. Based on the inspection of the study quoted by the applicant (KCP 3.6/03), GF-3307 had shown no loss of efficacy in control of RHYNSE, after precipitation following the treatment in 1 hour or in 30 minutes time. GF-3307 may therefore be claimed rainfast on barley, after 1h time following the application.

3.6.2 Characterisation of GF-3307 and visualisation of foliar spray deposits

Introduction

It is accepted that the application of GF-3307 will be necessary through drift reducing technology such as 75% (3*) nozzles. In order to evaluate the effect on the coverage of a leaf surface a series of studies were undertaken in 2016 by Silsoe Spray Applications Unit Ltd, UK to quantify the effect of formulation on the characteristics of sprays produced by agricultural nozzles and to provide qualitative information through photographic images on the characteristics of deposits on both real and artificial surfaces.

Two nozzles were used; (i) a conventional flat fan nozzle, FF110 03 (Hypro EU Ltd) at 3.0 bar; (ii) an air-induction nozzle, AIXR 03 (Spraying Systems Ltd) at 3.0 bar. GF-3307 was included as part of a wider screen with GF-3308 (50 g ai/L fenpicoxamid) and was compared to water and a common standard, Aviator Xpro which was used as it is widely accepted that the formulation matrix of Aviator Xpro has desirable characteristics.

Results and conclusions

The images of droplets containing GF-3308 show very little differences between the different application types, because (a) all nozzle types produce very large droplets with any size differences being relatively small, and (b) most importantly, the degree of spreading achieved by the droplets was sufficient to reach close to 100% coverage of the leaf surface, potentially overcoming any deficiencies in coverage that could be encountered with large droplet application techniques.

Based on observation from these photographs, it was concluded that the area of the leaf that is covered by spray liquids containing GF-3308 was independent of the nozzle design, level of drift reduction, forward speed or application volume and is close to 100%.

The two other products tested, Elatus Era and Aviator Xpro 235, do not demonstrate the same level of

spreading, and therefore the area of the leaf that is covered by spray liquid containing either of these products is likely to be lower. The ‘poorer’ coverage by Aviator Xpro in the 2017 experiment compared to the 2016 experiment could be attributed to the increased forward speed of 12 km/hr in the 2017 test compared to 8 km/hr in the 2016 test.

Reference report: Lane, O’Sullivan, Butler-Ellis, C; *et al*, Characterising deposits on plants for a range of formulations and application conditions, July 2017 report S0181, Silsoe Spray Applications Unit Ltd. (KCP 3.6/04)

Reference report: Butler-Ellis, C; *et al*, Characterising of sprays and visual deposits on leaf surfaces, June 2016 report S0140, Silsoe Spray Applications Unit Ltd.

Overall conclusions

Application of GF-3307 through drift reducing technology such as 75% (3*) nozzles will have no adverse effects on the coverage of a leaf surface and the effectiveness of the product on barley crops.

zRMS comments: Conclusions agreed. The study (Butler *et al.* 2017) (KCP 3.6/04) noted and recognized as valid.

3.6.3 Impact of water volumes and nozzle type on the efficacy of GF-3307

Materials and Methods

A field study coded DE14E7B017UB01C (KCP 3.6/02) was conducted in Germany in 2014 to evaluate the impact of water volume and nozzle type on the efficacy of GF-3307 against SEPTTR and the resulting yield response. For the experiment standard flat fan nozzles (SFF) and low drift nozzles (LDN) were compared using water volumes of 100 L/ha or 200 L/ha with each nozzle type.

GF-3307 was applied at 2 timings at 2.0 L/ha. The reference products included were Proline applied at 0.72 L/ha and Bravo 500 applied at 1.5 L/ha at the same timings as GF-3307. Further trial details are presented in Table 3.6-5 below.

Table 3.6-5: Material and methods

Trial details	Trial code	DE14E7B017UB01C
	EPPO climatic zone	Maritime
	Trial status	GEP
	Testing organisation	Agrartest, DE
	Country	Germany
	Trial location/Zip Code State/Region	65326 Panrod Hessen
Guidelines	Specific guidelines General guidelines	EPPO PP 1/26 EPPO PP 1/135, 1/152, 1/181, 1/225, 1/214, 1/213
Experimental design	Plot design	Split-Plot
	Plot size	2.5 m x 8 m
	Number of replications	4
Crop	Trials per crop	Winter wheat (1)
	Varieties per crop	JB Asano
	Drilling date	19-Oct-13
Application	Application timings, at crop BBCH	Timing A:23-Apr-2014 , BBCH 32-33 Timing B: 16-May-2014, BBCH 39-49 Application interval 23 days
	Spray volume L/ha	100 or 200
	Nozzle	XR11002VP (standard)* or air induction nozzle AI11002VP (low drift)*
	Air temperature °C	19.2/18.2
	Relative humidity	46/53
Assessment	Assessment types	Efficacy of SEPTTR as % foliar infection (severity), calculation of control according to Abbott, Phytotoxic effects as % injury to crop Yield, t/ha corrected to 86% dry matter, TGW
	Assessment dates	% infection at both application timings, 23DAAA, 35 DAAA/12DAAB, 53DAAA/30DAAB Injury 1 and 2 weeks after application and at every efficacy assessment Yield 108 DAAA/85 DAAB

* The XR11002VP flat fan nozzle was selected as a flat fan nozzle that is commonly mounted on conventional hydraulic spray booms. Operated at 2 bars the output of this nozzle is classified as FINE. The selection of a ‘02’ type nozzle was driven by the possibility to spray 200 and 100 L/ha at a pressure of 2 bars with the experimental spray equipment just changing the speed (7.2 km/ha and 3.6 km/h) and in a velocity range still feasible for spraying randomized plot trials and thus maintaining identical spray patterns. The drift reduced flat fan low drift nozzle AI11002VP was selected because at 2 bar it is accredited by LERAP of a 3 Stars low drift rating (< 25% drift). At 2 bar its output is classified as ULTRA COARSE (BCPT specs in accordance with ASABE Stand. S572.1). For further technical details and parameters see the BAD.

Formulations applied and rates

Table 3.6-6: Formulations applied and rates

Test products	Formulation type	Active substance	Rate product L/ha	Rate g a.s./ha
GF-3307	EC	Fenpicoxamid + prothioconazole	2.0	100+200
Proline	EC	Prothioconazole	0.72	200
Bravo 500	SC	Chlorothalonil	1.5	750

Results

A field study was conducted in Germany in 2014 to evaluate the efficacy of GF-3307 against SEPTTR when sprayed using standard flat fan nozzles (XR11002VP) or low drift nozzles (AI11002VP) each applied at a spray volume of 100 L/ha or of 200 L/ha. GF-3307 was applied at 2 timings at 2.0 L/ha at BBCH 32/33 and 39/49 of winter wheat to control SEPTTR. As shown in the BAD, ~~w~~the treatments with GF-3307 did not significantly affect the efficacy against SEPTTR and the resulting yield response of the winter wheat crop irrespective of the nozzle type and water volumes used. For the duration of the trial no phytotoxic effects on the winter wheat crop cv. JB Asano were observed in any of the treatments with GF-3307.

Studies conducted in the United Kingdom in 2015

Two further studies (KCP 3.6/06 and 3.6/07) were conducted in the UK in 2015 to evaluate the impact of water volume and nozzle type on the efficacy of GF-3307 against SEPTTR and the resulting yield response. For the experiment standard flat fan nozzles (SFF) and low drift nozzles (LDN) were compared using water volumes of 100 L/ha or 200 L/ha with each nozzle type.

GF-3307 was applied at 2 timings at 2.0 L/ha. The reference product included was Proline applied at 0.72 L/ha at the same timings as GF-3307. Further trial details are presented in Table 3.6-7.

Table 3.6-7: Materials and Methods

Trial details	Trial code	GB15E7B030MF01	GB15E7B030SD01
	EPPO climatic zone	Maritime	
	Trial status	GEP	
	Testing organisation	Dow AgroSciences Ltd, UK	
	Country	United Kingdom	
	Trial location/Zip Code State/Region	Wellesbourne, Warwickshire CV35 9EF	South Runcton, Norfolk, PE33 0EX
Guidelines	Specific guidelines General guidelines	EPPO PP 1/26 EPPO PP 1/135, 1/152, 1/181, 1/225, 1/214, 1/213	
	Plot design	Split-Plot	
Experimental design	Plot size	3 m x 12 m	2.5 m x 12 m
	Number of replications	4	
Crop	Trials per crop	Winter wheat (2)	
	Varieties per crop	Consort	Conqueror
	Drilling date	24-Sep-14	16-Oct-14
Application	Application timings, at crop BBCH	Timing A:16-Apr-2015, BBCH 31 Timing B: 15-May-2015, BBCH 39- 45	Timing A:3-May-2015, BBCH 32 Timing B: 21-May-2015, BBCH 39
	Spray volume L/ha	100 or 200	
	Nozzle	XR11002VP (standard)* or air induction nozzle AI11002VP (low drift)*	
	Air temperature °C	17.5/18.9	18/18
	Relative humidity	54.2/61.4	56/68
Assessment	Assessment types	Efficacy of SEPTTR as % foliar infection (severity), calculation of control according to Abbott, Phytotoxic effects as % injury to crop Yield, t/ha corrected to 86% dry matter, TGW	

* The XR11002VP flat fan nozzle was selected as a flat fan nozzle that is commonly mounted on conventional hydraulic spray booms. Operated at 2 bars the output of this nozzle is classified as FINE. The selection of a '02' type nozzle was driven by the possibility to spray 200 and 100 L/ha at a pressure of 2 bars with the experimental spray equipment just changing the speed (7.2 km/h and 3.6 km/h) and in a velocity range still feasible for spraying randomized plot trials and thus maintaining identical spray patterns. The drift reduced flat fan low drift nozzle AI11002VP was selected because at 2 bar it is accredited by LERAP of a 3 Stars low drift rating (< 25% drift). At 2 bar its output is classified as ULTRA COARSE (BCPT specs in accordance with ASABE Stand. S572.1). For further technical details and parameters see the BAD.

Formulations applied and rates

Test products	Formulation type	Active substance	Rate product L/ha	Rate g a.s./ha
GF-3307	EC	Fenpicoxamid + prothioconazole	2.0	100+200
Proline	EC	Prothioconazole	0.72	200

Results

Two field studies were carried out in the United Kingdom in 2015 to evaluate the efficacy of GF-3307 against SEPTTR when sprayed using standard flat fan nozzles (XR11002VP) or low drift nozzles (AI11002VP) each applied at a spray volume of 100 L/ha or of 200 L/ha. GF-3307 was applied at 2 timings at 2.0 L/ha at BBCH 31/32 and 39/45 of winter wheat to control SEPTTR. As shown in the BAD, the treatments with GF-3307 did not significantly affect the efficacy against SEPTTR and the resulting yield response of the winter wheat crop irrespective of the nozzle type and water volumes used. For the duration of the trial no phytotoxic effects on the winter wheat crops cv. Consort and Conqueror were observed in any of the treatments with GF-3307.

Conclusions

GF-3307 provides consistent and comparable levels of control of SEPTTR in wheat when applied at spray volumes between 100 and 200 L/ha using conventional or low drift nozzles. These findings are in line with the results of 154 efficacy trials presented under chapter 3.2.3 (*Efficacy tests*) which were carried out under a wide range of regional conditions across countries of the Maritime, North-East and South-East EPPO zones. In these efficacy trials no pattern was apparent when water volumes reduced down to 150 L/ha or the use of drift reduced nozzle types would negatively affect the efficacy of GF-3307.

It is considered that these conclusions are equally applicable to use in barley for control of RAMUCC, PYRNTE, RHYNSE, PUCCHD and ERYSGH and the lower water volume proposed (~~150~~ 100 L/ha) or the use of drift reduced nozzle types will have no negative effects on the effectiveness of GF-3307 to control diseases in barley.

zRMS comments:

Agreed, based on the trial reports DE14E7B017UB01C, GB15E7B030MF01 and GB15E7B030SD01 (KCP 3.6/02, /06 and /07, respectively).

3.7 List of test facilities including the corresponding certificates

The following facilities were involved in the trials and studies presented in this dossier:

Table 3.7-1: List of test facilities

TEST FACILITY	ADDRESS	GEP Certificate in trial reports (Yes or No)
AARHUS UNIVERSITY FLAKKEBJERG, DK	RESEARCH CENTRE FLAKKEBJERG, 4200 SLAGELSE, DENMARK	Yes
ADAS UK LTD	WOODTHORNE, WERGE ROAD, WOLVERHAMPTON, WV6 8TQ, UK	Yes
AGRARTEST, DE	HANS-WERNER SCHERF, PALMBACHSTR.37, 65326 AARBERGEN-PANROD, GERMANY	Yes
AGRO-CHECK	DORFSTRASSE 15, 16833 LENTZKE, GERMANY	Yes
AGROPROSPECT SRL	COMUNA HOGHIZ, SATUL FANTANA, NR. 1, JUDETUL BRASCOV, COD 507099, ROMANIA	Yes
AGROFIL SZAKTANACSADO MERNOKI IRODA KFT.	PETOFI SANDOR U. 7. PUSKI H-9235 HUNGARY	Yes
AGROLIS CONSULTING	Z.A. LA GRANDE MARINE-185, AVENUE ANDRÉ AMPÈRE-84800 L'ISLE-SUR-LA-SORGUE-FRANCE	Yes
AGROPASS HUNGARIA KFT.	NAPOLEON UTCA 10, GYOR, H-9028, HUNGARY	Yes
AMEGA SCIENCES LIMITED	17 LANCHESTER WAY, ROYAL OAK INDUSTRIAL ESTATE, DAVENTRY, NORTHAMPTONSHIRE. NN11 5PH, ENGLAND	No (non GEP)
ANADIAG BULGARIA LTD	244 4000 PLOVDIV, BULGARIA	Yes
ANADIAG POLSKA	UL. SADOWA 16/22, 95-100 ZGIERZ, POLAND	Yes
ARMSTRONG FISHER LTD, UK	8 BARN OWL CLOSE, LANGTOFT PETERBOROUGH, LINCOLNSHIRE PE6 9RG, UK	Yes
ATC - AGRO TRIAL CENTER GMBH, AT	VERSUCHSSTATION GERHAUS, 2471 ROHRAU, AUSTRIA	Yes
BIOCHEM AGRAR. DE	KUPFERSTR. 6, 04827 MACHERN OT GERICHSHAIN, GERMANY	Yes
BIOTEK AGRICULTURE LTD.	UNIT 5 WINTERBECK INDUSTRIAL ESTATE, ORSTON LANE, BOTTESFORD, NG13 0AU, UK	Yes
BIOTEK AGRICULTURE. FR	ROUTE DE VIELAINES - 10120 SAINT-POUANGE, FRANCE	Yes
BIOTEK AGRICULTURE HUNGARY KFT	H12013 POMAZ, MARTIROK UTJA 1-3, HUNGARY	Yes
CERESTIS	LA FERME DU PARC, ZI DE SAINT CHRISTOPHE, 10500 SAINT LEGER SOUS BRIENNE, FRANCE	Yes
CENTRE WALLON DE RECHERCHES AGRONOMIQUES (CRA-W), BE	CHAUSSEE DE NAMUR 24, 5030 GEMBLOUX, BELGIUM	Yes
CROPWORKS LTD	2 COULTERENNEY FARM STEADING, BANKFOOT, PERTH, PH1 4AQ, UK	Yes
CPR EUROPE KFT.	9700 SZOMBATHELY, TORAK, IGNAC U. 30 ADOSZ, HUNGARY	Yes
DITANA SPOL. S.R.O.	CSA 92, 78353 VELKA BYSTRICE, CZECH REPUBLIC	Yes
DOW AGROSCIENCES DEVELOPMENT STATION/ DOW AGROSCIENCES HUNGARY KFT.	SZOLNOK STATION, VIZPART KORUT 32, H-5000 SZOLNOK, HUNGARY	Yes

TEST FACILITY	ADDRESS	GEP Certificate in trial reports (Yes or No)
DOW AGROSCIENCES GMBH. DE	TRUDERINGER STRASSE 15, 81677 MUNICH, GERMANY	Yes
DOW AGROSCIENCES LTD, UK	WARWICK ENTERPRISE PARK, WELLESBOURNE, WARWICK, CV35 9EF, UK	Yes
DOW AGROSCIENCES LTD., KINGS LYNN. UK	CROSSBANK ROAD, KING'S LYNN, NORFOLK PE30 2JD, UNITED KINGDOM	Yes
DOW AGROSCIENCES SAS. FR	MARCO POLO B, 790 AV. DU DR. DONAT, 06250 MOUGINS, FRANCE	Yes
DOW AGROSCIENCES LLC	9330 ZIONSVILLE ROAD, INDIANAPOLIS, IN. 46268, USA	No (non GEP)
EUROFINS AGROSCIENCE SERVICES LTD, UK	SLADE LANE, WILSON, MELBOURNE, DERBYSHIRE, DE73 8AG. UNITED KINGDOM	Yes
EUROFINS AGROSCIENCE SERVICES GMBH, DE	CARL-GOERDELER-WEG 5, 21684 STADE, GERMANY	Yes
SC EUROFINS AGRICULTURAL SERVICES SRL	STR. MUNTELE MIC, NR. 20, GIARMAYA, JUD TIMIS, ROMANIA	Yes
FIELD ARM LIMITED	7 WYCKE LANE, TOLLESBURY, MALDON, ESSEX, CM9 8ST, UK	Yes
FYSE S.R.O.	SKOLSKA 88, 99109 KOLARE, SLOVAKIA	Yes
GEMERPRODUKT VALICE OVD	OKRUZNA 3771, 979 01 RIMAVSKA SOBOTA, SK	Yes
HETTERICH FIELDWORK GBR, DE	BAMBERGER STR. 50, 97359 SCHWARZACH, DE	Yes
INTEC AGRO TRIALS	BLATNICKA 179, 687 24 UHERSKY OSTROH, CZ	Yes
IOR SOSNICOWICE, PL	GLIWICKA STR. 29, 44-153 SOSNICOWICE, POLAND	Yes
LATVIAN PLANT PROTECTION RESEARCH CENTRE, (LAAPC)	STRUKTORU IELA 14A, RIGA LV1039, LATVIA	Yes
NARDI FUNDULEA, RO	N. TITULESCU STREET NO 1, FUNDULEA, CALARASI, 915200 ROMANIA	Yes
OSEVA PRO S.R.O. ODSTEPNY ZAVOD VYZKUMNY USTAV TRAVINARSKY ZUBRI. CZ	ZUBRI 698 756 54, CZECH REPUBLIC	Yes
OXFORD AG TRIALS, UK	WEST FARM BARN, STRATTON AUDLEY, BICESTER, OXON, OX27 9AS. UNITED KINGDOM	Yes
QUINTUS GMBH	LIEPEN 7, 17194 HOHEN WANGELIN, GERMANY	Yes
PHYLIAE, FR	3 IMPASSE DE LA VOIE ROMAINE, F76190 VEAUVILLE LES BAONS	Yes
SGS POLSKA SP. Z O.O.	83 BEMA ST, 01-233 WARSAW, POLAND	Yes
SILSOE SPRAY APPLICATIONS UNIT LIMITED	BUILDING 42, WREST PARK, SILSOE, BEDFORD, MK45 4HP, UK	No (non GEP)
STAPHYT, DE	LANGENBURGER STRASSE 35, 74572 BLAUFELDEN, GERMANY	Yes
STAPHYT SP. Z.O.O.	UL. ZIEBICKA 2, 60-164 POZNAN, POLAND	Yes
STAPHYT, FR	23, ROUTE DE MOEUVRES, 62860 INCHY EN ARTOIS, FRANCE	Yes
SUFFOLK AND CAMBRIDGE CROP STATION LTD	LOWER LEY BARN, WOODITTON ROAD, SETCHWORTH, NEWMARKET, CB8 9TX, UK	Yes
SYNTECH RESEARCH FR S.A.S. FR	LE BOIS DE LOYSE 71570 LA CHAPELLE DE GUINCHAY, FRANCE	Yes
SYNTECH RESEARCH HUNGARY KFT.	9761, TAPLANSZENTKERESZT,	Yes

TEST FACILITY	ADDRESS	GEP Certificate in trial reports (Yes or No)
	RAKOCZI U. 4. HUNGARY	
TRIAL-TEC GMBH	KAMPENREDDER5, 24363 HABY, GERMANY	Yes
UNIWERSYTET PRZYRODNICZY POZNAN, PL (Poznan University of Life Sciences)	MAZOWIECKA STR, 45/46, 60-623 POZNAN, POLAND	Yes
VYZKUMNY USTAV ROSTLINNE VYROBY, V.V.I. (Crop Research Institute)	DRNOVSKA 507 161 06 PRAHA 6 - RUZYNE, CZECH REPUBLIC	Yes
VYZKUMNY USTAV PICNINARSKY, SPOL. S R.O. (Research Institute for Fodder Crops, Ltd)	664 41 TROUBSKO, CZECH REPUBLIC	Yes
ZEMEDELKA ZKUSEBNI STANICE KUJAVY, S.R.O	KUJAVY 48, 742 44 KUJAVY, CZECH REPUBLIC	Yes
ZEMEDELSKY VYZKUMNY USTAV KROMERIZ, S.R.O. CZ	HAVLICKOVA 2787 767 01 KROMERIZ, CZECH REPUBLIC	Yes
ZKUSEBNI STANICE NECHANICE, S.R.O.	ŠTOLBOVA 319, 503 15 NECHANICE, CZECH REPUBLIC	Yes

Appendix 1 — Lists of data considered in support of the evaluation (acc. to original submission, July 2021)

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. — Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/01	Bounds, P.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of SEPTTR in Europe. 2013 GB13E7B022SE01C ADAS UK Ltd GEP Unpublished	N	DAS
KCP 6.1/02	Boutrais, J-M.	2012	What is the minimum effective dose XR 777 (GF 2800) + Prothioconazole for control of PuccST in winter wheat SZ, CZ, NZ 2012. FR12E7B014MC03C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/03	Cailliau, M.	2012	Evaluation of DE 777 (GF 2800) applied straight and in mixture with prothioconazole (GF 2979) against SEPTTR in wheat, Europe 2012 FR12E7B013MC02C Phyliae, FR GEP Unpublished	N	DAS
KCP 6.1/04	Cailliau, M.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of SEPTTR in Europe. 2013 FR13E7B022MC01 Dow AgroSciences, FR GEP Unpublished	N	DAS
KCP 6.1/05	Cailliau, M.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of SEPTTR in Europe. 2013 FR13E7B022MC03C Phyliae, FR GEP	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.1/06	Crestani, D.	2013	Evaluation of XDE 777 (GF 2925 & GF 3135) applied for the control of SEPTTR in wheat in Southern Europe. 2013 IT13E7B012DC01 GEP Unpublished	N	DAS
KCP 6.1/07	Crestani, D.	2012	What is efficacy of DE 777 (GF 2800) + Prothioconazole (GF 2979) for control PuccRT in winter wheat. Europe 2012 IT12E7B015DC01 Dow AgroSciences, Italia GEP Unpublished	N	DAS
KCP 6.1/08	Donner, M.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of SEPTTR in Europe. 2013 DE13E7B022DD01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/09	Donner, M.	2012	What is efficacy of DE 777 (GF 2800) + Prothioconazole (GF 2979) for control PuccRT in winter wheat. Europe 2012 DE12E7B015DD01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/10	Downey, S	2012	What is the minimum effective dose XR 777 (GF 2800) + Prothioconazole for control of PuccST in winter wheat SZ, CZ, NZ 2012. GB12E7B014SD01 Dow AgroSciences, UK GEP Unpublished	N	DAS
KCP 6.1/11	Fisher, S.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of PuccST in Europe. 2013 GB13E7B028SE01C	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Armstrong Fisher Ltd, UK GEP Unpublished		
KCP 6.1/12	Fraser, J.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of SEPTTR in Europe. 2013 GB13E7B022JF01 Dow AgroSciences, UK GEP Unpublished	N	DAS
KCP 6.1/13	Grisel, J.	2012	What is efficacy of DE 777 (GF 2800)+ Prothioconazole (GF 2979) for control PuccRT in winter wheat. Europe 2012 FR12E7B015JG02 Dow AgroSciences, FR GEP Unpublished	N	DAS
KCP 6.1/14	Kildea, S.	2012	Evaluation of DE 777 (GF 2800) applied straight and in mixture with prothioconazole (GF 2979) against SEPTTR in wheat, Europe 2012 IE12E7B013SE02C Teagasc GEP Unpublished	N	DAS
KCP 6.1/15	Litt, M.	2012	What is efficacy of DE 777 (GF 2800)+ Prothioconazole (GF 2979) for control PuccRT in winter wheat. Europe 2012 DE12E7B015ML01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/16	Lunzenfichter, D.	2012	What is efficacy of DE 777 (GF 2800)+ Prothioconazole (GF 2979) for control PuccRT in winter wheat. Europe 2012 FR12E7B015MC05C SRF, FR GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/17	Mathieson, T. <i>et al.</i>	2013	Effect of formulation type and adjuvants on efficacy of XDE 777 containing formulations Dow AgroSciences internal report # 2020479 Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/18	Mathieson, T, Kemmit, G	2014	Comparative mobility of three XDE 777 formulations and select commercial standards as measured by glasshouse bioassay with <i>Puccinia recondita</i> on wheat. Dow AgroSciences internal report # 2024367 Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/19	Mathieson, T, Leader, A	2018	How does the efficacy of Inatreq formulation GF 3307 (a combination) and GF 3308 (solo) compare to market references when tested against <i>Septoria tritici</i> (SEPTTR) and <i>Puccinia recondita</i> (PUCCRT) in greenhouse conditions? Dow AgroSciences internal report # 2051736, June 2018 Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/20	Myung K, Madary MW, Kemmit G, Annangudi SP, Yao C	2015	Effects of different formulations on retention, surface coverage, and uptake of XDE 777 in wheat plants. Dow AgroSciences internal report # 2026067, February 2015. Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/21	Nistrup Jørgensen, L.	2012	Evaluation of DE 777 (GF 2800) applied straight and in mixture with prothioconazole (GF 2979) against SEPTTR in wheat, Europe 2012 DK12E7B013MN01C Aarhus University – Flakkebjerg GEP Unpublished	N	DAS
KCP 6.1/22	Nistrup Jørgensen, L.	2012	What is the minimum effective dose XR 777 (GF 2800) + Prothioconazole for control of PUCCT in winter wheat SZ, CZ, NZ 2012. DK12E7B014MN01C Aarhus University – Flakkebjerg GEP Unpublished	N	DAS
KCP 6.1/23	Nistrup	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Jørgensen, L.		PUCCST in Europe. 2013 DK13E7B028MN01C DIAS – Danish Institute of Agricultural Sciences GEP Unpublished		
KCP 6.1/24	Owen, W.J. <i>et al.</i>	2011	XR 777 Discovery Advancement Report Dow AgroSciences internal report # 2009830 Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/25	Parker C.L.; Owen, J.	2013	Herbicide Activity of XDE 777 Dow AgroSciences internal report # DAI 1177 Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/26	Pitiot, S.	2012	What is efficacy of DE 777 (GF 2800)+ Prothioconazole (GF 2979) for control PUCCRT in winter wheat. Europe 2012 FR12E7B015MC04C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/27	Pitiot, S.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of PUCCRT in Europe: 2013 FR13E7B025MC02C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/28	Pitiot, S.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of PUCCST in Europe. 2013 FR13E7B028MC01C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/29	Richard, C.	2012	What is efficacy of DE 777 (GF 2800)+ Prothioconazole (GF 2979) for control PUCCRT in winter wheat. Europe 2012	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			FR12E7B015CR01 Dow AgroSciences, FR GEP Unpublished		
KCP 6.1/30	Ridgeway, J.	2012	Evaluation of DE 777 (GF 2800) applied straight and in mixture with prothioconazole (GF 2979) against SEPTTR in wheat, Europe 2012 GB12E7B013SE01C Eurofins Agroscience Services Ltd, UK GEP Unpublished	N	DAS
KCP 6.1/31	Ridgeway, J.	2012	What is the minimum effective dose XR 777 (GF 2800) + Prothioconazole for control of PuccST in winter wheat SZ, CZ, NZ 2012. GB12E7B014SE01C Eurofins Agroscience Services Ltd, UK GEP Unpublished	N	DAS
KCP 6.1/32	Rohr, J.	2012	Evaluation of DE 777 (GF 2800) applied straight and in mixture with prothioconazole (GF 2979) against SEPTTR in wheat, Europe 2012 DE12E7B013UB01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.1/33	Schnieder, F.	2012	Evaluation of DE 777 (GF 2800) applied straight and in mixture with prothioconazole (GF 2979) against SEPTTR in wheat, Europe 2012 DE12E7B013FS01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/34	Schulz, T.	2012	What is efficacy of DE 777 (GF 2800)+ Prothioconazole (GF 2979) for control PuccRT in winter wheat, Europe 2012 DE12E7B015TS01 Dow AgroSciences, DE GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/35	Stephan, A.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of SEPTTR in Europe. 2013 DE13E7B022AS01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/36	Sumner, K.	2012	What is the minimum effective dose XR 777 (GF 2800) + Prothioconazole for control of PuccST in winter wheat SZ, CZ, NZ 2012. GB12E7B014KS01 Dow AgroSciences, UK GEP Unpublished	N	DAS
KCP 6.1/37	Thibault, A.	2012	What is efficacy of DE 777 (GF 2800) + Prothioconazole (GF 2979) for control PuccRT in winter wheat. Europe 2012 FR12E7B015MC03C SRE, FR GEP Unpublished	N	DAS
KCP 6.1/38	Varret, F.	2013	Studies to find the most effective formulations and dose rate of DE 777 + Prothioconazole for control of SEPTTR in Europe. 2013 FR13E7B022MC02C Staphyt GEP Unpublished	N	DAS
KCP 6.1/39	Vriesman [REDACTED], M, Leader, A., Diehl, C., Wineglass, A., Loeffler, J.	2019	Evaluate and compare Dow agrosciences™ products Questar (GF 3308), Univoq (GF 3307), Adavelt (GF 3840), and XDE 481 (GF 4319) for control of barley scald (<i>Rhynchosporium secalis</i>) following a preventive application Dow agrosciences internal report Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/40	Vriesman [REDACTED], M, Leader, A., Diehl, C., Wineglass, A., Loeffler, J.	2019	Evaluate and compare Dow agrosciences™ products Questar (GF 3308), Univoq (GF 3307), Adavelt (GF 3840), and XDE 481 (GF 4319) for control of barley scald (<i>Rhynchosporium secalis</i>) following a curative application Dow agrosciences internal report Non GEP/non GLP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/41	Vriesman ██████, M., Karaïskou, G., Leader, A., Diehl, C., Wineglass, A., Loeffler, J.	2020	Volatility of GF 3308, GF 3307, Proline, and Aviator Xpro for control of barley powdery mildew (<i>Blumeria graminis</i> f. sp. <i>hordei</i>) on barley following a preventive application Dow agrosciences internal report Non GEP/non GLP Unpublished	N	DAS
KCP 6.1/42	Wessels, F., Owen, J.	2013	Insecticidal Activity of XDE 777 Dow AgroSciences internal report # DAI 1101 Non GEP/non GLP Unpublished	N	DAS
KCP 6.2/01	Babrik, Z.	2015	Efficacy and dose response of different XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, 2014. HU14E7B014AB01C Agrofil, HU GEP Unpublished	N	DAS
KCP 6.2/02	Babrik, Z.	2015	What is the efficacy of DE 777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB01C Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/03	Babrik, Z.	2015	What is the efficacy of DE 777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB02C Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/04	Babrik, Z.	2015	Efficacy and dose response of different DE 777 + Prothioconazole/pyraclostrobin EC formulations for control of SEPTTR in wheat. EU CZ SE EPPO, 2015. HU15E7B040AB02C Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/05	Banachowska, J	2014	Efficacy of XDE 777 + prothioconazole and XDE 777 + pyraclostrobin formulations for control of Puccinia in	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			wheat: EU-CZ, 2014. PL14E7B010AS02C IOR SOSNICOWICE, PL GEP Unpublished		
KCP-6.2/06	Banachowska, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS01C IOR SOSNICOWICE, PL GEP Unpublished	N	DAS
KCP-6.2/07	Banachowska, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS02C IOR SOSNICOWICE, PL GEP Unpublished	N	DAS
KCP-6.2/08	Bataille, C.	2020	Efficacy of one application of GF-3307 against barley diseases. EA19E7B004F-DYE02 (MAL2019-04b-report) CRA-W Centre wallon de Recherches agronomiques GEP Unpublished	N	DAS
KCP-6.2/09	Bataille, C.	2020	Efficacy of one application of GF-3307 against barley diseases. EA19E7B004F-DYE01 (MAL2019-04a-report) CRA-W Centre wallon de Recherches agronomiques GEP Unpublished	N	DAS
KCP-6.2/10	Beyreiss, S.	2017	Evaluation of the minimum effective dose of XR-659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012UB03C EUROFINS-AGROSCIENCE SERVICES GMBH, DE GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/11	Beyreiss, S	2018	Evaluation of the minimum effective dose of XR 659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye, EU 2017 DE17G1C012UB02C Eurofins Agroscience Services GEP Unpublished	N	DAS
KCP 6.2/12	Bezdiekova, A.	2015	What is the efficacy of XDE 777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application CZ15E7B041PV01C Ditana Spol. S.R.O. GEP Unpublished	N	DAS
KCP 6.2/13	Bezdiekova, A.	2016	The efficacy GF 3308 straight and mixture with partner fungicides for the control of foliar diseases of wheat, EU 2016 CZ16E7B038PV01C DITANA SPOL. S.R.O. GEP Unpublished	N	DAS
KCP 6.2/14	Biro, A.	2014	Efficacy of XDE 777 + prothioconazole and XDE 777 + pyraclostrobin formulations for control of Puccin on wheat, EU-CZ, 2014 HU14E7B010AB01 Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/15	Biro, A.	2015	What is the efficacy of XDE 777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011AB01C Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/16	Biro, A.	2015	What is the efficacy of XDE 777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011AB02C Dow AgroSciences Hungary	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/17	Biro, A.	2015	What is the efficacy of DE 777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB02 Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/18	Biro, A.	2016	Efficacy of Inatreq formulations against rusts and another various diseases in wheat. SE EPPO zone, 2016 HU16E7B029AB04 Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/19	Biro, A.	2019	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F DBI04 Corteva Agriscience GEP Unpublished, [REDACTED]	N	DAS
KCP 6.2/20	Biro, A.	2019	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F DBI04 Corteva Agriscience GEP Unpublished, [REDACTED]	N	DAS
KCP 6.2/21	Biro, A.	2019	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F DBI02 Corteva Agriscience GEP Unpublished, [REDACTED]	N	DAS
KCP 6.2/22	Biro, A.	2019	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F DBI03 Corteva Agriscience GEP Unpublished, [REDACTED]	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/23	Biro, A.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone HU16E7B030AB01 Dow Agrosiences Hungary Kft. GEP Unpublished	N	DAS
KCP 6.2/24	Botoman, C.	2020	Benchmark local programs for GF 3308 / GF 3307. T1 to support low doses Corteva Agriscience EA20E7B020F DHT048 GEP Unpublished	N	DAS
KCP 6.2/25	Botoman, C.	2020	Comparable efficacy of GF 3307 (50+100 g ai/4) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/4) against key diseases in wheat. Corteva Agriscience EA20E7B035F DHT074 GEP Unpublished	N	DAS
KCP 6.2/26	Bounds, P.	2015	XDE 777 straight and in combination with prothioconazole or pyraclostrobin for the control <i>Fusarium</i> head blight in wheat. EU 2015 GB15E7B018EB01C ADAS UK Limited GEP Unpublished	N	DAS
KCP 6.2/27	Burton, N.D.	2015	WHAT IS THE EFFICACY OF XDE 777 FORMULATIONS AGAINST PUCGST COMPARED TO REFERENCE STANDARDS? GB15E7B015EB04C Suffolk & Cambridge Crop Station Ltd GEP Unpublished	N	DAS
KCP 6.2/28	Cana, L.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat EU, 2016 RO16E7B046AP01C NARDI Fundulea GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/29	Cana, L.	2020	Benchmark local programs for GF 3308 / GF 3307. T1 to support low doses Corteva Agriscience EA20E7B020F DHT047 GEP Unpublished	N	DAS
KCP 6.2/30	Cana, L.	2020	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat. Corteva Agriscience EA20E7B035F DHT075 GEP Unpublished	N	DAS
KCP 6.2/31	Cana, L.	2020	Benchmark local programs for GF 3308 / GF 3307. T1 to support low doses. EA20E7B035F DPF047 Corteva Agriscience/NARDI Fundulea GEP Unpublished	N	DAS
KCP 6.2/32	Cap, J.	2021	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F DQD056 ZKUSEBNI STANICE NECHANICE, S.R.O., CZ GEP Unpublished	N	DAS
KCP 6.2/33	Chambon, J.	2019	GF 3307 (DE 777+prothioconazole) and DE 777 straight (GF 3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. FR18E7B012MC03C (CEE 18101, OR20180401081) Cerestis GEP Unpublished	N	DAS
KCP 6.2/34	Ciupa-Wylezalek, B.	2019	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2019 EA19F9B003F DPF01 Dow AgroSciences GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/35	Ciupa-Wyleżalek, B.	2020	Efficacy of Inatreq on PuccST in Triticale—benchmark program, Europe, 2020 EA20E7B018F-DPP025 Dow AgroSciences, Poland GEP Unpublished	N	DAS
KCP 6.2/36	Dietrichs, W.	2014	Efficacy of DE 777 + prothioconazole and DE 777 + pyraclostrobin formulations for control of PuccRT in wheat: EU CZ, 2014. DE14E7B010WD01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.2/37	Dietrichs, W.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, 2014. DE14E7B014WD01 Dow AgroSciences DE GEP Unpublished	N	DAS
KCP 6.2/38	Dietrichs, W.	2015	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin for the control of foliar diseases in triticale. EU 2015. DE15E7B003WD01 Dow AgroSciences GmbH. DE GEP Unpublished	N	DAS
KCP 6.2/39	Dietrichs, W.	2015	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034WD01 Dow AgroSciences GmbH. DE GEP Unpublished	N	DAS
KCP 6.2/40	Donner, M.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ, 2014. DE14E7B026DD01 Dow AgroSciences, DE GEP	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/41	Donner, M.	2016	What is the efficacy of XDE 777 formulations against PuccST compared to reference standards, EU 2016? DE16E7B027DD01 Dow AgroSciences GEP Unpublished	N	DAS
KCP 6.2/42	Downey, S.	2018	GF 3307 (DE 777+prothioconazole) and DE 777 straight (GF 3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. GB17E7B045SD01 Dow AgroSciences UK GEP Unpublished	N	DAS
KCP 6.2/43	Drzewiecki, S.	2021	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in barley. EA20E7B037F-DPF050 Dow AgroSciences, PL GEP Unpublished	N	DAS
KCP 6.2/44	Dubois, P.	2018	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019. FR17E7B041MC07C (BPE17/280/FG01, OR20170400609) BIOTEX Agriculture GEP Unpublished	N	DAS
KCP 6.2/45	Dubois, P.	2018	GF 3307 (DE 777+prothioconazole) and DE 777 straight (GF 3308) for the control of foliar diseases in barley. – France 2017. FR17E7B041MC04C (BPE17/280/FGC06, OR20170400606) BIOTEX Agriculture GEP Unpublished	N	DAS
KCP 6.2/46	Dubois, P.	2018	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. France 2017. FR17E7B042MC09C (BPE17/281/FG05, OR20170400620)	N	DAS

Data point	Author(s)	Year	Title Company Report No. ——— Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			BIOTEK Agriculture GEP Unpublished		
KCP 6.2/47	Fejes, A.	2020	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in barley. EA20E7B037F DHP064 BIOTEK Agriculture GEP Unpublished	N	DAS
KCP 6.2/48	Fejes, A.	2020	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B035F DHP066 BIOTEK Agriculture Hungary Kft. GEP Unpublished	N	DAS
KCP 6.2/49	Fejes, A.	2020	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B035F DHP067 BIOTEK Agriculture Hungary Kft. GEP Unpublished	N	DAS
KCP 6.2/50	Fisher, S.	2015	THE EFFICACY OF XDE 777 FORMULATIONS COMPARED TO REFERENCE STANDARDS FOR CONTROL OF Puccinia IN EUROPE? GB15E7B015EB01C ARMSTRONG FISHER LTD, UK GEP Unpublished	N	DAS
KCP 6.2/51	Frydrych, J.	2015	XDE 777 FORMULATIONS GF 3308, GF 3307, GF 3309, GF 3312A FOR THE CONTROL OF Puccinia. EU 2015. CZ15E7B014PV01C OSEVA PRO S.R.O. ODSTEPNY ZAVOD VYZKUMNY USTAV TRAVINARSKY ZUBRI. CZ GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/52	Frydrych, J.	2021	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F DQD057 Oseva Pro Ltd. GEP Unpublished	N	DAS
KCP 6.2/53	Gabor, K	2020	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+120 g ai/l) against key diseases in wheat. EA20E7B035F DHP069 Agropass Hungaria Kft. GEP Unpublished	N	DAS
KCP 6.2/54	Gazuska, A.	2014	Efficacy and dose response of different XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS02C Ior Sosnicowice, PL GEP Unpublished	N	DAS
KCP 6.2/55	Gazuska, A.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS01C IOR Sosnicowice, PL GEP Unpublished	N	DAS
KCP 6.2/56	Gazuska, A.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS02C IOR Sosnicowice, PL GEP Unpublished	N	DAS
KCP 6.2/57	Gazuska, A.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. PL17E7B045AS01C Dow AgroSciences	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/58	Gezova, V.	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone— 2018 CZ18E7B007PV02C (F 18 G 571 01) InTec Agro Trials GEP Unpublished	N	DAS
KCP 6.2/59	Hrabovsky, J.	2019	Evaluation of new formulation of Inatreq and Inatreq + Prothioconazole against foliar diseases in wheat. CZ Zone —2018 CZ18E7B017PV01C GEP Unpublished	N	DAS
KCP 6.2/60	Hrabovsky, J.	2021	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F-DQD058 Corteva Agriscience/Zemědělská zkušební stanice KUJAVY, s.r.o. GEP Unpublished	N	DAS
KCP 6.2/61	Hetterich, F	2019	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Blumeria graminis</i> in barley. EU 2019. EA19F9B023F-DPE01 Hetterich Fieldwork GbR GEP Unpublished	N	DAS
KCP 6.2/62	Hilton, R	2018	GF 3307 (DE 777+prothioconazole) and DE 777 straight (GF 3308) for the control of foliar diseases in barley. Europe 2017. GB17E7B046RH01 Dow AgroSciences Ltd GEP Unpublished	N	DAS
KCP 6.2/63	Hilton, R	2018	Efficacy of XR 659 and DE 777 alone and in mixture with prothioconazole for control of foliar diseases in bar- ley. Europe 2017 GB17E7B049RH02	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Dow AgroSciences Ltd GEP Unpublished		
KCP 6.2/64	Hilton, R.	2018	GF 3307 (DE 777+prothioconazole) and DE 777 straight (GF 3308) for the control of foliar diseases in barley. Europe 2017. GB17E7B046RH02 Dow AgroSciences Limited GEP Unpublished	N	DAS
KCP 6.2/65	Hilton, R.	2018	GF 3307 (DE 777+prothioconazole) and DE 777 straight (GF 3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. GB17E7B049RH01 Dow AgroSciences UK GEP Unpublished	N	DAS
KCP 6.2/66	Holeikova, D.	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/SE Zone— 2018. SK18E7B008PV02C (FYSE 141201802) FYSE, s.r.o. GEP Unpublished	N	DAS
KCP 6.2/67	Hunt, A.	2020	Efficacy of one application of GF 3307 against diseases (RHYNSE, PYRNTE, RAMUCC) of spring barley, Maritime EU, 2019. EA19E7B004F DIT02 (1299A 19 COR) OAT Ltd GEP Unpublished	N	DAS
KCP 6.2/68	Kiraly, B.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat —EU, 2016 HU16E7B046AB01C BIOTEK Agriculture Hungary Kft. GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. ——— Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP-6.2/69	Kiraly, B.	2017	Efficacy of Inatreq formulations against various diseases in wheat. Hungary, 2017 HU17E7B082AB01C BIOTEK Agriculture Hungary KFT GEP Unpublished	N	DAS
KCP-6.2/70	Kiraly, B.	2017	Efficacy of Inatreq formulations against various diseases in wheat. Hungary, 2017 HU17E7B082AB02C Biotek Agriculture Hungary KFT GEP Unpublished	N	DAS
KCP-6.2/71	Kiraly, B.	2018	Efficacy, selectivity of the mixture XDE 481 EC + SDHI (Fluxapyroxad) compared to commercial standards for control of barley diseases. EU 2018. HU18F9B029AB01C BIOTEK Agriculture Hungary Kft. GEP Unpublished	N	DAS
KCP-6.2/72	Kolarrik, P.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F-DQD055 Research Institute for Fodder Crops, Ltd. GEP Unpublished	N	DAS
KCP-6.2/73	Kovalova, I.	2018	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. GB17E7B045JK02 Dow AgroSciences Ltd GEP Unpublished	N	DAS
KCP-6.2/74	Kowalski, R.	2017	Efficacy and selectivity of Inatreq fungicides applied in TTLWI in POLAND 2017 PL17E7B089RK01C IOR Sosnowice, PL GEP Unpublished	N	DAS
KCP-6.2/75	Krawczuk, J.	2019	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone –	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			2018. PL18E7B009AS08C GS Polska Sp. z o.o. GEP Unpublished		
KCP 6.2/76	Lieveaux, G.	2018	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019. FR17E7B042MC12C (DAS FE17OH 01891 CB, OR20170501072) Antedis SAS GEP Unpublished	N	DAS
KCP 6.2/77	Maczynska, A.	2014	Efficacy and dose response of different XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. PL14E7B028AS01C Dow AgroSciences, Poland IOR SOSNICOWICE GEP Unpublished	N	DAS
KCP 6.2/78	Maczynska, A.	2015	What is the efficacy of DE 777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application PL15E7B041AS02C Dow AgroSciences, Poland GEP Unpublished	N	DAS
KCP 6.2/79	Marquardt, K.	2019	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2018 DE18F9B009AS03C Eurofins Agroscience Services GmbH GEP Unpublished	N	DAS
KCP 6.2/80	Menyhart, L.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ. 2014. HU14E7B026LM01 Dow AgroSciences, Hungary	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/81	Menyhart, L.	2015	What is the efficacy of DE 777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011LM01 Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/82	Menyhart, L.	2016	Efficacy of Inatreq formulations against rusts and another various diseases in wheat. SE EPPO zone, 2016 HU16E7B029LM03 Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/83	Menyhart, L.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone HU16E7B030LM03 Dow AgroSciences Hungary GEP Unpublished	N	DAS
KCP 6.2/84	Mills, R.	2019	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone— 2018. GB18E7B007EB02C Cropworks Ltd GEP Unpublished	N	DAS
KCP 6.2/85	Mills, R.	2020	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019. EA19F9B025F DEH01 Cropworks Limited GEP Unpublished	N	DAS
KCP 6.2/86	Nistrup Jorgensen, L.	2016	What is the minimum effective dose of GF 3307, GF 3309 and GF 3308 against PuccST, NZ, 2016 DK16E7B002KF01C AARHUS UNIVERSITY FLAKKEBJERG, DK	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/87	Nistrup Jorgensen, L.	2016	What is the minimum effective dose of GF 3307, GF 3309 and GF 3308 against Puccst, NZ, 2016 DK16E7B002KF02C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	DAS
KCP 6.2/88	Nistrup Jorgensen, L.	2016	What is the minimum effective dose of GF 3307, GF 3309 and GF 3308 against Puccst, NZ, 2016 DK16E7B002KF03C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	DAS
KCP 6.2/89	Nistrup Jorgensen, L.	2016	XDE 777 FORMULATIONS GF 3308, GF 3307, FOR THE CONTROL OF FUSAS and SEPTTR. EU 2016. DK16E7B032KF02C Aarhus University GEP Unpublished	N	DAS
KCP 6.2/90	Nistrup Jorgensen, L.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Nordie 2017. DK17E7B043KF01C (17385-1) Aarhus University GEP Unpublished	N	DAS
KCP 6.2/91	Nistrup Jorgensen, L.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Nordie 2017. DK17E7B043KF04C (17357-2) Aarhus University GEP Unpublished	N	DAS
KCP 6.2/92	Nistrup Jorgensen, L.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Nordie 2017. DK17E7B043KF05C (17357-3) Aarhus University GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/93	Nistrup Jorgensen, L.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. DK17E7B043KF02C (17385-2) Aarhus University GEP Unpublished	N	DAS
KCP 6.2/94	Odstreilova, L.	2015	What is the efficacy of XDE 777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application CZ15E7B041PV03C Vyzkumny Ustav Rostlinne Vyroby. CZ GEP Unpublished	N	DAS
KCP 6.2/95	Pawlak, A.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS03C STAPHYT GEP Unpublished	N	DAS
KCP 6.2/96	Pawlak, A.	2015	XDE 777 FORMULATIONS GF 3308, GF 3307, GF 3309, GF 3312A FOR THE CONTROL OF PUCCRT AND OTHER CEREAL DISEASES. Poland 2015. PL15E7B022AS03C STAPHYT, PL GEP Unpublished	N	DAS
KCP 6.2/97	Pawlak, A.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS04C STAPHYT, PL GEP Unpublished	N	DAS
KCP 6.2/98	Pawlak, A.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS05C STAPHYT, PL GEP	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/99	Pawlak, A.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS04C STAPHYT, PL GEP Unpublished	N	DAS
KCP 6.2/100	Pawlak, A.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS05C STAPHYT, PL GEP Unpublished	N	DAS
KCP 6.2/101	Pawlak, A.	2017	What Is the Efficacy of Inatreq Formulations Under North East Europe Conditions PL16E7B031AS04C Staphyt GEP Unpublished	N	DAS
KCP 6.2/102	Pawlak, A.	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone— 2018. PL18E7B009AS02C Staphyt Sp. z o.o. GEP Unpublished	N	DAS
KCP 6.2/103	Pietryga, J.	2020	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat EA20E7B035F DPF043 Dow AgroSciences, Poland GEP Unpublished	N	DAS
KCP 6.2/104	Plonka, P.	2019	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO-zones, 2019 EA19E7B003F DPF02. Dow AgroSciences	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/105	Pszczołkowski, M.	2020	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2019. EA19F9B003F DPF03 Staphyt Sp. z.o.o. GEP Unpublished	N	DAS
KCP 6.2/106	Pszczołkowski, M.	2020	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO-zones, 2019. EA19E7B003F DPF05. STAPHYT Sp. z.o.o. GEP Unpublished	N	DAS
KCP 6.2/107	Pszczołkowski, M.	2020	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO-zones, 2019. EA19E7B003F DPF06 STAPHYT Sp. z.o.o. GEP Unpublished	N	DAS
KCP 6.2/108	Pszczołkowski, M.	2020	Efficacy of Inatreq on PuccST in Triticale—Benchmark program, Europe, 2020. EA20E7B018F DPF027 Staphyt GEP Unpublished	N	DAS
KCP 6.2/109	Reisenhofer, A.	2015	XDE 777 FORMULATIONS GF 3308, GF 3307, GF 3309, GF 3312A FOR THE CONTROL OF PUCCRT. EU 2015. DE15E7B014UB06C ATC—AGRO TRIAL CENTER GMBH, AT GEP Unpublished	N	DAS
KCP 6.2/110	Reisenhofer, A.	2015	DE 777 straight and in combination with prothioconazole or pyraclostrobin for the control <i>Fusarium</i> head blight in wheat. EU 2015. DE15E7B018UB02C ATC—Agro Trial Center GmbH, AT GEP	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/111	Reisenhofer, A.	2016	DE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. DE16E7B032UB02C ATC—Agro Trial Center GmbH, AT GEP Unpublished	N	DAS
KCP 6.2/112	Reisenhofer, A.	2016	DE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. DE16E7B032UB03C ATC—Agro Trial Center GmbH, AT GEP Unpublished	N	DAS
KCP 6.2/113	Reisenhofer, A.	2015	XDE 777 formulations GF 3308, GF 3307, GF 3309, GF 3312A for the control of Puccin. EU 2015. DE15E7B014UB07C ATC—Agro Trial Center GEP Unpublished	N	DAS
KCP 6.2/114	Reisenhofer, A.	2017	XDE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of fungal diseases in winter barley GEP Trial, Austria, 2017. DE17E7B045UB09C (RIL 17 30518 AT03) ATC—Agro Trials Center GmbH GEP Unpublished	N	DAS
KCP 6.2/115	Rivet, J.P.	2017	Dose response of GF 3307 (DE 777 + prothioconazole) for the control of foliar diseases in barley. Europe 2017. FR17E7B042MC13C (17 14 F 01, OR20170400603) Essais+ GEP Unpublished	N	DAS
KCP 6.2/116	Rohr, J.	2014	Efficacy and dose response of XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of DTR and other diseases in wheat. EU . 2014. DE14E7B013UB02C AGRARTEST, DE	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/117	Rohr, J.	2014	DE 777 straight and in combination with prothioconazole for the control <i>Fusarium</i> head blight in wheat. EU 2014. DE14E7B023UB01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/118	Rohr, J.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002UB02C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/119	Rohr, J.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in triticale. EU 2015. DE15E7B003UB01C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/120	Rohr, J.	2015	XDE 777 FORMULATIONS GF 3308, GF 3307, GF 3309, GF 3312A FOR THE CONTROL OF PUCCRT. EU 2015. DE15E7B014UB02C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/121	Rohr, J.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB03C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/122	Rohr, J.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			rye. Germany 2015. DE15E7B033UB04C AGRARTEST, DE GEP Unpublished		
KCP 6.2/123	Rohr, J.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034UB02C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/124	Rohr, J.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034UB04C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/125	Rohr, J.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB02C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/126	Rohr, J.	2015	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/127	Rohr, J.	2015	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002UB03C Agrartest, DE GEP	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/128	Rohr, J.	2015	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002UB01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/129	Rohr, J.	2015	DE 777 straight and in combination with prothioconazole or pyraclostrobin for the control <i>Fusarium</i> head blight in wheat. EU 2015. DE15E7B018UB01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/130	Rohr, J.	2015	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB05C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/131	Rohr, J.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in rye. Europe 2016. DE16E7B019UB01C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/132	Rohr, J.	2016	DE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. DE16E7B032UB01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/133	Rohr, J.	2016	What is the minimum effective dose of GF 3307, GF 3309 and GF 3308 against DTR under NZ conditions? DE16E7B004UB01C	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Agrartest, DE GEP Unpublished		
KCP 6.2/134	Rohr, J.	2016	How does the efficacy-dose response of GF 3307 and GF 3309 against foliar diseases in triticale compare to the included reference product Proline? DE15E7B034UB03C AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/135	Rohr, J.	2017	Evaluation of the minimum effective dose of XR 659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012UB01C Agritest, DE GEP Unpublished	N	DAS
KCP 6.2/136	Rohr, J.	2017	Evaluation of the dose response of GF 3307 compared to new market competitors for the control of <i>Septoria tritici</i> in wheat. EU 2017 DE17E7B016UB02C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/137	Rohr, J.	2017	Dose response of GF 3307 (DE 777+ prothioconazole) for the control of foliar diseases in barley. Europe 2017. DE17E7B045UB03C AgrarTest GmbH GEP Unpublished	N	DAS
KCP 6.2/138	Rohr, J.	2017	Dose response of GF 3307 (DE 777+ prothioconazole) for the control of foliar diseases in barley. Europe 2017. DE17E7B045UB05C AgrarTest GmbH GEP Unpublished	N	DAS
KCP 6.2/139	Rohr, J.	2017	GF 3307 (DE 777+ prothioconazole) and DE 777 straight (GF 3308) for the control of foliar diseases in barley. Europe 2017.	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DE17E7B046UB04C AgrarTest GmbH GEP Unpublished		
KCP 6.2/140	Rohr, J.	2018	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2018 DE18F9B009AS01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.2/141	Rohr, J.	2018	Effective dose of GF 3307 (Inatreq + prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone— 2018 DE18E7B007UB04C Trial Tee GmbH GEP Unpublished	N	DAS
KCP 6.2/142	Rohr, J.	2019	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019. EA19F9B025F DPE01 Trial Tee GmbH GEP Unpublished	N	DAS
KCP 6.2/143	Rohr, J.	2019	To evaluate the efficacy of formulations of Adavelt for the control of RAMUCC in winter barley compared to leading industry standards. EA19G1C044F DNZ01 Trial Tee GmbH GEP Unpublished	N	DAS
KCP 6.2/144	Rohr, J.	2019	To evaluate the efficacy of formulations of Adavelt for the control of RAMUCC in winter barley compared to leading industry standards. EA19G1C044F DNZ02 Trial Tee GmbH GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/145	Rohr, J.	2020	Efficacy of Inatreq on PuccST in Triticale—Benchmark program, Europe, 2020. EA20E7B018F DNZ057 Trial-tee GmbH GEP Unpublished	N	DAS
KCP 6.2/146	Rohr, J.	2020	Efficacy of Inatreq on PuccST in Triticale—Benchmark program, Europe, 2020. EA20E7B018F DNZ058 Trial-tee GmbH GEP Unpublished	N	DAS
KCP 6.2/147	Rohr, J.	2020	Efficacy of Inatreq on PuccST in Triticale—Benchmark program, Europe, 2020. EA20E7B068F DNZ074 Trial-tee GmbH GEP Unpublished	N	DAS
KCP 6.2/148	Rohr, J.	2020	Efficacy of Inatreq on PuccST in Triticale—Benchmark program, Europe, 2020. EA20E7B068F DNZ075 Trial-tee GmbH GEP Unpublished	N	DAS
KCP 6.2/149	Rohr, J.	2020	Efficacy and dose response of XDE 481 EC (GF 4480) and SC (GF 4505 + GF 4493) on <i>Puccinia striiformis</i> and other key diseases in triticale. EU 2020 EA20F9B007F DPE013 Trial-tee GmbH GEP Unpublished	N	DAS
KCP 6.2/150	Roj, J.	2016	DE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. PL16E7B032AS01C Ior Sosnicowice, PL GEP Unpublished	N	DAS
KCP 6.2/151	Roj, J.	2016	What Is the Efficacy of Inatreq Formulations Under North-East Europe Conditions	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			PL16E7B031AS01C Dow AgroSciences GEP Unpublished		
KCP 6.2/152	Roj, J.	2016	WHAT IS THE EFFICACY OF INATREQ FOR LUATIONS UNDER NORTH EAST EUROPE CONDITIONS PL16E7B031AS03C Dow AgroSciences, Poland GEP Unpublished	N	DAS
KCP 6.2/153	Roy, J.	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone— 2018. PL18E7B009AS04C Dow AgroSciences GEP Unpublished	N	DAS
KCP 6.2/154	Rose Gray, S	2019	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone— 2018. DE18E7B007UB02C (SRY 18 35431 AT02) Staphyt Austria GmbH GEP Unpublished	N	DAS
KCP 6.2/155	Rose Gray, S.	2019	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone— 2018 DE18E7B007UB01C (SRY 18 35431 AT01) Staphyt Austria GmbH GEP Unpublished	N	DAS
KCP 6.2/156	Sawinska, Z.	2014	Efficacy of XDE 777 + prothioconazole and XDE 777 + pyraclostrobin formulations for control of Puccin in wheat: EU-CZ, 2014. PL14E7B010AS01C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/157	Sawinska, Z.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS01C Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/158	Sawinska, Z.	2015	XDE 777 FORMULATIONS GF 3308, GF 3307, GF 3309, GF 3312 FOR THE CONTROL OF PUCCRT AND OTHER CEREAL DISEASES. Poland 2015. PL15E7B022AS01C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	DAS
KCP 6.2/159	Sawinska, Z.	2015	XDE 777 FORMULATIONS GF 3308, GF 3307, GF 3309, GF 3312A FOR THE CONTROL OF PUCCRT AND OTHER CEREAL DISEASES. Poland 2015. PL15E7B022AS02C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	DAS
KCP 6.2/160	Sawinska, Z.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat —EU, 2016. PL16E7B046AS02C Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/161	Sawinska, Z.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS03C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	DAS
KCP 6.2/162	Sawinska, Z.	2016	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin and DE 777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS03C UNIWERSYTET PRZYRODNICZY POZNAN, PL	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/163	Sawinska, Z.	2016	The efficacy GF 3308 straight and in mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016. PL16E7B038AS01C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	DAS
KCP 6.2/164	Sawinska, Z.	2018	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticales. EU 2018 PL18F9B009AS01C Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	DAS
KCP 6.2/165	Sawinska, Z.	2018	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticales. EU 2018 PL18F9B009AS02C Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	DAS
KCP 6.2/166	Sawinska, Z.	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone— 2018. PL18E7B009AS05C (AF/18/JO/32/KO/S05C) Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/167	Sawinska, Z.	2018	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticales. EU 2018 PL18F9B009AS03C Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/168	Sawinska, Z.	2019	Efficacy of XDE 481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticales. EU 2019 EA19F9B003F DPF02 Poznan University of Life Sciences GEP	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/169	Sawinska, Z.	2019	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F DPF03 (AF/19/JJ/8/Br/DPF03/E7) Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/170	Sawinska, Z.	2019	Efficacy of GF 3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F DPF04 (AF/19/JJ/8/SL/DPF04/E7) Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/171	Sawinska, Z.	2020	Efficacy of Inatreq on Puccst in Triticale—Benchmark program, Europe, 2020. EA20E7B018F DPF026 UNIWERSYTET PRZYRODNICZY POZNAN GEP Unpublished	N	DAS
KCP 6.2/172	Sawinska, Z.	2020	Comparable efficacy of GF 3307 (50+100 g ai/4) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/4) against key diseases in barley. EA20E7B037F DPF052 Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	DAS
KCP 6.2/173	Sawinska, Z.	2020	Comparable efficacy of GF 3307 (50+100 g ai/4) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/4) against key diseases in barley. EA20E7B037F DPF051 Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	DAS
KCP 6.2/174	Sawinska, Z.	2020	Comparable efficacy of GF 3307 (50+100 g ai/4) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/4) against key diseases in wheat EA20E7B035F DPF044 Poznan University of Life Sciences GEP	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/175	Sawinska, Z.	2020	Comparable efficacy of GF 3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/l) against key diseases in wheat EA20E7B035F-DPF045 Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/176	Schmidt, I.	2017	XDE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of fungal diseases in winter barley GEP Trial, GERMANY, 2017. DE17E7B045UB11C (R/L 17 30724 DE01) Staphyt GmbH GEP Unpublished	N	DAS
KCP 6.2/177	Schnieder, F.	2014	Efficacy and dose response of different XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, - 2014. DE14E7B014FS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS
KCP 6.2/178	Schnieder, F.	2015	XDE 777 formulations GF 3308, GF 3307, GF 3309, GF 3312 for the control of PYRNTR. EU 2015. DE15E7B016FS01 Dow AgroSciences GmbH, DE GEP Unpublished	N	DAS
KCP 6.2/179	Schnieder, F.	2016	DE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. DE16E7B032FS01 Dow AgroSciences GmbH. DE GEP Unpublished	N	DAS
KCP 6.2/180	Schnieder, F.	2020	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019 EA19F9B025F-DNZ01	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Dow AgroSciences GmbH GEP Unpublished		
KCP 6.2/181	Schulz, T.	2014	Efficacy and dose response of different XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU-CZ. 2014. DE14E7B028TS01 Dow AgroSciences GEP Unpublished	N	DAS
KCP 6.2/182	Schulz, T.	2015	Dose response of XDE 777+prothioconazole and XDE 777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002TS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS
KCP 6.2/183	Schultz, T	2017	Evaluation of the minimum effective dose of XR 659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012TS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	DAS
KCP 6.2/184	Schulz, T	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone—2018 DE18E7B007TS01 Dow AgroSciences GmbH GEP Unpublished	N	DAS
KCP 6.2/185	Stephan, A.	2015	Dose response of DE 777+prothioconazole and DE 777+pyraclostrobin for the control of foliar diseases in triticale. EU 2015. DE15E7B003AS01 Dow AgroSciences GmbH. DE GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/186	Stephan, A.	2015	XDE 777 formulations GF 3308, GF 3307, GF 3309, GF 3312a for the control of PuccRT. EU 2015 DE15E7B014AS01 DOW AGROSCIENCES GMBH GEP Unpublished	N	DAS
KCP 6.2/187	Stephan, A.	2017	Evaluation of the minimum effective dose of XR 659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012AS01 Dow AgroSciences GEP Unpublished	N	DAS
KCP 6.2/188	Stephan, A.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. DE17E7B045AS01 Dow AgroSciences GmbH GEP Unpublished	N	DAS
KCP 6.2/189	Stephan, A.	2020	What is the optimum dose of XDE 481 EC and fenpicoxamid EC in mixtures for <i>Septoria tritici</i> control in wheat? EA19F9B017F DPE01 Dow AgroSciences GEP Unpublished	N	DAS
KCP 6.2/190	Stephan, A.	2020	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Puccinia hordei</i> in barley. EU 2019. EA19F9B024F DPE02 Dow AgroSciences GmbH GEP Unpublished	N	DAS
KCP 6.2/191	Stephan, A.	2020	Efficacy of one application of GF 3307 against diseases (RHYNSE, PYRNTE, RAMUCC) of spring barley, Maritime EU, 2019. EA19E7B004F DPE01 Dow AgroSciences GmbH GEP Unpublished	N	DAS
KCP 6.2/192	Stephan, A.	2020	Efficacy and dose response of XDE 481 EC (GF 4480) and SC (GF 4505 + GF 4493) on <i>Puccinia striiformis</i> and	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			other key diseases in triticales. EU 2020 EA20F9B007F DPE012 Dow AgroSciences GEP Unpublished		
KCP 6.2/193	Stepien, A.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. PL14E7B028AS02C Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/194	Stepien, A.	2015	What is the efficacy of DE 777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application PL15E7B041AS01C Poznan University of Life Sciences GEP Unpublished	N	DAS
KCP 6.2/195	Strobele, U.	2020	GF 3307 (DE 777+prothioconazole) and DE 777 straight (GF 3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. DE18E7B012UB05C (H 122 QUI 18 187) Quintus GmbH GEP Unpublished	N	DAS
KCP 6.2/196	Strobele, U.	2020	Efficacy and dose response of XDE 481 EC straight and in mixtures on <i>Blumeria graminis</i> in barley. EU 2019 EA19F9B023F DPE02 (I 122 QUI 19 168) Quintus GmbH GEP Unpublished	N	DAS
KCP 6.2/197	Tartier, J.	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. SZ/MED & SZ/MAR Zone— 2018. FR18E7B006MC07C (BPE18/254/FGC01, OR20180401077) BIOTEX Agriculture GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/198	Thibault, A.	2018	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. FR17E7B042MC11C (OR20170400357, SRFR17-163-52FE) BIOTEK Agriculture GEP Unpublished	N	DAS
KCP 6.2/199	Toth, F.	2018	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/SE Zone – 2018. SK18E7B008PV01C Gemerprodukt Valice OVD GEP Unpublished	N	DAS
KCP 6.2/200	Touche, C	2018	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. FR17E7B042MC03C (CTE 17-30328-FR03, OR20170400632) STAPHYT GEP Unpublished	N	DAS
KCP 6.2/201	Treikale, O.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. LV14E7B028MN02C Latvian Plant Protection Research Centre Ltd. GEP Unpublished	N	DAS
KCP 6.2/202	Treikale, O.	2015	WHAT IS THE EFFICACY OF XDE 777 PRODUCTS AGAINST SEPTTR AT B33-69, WHEN APPLIED AS A SINGLE APPLICATION IN NORTHERN EUROPEAN CONDITIONS? LV15E7B019MN03C Latvian Plant Protection Research Centre, LPPRC GEP Unpublished	N	DAS
KCP 6.2/203	Treikale, O.	2015	What is the efficacy of XDE 777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a single and split application? LV15E7B009MN04C Latvian Plant Protection Research Centre Ltd GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/204	Treikale, O.	2015	Efficacy and dose response of different XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of LEPTNO in wheat. EU SZ. 2014. LV14E7B012MN01C Latvian Plant Protection Research Centre Ltd GEP Unpublished	N	DAS
KCP 6.2/205	Treikale, O.	2016	What is the efficacy of Inatreq formulations under North East Europe conditions? LV16E7B031KF01C Latvian Plant Protection Research Centre GEP Unpublished	N	DAS
KCP 6.2/206	Treikale, O.	2016	WHAT IS THE EFFICACY OF INATREQ FORLUATIONS AGAINST DISEASES OF WHEAT UNDER NORTH EAST EUROPE CONDITIONS? LV16E7B031KF03C Latvian Plant Protection Research Centre, LPPRC GEP Unpublished	N	DAS
KCP 6.2/207	Treikale, O.	2017	What is the effective dose of GF 3307 and GF 3308 for the control of foliar diseases (specific RAMUCC) in barley. Nordic 2017. LV17E7B039KF01C LAAPC GEP Unpublished	N	DAS
KCP 6.2/208	Treikale, O.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. LV17E7B043KF02C LAAPC GEP Unpublished	N	DAS
KCP 6.2/209	Treikale, O.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. LV17E7B043KF03C LAAPC GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/210	Treikale, O.	2017	Dose response of GF 3307 (DE 777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. LV17E7B043KF01C LAAPC GEP Unpublished	N	DAS
KCP 6.2/211	Treikale, O.	2018	What is the effective dose of GF 3307 for the control of foliar diseases (North-East EPPO-zone). LV18E7B011KF01C LAAPC GEP Unpublished	N	DAS
KCP 6.2/212	Treikale, O.	2019	What is the minimum effective dose of GF 3307 to control diseases of winter and spring barley in Northern zone countries? EA19E7B007F-DHW09 LAAPC GEP Unpublished	N	DAS
KCP 6.2/213	Tuna, V.	2021	Comparable efficacy of GF 3307 (50+100 g ai/4) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/4) against key diseases in wheat EA20E7B035F-DHT072 Corteva Agriscience GEP Unpublished	N	DAS
KCP 6.2/214	Tuna, V.	2021	Comparable efficacy of GF 3307 (50+100 g ai/4) and a new ratio of fenpicoxamid+prothioconazole GF 4637 (40+80 g ai/4) against key diseases in wheat. EA20E7B035F-DHT073 Corteva Agriscience GEP Unpublished	N	DAS
KCP 6.2/215	Tuna, V.	2021	Benchmark local programs for GF 3308 / GF 3307. T1 to support low doses EA20E7B020F-DHT046 Corteva Agriscience GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/216	Tuna, V.	2021	Benefit trials local programs for GF 3308. T2 support low doses. Romania 2020. EA20E7B065F DHT070 Corteva Agriscience GEP Unpublished	N	DAS
KCP 6.2/217	Tuna, V.	2021	Benefit trials local programs for GF 3308. T2 support low doses. Romania 2020. EA20E7B065F DHT076 Corteva Agriscience GEP Unpublished	N	DAS
KCP 6.2/218	Tuna, V.	2021	Benchmark local programs for GF 3308 / GF 3307. T1 to support low doses Corteva Agriscience EA20E7B020F DHT084 GEP Unpublished	N	DAS
KCP 6.2/219	Tuna, V.	2021	Benefit trials local programs for GF 3308. T2 to support low doses, Romania 2020. Corteva Agriscience EA20E7B065F DHT071 GEP Unpublished	N	DAS
KCP 6.2/220	Tvaruzek, L.	2014	Efficacy and dose response of different XDE 777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. CZ14E7B028PV01C ZEMEDELSKY VYZKUMNY USTAV KROMERIZ, S.R.O. CZ GEP Unpublished	N	DAS
KCP 6.2/221	Tvaruzek, L.	2015	What is the efficacy of XDE 777 formulations against cereal diseases in wheat in North East Europe EPPO. CZ15E7B010PV01C Zemedelsky Vyzkumny Ustav Kromeriz, S.R.O. CZ GEP Unpublished	N	DAS
KCP 6.2/222	Tvaruzek, L.	2016	The efficacy GF 3308 straight and in mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016.	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			CZ16E7B038PV02C ZEMEDELSKY VYZKUMNY USTAV KROMERIZ, S.R.O. CZ GEP Unpublished		
KCP 6.2/223	Varret, F.	2016	DE 777 straight (GF 3308) and in combination with prothioconazole (GF 3307) for the control of <i>Fusarium</i> head blight in wheat. EU SZ 2016. FR16E7B035MC01C Staphyt. FR GEP Unpublished	N	DAS
KCP 6.2/224	Vourkos, F.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone BG16E7B030VA01C ANADIAG Bulgaria Ltd GEP Unpublished	N	DAS
KCP 6.2/225	Vourkos, F.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone BG16E7B030VA02C ANADIAG Bulgaria Ltd GEP Unpublished	N	DAS
KCP 6.2/226	Vourkos, F.	2019	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. SZ/MED and SE Zone— 2018. BG18E7B004KP03C Anadiag Bulgaria Ltd GEP Unpublished	N	DAS
KCP 6.2/227	Vourkos, F.	2019	Effective dose of GF 3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. SZ/MED and SE Zone— 2018. BG18E7B004KP04C Anadiag Bulgaria Ltd GEP Unpublished	N	DAS
KCP 6.2/228	Wagner, G.	2014	Efficacy and dose response of different DE 777 + Prothioconazole/pyraclostrobin EC formulations for control of	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			foliar diseases in wheat. EU CZ, 2014. EA14E7B028AB01C SynTech Research Hungary Kft. GEP Unpublished		
KCP 6.2/229	Wonckhaus, S	2020	Efficacy and dose response of XDE 481 EC (GF 4480) and SC (GF 4505 + GF 4493) on <i>Puccinia striiformis</i> and other key diseases in triticale. EU 2020 EA20F9B007F DPE014 AGRARTEST, DE GEP Unpublished	N	DAS
KCP 6.2/230	Ziebart, U.	2014	Efficacy and dose response of different XDE 777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ, 2014. DE14E7B026UB01C BIOCHEM AGRAR, DE GEP Unpublished	N	DAS
KCP 6.2/231	Zoller, P.	2015	XDE 777 FORMULATIONS GF 3308, GF 3307, GF 3309, GF 3312A FOR THE CONTROL OF PUCCRT. EU 2015. DE15E7B014UB04C EUROFINS AGROSCIENCE SERVICES GMBH, DE GEP Unpublished	N	DAS
KCP 6.2/232	Zoller, P.	2016	What is the minimum effective dose of GF 3307, GF 3309 and GF 3308 against DTR under NZ conditions? DE16E7B004UB02C Eurofins Agroscience Services GEP Unpublished	N	DAS
KCP 6.3/01	Kemmit, G.	2012	XDE 777 Septoria tritici (<i>Mycosphaerella graminicola</i>) sensitivity baseline generation Year 1 2011 season. DAS internal report # 2011920. non-GEP Unpublished	N	DAS
KCP 6.3/02	Kemmit, G.	2013	XDE 777 Septoria tritici (<i>Mycosphaerella graminicola</i>) sensitivity baseline generation Year 2 2012 season	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Europe. DAS internal report # 2020427. non-GEP Unpublished		
KCP 6.3/03	Kemmit, G.	2014	XDE 777 Septoria tritici (<i>Mycosphaerella graminicola</i>) sensitivity baseline generation Year 3 2013 season Europe. DAS internal report # 2021524 non-GEP Unpublished	N	DAS
KCP 6.3/04	Kemmit, G.	2015	XDE 777 Septoria tritici (<i>Mycosphaerella graminicola</i>) sensitivity baseline generation Year 4 2014 season Europe. DAS internal report # 2025137. non-GEP Unpublished	N	DAS
KCP 6.3/05	Kemmit, G.	2015	Inatreq (DE 777) Puccinia triticina (Wheat Brown Rust) sensitivity baseline generation. Year 1 2015 season, Europe. DAS internal research report no. DAI 2032179 Non-GEP Unpublished	N	DAS
KCP 6.3/06	Kemmitt, G.M.	2019	Inatreq, Fenpicoxamid, (DE 777) — Ramularia leaf spot of Barley (<i>Ramularia collo-cygni</i>) baseline sensitivity establishment — summary and raw data. Year 1 — 2018 season Europe. (2019). Dow agrosciences Internal report No. 2081349. Dow agrosciences GLP Unpublished	N	DAS
KCP 6.3/07	Kemmitt, G.M.	2019	Inatreq, Fenpicoxamid, (DE 777) — Barley Net Blotch (<i>Pyrenophora teres</i>) baseline sensitivity establishment — summary and raw data. Year 1 — 2018 season Europe. (2019). Dow agrosciences Internal report No. 2081350. Dow agrosciences GLP Unpublished	N	DAS
KCP 6.3/08	Myung K., Yao C., Owen, W.,	2011	Uptake, redistribution and metabolism of picolinamides (XR 777 and UK 2A) and neo-picolinamides (X12072033 and X12070381) in wheat and Septoria tritici.	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Meyer, K.G. and Nugent B.M.,		DAS internal research report no. DAI 1074 Non GEP Unpublished		
KCP 6.3/09	Myung, K., Young, D., Meyer, S.T., Kemmitt, G., Owen, W.J.	2016	Metabolism of Inatreq™ active to UK 2A by Zymoseptoria tritici DAS internal research report no. DAI 1517 Non GEP Unpublished	N	DAS
KCP 6.3/10	Owen, W.J. et al.	2011	XR 777 Discovery Advancement Report Dow AgroSciences internal report DAI 1040 Non GEP/non GLP Unpublished	N	DAS
KCP 6.3/09	Young D.H. and Wang N.	2005	Insights into the binding of UK 2A to cytochrome bc1 from cross-resistance analyses using antimycin-resistant Saccharomyces cerevisiae mutants and molecular docking studies. DAI 1077 non GEP Unpublished	N	DAS
KCP 6.4/01	Babrik, Z.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU HU14E7B016AB01C AGROFIL SZAKTANACSADO MERNOKI IRODA KFT. GEP Unpublished	N	DAS
KCP 6.4/02	Banachowska, J.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU PL14E7B016AS01C IOR SOSNICOWICE, PL GEP Unpublished	N	DAS
KCP 6.4/03	Bouteneigre, J.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU FR14E7B016MC01C Biotek Agriculture, FR GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. ——— Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.4/04	Cunningham, A.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU GB14E7B016EB02C OXFORD AG TRIALS, UK GEP Unpublished	N	DAS
KCP 6.4/05	Dubois, P.	2018	Evaluation of GF 3307 on brewery processes on winter and spring barley—France 2017. FR17E7B044MC02C (OR20170501079) BIOTEK Agriculture GEP Unpublished	N	DAS
KCP 6.4/06	Dubois, P.	2018	Evaluation of GF 3307 on brewery processes on winter and spring barley—France 2017. FR17E7B044MC04C (OR20170501077) BIOTEK Agriculture GEP Unpublished	N	DAS
KCP 6.4/07	Dubois, P.	2018	Evaluation of GF 3307 on brewery processes on winter and spring barley—France 2017. FR17E7B044MC05C (OR20170501580) BIOTEK Agriculture GEP Unpublished	N	DAS
KCP 6.4/08	Dubois, P.	2018	Evaluation of GF 3307 on brewery processes on winter and spring barley—France 2017. FR17E7B044MC08C (OR20170501720) BIOTEK Agriculture GEP Unpublished	N	DAS
KCP 6.4/09	Duval, M.	2015	Evaluation of XDE 777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC01C Biotek agriculture GEP Unpublished	N	DAS
KCP 6.4/10	Fairfax, M.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU GB14E7B042MF01 Dow AgroSciences Ltd, UK	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.4/11	Fisher, S.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU GB14E7B016EB01C ARMSTRONG FISHER LTD, UK GEP Unpublished	N	DAS
KCP 6.4/12	Gless, A.E.	2018	Study of unintentional effects of phytopharmaceutical products on malt and beer quality and process 17/105-E1025 IFBM GLP Unpublished	N	DAS
KCP 6.4/13	Kästner, K.	2016	Field study to generate specimen of Beer from RAC Wheat treated with GF 3307 or GF 3309 for subsequent triangle taint testing and determination of quality parameters, 2 Sites in Germany 2015 BioChem Project No 15-1047-2114 GEP Unpublished	N	DAS
KCP 6.4/14	Owen J, Slanee T	2015	Impact of carbon source on growth inhibition of Saccharomyces cerevisiae by XDE 777 and UK 2A Report DAH399 DOW AgroSciences Indianapolis Non GLP/non GEP Unpublished	N	DAS
KCP 6.4/15	Tartier, J.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU FR14E7B016MC02C BIOTEK AGRICULTURE. FR GEP Unpublished	N	DAS
KCP 6.4/16	Tartier, J.	2015	Evaluation of XDE 777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC01C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.4/17	Tartier, J.	2015	Evaluation of XDE 777 formulations in wheat with grain used for bread-making. EU 2015. FR15E7B006MC02C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS
KCP 6.4/18	Tartier, J.	2015	Evaluation of XDE 777 formulations in wheat with grain used for bread-making. EU 2015. FR15E7B006MC03C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS
KCP 6.4/19	Tartier, J.	2015	Evaluation of XDE 777 formulations in wheat with grain used for bread-making. EU 2015. FR15E7B006MC04C BIOTEK AGRICULTURE, FR GEP Unpublished	N	DAS
KCP 6.4/20	Treikale, O.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU LV14E7B016MN02 Latvian Plant Protection Research Centre GEP Unpublished	N	DAS
KCP 6.4/21	Zickart, U.	2014	Selectivity of XDE 777 + Prothioconazole EC and XDE 777+pyraclostrobin EC in cereals, 2014. EU DE14E7B016UB01C BIOCHEM AGRAR, DE GEP Unpublished	N	DAS
KCP 6.4/22	Zickart, U.	2015	Impact of GF 3307 and GF 3309 on beer making process – field phase. Germany 2015. DE15E7B005UB02C BioChem Agrar GmbH GEP Unpublished	N	DAS
KCP 6.5/01	Brockmann	2014	GF 3307 (XDE 777 + prothioconazole 50 + 100 g as/L, EC): A Seedling Emergence and Seedling Growth Test with ten Non Target Plant Species, GLP Terrestrial Non Target Plants (based on OECD Guideline 208) – Europe 2014	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			AC/DOW/14/03 Agro-check GLP Unpublished		
KCP 6.5/02	Brockmann	2014	GF 3307 (XDE 777 + prothioconazole 50 + 100 g as/L, EC): A Vegetative Vigour Test with ten Non-Target Plant Species, GLP Terrestrial Non-Target Plants (based on OECD Guideline 227) — Europe 2014 AC/DOW/14/04 Agro-check GLP Unpublished	N	DAS
KCP 6.5/03	Topham, D.	2016	Dow AgroSciences Clean-Out Report for Fungicides: GF 2925, GF 3307, GF 3308, GF 3309, GF 3312 LES 10126 Amega Sciences Unpublished	N	DAS
3.6-Other/ special studies	Butler-Ellis C, Lane A, Tuck C	2016	CHARACTERISATION OF SPRAYS AND VISUALISATION OF DEPOSITS ON SURFACES Report S0140/1 Silsoe Spray Applications Unit Limited Non GEP Unpublished	N	DAS
3.6-Other/ special studies	Downey, S.	2015	EU 2015: Efficacy of GF 3307 and GF 3309 for the control of cereal diseases using LD Nozzles compared to std. Flat Fan nozzles at different water volumes GB15E7B030SD01 Dow AgroSciences Ltd, UK GEP Unpublished	N	DAS
3.6-Other/ special studies	Fairfax, M.	2015	EU 2015: Efficacy of GF 3307 and GF 3309 for the control of cereal diseases using LD Nozzles compared to std. Flat Fan nozzles at different water volumes GB15E7B030MF01 Dow AgroSciences Ltd, UK GEP Unpublished	N	DAS
3.6-Other/ special studies	Lane A, O'Sullivan C,	2017	Characterising deposits on plants for a range of formulations and application conditions Report S0181	N	DAS

Data point	Author(s)	Year	Title Company Report No. _____ Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Butler Ellis C		Silsoe Spray Applications Unit Limited Non GEP Unpublished		
3.6 Other/ special studies	Mathieson, T. et al.	2016	Rainfast studies to compare the rainfast ability of new Dow AgroSciences fungicide formulations of DE-777(Inatreq) to current market fungicides DOW AGROSCIENCES LLC Non GEP/non GLP Unpublished	N	DAS
3.6 Other/ special studies	Mathieson, T.	2016	Rainfast studies to compare the rainfast ability of new Dow AgroSciences fungicide formulations to current market fungicides 2038583 Dow AgroSciences LLC Unpublished	N	DAS
3.6 Other/ special studies	Rohr, H.	2014	Efficacy of GF 3307 and GF 2925 for the control of cereal diseases using LD Nozzles compared to Flat Fan nozzles at different water volumes. EU 2014 DE14E7B017UB01C Agrartest, DE GEP Unpublished	N	DAS
3.6 Other/ special studies	Vriesman, M., Leader, A., Diehl, C., Wineglass, A., Loeffler, J.	2019	Rainfastness performance of Dow agrosciences™ products GF 3308 and GF 3307, and Proline, and Aviator Xpro for control of barley scald (<i>Rhynchosporium secalis</i>) on barley following a preventive application and a simulated 30 mm rain 30 minutes or 1 hour after application Dow agrosciences internal report Non GEP/non GLP Unpublished	N	DAS

Appendix 1

Lists of data considered in support of the evaluation (updated, May 2022)

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/01	Crestani, D.	2013	Evaluation of XDE-777 (GF-2925 & GF-3135) applied for the control of SEPTTR in wheat in Southern Europe. 2013 IT13E7B012DC01 GEP Unpublished	N	Corteva Agriscience
KCP 6.1/02	Mathieson, T. <i>et al.</i>	2013	Effect of formulation type and adjuvants on efficacy of XDE-777 containing formulations Dow AgroSciences internal report # 2020479 Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/03	Mathieson, T, Kemmit, G	2014	Comparative mobility of three XDE-777 formulations and select commercial standards as measured by glasshouse bioassay with Puccinia recondita on wheat. Dow AgroSciences internal report # 2024367 Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/04	Mathieson, T, Leader, A	2018	How does the efficacy of Inatreq formulation GF-3307 (a combination) and GF-3308 (solo) compare to market references when tested against Septoria tritici (SEPTTR) and Puccinia recondita (PUCCRT) in greenhouse conditions? Dow AgroSciences internal report # 2051736, June 2018 Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/05	Myung K, Madary MW, Kemmit G, Annangudi SP, Yao C	2015	Effects of different formulations on retention, surface coverage, and uptake of XDE-777 in wheat plants. Dow AgroSciences internal report # 2026067, February 2015. Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/06	Owen, W.J. <i>et al.</i>	2011	XR-777 Discovery Advancement Report Dow AgroSciences internal report # 2009830 Non GEP/non GLP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/07	Parker C.L.; Owen, J.	2013	Herbicide Activity of XDE-777 Dow AgroSciences internal report # DAI 1177 Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/08	Vriesman, M, Leader, A, Diehl, C., Wineglass, A., Loeffler, J.	2019	Evaluate and compare Dow agrosociences™ products Questar (GF-3308), Univoq (GF-3307), Adavelt (GF-3840), and XDE-481 (GF-4319) for control of barley scald (<i>Rhynchosporium secalis</i>) following a preventive application Dow agrosociences internal report Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/09	Vriesman, M, Leader, A, Diehl, C., Wineglass, A., Loeffler, J.	2019	Evaluate and compare Dow agrosociences™ products Questar (GF-3308), Univoq (GF-3307), Adavelt (GF-3840), and XDE-481 (GF-4319) for control of barley scald (<i>Rhynchosporium secalis</i>) following a curative application Dow agrosociences internal report Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/10	Vriesman, M, Karaiskou, G., Leader, A, Diehl, C., Wineglass, A., Loeffler, J.	2020	Volatility of GF-3308, GF-3307, Proline, and Aviator Xpro for control of barley powdery mildew (<i>Blumeria graminis</i> f. sp. <i>hordei</i>) on barley following a preventive application Dow agrosociences internal report Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.1/11	Wessels, F., Owen, J.	2013	Insecticidal Activity of XDE-777 Dow AgroSciences internal report # DAI 1101 Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.2/01	Babrik, Z.	2015	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. HU14E7B014AB01C Agrofil, HU GEP Unpublished	N	Corteva Agriscience
KCP 6.2/02	Babrik, Z.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB01C Dow AgroSciences Hungary GEP	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/03	Babrik, Z.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB02C Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/04	Babrik, Z.	2015	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of SEPTTR in wheat. EU CZ SE EPPO, 2015. HU15E7B040AB02C Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/05	Banachowska, J	2014	Efficacy of XDE-777 + prothioconazole and XDE-777 + pyraclostrobin formulations for control of Puccin in wheat: EU CZ, 2014. PL14E7B010AS02C IOR SOSNICOWICE, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/06	Banachowska, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS01C IOR SOSNICOWICE, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/07	Banachowska, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS02C IOR SOSNICOWICE, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/08	Bataille, C.	2020	Efficacy of one application of GF-3307 against barley diseases. EA19E7B004F-DYE02 (MAL2019-04b-report) CRA-W Centre wallon de Recherches agronomiques	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/09	Bataille, C.	2020	Efficacy of one application of GF-3307 against barley diseases. EA19E7B004F-DYE01 (MAL2019-04a-report) CRA-W Centre wallon de Recherches agronomiques GEP Unpublished	N	Corteva Agriscience
KCP 6.2/10	Beyreiss, S	2017	Evaluation of the minimum effective dose of XR-659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012UB03C EUROFINS AGROSCIENCE SERVICES GMBH, DE GEP GEP Unpublished	N	Corteva Agriscience
KCP 6.2/11	Beyreiss, S	2018	Evaluation of the minimum effective dose of XR-659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye, EU 2017 DE17G1C012UB02C Eurofins Agriscience Services GEP Unpublished	N	Corteva Agriscience
KCP 6.2/12	Bezdicikova, A.	2015	What is the efficacy of XDE-777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application CZ15E7B041PV01C Ditana Spol. S.R.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/13	Bezdicikova, A.	2016	The efficacy GF-3308 straight and mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016 CZ16E7B038PV01C DITANA SPOL. S.R.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/14	Bezdicikova,	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EA21E7B058F-DQD034 Ditana Spol. S.R.O. GEP Unpublished		
KCP 6.2/15	Biro, A.	2014	Efficacy of XDE-777 + prothioconazole and XDE-777 + pyraclostrobin formulations for control of Puccinia in wheat: EU CZ, 2014 HU14E7B010AB01 Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/16	Biro, A.	2015	What is the efficacy of XDE-777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011AB01C Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/17	Biro, A.	2015	What is the efficacy of XDE-777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011AB02C Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/18	Biro, A.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO HU15E7B012AB02 Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/19	Biro, A.	2016	Efficacy of Inatreq formulations against rusts and another various diseases in wheat. SE EPPO zone, 2016 HU16E7B029AB04 Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/20	Biro, A.	2019	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019.	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EA19E7B003F-DBI04 Corteva Agriscience GEP Unpublished		Agriscience
KCP 6.2/21	Biro, A	2019	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F-DBI01 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/22	Biro, A	2019	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F-DBI02 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/23	Biro, A	2019	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F-DBI03 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/24	Biro, A	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone HU16E7B030AB01 Dow Agrosciences Hungary Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/25	Biro, A.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-EAN032 BIOTEK Agriculture Hungary Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/26	Botoman, C.	2020	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses Corteva Agriscience EA20E7B020F-DHT048	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/27	Botoman, C..	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. Corteva Agriscience EA20E7B035F-DHT074 GEP Unpublished	N	Corteva Agriscience
KCP 6.2/28	Botoman, C.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat in Romania 2021 EA21E7B059F-AMT049 Corteva Agriscience/AgroProspect SRL. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/29	Botoman, C.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-AMT054 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/30	Botoman, C.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-AMT055 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/31	Bounds, P.	2015	XDE-777 straight and in combination with prothioconazole or pyraclostrobin for the control <i>Fusarium</i> head blight in wheat. EU 2015 GB15E7B018EB01C ADAS UK Limited GEP Unpublished	N	Corteva Agriscience
KCP 6.2/32	Burton, N.D..	2015	WHAT IS THE EFFICACY OF XDE-777 FORMULATIONS AGAINST PUCCST COMPARED TO	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			REFERENCE STANDARDS? GB15E7B015EB04C Suffolk & Cambridge Crop Station Ltd GEP Unpublished		Agriscience
KCP 6.2/33	Cana, L.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat EU, 2016 RO16E7B046AP01C NARDI Fundulea GEP Unpublished	N	Corteva Agriscience
KCP 6.2/34	Cana, L.	2020	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses Corteva Agriscience EA20E7B020F-DHT047 GEP Unpublished	N	Corteva Agriscience
KCP 6.2/35	Cana, L.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B035F-DHT075 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/36	Cana, L.	2020	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses. EA20E7B035F-DPF047 Corteva Agriscience/NARDI Fundulea GEP Unpublished	N	Corteva Agriscience
KCP 6.2/37	Cap, J.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F-DQD056 ZKUSEBNI STANICE NECHANICE, S.R.O., CZ GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/38	Cap, J.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B058F-DQD032 ZKUSEBNI STANICE NECHANICE, S.R.O., CZ GEP Unpublished	N	Corteva Agriscience
KCP 6.2/39	Chambon, J.	2019	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. FR18E7B012MC03C (CEE-18101, OR20180401081) Cerestis GEP Unpublished	N	Corteva Agriscience
KCP 6.2/40	Ciupa-Wylezalek, B.	2019	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2019 EA19F9B003F-DPF01 Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/41	Ciupa-Wylezalek, B.	2020	Efficacy of Inatreq on PuccST in Triticale - benchmark program, Europe, 2020 EA20E7B018F-DPF025 Dow AgroSciences, Poland GEP Unpublished	N	Corteva Agriscience
KCP 6.2/42	Dietrichs, W.	2014	Efficacy of DE-777 + prothioconazole and DE-777 + pyraclostrobin formulations for control of PuccRT in wheat: EU CZ, 2014. DE14E7B010WD01 Dow AgroSciences, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/43	Dietrichs, W.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, 2014. DE14E7B014WD01 Dow AgroSciences DE GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/44	Dietrichs, W.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in triticale. EU 2015. DE15E7B003WD01 Dow AgroSciences GmbH. DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/45	Dietrichs, W.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034WD01 Dow AgroSciences GmbH. DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/46	Donner, M.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ, 2014. DE14E7B026DD01 Dow AgroSciences, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/47	Donner, M.	2016	What is the efficacy of XDE-777 formulations against Puccinia compared to reference standards, EU 2016? DE16E7B027DD01 Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/48	Downey, S.	2018	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. GB17E7B045SD01 Dow AgroSciences UK GEP Unpublished	N	Corteva Agriscience
KCP 6.2/49	Drzewiecki, S.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in barley. EA20E7B037F-DPF050 Dow AgroSciences, PL	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/50	Dubois, P	2018	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019. FR17E7B041MC07C (BPE17/280/FG01, OR20170400609) BIOTEX Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.2/51	Dubois, P.	2018	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of foliar diseases in barley. - France 2017. FR17E7B041MC04C (BPE17/280/FGC06, OR20170400606) BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.2/52	Dubois, P.	2018	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. France 2017. FR17E7B042MC09C (BPE17/281/FG05, OR20170400620) BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.2/53	Fejes, A.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in barley EA20E7B037F-DHP064 BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.2/54	Fejes, A	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B035F-DHP066 BIOTEK Agriculture Hungary Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/55	Fejes, A	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat.	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EA20E7B035F-DHP067 BIOTEK Agriculture Hungary Kft. GEP Unpublished		
KCP 6.2/56	Fisher, S.	2015	THE EFFICACY OF XDE-777 FORMULATIONS COMPARED TO REFERENCE STANDARDS FOR CONTROL OF PUCST IN EUROPE? GB15E7B015EB01C ARMSTRONG FISHER LTD, UK GEP Unpublished	N	Corteva Agriscience
KCP 6.2/57	Fitos-Bedő, V.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-EAN030 Agrofil Szaktanacsado Mernoki Iroda Kft GEP Unpublished	N	Corteva Agriscience
KCP 6.2/58	Frydrych, J.	2015	XDE-777 FORMULATIONS GF-3308, GF-3307, GF-3309, GF-3312A FOR THE CONTROL OF PUCCRT. EU 2015. CZ15E7B014PV01C OSEVA PRO S.R.O. ODSTEPNY ZAVOD VYZKUMNY USTAV TRAVINARSKY ZUBRI. CZ GEP Unpublished	N	Corteva Agriscience
KCP 6.2/59	Frydrych, J.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F-DQD057 Oseva Pro Ltd. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/60	Gabor, K	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in wheat. EA20E7B035F-DHP069 AgropPass Hungaria Kft. GEP	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/61	Gabor, K	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat in HU and SL 2021 EA21E7B060F-EAN023 AgropPass Hungaria Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/62	Gabor, K.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-EAN031 AGROPASS Hungária Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/63	Gazuska, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS01C IOR Sosnicowice, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/64	Gazuska, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS02C IOR Sosnicowice, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/65	Galuska, A.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. PL17E7B045AS01C Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/66	Gezova, V.	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone – 2018 CZ18E7B007PV02C (F-18-G-571-01)	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			InTec Agro Trials GEP Unpublished		
KCP 6.2/67	Halmágyi, T.	2021	WBN66 (GF-3881) and GF-4637 efficacy on Fusarium head blight in wheat, CEU 2021. EA21WBN66001F-EAN011 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/68	Hamkało, N.	2022	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B054F-DPF036 SGS POLSKA SP. Z O.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/69	Hamkało, N.	2022	GF-3307 and GF-4637 efficacy on Fusarium head blight in wheat, Poland 2021. EA21E7B054F-DPF037 SGS POLSKA SP. Z O.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/70	Hamkało, N.	2022	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B054F-DPF038 SGS POLSKA SP. Z O.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/71	Hamkało, N.	2022	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in rye, CEEU, 2021 EA21E7B056F-DPF057 SGS POLSKA SP. Z O.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/72	Hamkało, N.	2022	GF-3307 and GF-4637 efficacy on Fusarium head blight in wheat, Poland 2021. EA21E7B130F-DPF059 SGS POLSKA SP. Z O.O.	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/73	Hamkało, N.	2022	GF-3307 and GF-4637 efficacy on Fusarium head blight in wheat, Poland 2021. EA21E7B130F-DPF060 SGS POLSKA SP. Z O.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/74	Hamkało, N.	2022	WBN66 (GF-3881) and GF-4637 efficacy on Fusarium head blight in wheat, CEU 2021 EA21WBN66001F-DPF017 SGS POLSKA SP. Z O.O. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/75	Hrabovsky, J.	2019	Evaluation of new formulation of Inatreq and Inatreq + Prothioconazole against foliar diseases in wheat. CZ Zone - 2018 CZ18E7B017PV01C GEP Unpublished	N	Corteva Agriscience
KCP 6.2/76	Hrabovsky, J.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F-DQD058 Corteva Agriscience/Zemědělská zkušební stanice KUJAVY, s.r.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/77	Hetterich, F	2019	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Blumeria graminis</i> in barley. EU 2019. EA19F9B023F-DPE01 Hetterich Fieldwork GbR GEP Unpublished	N	Corteva Agriscience
KCP 6.2/78	Hilton, R	2018	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of foliar diseases in barley. Europe 2017. GB17E7B046RH01 Dow AgroSciences Ltd GEP	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.2/79	Hilton, R	2018	Efficacy of XR-659 and DE-777 alone and in mixture with prothioconazole for control of foliar diseases in barley. Europe 2017. GB17E7B049RH02 Dow AgroSciences Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/80	Hilton, R	2018	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of foliar diseases in barley. Europe 2017. GB17E7B046RH02 Dow AgroSciences Limited GEP Unpublished	N	Corteva Agriscience
KCP 6.2/81	Hilton, R.	2018	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. GB17E7B049RH01 Dow AgroSciences UK GEP Unpublished	N	Corteva Agriscience
KCP 6.2/82	Holcikova, D.	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/SE Zone - 2018. SK18E7B008PV02C (FYSE-141201802) FYSE, s.r.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/83	Hunt, A	2020	Efficacy of one application of GF-3307 against diseases (RHYNSE, PYRNTE, RAMUCC) of spring barley, Maritime EU, 2019. EA19E7B004F-DIT02 (1299A-19-COR) OAT Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/84	Jaczak, J.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EA21E7B054F-DPF042 Anadiag Polska GEP Unpublished		
KCP 6.2/85	Jombikova, K.	2022	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat in HU and SL 2021 EA21E7B060F-DQD24 FYSE s.r.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/86	Kasztner, G.	2021	WBN66 (GF-3881) and GF-4637 efficacy on Fusarium head blight in wheat, CEU 2021. EA21WBN66001F-EAN010 Agrofil-SZMI Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/87	Kiraly, B.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat - EU, 2016 HU16E7B046AB01C BIOTEK Agriculture Hungary Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/88	Kiraly, B.	2017	Efficacy of Inatreq formulations against various diseases in wheat. Hungary, 2017 HU17E7B082AB01C BIOTEK Agriculture Hungary KFT GEP Unpublished	N	Corteva Agriscience
KCP 6.2/89	Kiraly, B.	2017	Efficacy of Inatreq formulations against various diseases in wheat. Hungary, 2017 HU17E7B082AB02C Biotek Agriculture Hungary KFT GEP Unpublished	N	Corteva Agriscience
KCP 6.2/90	Kiraly, B.	2018	Efficacy, selectivity of the mixture XDE-481 EC + SDHI (Fluxapyroxad) compared to commercial standards for control of barley diseases. EU 2018.	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			HU18F9B029AB01C BIOTEK Agriculture Hungary Kft. GEP Unpublished		
KCP 6.2/91	Kolarrik, P.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B036F-DQD055 Research Institute for Fodder Crops, Ltd. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/92	Kolarrik, P.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B058F-DQD029 Research Institute for Fodder Crops, Ltd. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/93	Kovalova, I.	2018	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. GB17E7B045JK02 Dow AgroSciences Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/94	Kowalski, R.	2017	Efficacy and selectivity of Inatreq fungicides applied in TTLWI in POLAND 2017 PL17E7B089RK01C IOR Sosnowice, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/95	Krawczuk, J.	2019	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone - 2018. PL18E7B009AS08C GS Polska Sp. z.o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/96	Lieveaux, G.	2018	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			2019. FR17E7B042MC12C (DAS-FE17OH-01891-CB, OR20170501072) Antedis SAS GEP Unpublished		Agriscience
KCP 6.2/97	Luca, A-M.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat in Romania 2021 EA21E7B059F-AMT051 Corteva Agriscience/EUROFINS AGROSCIENCE SERVICES S.R.L. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/98	Lunca, A-M.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-AMT056 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/199	Lunca, A-M.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-AMT057 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/100	Lunca, A-M.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-AMT058 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/101	Maczynska, A.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. PL14E7B028AS01C Dow AgroSciences, Poland IOR SOSNICOWICE	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/102	Maczynska, A.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application PL15E7B041AS02C Dow AgroSciences, Poland GEP Unpublished	N	Corteva Agriscience
KCP 6.2/103	Mączyńska, A.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B054F-DPF031 Corteva Agriscience/IOR GEP Unpublished	N	Corteva Agriscience
KCP 6.2/104	Mączyńska, A	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B054F-DPF032 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/105	Mako, I.	2021	WBN66 (GF-3881) and GF-4637 efficacy on Fusarium head blight in wheat, CEU 2021 EA21WBN66001F-EAN009 CPR Europe Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/106	Marquardt, K.	2019	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2018 DE18F9B009AS03C Eurofins Agrosience Services GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/107	Menyhart, L.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ, 2014.	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			HU14E7B026LM01 Dow AgroSciences, Hungary GEP Unpublished		
KCP 6.2/108	Menyhart, L.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in South East Europe EPPO when applied as a single application. HU15E7B011LM01 Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/109	Menyhart, L.	2016	Efficacy of Inatreq formulations against rusts and another various diseases in wheat. SE EPPO zone, 2016 HU16E7B029LM03 Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/110	Menyhart, L.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone HU16E7B030LM03 Dow AgroSciences Hungary GEP Unpublished	N	Corteva Agriscience
KCP 6.2/111	Mills, R.	2020	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019. EA19F9B025F-DEH01 Cropworks Limited GEP Unpublished	N	Corteva Agriscience
KCP 6.2/112	Németh, S.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+120 g ai/l) against key diseases in barley. EA21E7B061F-EAN029 CPR Europe Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/113	Nistrup	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against PuccST, NZ, 2016	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
	Jørgensen, L.		DK16E7B002KF01C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished		Agriscience
KCP 6.2/114	Nistrup Jørgensen, L.	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against PUCST, NZ, 2016 DK16E7B002KF02C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	Corteva Agriscience
KCP 6.2/115	Nistrup Jørgensen, L.	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against PUCST, NZ, 2016 DK16E7B002KF03C AARHUS UNIVERSITY FLAKKEBJERG, DK GEP Unpublished	N	Corteva Agriscience
KCP 6.2/116	Nistrup Jørgensen, L.	2016	XDE-777 FORMULATIONS GF-3308, GF-3307, FOR THE CONTROL OF FUSASP and SEPTTR. EU 2016. DK16E7B032KF02C Aarhus University GEP Unpublished	N	Corteva Agriscience
KCP 6.2/117	Nistrup Jørgensen, L.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. DK17E7B043KF01C (17385-1) Aarhus University GEP Unpublished	N	Corteva Agriscience
KCP 6.2/118	Nistrup Jørgensen, L.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. DK17E7B043KF04C (17357-2) Aarhus University GEP Unpublished	N	Corteva Agriscience
KCP 6.2/119	Nistrup Jørgensen, L.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. DK17E7B043KF05C (17357-3) Aarhus University	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/120	Nistrup Jorgensen, L.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. DK17E7B043KF02C (17385-2) Aarhus University GEP Unpublished	N	Corteva Agriscience
KCP 6.2/121	Odstreilova, L.	2015	What is the efficacy of XDE-777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application CZ15E7B041PV03C Vyzkumny Ustav Rostlinne Vyroby. CZ GEP Unpublished	N	Corteva Agriscience
KCP 6.2/122	Pawlak, A.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS03C STAPHYT GEP Unpublished	N	Corteva Agriscience
KCP 6.2/123	Pawlak, A.	2015	XDE-777 FORMULATIONS GF-3308, GF-3307, GF-3309, GF-3312A FOR THE CONTROL OF PUCCRT AND OTHER CEREAL DISEASES. Poland 2015. PL15E7B022AS03C STAPHYT, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/124	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS04C STAPHYT, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/125	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016.	N	Corteva Agriscience

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			PL16E7B019AS05C STAPHYT, PL GEP Unpublished		
KCP 6.2/126	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS04C STAPHYT, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/127	Pawlak, A.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS05C STAPHYT, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/128	Pawlak, A	2017	What Is the Efficacy of Inatreq Formulations Under North East Europe Conditions PL16E7B031AS04C Staphyt GEP Unpublished	N	Corteva Agriscience
KCP 6.2/129	Pawlak, A.	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone – 2018. PL18E7B009AS02C Staphyt Sp. z.o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/130	Pietryga, J.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat EA20E7B035F-DPF043 Dow AgroSciences, Poland GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/131	Plonka, P.	2019	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019 EA19E7B003F-DPF02. Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/132	Plonka, P.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in barley, CEEU, 2021. EA21E7B057F-DPF022 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/133	Pszczółkowski, M.	2020	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2019. EA19F9B003F-DPF03 Staphyt Sp. z.o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/134	Pszczolkowski, M.	2020	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F-DPF05. STAPHYT Sp. z.o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/135	Pszczolkowski, M.	2020	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F-DPF06 STAPHYT Sp. z.o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/136	Pszczolkowski, M.	2020	Efficacy of Inatreq on PuccST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DPF027 Staphyt GEP Unpublished	N	Corteva Agriscience
KCP 6.2/137	Pszczółkowski, M.	2022	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EA21E7B054F-DPF039 Staphyt Sp. z o.o. GEP Unpublished		
KCP 6.2/138	Pszczółkowski, M.	2022	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in rye, CEEU, 2021 EA21E7B056F-DPF058 Staphyt Sp. z o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/139	Pszczółkowski, M.	2021	GF-3307 and GF-4637 efficacy on Fusarium head blight in wheat, Poland 2021. EA21E7B130F-DPF061 Staphyt Sp. z o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/140	Pszczółkowski, M.	2021	GF-3307 and GF-4637 efficacy on Fusarium head blight in wheat, Poland 2021. EA21E7B130F-DPF063 Staphyt Sp. z o.o. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/141	Reisenhofer, A.	2015	XDE-777 FORMULATIONS GF-3308, GF-3307, GF-3309, GF-3312A FOR THE CONTROL OF PUCCRT. EU 2015. DE15E7B014UB06C ATC - AGRO TRIAL CENTER GMBH, AT GEP Unpublished	N	Corteva Agriscience
KCP 6.2/142	Reisenhofer, A.	2015	DE-777 straight and in combination with prothioconazole or pyraclostrobin for the control <i>Fusarium</i> head blight in wheat. EU 2015. DE15E7B018UB02C ATC - Agro Trial Center GmbH, AT GEP Unpublished	N	Corteva Agriscience
KCP 6.2/143	Reisenhofer, A.	2016	DE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of <i>Fusarium</i> head	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			blight in wheat. EU CZ 2016. DE16E7B032UB02C ATC - Agro Trial Center GmbH, AT GEP Unpublished		Agriscience
KCP 6.2/144	Reisenhofer, A.	2016	DE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. DE16E7B032UB03C ATC - Agro Trial Center GmbH, AT GEP Unpublished	N	Corteva Agriscience
KCP 6.2/145	Reisenhofer, A.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312A for the control of Puccin. EU 2015. DE15E7B014UB07C ATC-Agro Trial Center GEP Unpublished	N	Corteva Agriscience
KCP 6.2/146	Reisenhofer, A.	2017	XDE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of fungal diseases in winter barley GEP Trial, Austria, 2017 DE17E7B045UB09C (RJL-17-30518-AT03) ATC-Agro Trials Center GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/147	Rivet, J-P..	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. FR17E7B042MC13C (17 14 F 01, OR20170400603) Essais+ GEP Unpublished	N	Corteva Agriscience
KCP 6.2/148	Rohr, J.	2014	Efficacy and dose response of XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of DTR and other diseases in wheat. EU . 2014. DE14E7B013UB02C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/149	Rohr, J.	2014	DE-777 straight and in combination with prothioconazole for the control <i>Fusarium</i> head blight in wheat. EU 2014. DE14E7B023UB01C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/150	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002UB02C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/151	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in triticale. EU 2015. DE15E7B003UB01C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/152	Rohr, J.	2015	XDE-777 FORMULATIONS GF-3308, GF-3307, GF-3309, GF-3312A FOR THE CONTROL OF PUCCRT. EU 2015. DE15E7B014UB02C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/153	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB03C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/154	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB04C AGRARTEST, DE	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/155	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034UB02C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/156	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in triticale. Germany 2015. DE15E7B034UB04C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/157	Rohr, J.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB02C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/158	Rohr, J.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB01C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/159	Rohr, J.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002UB03C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/160	Rohr, J.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in rye.	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EU 2015. DE15E7B002UB01C Agrartest, DE GEP Unpublished		Agriscience
KCP 6.2/161	Rohr, J.	2015	DE-777 straight and in combination with prothioconazole or pyraclostrobin for the control <i>Fusarium</i> head blight in wheat. EU 2015. DE15E7B018UB01C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/162	Rohr, J.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in rye. Germany 2015. DE15E7B033UB05C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/163	Rohr, J.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. DE16E7B019UB01C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/164	Rohr, J.	2016	DE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. DE16E7B032UB01C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/165	Rohr, J.	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against DTR under NZ conditions? DE16E7B004UB01C Agrartest, DE GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/166	Rohr, J	2016	How does the efficacy dose response of GF-3307 and GF-3309 against foliar diseases in triticale compare to the included reference product Proline? DE15E7B034UB03C AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/167	Rohr, J.	2017	Evaluation of the minimum effective dose of XR-659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012UB01C Agritest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/168	Rohr, J.	2017	Evaluation of the dose response of GF-3307 compared to new market competitors for the control of <i>Septoria tritici</i> in wheat. EU 2017 DE17E7B016UB02C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/169	Rohr, J	2017	Dose response of GF-3307 (DE-777+ prothioconazole) for the control of foliar diseases in barley. Europe 2017. DE17E7B045UB03C AgrarTest GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/170	Rohr, J	2017	Dose response of GF-3307 (DE-777+ prothioconazole) for the control of foliar diseases in barley. Europe 2017. DE17E7B045UB05C AgrarTest GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/171	Rohr, J.	2017	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of foliar diseases in barley. Europe 2017. DE17E7B046UB04C AgrarTest GmbH GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/172	Rohr, J.	2018	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2018 DE18F9B009AS01C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/173	Rohr, J.	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone – 2018 DE18E7B007UB04C Trial-Tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/174	Rohr, J.	2019	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019. EA19F9B025F-DPE01 Trial-Tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/175	Rohr, J.	2019	To evaluate the efficacy of formulations of Adavelt for the control of RAMUCC in winter barley compared to leading industry standards. EA19G1C044F-DNZ01 Trial-Tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/176	Rohr, J.	2019	To evaluate the efficacy of formulations of Adavelt for the control of RAMUCC in winter barley compared to leading industry standards. EA19G1C044F-DNZ02 Trial-Tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/177	Rohr, J.	2020	Efficacy of Inatreq on PUCCST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DNZ057 Trial-tec GmbH GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/178	Rohr, J.	2020	Efficacy of Inatreq on PuccST in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DNZ058 Trial-tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/179	Rohr, J.	2020	Efficacy of Inatreq on PuccST in Triticale - Benchmark program, Europe, 2020. EA20E7B068F-DNZ074 Trial-tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/180	Rohr, J.	2020	Efficacy of Inatreq on PuccST in Triticale - Benchmark program, Europe, 2020. EA20E7B068F-DNZ075 Trial-tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/181	Rohr, J.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on <i>Puccinia striiformis</i> and other key diseases in triticale. EU 2020 EA20F9B007F-DPE013 Trial-tec GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/182	Roj, J.	2016	DE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. PL16E7B032AS01C Ior Sosnicowice, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/183	Roj, J.	2016	What Is the Efficacy of Inatreq Formulations Under North East Europe Conditions PL16E7B031AS01C Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/184	Roj, J.	2016	WHAT IS THE EFFICACY OF INATREQ FORLUATIONS UNDER NORTH EAST EUROPE CONDITIONS	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			PL16E7B031AS03C Dow AgroSciences, Poland GEP Unpublished		Agriscience
KCP 6.2/185	Roy, J.	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone – 2018. PL18E7B009AS04C Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/186	Rose Gray, S	2019	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone - 2018. DE18E7B007UB02C (SRY-18-35431-AT02) Staphyt Austria GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/187	Rose-Gray, S.	2019	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone – 2018 DE18E7B007UB01C (SRY-18-35431-AT01) Staphyt Austria GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/188	Sawinska, Z.	2014	Efficacy of XDE-777 + prothioconazole and XDE-777 + pyraclostrobin formulations for control of Puccinia in wheat: EU CZ, 2014. PL14E7B010AS01C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/189	Sawinska, Z.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS01C Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/190	Sawinska, Z.	2015	XDE-777 FORMULATIONS GF-3308, GF-3307, GF-3309, GF-3312 FOR THE CONTROL OF PUCCRT AND OTHER CEREAL DISEASES. Poland 2015. PL15E7B022AS01C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/191	Sawinska, Z.	2015	XDE-777 FORMULATIONS GF-3308, GF-3307, GF-3309, GF-3312A FOR THE CONTROL OF PUCCRT AND OTHER CEREAL DISEASES. Poland 2015. PL15E7B022AS02C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/192	Sawinska, Z.	2016	Efficacy of Inatreq formulations compare DuPont cereal fungicide when applied against various diseases in wheat – EU, 2016. PL16E7B046AS02C Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/193	Sawinska, Z.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in rye. Europe 2016. PL16E7B019AS03C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/194	Sawinska, Z.	2016	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin and DE-777 straight for the control of foliar diseases in triticale. Europe 2016. PL16E7B020AS03C UNIWERSYTET PRZYRODNICZY POZNAN, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/195	Sawinska, Z.	2016	The efficacy GF-3308 straight and in mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016. PL16E7B038AS01C UNIWERSYTET PRZYRODNICZY POZNAN, PL	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/196	Sawinska, Z.	2018	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2018 PL18F9B009AS01C Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/197	Sawinska, Z.	2018	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2018 PL18F9B009AS02C Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/198	Sawinska, Z	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/NE Zone – 2018. PL18E7B009AS05C (AF/18/JO/32/KO/S05C) Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/199	Sawinska, Z	2018	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2018 PL18F9B009AS03C Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/200	Sawinska, Z	2019	Efficacy of XDE-481 on <i>Puccinia striiformis</i> , <i>Septoria</i> species and other diseases in triticale. EU 2019 EA19F9B003F-DPF02 Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/201	Sawinska, Z	2019	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F-DPF03 (AF/19/JJ/8/Br/DPF03/E7) Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/202	Sawinska, Z	2019	Efficacy of GF-3307 for control of diseases in barley in SE and NE EPPO zones, 2019. EA19E7B003F-DPF04 (AF/19/JJ/8/SL/DPF04/E7) Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/203	Sawinska, Z.	2020	Efficacy of Inatreq on Puccst in Triticale - Benchmark program, Europe, 2020. EA20E7B018F-DPF026 UNIwersytet PRzyroDniczy POZnan GEP Unpublished	N	Corteva Agriscience
KCP 6.2/204	Sawinska, Z	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in barley. EA20E7B037F-DPF052 Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/205	Sawinska, Z	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in barley. EA20E7B037F-DPF051 Uniwersytet Przyrodniczy Poznan, PL GEP Unpublished	N	Corteva Agriscience
KCP 6.2/206	Sawinska, Z.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat EA20E7B035F-DPF044 Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/207	Sawinska, Z.	2020	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat EA20E7B035F-DPF045 Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/208	Sawinska, Z.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B054F-DPF033 Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/209	Sawinska, Z.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in wheat, CEEU, 2021 EA21E7B054F-DPF034 Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/210	Sawinska, Z.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in triticale, CEEU, 2021 EA21E7B055F-DPF049 Poznań University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/211	Sawinska, Z.	2021	Efficacy of new ratio fenpicoxamid + prothioconazole GF-4637 (40 + 120) against key diseases in barley, CEEU, 2021. EA21E7B057F-DPF025 Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/212	Schmidt, I.	2017	XDE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of fungal diseases in winter barley GEP Trial, GERMANY, 2017. DE17E7B045UB11C (RJL-17-30724-DE01) Staphyt GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/213	Schnieder, F.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. DE14E7B014FS01 DOW AGROSCIENCES GMBH. DE	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.2/214	Schnieder, F.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312 for the control of PYRNTR. EU 2015. DE15E7B016FS01 Dow AgroSciences GmbH, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/215	Schnieder, F.	2016	DE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of <i>Fusarium</i> head blight in wheat. EU CZ 2016. DE16E7B032FS01 Dow AgroSciences GmbH. DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/216	Schnieder, F.	2020	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Rhynchosporium secalis</i> in barley. EU 2019 EA19F9B025F-DNZ01 Dow AgroSciences GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/217	Schulz, T.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. DE14E7B028TS01 Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/218	Schulz, T.	2015	Dose response of XDE-777+prothioconazole and XDE-777+pyraclostrobin for the control of foliar diseases in rye. EU 2015. DE15E7B002TS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/219	Schultz, T	2017	Evaluation of the minimum effective dose of XR-659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017.	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DE17G1C012TS01 DOW AGROSCIENCES GMBH. DE GEP Unpublished		
KCP 6.2/220	Schulz, T	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone – 2018 DE18E7B007TS01 Dow AgroSciences GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/221	Stephan, A.	2015	Dose response of DE-777+prothioconazole and DE-777+pyraclostrobin for the control of foliar diseases in triticale. EU 2015. DE15E7B003AS01 Dow AgroSciences GmbH. DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/222	Stephan, A.	2015	XDE-777 formulations GF-3308, GF-3307, GF-3309, GF-3312a for the control of Puccinia. EU 2015 DE15E7B014AS01 DOW AGROSCIENCES GMBH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/223	Stephan, A	2017	Evaluation of the minimum effective dose of XR-659 for the control of <i>Septoria tritici</i> in wheat and triticale and RHYNSE in rye. EU 2017. DE17G1C012AS01 Dow AgroSciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/224	Stephan, A.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. DE17E7B045AS01 Dow AgroSciences GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/225	Stephan, A.	2020	What is the optimum dose of XDE-481 EC and fenpicoxamid EC in mixtures for <i>Septoria tritici</i> control in wheat?	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EA19F9B017F-DPE01 Dow AgroSciences GEP Unpublished		Agriscience
KCP 6.2/226	Stephan, A.	2020	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Puccinia hordei</i> in barley. EU 2019. EA19F9B024F-DPE02 Dow AgroSciences GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/227	Stephan, A.	2020	Efficacy of one application of GF-3307 against diseases (RHYNSE, PYRNTE, RAMUCC) of spring barley, Maritime EU, 2019. EA19E7B004F-DPE01 Dow AgroSciences GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/228	Stepien, A.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. PL14E7B028AS02C Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/229	Stepien, A.	2015	What is the efficacy of DE-777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a repeat application PL15E7B041AS01C Poznan University of Life Sciences GEP Unpublished	N	Corteva Agriscience
KCP 6.2/230	Strobele, U.	2020	GF-3307 (DE-777+prothioconazole) and DE-777 straight (GF-3308) for the control of <i>Ramularia</i> and other foliar diseases in barley. Europe 2018. DE18E7B012UB05C (H-122-QUI-18-187) Quintus GmbH GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/231	Strobele, U.	2020	Efficacy and dose response of XDE-481 EC straight and in mixtures on <i>Blumeria graminis</i> in barley. EU 2019 EA19F9B023F-DPE02 (I-122-QUI-19-168) Quintus GmbH GEP Unpublished	N	Corteva Agriscience
KCP 6.2/232	Szymura, A.	2021	WBN66 (GF-3881) and GF-4637 efficacy on Fusarium head blight in wheat, CEU 2021 EA21WBN66001F-DPF016 Dow AgroSciences/IOR GEP Unpublished	N	Corteva Agriscience
KCP 6.2/233	Tartier, J.	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. SZ/MED & SZ/MAR Zone – 2018. FR18E7B006MC07C (BPE18/254/FGC01, OR20180401077) BIOTEX Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.2/234	Thibault, A.	2018	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. FR17E7B042MC11C (OR20170400357, SRFR17-163-52FE) BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.2/235	Toth, F.	2018	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/SE Zone – 2018. SK18E7B008PV01C Gemerprodukt Valice OVD GEP Unpublished	N	Corteva Agriscience
KCP 6.2/236	Touche, C	2018	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Europe 2017. FR17E7B042MC03C (CTE-17-30328-FR03, OR20170400632) STAPHYT GEP Unpublished	N	Corteva Agriscience
KCP 6.2/237	Treikale, O.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			foliar diseases in wheat. EU CZ. 2014. LV14E7B028MN02C Latvian Plant Protection Research Centre Ltd. GEP Unpublished		Agriscience
KCP 6.2/238	Treikale, O.	2015	WHAT IS THE EFFICACY OF XDE-777 PRODUCTS AGAINST SEPTTR AT B33-69, WHEN APPLIED AS A SINGLE APPLICATION IN NORTHERN EUROPEAN CONDITIONS? LV15E7B019MN03C Latvian Plant Protection Research Centre, LPPRC GEP Unpublished	N	Corteva Agriscience
KCP 6.2/239	Treikale, O.	2015	What is the efficacy of XDE-777 formulations against SEPTTR in wheat in Poland and Baltics when applied as a single and split application? LV15E7B009MN04C Latvian Plant Protection Research Centre Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/240	Treikale, O.	2015	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of LEPTNO in wheat. EU SZ. 2014. LV14E7B012MN01C Latvian Plant Protection Research Centre Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/241	Treikale, O.	2016	What is the efficacy of Inatreq formulations under North East Europe conditions? LV16E7B031KF01C Latvian Plant Protection Research Centre GEP Unpublished	N	Corteva Agriscience
KCP 6.2/242	Treikale, O.	2016	WHAT IS THE EFFICACY OF INATREQ FORLUATIONS AGAINST DISEASES OF WHEAT UNDER NORTH EAST EUROPE CONDITIONS? LV16E7B031KF03C Latvian Plant Protection Research Centre, LPPRC GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/243	Treikale, O.	2017	What is the effective dose of GF-3307 and GF-3308 for the control of foliar diseases (specific RAMUCC) in barley. Nordic 2017. LV17E7B039KF01C LAAPC GEP Unpublished	N	Corteva Agriscience
KCP 6.2/244	Treikale, O.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. LV17E7B043KF02C LAAPC GEP Unpublished	N	Corteva Agriscience
KCP 6.2/245	Treikale, O.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. LV17E7B043KF03C LAAPC GEP Unpublished	N	Corteva Agriscience
KCP 6.2/246	Treikale, O.	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley. Nordic 2017. LV17E7B043KF01C LAAPC GEP Unpublished	N	Corteva Agriscience
KCP 6.2/247	Treikale, O.	2018	What is the effective dose of GF-3307 for the control of foliar diseases (North-East EPPO zone). LV18E7B011KF01C LAAPC GEP Unpublished	N	Corteva Agriscience
KCP 6.2/248	Treikale, O.	2019	What is the minimum effective dose of GF-3307 to control diseases of winter and spring barley in Northern zone countries? EA19E7B007F-DHW09 LAAPC GEP Unpublished	N	Corteva Agriscience
KCP 6.2/249	Tuna, V.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			(40+80 g ai/l) against key diseases in wheat EA20E7B035F-DHT072 Corteva Agriscience GEP Unpublished		Agriscience
KCP 6.2/250	Tuna, V.	2021	Comparable efficacy of GF-3307 (50+100 g ai/l) and a new ratio of fenpicoxamid+prothioconazole GF-4637 (40+80 g ai/l) against key diseases in wheat. EA20E7B035F-DHT073 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/251	Tuna, V.	2021	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses EA20E7B020F-DHT046 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/252	Tuna, V.	2021	Benefit trials local programs for GF-3308. T2 support low doses. Romania 2020. EA20E7B065F-DHT070 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/253	Tuna, V.	2021	Benefit trials local programs for GF-3308. T2 support low doses. Romania 2020. EA20E7B065F-DHT076 Corteva Agriscience GEP Unpublished	N	Corteva Agriscience
KCP 6.2/254	Tuna, V.	2021	Benchmark local programs for GF-3308 / GF-3307. T1 to support low doses Corteva Agriscience EA20E7B020F-DHT084 GEP Unpublished	N	Corteva Agriscience
KCP 6.2/255	Tuna, V.	2021	Benefit trials local programs for GF-3308. T2 to support low doses, Romania 2020. Corteva Agriscience	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			EA20E7B065F-DHT071 GEP Unpublished		
KCP 6.2/256	Tvaruzek, L.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. CZ14E7B028PV01C ZEMEDELsky VYZKUMNY USTAV KROMERIZ, S.R.O. CZ GEP Unpublished	N	Corteva Agriscience
KCP 6.2/257	Tvaruzek, I.	2015	What is the efficacy of XDE-777 formulations against cereal diseases in wheat in North East Europe EPPO . CZ15E7B010PV01C Zemedelsky Vyzkumny Ustav Kromeriz, S.R.O. CZ GEP Unpublished	N	Corteva Agriscience
KCP 6.2/258	Tvaruzek, L.	2016	The efficacy GF-3308 straight and in mixture with partner fungicides for the control of foliar diseases of wheat. EU 2016. CZ16E7B038PV02C ZEMEDELsky VYZKUMNY USTAV KROMERIZ, S.R.O. CZ GEP Unpublished	N	Corteva Agriscience
KCP 6.2/259	Varret, F.	2016	DE-777 straight (GF-3308) and in combination with prothioconazole (GF-3307) for the control of <i>Fusarium</i> head blight in wheat. EU SZ 2016. FR16E7B035MC01C Staphyt. FR GEP Unpublished	N	Corteva Agriscience
KCP 6.2/260	Vourkos, F.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone BG16E7B030VA01C ANADIAG Bulgaria Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/261	Vourkos, F.	2016	Efficacy of Inatreq formulations when applied against various diseases in wheat in SE EPPO Zone BG16E7B030VA02C	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			ANADIAG Bulgaria Ltd GEP Unpublished		
KCP 6.2/262	Vourkos, F.	2019	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. SZ/MED and SE Zone – 2018. BG18E7B004KP03C Anadiag Bulgaria Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/263	Vourkos, F.	2019	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. SZ/MED and SE Zone – 2018. BG18E7B004KP04C Anadiag Bulgaria Ltd GEP Unpublished	N	Corteva Agriscience
KCP 6.2/264	Wagner, G.	2014	Efficacy and dose response of different DE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. EA14E7B028AB01C SynTech Research Hungary Kft. GEP Unpublished	N	Corteva Agriscience
KCP 6.2/265	Wonckhaus, S	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on <i>Puccinia striiformis</i> and other key diseases in triticale. EU 2020 EA20F9B007F-DPE014 AGRARTEST, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.2/266	Zickart, U.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/fenbuconazole EC formulations for control of foliar diseases in wheat. EU CZ, 2014. DE14E7B026UB01C BIOCHEM AGRAR. DE GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/267	Zoller, P.	2015	XDE-777 FORMULATIONS GF-3308, GF-3307, GF-3309, GF-3312A FOR THE CONTROL OF PUCCRT. EU 2015. DE15E7B014UB04C EUROFINS AGROSCIENCE SERVICES GMBH, DE GEP Unpublished	N	Corteva Agriscience
KCP 6.3/01	Kemmit, G.	2012	XDE-777 Septoria tritici (Mycosphaerella graminicola) sensitivity baseline generation Year 1 2011 season. DAS internal report # 2011920. non GEP Unpublished	N	Corteva Agriscience
KCP 6.3/02	Kemmit, G.	2013	XDE-777 Septoria tritici (Mycosphaerella graminicola) sensitivity baseline generation Year 2 2012 season Europe. DAS internal report # 2020427. non GEP Unpublished	N	Corteva Agriscience
KCP 6.3/03	Kemmit, G.	2014	XDE-777 Septoria tritici (Mycosphaerella graminicola) sensitivity baseline generation Year 3 2013 season Europe. DAS internal report # 2021524 non GEP Unpublished	N	Corteva Agriscience
KCP 6.3/04	Kemmit, G.	2015	XDE-777 Septoria tritici (Mycosphaerella graminicola) sensitivity baseline generation Year 4 2014 season Europe. DAS internal report # 2025137. non GEP Unpublished	N	Corteva Agriscience
KCP 6.3/05	Kemmit, G.	2015	Inatreq (DE-777) Puccinia triticina (Wheat Brown Rust) sensitivity baseline generation. Year 1 2015 season, Europe. DAS internal research report no. DAI 2032179 Non GEP Unpublished	N	Corteva Agriscience
KCP 6.3/06	Kemmitt, G.M..	2019	Inatreq, Fenpicoxamid, (DE-777) - Ramularia leaf spot of Barley (<i>Ramularia collo-cygni</i>) baseline sensitivity establishment – summary and raw data. Year 1 - 2018 season Europe. (2019). Dow agrosiences Internal report No. 2081349.	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Dow agrosiences GLP Unpublished		
KCP 6.3/07	Kemmitt, G.M.	2019	Inatreq, Fenpicoxamid, (DE-777) - Barley Net Blotch (<i>Pyrenophora teres</i>) baseline sensitivity establishment – summary and raw data. Year 1 - 2018 season Europe. (2019). Dow agrosiences Internal report No. 2081350. Dow agrosiences GLP Unpublished	N	Corteva Agriscience
KCP 6.3/08	Mboup, M., K., Leader A.	2022	Sensitivity baseline for European <i>Ramularia collo-cygni</i> populations versus Fenpicoxamid. 2019-2021 season Europe TITLE OF THE SUBMITTED DOCUMENT READS: Inatreq, Fenpicoxamid, (DE-777) – Ramularia leaf spot of Barley (<i>Ramularia collo-cygni</i>)-RAMUCC. Baseline sensitivity establishment – summary across years 2018-2020 and raw data. Year 2/3 – 2019-2020 season Europe. THE REPORT INTERNAL NUMBER IS ABSENT. Corteva Agrisciences Internal report Corteva Agrisciences Non-GLP Unpublished	N	Corteva Agriscience
KCP 6.3/09	Mboup, M., K., Leader A.	2022	Sensitivity baseline for European <i>Pyrenophora teres</i> populations versus Fenpicoxamid. 2019-2021 season Europe TITLE OF THE SUBMITTED DOCUMENT READS: Inatreq, Fenpicoxamid, (DE-777) – Netblotch of Barley (<i>Pyrenophora teres</i>)-PYRNTE. Baseline sensitivity establishment – summary across years 2018-2021 and raw data. Year 2/3/4 – 2019-2021 season Europe. THE REPORT INTERNAL NUMBER IS ABSENT. Corteva Agrisciences Internal report Corteva Agrisciences Non-GLP Unpublished	N	Corteva Agriscience
KCP 6.3/10	Mboup, M., K., Leader A.	2022	Sensitivity baseline for European <i>Pyrenophora teres</i> populations versus prothioconazole. 2021 season Europe TITLE OF THE SUBMITTED DOCUMENT READS: Prothioconazole – Netblotch of Barley (<i>Pyrenophora teres</i>)-PYRNTE. Baseline sensitivity establishment – summary 2021 and raw data. Year 1 –2021 season Europe. THE REPORT INTERNAL NUMBER IS ABSENT. Corteva Agrisciences Internal report	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Corteva Agrisciences Non-GLP Unpublished		
KCP 6.3/11 KCP 6.1	Myung K., Yao C., Owen, W., Meyer, K.G. and Nugent B.M.,	2011	Uptake, redistribution and metabolism of picolinamides (XR-777 and UK-2A) and neo-picolinamides (X12072033 and X12070381) in wheat and Septoria tritici. DAS internal research report no. DAI 1074 Non GEP Unpublished Not listed by the applicant in KCP 6.1, but submitted and evaluated with reference to KCP 6.1	N	Corteva Agriscience
KCP 6.3/12 KCP 6.1	Myung, K., Young, D., Meyer, S.T., Kemmitt, G., Owen, W.J.	2016	Metabolism of Inatreq™ active to UK-2A by Zymoseptoria tritici DAS internal research report no. DAI 1517 Non GEP Unpublished Not listed by the applicant in KCP 6.1, but submitted and evaluated with reference to KCP 6.1	N	Corteva Agriscience
KCP 6.3/13 KCP 6.1/06	Owen, W.J. et al.	2011	XR-777 Discovery Advancement Report Dow AgroSciences internal report DAI 1040 Non GEP/non GLP Unpublished, Not listed by the applicant in KCP 6.1, but submitted and evaluated with reference to KCP 6.1	N	Corteva Agriscience
KCP 6.3/14	Young D.H. and Wang N.	2005	Insights into the binding of UK-2A to cytochrome bc1 from cross-resistance analyses using antimycin-resistant Saccharomyces cerevisiae mutants and molecular docking studies. DAI 1077 non GEP Unpublished	N	Corteva Agriscience
KCP 6.4/01	Babrik, Z.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU HU14E7B016AB01C AGROFIL SZAKTANACSADO MERNOKI IRODA KFT. GEP Unpublished	N	Corteva Agriscience
KCP 6.4/02	Banachowska, J.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU PL14E7B016AS01C IOR SOSNICOWICE, PL GEP	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.4/03	Bouteneigre, J.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU FR14E7B016MC01C Biotek Agriculture, FR GEP Unpublished	N	Corteva Agriscience
KCP 6.4/04	Cunningham, A.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU GB14E7B016EB02C OXFORD AG TRIALS, UK GEP Unpublished	N	Corteva Agriscience
KCP 6.4/05	Dubois, P.	2018	Evaluation of GF-3307 on brewery processes on winter and spring barley - France 2017. FR17E7B044MC02C (OR20170501079) BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.4/06	Dubois, P.	2018	Evaluation of GF-3307 on brewery processes on winter and spring barley - France 2017. FR17E7B044MC04C (OR20170501077) BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.4/07	Dubois, P.	2018	Evaluation of GF-3307 on brewery processes on winter and spring barley - France 2017. FR17E7B044MC05C (OR20170501580) BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.4/08	Dubois, P.	2018	Evaluation of GF-3307 on brewery processes on winter and spring barley - France 2017. FR17E7B044MC08C (OR20170501720) BIOTEK Agriculture GEP Unpublished	N	Corteva Agriscience
KCP 6.4/09	Duval, M.	2015	Evaluation of XDE 777 formulations in wheat with grain used for bread making. EU 2015.	N	Corteva

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			FR15E7B006MC01C Biotek-agriculture GEP Unpublished Study referred to twice, although only used in the effect on bread baking assessment. Properly listed as: KCP 6.4/16		Agriscience
KCP 6.4/10	Fairfax, M.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU GB14E7B042MF01 Dow AgroSciences Ltd, UK GEP Unpublished	N	Corteva Agriscience
KCP 6.4/11	Fisher, S.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU GB14E7B016EB01C ARMSTRONG FISHER LTD, UK GEP Unpublished	N	Corteva Agriscience
KCP 6.4/12	Gless, A-E.	2018	Study of unintentional effects of phytopharmaceutical products on malt and beer quality and process 17/105-E1025 IFBM GLP Unpublished	N	Corteva Agriscience
KCP 6.4/13	Zickart U., Kästner, K.	2016	Field study to generate specimen of Beer from RAC Wheat treated with GF-3307 or GF-3309 for subsequent triangle taint testing and determination of quality parameters, 2 Sites in Germany 2015 BioChem Project No 15 1047 2114 Impact of GF-3307 and GF-3309 on beer making process - field phase. Germany 2015. Field phase trial 1 DE15E7B005UB01C Field phase trial 2 DE15E7B005UB02C GEP Unpublished	N	Corteva Agriscience
KCP 6.4/14	Owen J, Slanec T	2015	Impact of carbon source on growth inhibition of Saccharomyces cerevisiae by XDE-777 and UK-2A Report DAI1399 DOW AgroSciences Indianapolis Non GLP/non GEP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.4/16	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC01C BIOTEK AGRICULTURE, FR GEP Unpublished	N	Corteva Agriscience
KCP 6.4/17	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC02C BIOTEK AGRICULTURE, FR GEP Unpublished	N	Corteva Agriscience
KCP 6.4/18	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC03C BIOTEK AGRICULTURE, FR GEP Unpublished	N	Corteva Agriscience
KCP 6.4/19	Tartier, J.	2015	Evaluation of XDE-777 formulations in wheat with grain used for bread making. EU 2015. FR15E7B006MC04C BIOTEK AGRICULTURE, FR GEP Unpublished	N	Corteva Agriscience
KCP 6.4/20	Treikale, O.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU LV14E7B016MN02 Latvian Plant Protection Research Centre GEP Unpublished	N	Corteva Agriscience
KCP 6.4/21	Zickart, U.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU DE14E7B016UB01C BIOCHEM AGRAR. DE GEP Unpublished	N	Corteva Agriscience
KCP 6.4/22	Zickart, U.	2015	Impact of GF-3307 and GF-3309 on beer making process – field phase. Germany 2015. DE15E7B005UB02C BioChem Agrar GmbH	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished See KCP 6.4/13 described properly by zRMS. This is the same study listed twice by the applicant, for there are two field-phase trials, both reported in the same document.		
KCP 6.5/01	Brockmann, A.	2014	GF-3307 (XDE-777 + prothiconazole 50 + 100 g as/L, EC): A Seedling Emergence and Seedling Growth Test with ten Non Target Plant Species, GLP Terrestrial Non Target Plants (based on OECD Guideline 208) – Europe 2014 AC/DOW/14/03 Agro-check GLP Unpublished	N	Corteva Agriscience
KCP 6.5/02	Brockmann, A., Teresiak H.	2014	GF-3307 (XDE-777 + prothioconazole 50 + 100 g as/L, EC): A Vegetative Vigour Test with ten Non Target Plant Species, GLP Terrestrial Non Target Plants (based on OECD Guideline 227) – Europe 2014 AC/DOW/14/04 Agro-check GLP Unpublished	N	Corteva Agriscience
KCP 6.5/03	Topham, D.	2016	Dow AgroSciences Clean Out Report for Fungicides: GF-2925, GF-3307, GF-3308, GF-3309, GF-3312 LES 10126 Amega Sciences Unpublished	N	Corteva Agriscience
3.6/05 Other/ special studies	Butler Ellis C, Lane A, Tuck C	2016	CHARACTERISATION OF SPRAYS AND VISUALISATION OF DEPOSITS ON SURFACES Report S0140/1 Silsoe Spray Applications Unit Limited Non GEP Unpublished	N	Corteva Agriscience
					Corteva Agriscience
3.6/06 Other/ special studies	Downey, S.	2015	EU 2015: Efficacy of GF-3307 and GF-3309 for the control of cereal diseases using LD Nozzles compared to std. Flat Fan nozzles at different water volumes GB15E7B030SD01 Dow AgroSciences Ltd, UK GEP	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
3.6/07 Other/ special studies	Fairfax, M.	2015	EU 2015: Efficacy of GF-3307 and GF-3309 for the control of cereal diseases using LD Nozzles compared to std. Flat Fan nozzles at different water volumes GB15E7B030MF01 Dow AgroSciences Ltd, UK GEP Unpublished	N	Corteva Agriscience
3.6/04 Other/ special studies	Lane A, O'Sullivan C, Butler Ellis C	2017	Characterising deposits on plants for a range of formulations and application conditions Report S0181 Silsoe Spray Applications Unit Limited Non GEP Unpublished	N	Corteva Agriscience
3.6/01 Other/ special studies	Mathieson, T.	2016	Rainfast studies to compare the rainfast ability of new Dow AgroSciences fungicide formulations to current market fungicides 2038583 Dow AgroSciences LLC Unpublished	N	Corteva Agriscience
3.6/02 Other/ special studies	Rohr, H.	2014	Efficacy of GF-3307 and GF-2925 for the control of cereal diseases using LD Nozzles compared to Flat Fan nozzles at different water volumes. EU 2014 DE14E7B017UB01C Agrartest, DE GEP Unpublished	N	Corteva Agriscience
3.6/03 Other/ special studies	Vriesman, M, Leader, A, Diehl, C., Wineglass, A., Loeffler, J.	2019	Rainfastness performance of Dow agrosociences™ products GF-3308 and GF-3307, and Proline, and Aviator Xpro for control of barley scald (<i>Rhynchosporium secalis</i>) on barley following a preventive application and a simulated 30 mm rain 30 minutes or 1 hour after application Dow agrosociences internal report Non GEP/non GLP Unpublished	N	Corteva Agriscience
KCP 6.2/232	Sawinska, Z	2022	Dose response of Adavelt (GF-3840) applied as a single timing for control of SEPTSP on triticale in Europe, PL22G1C013F-ASF08C Non GLP Unpublished	N	Corteva Agriscience

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/233	Barbara Ciupa-Wyleżałek	2021	To determine the efficacy of rates of Adavelt (GF-3840) when applied as a single timing for the control of SEPTSP on triticale, Europe EA21G1C004F-DPF006 Non GLP Unpublished	N	Corteva Agriscience
KCP 6.2/234	Barbara Ciupa-Wyleżałek	2021	Efficacy of new ratio fenpicoxamide + prothioconazole GF-4637 (40 + 120) against key diseases in triticale, CEEU, 2021 EA21E7B055F-DPF048 Non GLP Unpublished	N	Corteva Agriscience

List of data submitted by the applicant and , evaluated by zRMS, but not relied on (studies not used in the dRR text nor in the BAD text, and absent from their Appendices) – 22 trials

Data point*	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1	Rošapil J.	2015	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of SEPTTR in wheat. EU CZ, 2015. CZ15E7B017PV01C ZZS Kujavy GEP Unpublished	N	DAS
KCP 6.1	Kolaříková K.	2015	Efficacy and dose response of different XDE-777 formulations for control of SEPTTR in spring wheat. EU CZ, 2015. CZ15E7B072PV02C VYZKUMNY USTAV PICNINARSKY, SPOL. S R.O. TROUBSKO. CZ, 664 41 TROUBSKO, CZECH REPUBLIC GEP Unpublished	N	DAS
KCP 6.1	Rohr J.	2015	What is the MED (minimum effective dose that delivers 80%+ control) of GF-3307 and GF-3309 against SEPTTR and other foliar disease when compared to the reference product Aviator Xpro in Maratime EPPO countries? DE15E7B017UB01C Agrartest GmbH GEP Unpublished	N	DAS
KCP 6.1	Zoller P.	2015	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of SEPTTR in wheat. EU CZ, 2015. DE15E7B017UB02C Eurofins GEP Unpublished	N	DAS
KCP 6.1	Nistrup Jørgensen L.	2015	WHAT IS THE EFFICACY OF XDE-777 PRODUCTS AGAINST PUCCST SPLIT APPLICATION IN NORTHERN EUROPEAN CONDITIONS? DK15E7B039MN01C Aarhus University Department of Agroecology	N	DAS

Data point*	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.1	Nistrup Jørgensen L.	2015	WHAT IS THE EFFICACY OF XDE-777 PRODUCTS AGAINST PUCST AS A SINGLE APPLICATION IN NORTHERN EUROPEAN CONDITIONS? DK15E7B020MN03C Aarhus University Department of Agroecology GEP Unpublished	N	DAS
KCP 6.1	Grisel J.	2014	Efficacy of XDE-777 + prothioconazole and XDE-777 + pyraclostrobin EC formulations for control of PUCST in wheat: EU SZ, 2014. FR14E7B009JG02 DAS GEP Unpublished	N	DAS
KCP 6.1	LUNZENFICHTER D.	2014	EFFICACY OF XDE-777 + PROTHIOCONAZOLE AND XDE-777 + PYRACLOSTROBIN EC FORMULATIONS FOR CONTROL OF PUCST IN WHEAT: EU SZ, 2014. FR14E7B009MC06C SynTech Research France S.A.S GEP Unpublished	N	DAS
KCP 6.1	LUNZENFICHTER D.	2014	EFFICACY OF XDE-777 + PROTHIOCONAZOLE AND XDE-777 + PYRACLOSTROBIN EC FORMULATIONS FOR CONTROL OF PUCST IN WHEAT: EU SZ, 2014. FR14E7B009MC07C SynTech Research France S.A.S GEP Unpublished	N	DAS
KCP 6.1	LEVASSEUR T.	2014	Efficacy and dose response of different XDE-777 + prothioconazol/pyraclostrobin EC formulations for control of PUCST in wheat FR14E7B011MC03C SARL PHYLIAE, 3 impasse de la voie romaine, F76190 VEAUVILLE LES BAONS GEP Unpublished	N	DAS

Data point*	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1	Varret F.	2014	Efficacy and dose response of different XDE-777 + prothioconazole / pyraclostrobin EC formulations for control of foliar diseases in wheat, Europe 2014. FR14E7B015MC05C STAPHYT – 23 Route de Moeuvres – 62860 INCHY EN ARTOIS- France GEP Unpublished	N	DAS
KCP 6.1	LEVASSEUR T.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat FR14E7B015MC13C SARL PHYLIAE, 3 impasse de la voie romaine, F76190 VEAUVILLE LES BAONS GEP Unpublished	N	DAS
KCP 6.1	Colombo R.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU SZ. 2014. FR14E7B015RC02 Dow AgroSciences, France GEP Unpublished	N	DAS
KCP 6.1	Fisher S.	2014	WHAT IS THE COMMERCIALY ACCEPTABLE RATE OF XDE-777 MIXTURES FOR CONTROL OF PUCST IN EUROPE?. EU 2014 GB14E7B011EB01C Armstrong Fisher Ltd GEP Unpublished	N	DAS
KCP 6.1	Kovalova I.	2015	WHAT IS THE EFFICACY OF XDE-777 FORMULATIONS AGAINST PUCST COMPARED TO REFERENCE STANDARDS? GB15E7B015JK01 Dow AgroSciences, UK GEP Unpublished	N	DAS
KCP 6.1	Fisher S.	2014	WHAT IS THE COMMERCIALY ACCEPTABLE RATE OF XDE-777 MIXTURES FOR CONTROL OF PUCST IN EUROPE? EU 2014 GB14E7B011EB02C	N	DAS

Data point*	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Armstrong Fisher Ltd GEP Unpublished		
KCP 6.1	Elias N.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014 GB14E7B028NE01 Dow AgroSciences, UK GEP Unpublished	N	DAS
KCP 6.1	Packwood J.	2015	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of SEPTTR in wheat. EU CZ, 2015. IE15E7B017EB02C EUROFINS AGROSCIENCE SERVICES LTD, UK, SLADE LANE, WILSON, MELBOURNE, DERBYSHIRE, DE73 8AG. UNITED KINGDOM GEP Unpublished	N	DAS
KCP 6.1	Akos Biro	2015	Efficacy and dose response of different XDE-777 formulations for control of SEPTTR in spring wheat. EU CZ, 2015. HU15E7B072AB01 DOW AGROSCIENCES DEVELOPMENT STATION. HU SZOLNOK STATION, VIZPART KORUT 32, H-5000 SZOLNOK, HUNGARY GEP Unpublished	N	DAS
KCP 6.1	Pet I.	2015	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of SEPTTR in wheat. EU CZ SE EPPO, 2015. RO15E7B040AP03C Eurofins Agroscience Services S.R.L.GEP Unpublished	N	DAS
KCP 6.1	Lise Nistrup Jørgensen	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ. 2014. DK14E7B028MN01C Aarhus University Department of Agroecology GEP	N	DAS

Data point*	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.1	Christian Touche	2017	Dose response of GF-3307 (DE-777+prothioconazole) for the control of foliar diseases in barley Europe 2017. FR17E7B042MC01C STAPHYT – 23 Route de Moeuvres – 62860 INCHY EN ARTOIS- France GEP Unpublished	N	DAS

*All studies assigned to KCP 6.1 by zRMS only, based on their content; none of them had been assigned to any dRR section by the applicant – the studies were submitted but were not used while producing this dRR

List of data evaluated by zRMS but not relied on (studies withdrawn by the applicant as the result of the dRR update in May 2022) - 31 preliminary trials and 4 efficacy trials)

Data point (acc. to dossier before the update)	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/01	Bounds, P.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of SEPTTR in Europe. 2013 GB13E7B022SE01C ADAS UK Ltd GEP Unpublished	N	DAS
KCP 6.1/02	Boutrais, J-M.	2012	What is the minimum effective dose XR-777 (GF-2800) + Prothioconazole for control of PUCST in winter wheat SZ, CZ, NZ 2012. FR12E7B014MC03C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/03	Cailliau, M.	2012	Evaluation of DE-777 (GF-2800) applied straight and in mixture with prothioconazole (GF-2979) against SEPTTR in wheat, Europe 2012 FR12E7B013MC02C Phyliae, FR GEP Unpublished	N	DAS
KCP 6.1/04	Cailliau, M.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of SEPTTR in Europe. 2013 FR13E7B022MC01 Dow AgroSciences, FR GEP Unpublished	N	DAS
KCP 6.1/05	Cailliau, M.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of SEPTTR in Europe. 2013 FR13E7B022MC03C Phyliae, FR GEP Unpublished	N	DAS
KCP 6.1/07	Crestani, D.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control PUCCRT in winter wheat.	N	DAS

Data point (acc. to dossier before the update)	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Europe 2012 IT12E7B015DC01 Dow AgroSciences, Italia GEP Unpublished		
KCP 6.1/08	Donner, M.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of SEPTTR in Europe. 2013 DE13E7B022DD01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/09	Donner, M.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control PUCCRT in winter wheat. Europe 2012 DE12E7B015DD01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/10	Downey, S	2012	What is the minimum effective dose XR-777 (GF-2800) + Prothioconazole for control of PUCST in winter wheat SZ, CZ, NZ 2012. GB12E7B014SD01 Dow AgroSciences, UK GEP Unpublished	N	DAS
KCP 6.1/11	Fisher, S.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of PUCST in Europe. 2013 GB13E7B028SE01C Armstrong Fisher Ltd, UK GEP Unpublished	N	DAS
KCP 6.1/12	Fraser, J.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of SEPTTR in Europe. 2013 GB13E7B022JF01 Dow AgroSciences, UK GEP	N	DAS

Data point (acc. to dossier before the update)	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Unpublished		
KCP 6.1/13	Grisel, J.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control Puccin on winter wheat. Europe 2012 FR12E7B015JG02 Dow AgroSciences, FR GEP Unpublished	N	DAS
KCP 6.1/14	Kildea, S.	2012	Evaluation of DE-777 (GF-2800) applied straight and in mixture with prothioconazole (GF-2979) against SEPTTR in wheat, Europe 2012 IE12E7B013SE02C Teagasc GEP Unpublished	N	DAS
KCP 6.1/15	Litt, M.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control Puccin on winter wheat. Europe 2012 DE12E7B015ML01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/16	Lunzenfichter, D.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control Puccin on winter wheat. Europe 2012 FR12E7B015MC05C SRF, FR GEP Unpublished	N	DAS
KCP 6.1/21	Nistrup Jørgensen, L.	2012	Evaluation of DE-777 (GF-2800) applied straight and in mixture with prothioconazole (GF-2979) against SEPTTR in wheat, Europe 2012 DK12E7B013MN01C Aarhus University - Flakkebjerg GEP Unpublished	N	DAS
KCP 6.1/22	Nistrup Jørgensen, L.	2012	What is the minimum effective dose XR-777 (GF-2800) + Prothioconazole for control of Puccin on winter wheat SZ, CZ, NZ 2012.	N	DAS

Data point (acc. to dossier before the update)	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			DK12E7B014MN01C Aarhus University - Flakkebjerg GEP Unpublished		
KCP 6.1/23	Nistrup Jørgensen, L.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of Puccst in Europe. 2013 DK13E7B028MN01C DIAS - Danish Institute of Agricultural Sciences GEP Unpublished	N	DAS
KCP 6.1/26	Pitiot, S.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control Puccrt in winter wheat. Europe 2012 FR12E7B015MC04C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/27	Pitiot, S.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of Puccrt in Europe: 2013 FR13E7B025MC02C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/28	Pitiot, S.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of Puccst in Europe. 2013 FR13E7B028MC01C Anadiag France GEP Unpublished	N	DAS
KCP 6.1/29	Richard, C.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control Puccrt in winter wheat. Europe 2012 FR12E7B015CR01 Dow AgroSciences, FR GEP Unpublished	N	DAS

Data point (acc. to dossier before the update)	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.1/30	Ridgeway, J.	2012	Evaluation of DE-777 (GF-2800) applied straight and in mixture with prothioconazole (GF-2979) against SEPTTR in wheat, Europe 2012 GB12E7B013SE01C Eurofins Agroscience Services Ltd, UK GEP Unpublished	N	DAS
KCP 6.1/31	Ridgeway, J.	2012	What is the minimum effective dose XR-777 (GF-2800) + Prothioconazole for control of Puccst in winter wheat SZ, CZ, NZ 2012. GB12E7B014SE01C Eurofins Agroscience Services Ltd, UK GEP Unpublished	N	DAS
KCP 6.1/32	Rohr, J.	2012	Evaluation of DE-777 (GF-2800) applied straight and in mixture with prothioconazole (GF-2979) against SEPTTR in wheat, Europe 2012 DE12E7B013UB01C Agrartest, DE GEP Unpublished	N	DAS
KCP 6.1/33	Schnieder, F.	2012	Evaluation of DE-777 (GF-2800) applied straight and in mixture with prothioconazole (GF-2979) against SEPTTR in wheat, Europe 2012 DE12E7B013FS01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/34	Schulz, T.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control Puccrt in winter wheat. Europe 2012 DE12E7B015TS01 Dow AgroSciences, DE GEP Unpublished	N	DAS
KCP 6.1/35	Stephan, A.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of SEPTTR in Europe. 2013 DE13E7B022AS01 Dow AgroSciences, DE	N	DAS

Data point (acc. to dossier before the update)	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GEP Unpublished		
KCP 6.1/36	Sumner, K.	2012	What is the minimum effective dose XR-777 (GF-2800) + Prothioconazole for control of PuccST in winter wheat SZ, CZ, NZ 2012. GB12E7B014KS01 Dow AgroSciences, UK GEP Unpublished	N	DAS
KCP 6.1/37	Thibault, A.	2012	What is efficacy of DE-777 (GF-2800)+ Prothioconazole (GF-2979) for control PuccRT in winter wheat. Europe 2012 FR12E7B015MC03C SRF, FR GEP Unpublished	N	DAS
KCP 6.1/38	Varret, F.	2013	Studies to find the most effective formulations and dose rate of DE-777 + Prothioconazole for control of SEPTTR in Europe. 2013 FR13E7B022MC02C Staphyt GEP Unpublished	N	DAS
KCP 6.2/54	Gazuska, A.	2014	Efficacy and dose response of different XDE-777 + Prothioconazole/pyraclostrobin EC formulations for control of foliar diseases in wheat. EU CZ, . 2014. PL14E7B014AS02C Ior Sosnicowice, PL GEP Unpublished	N	DAS
KCP 6.2/84	Mills, R.	2019	Effective dose of GF-3307 (Inatreq+prothioconazole) for the control of foliar diseases in barley. CZ/MAR Zone – 2018. GB18E7B007EB02C Cropworks Ltd GEP Unpublished	N	DAS
KCP	Stephan, A.	2020	Efficacy and dose response of XDE-481 EC (GF-4480) and SC (GF-4505 + GF-4493) on <i>Puccinia striiformis</i>	N	DAS

Data point (acc. to dossier before the update)	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
6.2/192			and other key diseases in triticales. EU 2020 EA20F9B007F-DPE012 Dow AgroSciences GEP Unpublished		
KCP 6.2/232	Zoller, P.	2016	What is the minimum effective dose of GF-3307, GF-3309 and GF-3308 against DTR under NZ conditions? DE16E7B004UB02C Eurofins Agroscience Services GEP Unpublished	N	DAS

Trials listed by the applicant but not submitted and not relied on

KCP 6.4/15	Tartier, J.	2014	Selectivity of XDE-777 + Prothioconazole EC and XDE-777+pyraclostrobin EC in cereals, 2014. EU FR14E7B016MC02C BIOTEK AGRICULTURE. FR GEP Unpublished	N	Corteva Agriscience
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