

REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: ADM.03503.F.1.A

Product name(s): See part A.

Chemical active substance(s):

Fluxapyroxad + Prothioconazole

75 + 150 g/L

Central registration zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Sponsor: ADAMA Makhteshim Ltd

Applicant: Country organisation/representative as specified
in Part A

Submission date: April 2022, updated April 2023, June 2023

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November 2023 (final Core Assessment)

Version history

When	What
April 2022	Initial dRR - ADAMA
April 2023	Version 2 Applicant – Chapters 3.5.1 and 3.5.2 updated Chapter 3.4.4 Effects on transformation processes, updated with data tables added
June 2023	Version 3 Applicant – report LV21FETTLSS461A added to the reference list
July 2023	Initial assessment by the zRMS 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. Not agreed or not relevant information are struck through and shaded for transparency. Following the evaluation and before sending the document for commenting, all coloured highlighting was removed from the parts updated by the Applicant, for better legibility.
November 2023	Final report (Core Assessment updated following the commenting period) 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.

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

Comments of zRMS:

Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. Textual changes were done using grey highlights in the text. The parts of the text amended or added by the zRMS evaluator are highlighted in grey, whereas the parts struck off are visibly marked with the grey font.

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

Abstract by zRMS

For the reader's convenience, the main zRMS comments located in different parts of the document, referred to in the abstract, are **linked back to abstract** by their end.

Introduction

ADM.03503.F.1.A. is an EC formulation of 75 g/L fluxapyroxad and 150 g/L prothioconazole, a fungicide intended for use in control of foliar and ear diseases of cereals within the Central registration zone. The Member States concerned with the authorization are Austria, Belgium, Czech Republic, Germany, Netherlands, Ireland, Slovenia, Hungary and Slovakia.

The Data Submitted

Accompanying this dRR are **318** reports from efficacy trials, carried out in the EU Central and North zones, the latter including 8 trials from DK, SE, LV and LT (EPPO Maritime and North-Eastern zones). Trials include winter wheat (166), winter barley (111), spring barley (10), winter rye (11) and winter triticale (19). Out of the 317 trials, **37 have been excluded** from the assessment by the applicant for the reasons given in 4 respective tables in the BAD: most often low level of, or no infection; these trials are nevertheless submitted, as many of them have shown useful in selectivity assessment.

As the result, the data set used in the efficacy evaluation includes **281 trials**: 150 in winter wheat, 93 in winter barley, 9 in spring barley, 10 in winter rye and 19 in winter triticale (see also Table 3.2-7).

The zRMS [comments](#) on the applicant's trial design strategy.

Preliminary trials

[Co-formulation comment](#).

[Ratio comment](#).

Minimum Effective Dose

Based on the set of submitted trials the dose rate of 1,25 L/ha of the ADM.03503.F.1.A. should be considered as the minimum effective dose. For Poland, Hungary, Slovenia and Slovakia a dose rate **range** is requested by the applicant, of 1.00 - 1.25 L/ha. The issue is discussed by the zRMS in light of the submitted data in the commenting box following that chapter: [zRMS comments on MED](#) .

Efficacy:

The concise information on the level of acceptance of particular uses is given as usually in the GAP table. The justification and other details can be found in four commenting boxes referred to by the links below. All the commenting boxes are **linked** to one another, as well as back to this abstract.

[WHEAT, BARLEY, RYE, TRITICALE](#)

Please note, that where a particular use is marked blue in the GAP table, it means that taking individual decision on that use by the respective cMS is welcome. It should not be understood as an off-loading, of the decision-taking, by the zRMS onto the cMS. Instead, it aims at allowing the cMSs to take decisions different from that taken by zRMS for their own country, in recognition of the cMSs' different national requirements or preferences. Bearing that in mind, zRMS has discussed, in the commenting boxes, any doubtful issues, highlighting positive efficacy results where relevant, while also sharing with cMSs the reasons for which taking other decisions may be justified in different zones.

In case of the draft Registration Report there is still time for any cMS to express their view and argue, in favour or against the authorization in their country. That is why the zRMS is kindly asking the cMSs to not

only take their decisions, but also to share the underlying information with the zRMS PL, within the commenting period framework. Only then will the zRMS be able to complete the GAP table unambiguously, in the final Registration Report, for all the EPPO zones and for all the concerned Member States, for which the present dossier has been submitted.

Selectivity and yield data from the efficacy trials

Phytotoxicity symptoms have been observed in none of the efficacy trials carried out in wheat, barley, rye or triticale. Consequently, no specific selectivity trials have been submitted. The yield data are included in the submitted efficacy trials and they also do not testify to any kind of detrimental effect on the yield or its quality. Therefore the non-submission of the dedicated selectivity trials or the yield data in the dRR has been accepted by zRMS based on the EPPO guideline PP 1/135 (4) *Phytotoxicity assessment*.

The Effect on Transformation Process

No effect on the transformation process has been detected. For details see the respective zRMS summaries and comments pertaining to [baking](#) and [brewing](#) process.

The Succeeding and the Adjacent Crops

No risk of phytotoxic effects for the succeeding or the adjacent crops is expected as the result of the application of ADM.03503.F.1.A at the target dose rate of 1.25 L/ha. The data referred to in support of the conclusion are quoted by the applicant from the Ecotoxicology Section. Conclusions for the adjacent crops have been accepted based on the dose-response data and the assumed drift pattern. Since succeeding crops represent lower exposure scenario compared to adjacent crops, the conclusions are valid for them either.

Resistance Risk

The theoretical estimation of resistance risk, according to the PP 1/213(3) EPPO guideline and following the method of risk quantification assumed by FRAC, points at two (three) targets of the highest combined risk of resistance to both actives of the ADM.03503.F.1.A: *B. graminis* (in both wheat and barley) and *R. collo-cygni* in barley. The risk-mitigating measures listed in the product label should include as follows:

- 1) Single application per growth season and predominant preventive use. Curative application should be avoided (in line with FRAC recommendations for **both** SDHIs and DMIs).
- 2) The assumed spraying program should contain fungicides of other MoA groups, including multi-site MoA fungicides, where possible (a number of multiple MoA fungicides have been phased out recently, including uses in cereals).
- 3) The dose rates recommended by the manufacturer must be observed and followed at all time, irrespective of the intensity of infection.
- 4) Commonly acknowledged agronomic means capable of reducing the infection levels, such as appropriate crop rotation, use of resistant cultivars and **non-reduced** soil tillage, must all be used along with the chemical protection.

The cMSs are kindly advised to incorporate content to the similar meaning in their own, national labels. More extensive information underlying the above conclusions on resistance are in the [commenting box](#) following the Resistance Risk Chapter.

Table 3.1-1: 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. (e)	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg 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	Belgium	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. <i>sp. tritici</i> , <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; Fusarium - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A C <i>Fusarium</i>
2	Belgium	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. <i>sp. hordei</i>	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
3	Belgium	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
4	Belgium	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
5	Netherlands	Winter wheat (TRZAW)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR)		-/ BBCH 30-69 spring;	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5	125-400			A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
		Spring wheat (TRZAS)		<i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis f.</i> <i>sp. tritici</i> , <i>Fusarium +microdo-</i> <i>ehium</i>	foliar, spray- ing, overall	<i>Fusarium -</i> BBCH 61-69				b) 93.75 / 187.5				C <i>Fusarium</i>
6	Netherlands	Winter bar- ley (HORVW) Spring bar- ley (HORVS)	F	<i>Rhynchosporium</i> <i>secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis f.</i> <i>sp. hordei</i>	foliar, spray- ing, overall	-/ BBCH 30- 65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
7	Netherlands	Rye (SECCW)	F	<i>Rhynchosporium</i> <i>secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spray- ing, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
8	Netherlands	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-</i> <i>repentis (DTR)</i> <i>Blumeria graminis</i>	foliar, spray- ing, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
9	Czechia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-</i> <i>repentis (DTR)</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis f.</i> <i>sp. tritici</i> , <i>Fusarium +microdo-</i> <i>ehium</i>	foliar, spray- ing, overall	-/ BBCH 30- 69 spring; <i>Fusarium -</i> BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A CA <i>Fusarium</i>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
10	Czechia	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis f. sp. hordei</i>	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
11	Czechia	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A-C
12	Czechia	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A-C
13	Germany	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis f. sp. Tritici</i> Erysiphe graminis , <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30- 69 59 spring; Fusarium - BBCH 60-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150 - 400			A
														C A Fusarium

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
14	Germany	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis</i> f. <i>sp.-hordei</i> <i>Erysiphe graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 59 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150- 400			A
15	Germany	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150- 400			A/N
16	Germany	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Blumeria graminis</i> <i>Erysiphe graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125 150- 400			A/N
17	Ireland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis</i> (DTR) <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis</i> f. <i>sp. tritici</i> , <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; <i>Fusarium</i> - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
														C <i>Fusarium</i>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
18	Ireland	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis f. sp. hordei</i>	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
19	Ireland	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
20	Ireland	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400			A
21	Poland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis f. sp. tritici</i> , <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring; Fusarium - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
22	Poland	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> in HORVW only, <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis f. sp. hordei</i>	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
23	Poland	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	N
24	Poland	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
25	Slovakia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis f. sp. tritici</i> , <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30-69 spring; Fusarium - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
														C <i>Fusarium</i>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
26	Slovakia	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis f. sp. hordei</i>	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A
27	Slovakia	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A
28	Slovakia	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A <i>P. recondita</i> , <i>B. graminis</i> C <i>Z. tritici</i> , <i>D. tritici-repentis</i>
29	Hungary	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis f. sp. tritici</i> , <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring; Fusarium - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A C <i>Fusarium</i>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
30	Hungary	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis f. sp. hordei</i>	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A
31	Hungary	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A
32	Hungary	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A <i>P. recondita</i> , <i>B. graminis</i> C <i>Z. tritici</i> , <i>D. tritici-repentis</i>
33	Slovenia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	<i>Zymoseptoria tritici</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Puccinia striiformis</i> <i>Puccinia recondita</i> , <i>Blumeria graminis f. sp. tritici</i> , <i>Fusarium + microdochium</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring; Fusarium - BBCH 61-69	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A C <i>Fusarium</i>

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use- No. (e)	Member state(s)	Crop and/ or situa- tion (crop des- tination / purpose of crop)	F, Fn, Fp n G, Gn , Gp n or I	Pests or Group of pests controlled (additionally: develop- mental stages of the pest or pest group)	Application				Application rate			PHI (day s)	Remarks: e.g. saf- ener/synergist per ha e.g. recom- mended or mandatory tank mixtures (f)	zRMS conclusion
					Method / Kind	Timing / Growth stage of crop (BBCH) & season	Max. num- ber a) per use b) per crop/ sea- son	Min. in- terval between applica- tions (days)	kg, L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/ season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/ season	Water L/ha min / max			
34	Slovenia	Winter barley (HORVW) Spring barley (HORVS)	F	<i>Rhynchosporium secalis</i> <i>Pyrenophora teres</i> <i>Ramularia collo-cygni</i> <i>Puccinia hordei</i> <i>Blumeria graminis f. sp. hordei</i>	foliar, spraying, overall	-/ BBCH 30- 65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A
35	Slovenia	Rye (SECCW)	F	<i>Rhynchosporium secalis</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A
36	Slovenia	Triticale (TTLSS)	F	<i>Zymoseptoria tritici</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Drechslera tritici-repentis (DTR)</i> <i>Blumeria graminis</i>	foliar, spraying, overall	-/ BBCH 30- 69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125- 400		Range of rates 1.0-1.25L	A <i>P. recondita</i> , <i>B. graminis</i>
														C <i>Z. tritici</i> , <i>D. tritici-repentis</i>

* 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

3.2 Efficacy data (KCP 6)

Introduction

This draft Registration Report summary supports an Article 33 submission for the authorisation of a new fungicide, ADM.03503.F.1.A. This product contains the active substances fluxapyroxad (75 g/L) and prothioconazole (150 g/L), formulated an Emulsifiable Concentrate (EC). Its intended use as a fungicide for the control of foliar and ear diseases of cereals within the Central registration zone.

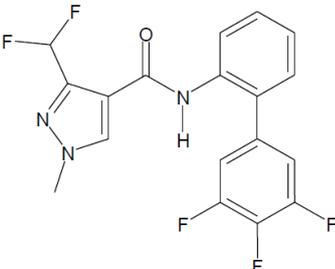
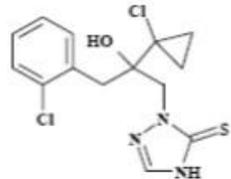
Both actives are included into Regulation (EC) No 1107/2009 (Commission Implementing Regulation (EU) 2020/2007 of 8 December 2020 amending Implementing Regulation (EU) No 540/2011 and (EU) 2021/745 of 6 May 2021 amending Implementing Regulation (EU) No 540/2011, respectively). The SANCO report for fluxapyroxad (SANCO/10692/2012 Rev 2) and for prothioconazole (SANCO/3923/07 final) are considered to provide the relevant review information or a reference to where such information can be found.

zRMS in charge of the evaluation of this preparation is Poland. Member States concerned by the authorization (cMS = concerned Member State) are Austria, Belgium, Czech Republic, Germany, Netherlands, Ireland, Slovenia, Hungary and Slovakia.

Description of active substances

Active substances properties are summarised in Table 3.2-1.

Table 3.2-1: Details of the active substances

Active substance	Fluxapyroxad	Prothioconazole
Concentration	75 g/L	150 g/L
Chemical name (IUPAC)	3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluorobiphenyl-2-yl)pyrazole-4-carboxamide	(RS)-2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2-hydroxypropyl]-2,4-dihydro-1,2,4-triazole-3- thione
Chemical name (CA)	3-(difluoromethyl)-1-methyl-N-(3',4',5'-trifluoro[1,1'-biphenyl]-2-yl)-1 <i>H</i> -pyrazole-4-carboxamide	2-[2-(1-chlorocyclopropyl)-3-(2-chlorophenyl)-2- hydroxypropyl]-1,2-dihydro-3 <i>H</i> -1,2,4-triazole-3- thione
CAS No	907204-31-3	178928-70-6
Molecular formula	C ₁₈ H ₁₂ F ₅ N ₃ O	C ₁₄ H ₁₅ Cl ₂ N ₃ O S
Molecular mass	381.30 g/mol	344.26 g/mol
Structural formula		
Chemical group	Pyrazole-4-carboxamides	Triazole
Group name	SDHI (Succinate dehydrogenase inhibitors)	DMI-fungicides (DeMethylation Inhibitors) (SBI: Class I)
Mode of action	Inhibition of succinate dehydrogenase in complex II of the mitochondrial respiratory chain FRAC Code C2 New FRAC group : Group 7	Inhibition of sterol biosynthesis in membranes FRAC Code G1 New FRAC group : Group 3
Biological action	Systemic (preventive and curative)	Curative and Protectant foliar fungicide, contact/residual with translaminar properties

Mode of action

Fluxapyroxad belongs to the carboxamide class of chemicals and its mode of action is inhibition of succinate dehydrogenase in complex II of the mitochondrial respiratory chain, which results in inhibition of spore germination, germ tubes, and mycelial growth within the fungus target species. Thus, fluxapyroxad is a SDHI fungicide with activity against a broad spectrum of plant pathogens (FRAC

Group 7). Fluxapyroxad has the same biochemical target site as fungicides like benzovindiflupyr, bixafen, boscalid, fluopyram, isofetamid, isopyrazam, penthiopyrad, penflufen, and sedaxane. Prothioconazole is a broad-spectrum synthetic fungicide of the triazolinthione family of compounds with curative, preventative and eradicated action (FRAC Group 3). It can be used as both a seed treatment and a foliar treatment. After absorption, it moves into cells of the target organisms, effecting 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 soft wheat, spring soft wheat, durum wheat), oats, rye and triticale. Prothioconazole is sold in combination with numerous other fungicides, including bixafen, spiroxamine, tebuconazole, fluoxastrobin, trifloxystrobin and fluopyram.

Description of the plant protection product

ADM.03503.F.1.A is an Emulsifiable Concentrate (EC) preparation containing 75 g/L fluxapyroxad and 150 g/L prothioconazole addressed to control foliar and ear diseases of cereals by foliar application method.

ADM.03503.F.1.A is a new co-formulated product containing fluxapyroxad and prothioconazole. In all requested countries of Central registration zone, several preparations containing fluxapyroxad or prothioconazole are currently registered on cereals. In addition, several preparation containing fluxapyroxad and triazole active substance (metconazole, mefentrifluconazole or difenoconazole) are also registered across Central registration zone.

The data presented in this dRR showed that this combination of active substances was complimentary in two ways:

i) Where one active substance was less proficient versus a target disease, the other active substance was more proficient. Thus, the combination of the two creates a robust product, with good efficacy across a range of diseases.

Crop disease manifestation is not always predictable, where one or several diseases may occur within a farmer's crop at any one time. Within the Central registration zone, it is common practice to apply multiple products / active substances in spray programmes pre-emptive of disease. The application of a robust product can be attractive to a grower.

ii) The efficacy benefit from the association of these two active substances was found to be additive in almost all instances, where the co-formulated product ADM.03503.F.1.A efficacy exceeded the efficacy of the active substances applied individually.

Table 3.2-2 summarises the spectrum known for each active substance based on the products label or the publication of the French cereals institute (Arvalis).

Table 3.2-2: Summary of spectrum for fluxapyroxad and prothioconazole^{1 2}

Active substance	Fluxapyroxad	Prothioconazole
Dose (g a.s./ha)	125	200
PUCCRT	++	++
PUCST	++	+++
LEPTNO	+++	++
SEPTTR	+++	++
PYRNTR		++
PYRNTE	++	++
RHYNSE	+++	+++
PUCCHD	++	+++
RAMUCC	+	+
FUSASP	+	+++
MONGNI		+

-	No information	++	Good efficacy
+	Medium efficacy	+++	Very good efficacy

This is also supported by the UK’s Agriculture and Horticulture Development Board (AHDB), who regularly publish “fungicide performance in cereals” within the United Kingdom. These publications, based on AHDB performance trials & other ongoing research projects are, summarised the activity of the active substances individually in the United Kingdom in 2018 (Table 3.2-3).

Table 3.2-3: Fungicide activity and performance in wheat in the United Kingdom in 2018^{3 4}

Active substance	Fluxapyroxad	Prothioconazole
ERYSGT	-	3
SEPTTR	4	3
PUCCRT	4	2
PUCST	3	4
FUSASP	-	4
ERYSGR	2	3
PYRNTE	3	3
RHYNSE	4	3
PUCCHD	3	2
RAMUCC	-	1

Control Level; 5 = highest, 1 = lowest, - = insufficient data

This clearly demonstrates that the DMI and the SDHI fungicide groups vary in their efficacy across the disease spectrum and suggests combination of prothioconazole and fluxapyroxad would either have additive efficacy or increase the spectrum of control versus the various diseases.

Moreover, the association of these two active substances is interesting for the resistance management on many pathogens with two different mode of action without cross-resistance (see section 3.3). Overall, Fluxapyroxad recommendation is to use in tank mix with a fungicide of a different mode of action in accordance with FRAC guidance.

The simplified recommendations proposed for ADM.03503.F.1.A are presented in Table 3.2-4. Further details are in the table “All intended uses” in Part B - Section 0.

For Poland, Hungary, ~~Czech Republic~~ Slovenia and Slovakia a range is requested from 1.00 L/ha up to 1.25 L/ha (see detailed GAPs).

¹ Lutte contre les maladies - Arvalis - Institut du Végétal - 2021

² PROLINE label

³ Available online at:

<https://projectblue.blob.core.windows.net/media/Default/Imported%20Publication%20Docs/IS63%20Fungicide%20activity%20and%20performance%20in%20wheat.pdf>

⁴ Available online at: <https://projectblue.blob.core.windows.net/media/Default/Imported%20Publication%20Docs/IS62%20fungicide%20activity%20and%20performance%20in%20barley.pdf>

Table 3.2-4: Simplified table of requested uses for ADM.03503.F.1.A

Uses		Member State	Maximum requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Winter wheat (TRZAW) Spring wheat (TRZAS)	Leaf spot of wheat (<i>Zymoseptoria tritici</i>) SEPTTR	AT, BE, CZ, DE, NL, IE, HU, SK, SI, PL, UK	1.25 L/ha	1 application BBCH 30-69 125 to 400 L/ha
	Brown rust of wheat (<i>Puccinia recondita</i>) PUCCRT			
	Yellow rust of wheat (<i>Puccinia striiformis</i>) PUC CST			
	Powdery mildew of wheat (<i>Blumeria graminis</i>) ERYSGT			
	Tan spot of wheat (<i>Pyrenophora tritici-repentis</i>) PYRNTR			
	<i>Fusarium</i> of wheat (<i>Fusarium</i> sp.) FUSASS FUSASP			
Head blight of wheat (<i>Microdochium nivale</i>) MONGNI				
Winter barley (HORVW) Spring barley (HORVS)	Leaf blotch of barley (<i>Rhynchosporium secalis</i>) RHYNSE	AT, BE, CZ, DE, NL, IE, HU, SK, SI, PL, UK	1.25 L/ha	1 application BBCH 30-65 125 to 400 L/ha
	Net blotch of barley (<i>Pyrenophora teres</i>) PYRNTE			
	Brown rust of barley (<i>Puccinia hordei</i>) PUCCHD			
	Powdery mildew of barley (<i>Blumeria graminis</i>) ERYSGH			
	Ramularia leaf spot of barley (<i>Ramularia collo-cygni</i>) RAMUCC			
Rye (SECCW)	Leaf blotch of rye (<i>Rhynchosporium secalis</i>) RHYNSE	AT, BE, CZ, DE, NL, IE, HU, SK, SI, PL, UK	1.25 L/ha	1 application BBCH 30-69 125 to 400 L/ha
	Brown rust of rye (<i>Puccinia recondita</i>) PUCCRE			
	Yellow rust of wheat (<i>Puccinia striiformis</i>) PUC CST			

Uses		Member State	Maximum requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)			
Triticale (TTLSS)	Leaf spot of triticale (<i>Zymoseptoria tritici</i>) SEPTTR	AT, BE, CZ, DE, NL, IE, HU, SK, SI, PL, UK	1.25 L/ha	1 application BBCH 30-69 125 to 400 L/ha
	Brown rust of triticale (<i>Puccinia recondita</i>) PUCCRE			
	Yellow rust of wheat (<i>Puccinia striiformis</i>) PUCCST			
	Powdery mildew of wheat (<i>Blumeria graminis</i>) ERYSGT			
	Tan spot of wheat (<i>Pyrenophora tritici-repentis</i>) PYRNTR			

Description of the target diseases

The list of target diseases (EPPO code and scientific name) presented in this Section 3 is available in Table 3.2-5.

Table 3.2-5: Glossary of diseases mentioned in the dossier

EPPO code	Scientific name	Common name
ERYSGH	<i>Blumeria graminis</i> f. sp. <i>hordei</i>	Powdery mildew of barley
ERYSGR	<i>Blumeria graminis</i>	Powdery mildew of cereals
ERYSGT	<i>Blumeria graminis</i> f. sp. <i>tritici</i>	Powdery mildew of wheat
FUSASS FUSASP	<i>Fusarium</i> sp.	<i>Fusarium</i> of wheat
MONGNI	<i>Microdochium nivale</i>	Head blight of wheat
PUCCHD	<i>Puccinia hordei</i>	Brown rust of barley
PUCCRE	<i>Puccinia recondita</i>	Brown rust of cereals
PUCCRT	<i>Puccinia recondita</i> f. sp. <i>triticea</i>	Brown rust of wheat
PUCCSI	<i>Puccinia striiformis</i> f. sp. <i>tritici</i>	Yellow rust of wheat
PUCCST	<i>Puccinia striiformis</i>	Yellow rust of cereals
PYRNTE	<i>Pyrenophora teres</i>	Net blotch
PYRNTR	<i>Pyrenophora tritici-repentis</i>	Tan spot
RAMUCC	<i>Ramularia collo-cygni</i>	Ramularia leaf spot of barley
RHYNSE	<i>Rhynchosporium secalis</i>	Leaf blotch of barley
SEPTTR	<i>Zymoseptoria tritici</i>	Leaf spot of wheat

Description of crops

Table 3.2-6 presents the status of each crop and each use in the zonal Rapporteur Member State and concerned Member States.

Table 3.2-6: Major / minor status of intended uses for zRMS and all cMS in the Central registration zone

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
Winter wheat (TRZAW) Spring wheat (TRZAS)	AT, BE, CZ, DE, NL, IE, HU, SK, SI, PL, UK	-	<i>Zymoseptoria tritici</i> (SEPTTR)	AT, BE, CZ, DE, NL, IE, HU, SK, SI, PL, UK	-
			<i>Puccinia recondita</i> (PUCCRT)		
			<i>Puccinia striiformis</i> (PUCCST)		
			<i>Blumeria graminis</i> (ERYSGT)		
			<i>Fusarium</i> sp. (FUSASS FUSASP)	AT, BE, CZ, DE, NL, IE, HU, SK, SI, PL	UK
<i>Pyrenophora tritici-repentis</i> (PYRNTR)	AT, CZ, DE, HU, SK, SI, PL	BE, NL, IE, UK			

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	Minor		Major	Minor
			<i>Microdochium nivale</i> (MONGNI)	UK	AT, BE, CZ, DE, NL, IE, SI , HU, SK, PL
Winter barley (HORVW) Spring barley (HORVS)	AT, BE, CZ, DE, IE, SI, HU, SK, PL, UK, NL	NL	<i>Rhynchosporium secalis</i> (RHYNSE)	AT, BE, CZ, DE, IE, SI, HU, SK, PL, UK	NL
			<i>Pyrenophora teres</i> (PYRNTE)		
			<i>Puccinia hordei</i> (PUCCHD)		
			<i>Ramularia collo-cygni</i> (RAMUCC)		
			<i>Blumeria graminis</i> (ERYSGH)		
Rye (SECCW)	AT, CZ, DE, PL	BE, IE, NL, SI, HU, SK, UK	<i>Rhynchosporium secalis</i> (RHYNSE)	AT, BE, CZ, DE, IE, SI, HU, SK, PL, UK	NL
			<i>Puccinia recondita</i> (PUCCRE)		
			<i>Puccinia striiformis</i> (PUC CST)		
Triticale (TTLSS)	AT, CZ, DE, PL	BE, IE, NL, SI, HU, SK, UK	<i>Zymoseptoria tritici</i> (SEPTTR)	AT, BE, CZ, DE, IE, SI, HU, SK, PL, UK	NL
			<i>Puccinia recondita</i> (PUCCRE)		
			<i>Puccinia striiformis</i> (PUC CST)		
			<i>Pyrenophora tritici-repentis</i> (PYRNTR)		
			<i>Blumeria graminis</i> (ERYSGT)		

Compliance with the Uniform Principles

The overall assessment was performed according to the uniform principles.

This dossier supplied is 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 1107/2009. 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 interest of the association, the minimum effective dose, the efficacy at the proposed label rate, 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 abundant. The primary guidelines used were the following:

- PP1/26 Foliar and ear diseases on cereals
- ~~PP1/78 Root, stem, foliar and pod diseases of rape~~
- PP 1/225 Minimum effective dose
- 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
- CEB, Méthode N° 185, Qualité malt bière (2012)
- CEB, Méthode N°218, Méthode d'études pour l'évaluation de la qualité du blé et produits de transformation (2012)
- CRD (PSD) Efficacy Guideline 302 "Cleaning Application Equipment – Efficacy Aspects" (September 2005)

Information on trials submitted (3.1 Efficacy data)

Data to confirm efficacy claims for applications of ADM.03503.F.1.A were taken from a set of **231 efficacy trials** carried out **from 2019 to 2021** in Austria (2 trials), Belgium (2 trials), Czech Republic (12 trials), Germany (55 trials), The Netherlands (2 trials), Ireland (10 trials), Poland (46 trials), Hungary (37 trials), Romania (39 trials) and Slovakia (26 trials) on cereals.

In addition, to complete the data package on wheat and barley, **79 efficacy trials** performed **from 2019 to 2021** in the Maritime EPPO climatic zone (as defined by EPPO standard PP 1/241(2)) from France (47 trials) and the United Kingdom (32 trials) are also provided.

Moreover, to complete the data package on rye and triticale, **8 efficacy trials** performed **from 2020 to 2021** in the Maritime and the Northeast EPPO climatic zones (as defined by EPPO standard PP 1/241(2)) from Denmark (1 trial), Sweden (2 trials), Latvia (4 trials) and Lithuania (1 trial) are also provided.

The trials were undertaken by contractors' test facilities, all of which follow the EPPO guidelines and have Official Recognition status for undertaking efficacy trials in accordance with the principles of Good Experimental Practice (GEP).

Table 3.2-7 presents a summary of all efficacy trials provided in the BAD.

Table 3.2-7: Efficacy trials - Repartition distribution of trials (valid trials number per use)

Crop	EPPO Climatic zone	Country	Year			Total
			2019	2020	2021	
Winter Wheat TRZAX TRZAW	Maritime	Austria	-	2 (2)	-	2 (2)
		Belgium	-	-	1 (1)	1 (1)
		Czech Republic	-	4 (4)	2 (2)	6 (6)
		Germany	8 (8)	11 (11)	11 (11)	30 (30)
		Ireland	-	1 (1)	2 (1)	3 (2)
		Netherlands	-	2 (2)	-	2 (2)
		United Kingdom	3 (3)	7 (7)	5 (5)	15 (15)
	France	8 (8)	11 (11)	7 (7)	26 (26)	
	Northeast	Poland	-	12 (12)	12 (9)	24 (21)
	Southeast	Hungary	1 (1)	13 (5)	7 (4)	21 (10)
Romania		2 (2)	10 (10)	10 (9)	22 (21)	
Slovakia		1 (1)	8 (8)	5 (5)	14 (14)	
Total			23 (23)	81 (73)	62 (54)	166 (150)
Barley HORVX HORVW 111(93) HORVS 10 (9)	Maritime	Belgium	-	-	1 (1)	1 (1)
		Czech Republic	1 (1)	2 (2)	2 (2)	5 (5)
		Germany	3 (3)	8 (8)	7 (7)	18 (18)
		Ireland	-	4 (2)	3 (3)	7 (5)
		United Kingdom	3 (2)	7 (6)	7 (5)	17 (13)
	France	4 (3)	10 (9)	7 (7)	21 (19)	
	Northeast	Poland	-	8 (8)	8 (7)	16 (15)
	Southeast	Hungary	-	8 (1)	2 (1)	10 (2)
		Romania	1 (1)	6 (5)	7 (7)	14 (13)
Slovakia		1 (1)	6 (5)	5 (5)	12 (11)	
Total			13 (11)	59 (46)	49 (45)	121 (102)
Winter Rye SECCS SECCW	Maritime	Germany	-	2 (2)	2 (2)	4 (4)
	Northeast	Poland	-	1 (1)	1 (1)	2 (2)
		Lithuania	-	1 (1)	-	1 (1)
		Latvia	-	-	1 (1)	1 (1)
	Southeast	Hungary	-	1 (0)	-	1 (0)
Romania	-	-	2 (2)	2 (2)		
Total			-	5 (4)	6 (6)	11 (10)
Winter Triticale TTLSS TTLWI	Maritime	Czech Republic	-	1 (1)	-	1 (1)
		Germany	-	2 (2)	1 (1)	3 (3)
		Denmark	-	-	1 (1)	1 (1)
		Sweden	-	2 (2)	-	2 (2)
	Northeast	Poland	-	2 (2)	2 (2)	4 (4)
		Lithuania	-	1 (1) 0	-	1 (1) 0
		Latvia	-	1 (1)	2 (2)	3 (3)
	Southeast	Hungary	-	4 (3)	1 (1)	5 (4)
		Romania	-	-	1 (1)	1 (1)
Total			-	13 (12) 12 (11)	8 (8)	21 (20) 20 (19)
Number of trials					318 (281) 318 (281)	

An overview of available trials is provided in Table 3.2-8. To cover the largest spectrum of climatic and soil conditions and crop varieties, the efficacy trials were located in the Maritime, the Northeast and the

Southeast EPPO climatic zones on the main of the crops production in Czech Republic, Germany, The Netherlands, Belgium, Ireland, Poland, Hungary, Romania, Slovakia, the United Kingdom and France.

Table 3.2-8: Efficacy trials - Presentation of trials

Crop(s) ⁽¹⁾	Target(s) assessed	EPPO climatic zone ⁽²⁾	Country	Year	Type of trial ⁽³⁾	No. of trials	GEP, non-GEP, official ⁽⁴⁾
Wheat	Wheat diseases	Maritime	Austria	2020	MED + E + S + Y + Q	2	GEP
			Belgium	2021	MED + E + S + Y + Q	1	
			Czech Republic	2020-2021	P + MED + E + S + Y + Q	2	
				2020-2021	MED + E + S + Y + Q	4	
			Germany	2019	P	2	
				2019-2021	P + MED + E + S + Y + Q	7	
				2020-2021	MED + E + S + Y + Q	21	
			Ireland	2020-2021	P + MED + E + S + Y + Q	2	
				2021	S + Y + Q	1	
			Netherlands	2020	P + MED + E + S + Y + Q	1	
				2020	MED + E + S + Y + Q	1	
			United Kingdom	2019	P	1	
				2019	P + MED + E + S	1	
				2019	P + MED + E + S + Y	1	
				2020-2021	P + MED + E + S + Y + Q	2	
				2020-2021	MED + E + S + Y + Q	10	
			France	2019	P	3	
				2020	P + MED + E + S	1	
		2019-2021		P + MED + E + S + Y + Q	8		
		2020-2021		MED + E + S	2		
		2020-2021		MED + E + S + Y + Q	12		
		Northeast	Poland	2020-2021	P + MED + E + S + Y + Q	3	
				2020-2021	MED + E + S + Y + Q	18	
				2021	S + Y + Q	3	
		Southeast	Hungary	2019	P	1	
				2020-2021	MED + E + S + Y + Q	9	
				2020-2021	S + Y + Q	11	
			Romania	2019-2021	P + MED + E + S + Y + Q	6	
				2020-2021	MED + E + S + Y + Q	15	
				2021	S + Y + Q	1	
Slovakia	2019-2021		P + MED + E + S + Y + Q	4			
	2020-2021	MED + E + S + Y + Q	10				

Crop(s) ⁽¹⁾	Target(s) assessed	EPPO climatic zone ⁽²⁾	Country	Year	Type of trial ⁽³⁾	No. of trials	GEP, non-GEP, official ⁽⁴⁾	
Barley	Barley diseases	Maritime	Belgium	2021	P + MED + E + S + Y + Q	1	GEP	
			Czech Republic	2019	P	1		
				2020-2021	P + MED + E + S + Y + Q	1		
				2020-2021	MED + E + S + Y + Q	3		
			Germany	2019-2021	P + MED + E + S + Y + Q	10		
				2021	MED + E + S	1		
				2020-2021	MED + E + S + Y + Q	7		
			Ireland	2020-2021	P + MED + E + S + Y + Q	5		
				2020	S + Y + Q	2		
			United Kingdom	2019	P	1		
				2020	P + MED + E + S + Y	1		
				2019-2021	P + MED + E + S + Y + Q	4		
				2020	MED + E + S + Y	1		
				2020-2021	MED + E + S + Y + Q	6		
			France	2019-2021	S + Y + Q	4		
				2019	P	1		
				2019-2020	P + MED + E + S	3		
				2019-2021	P + MED + E + S + Y + Q	8		
				2020	MED + E + S	1		
			Northeast	Poland	2020-2021	P + MED + E + S + Y + Q		7
					2020-2021	MED + E + S + Y + Q		8
					2021	S + Y + Q		1
			Southeast	Hungary	2020-2021	MED + E + S + Y + Q		2
					2020-2021	S + Y + Q		8
Romania	2019-2021	P + MED + E + S + Y + Q		7				
	2020-2021	MED + E + S + Y + Q		6				
	2020	S + Y + Q		1				
Slovakia	2019-2021	P + MED + E + S + Y + Q		6				
	2020-2021	MED + E + S + Y + Q		5				
	2020	S + Y + Q	1					
Rye	Rye disease	Maritime	Germany	2020-2021	P + MED + E + S + Y + Q	4	GEP	
		Northeast	Poland	2020-2021	P + MED + E + S + Y + Q	2		
			Latvia	2020	MED + E	1		
			Lithuania	2020	MED + E	1		
		Southeast	Hungary	2020	S	1		
			Romania	2021	P + MED + E + S + Y +	2		

Crop(s) ⁽¹⁾	Target(s) assessed	EPPO climatic zone ⁽²⁾	Country	Year	Type of trial ⁽³⁾	No. of trials	GEP, non-GEP, official ⁽⁴⁾
					Q		
Triticale	Triticale disease	Maritime	Czech Republic	2020	MED + E + S + Y + Q	1	GEP
			Germany	2020-2021	MED + E + S + Y + Q	3	
			Denmark	2021	MED + E	1	
			Sweden	2020	MED + E	2	
		Northeast	Poland	2020-2021	MED + E + S + Y + Q	4	
			Latvia	2020-2021	MED + E	3	
		Southeast	Hungary	2020-2021	MED + E + S + Y + Q	3 4	
				2020	S	1	
			Romania	2021	MED + E + S + Y + Q	1	
TOTAL:						317 318	

⁽¹⁾ According to the GAP table.

⁽²⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽³⁾ P = preliminary trial, MED = minimum effective dose, E = efficacy trial, S = Phytotoxicity assessment, Y: Harvested trial, Q: Quality parameters measures (moist content, specific weight and/or Thousand grain weight).

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

Several maps showing this **Repartition distribution** in Europe of efficacy trials are presented Figure 3.2-1 (wheat), Figure 3.2-2 (barley), Figure 3.2-3 (rye), and Figure 3.2-4 (triticale).

Table 3.2-9 presents the plant protection products used as reference standard and the dose rates applied in the efficacy trials.

In trials carried out in 2019, the product code ADM.3503.F.1.A was used. This product is identical to ADM.03503.F.1.A.

In all efficacy trials, the efficacy of ADM.03503.F.1.A was compared to the efficacy of reference standards containing fluxapyroxad and metconazole at 125+90 g a.s./ha under different tradenames. This reference standard used to justify the efficacy of ADM.03503.F.1.A, are grouped under a single tradename: LIBRAX. In countries where this transversal reference standard is not registered, a local reference standard was also used to validate the trial. To simplify this dRR, this local reference standard was not used, but it was available in each trial report.

In some efficacy trials, the efficacy of ADM.03503.F.1.A was also compared to the efficacy of the reference standard containing only fluxapyroxad at 93.75 g a.s./ha, to understand the benefit of combining 187.5 g a.s./ha prothioconazole with fluxapyroxad 93.75 g a.s./ha in the co-formulated product, ADM.03503.F.1.A. The various fluxapyroxad based products used in the trials have been grouped under a single tradename: IMTRES.

In some efficacy trials, the efficacy of ADM.03503.F.1.A was compared to the efficacy of reference standards containing only prothioconazole at 187.5 g a.s./ha to understand the benefit of combining prothioconazole 187.5 g a.s./ha with fluxapyroxad 93.75 g a.s./ha in the co-formulated product, ADM.03503.F.1.A. The various prothioconazole based products used in the trials have been grouped under a single tradename: PROLINE.

In supportive efficacy trials, the efficacy of ADM.03503.F.1.A was compared to the efficacy of reference standards containing fluxapyroxad and mefentrifluconazole at 66.7+66.7 g a.s./ha (REVYTRES) or 100+50 g a.s./ha (REVYSTAR XL). Theses references standard used to justify the efficacy of ADM.03503.F.1.A, are merged in the synthesis tables.

Figure 3.2-1 Efficacy trials - Wheat - Location of the trial sites

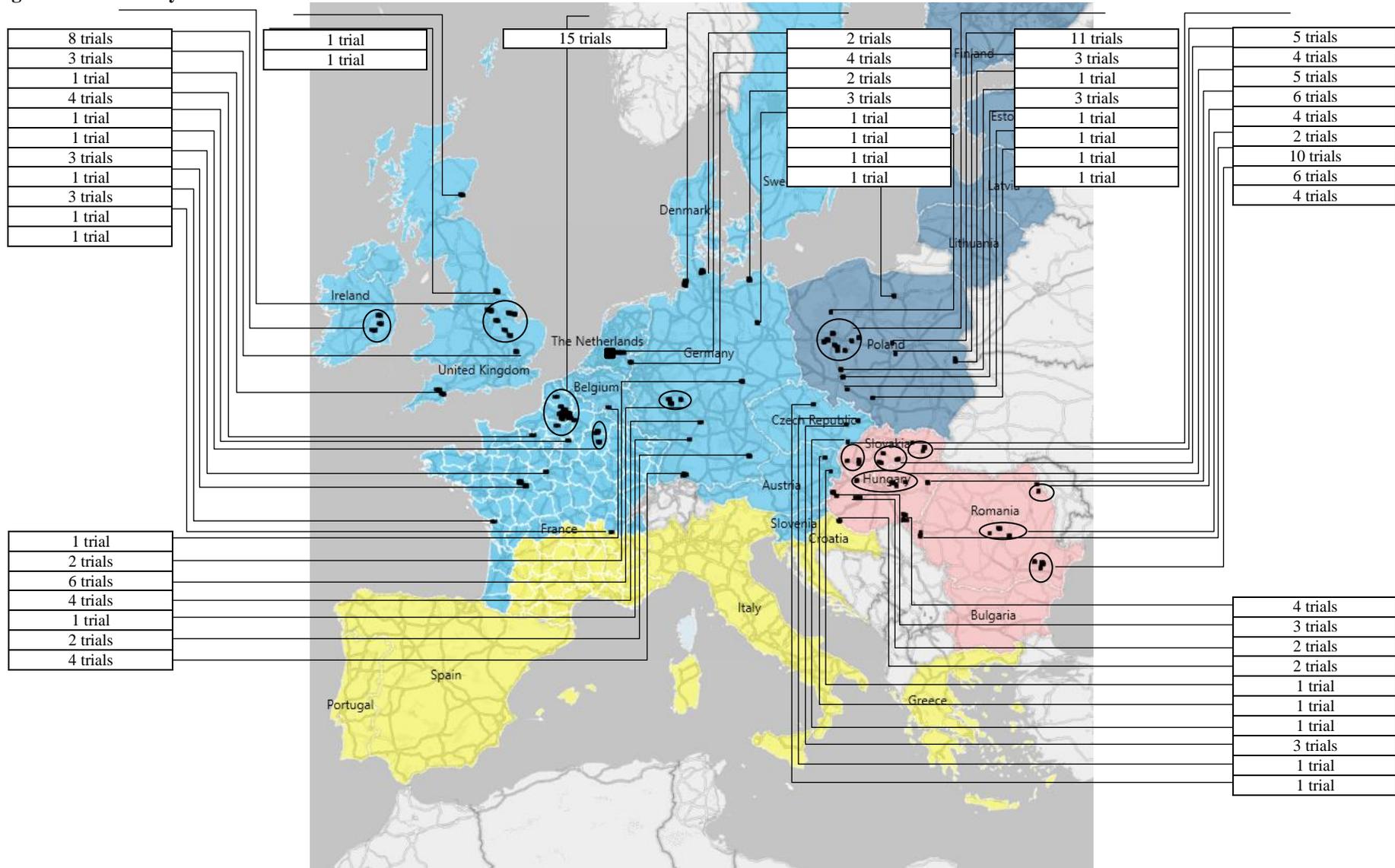


Figure 3.2-2 Efficacy trials - Barley - Location of the trial sites

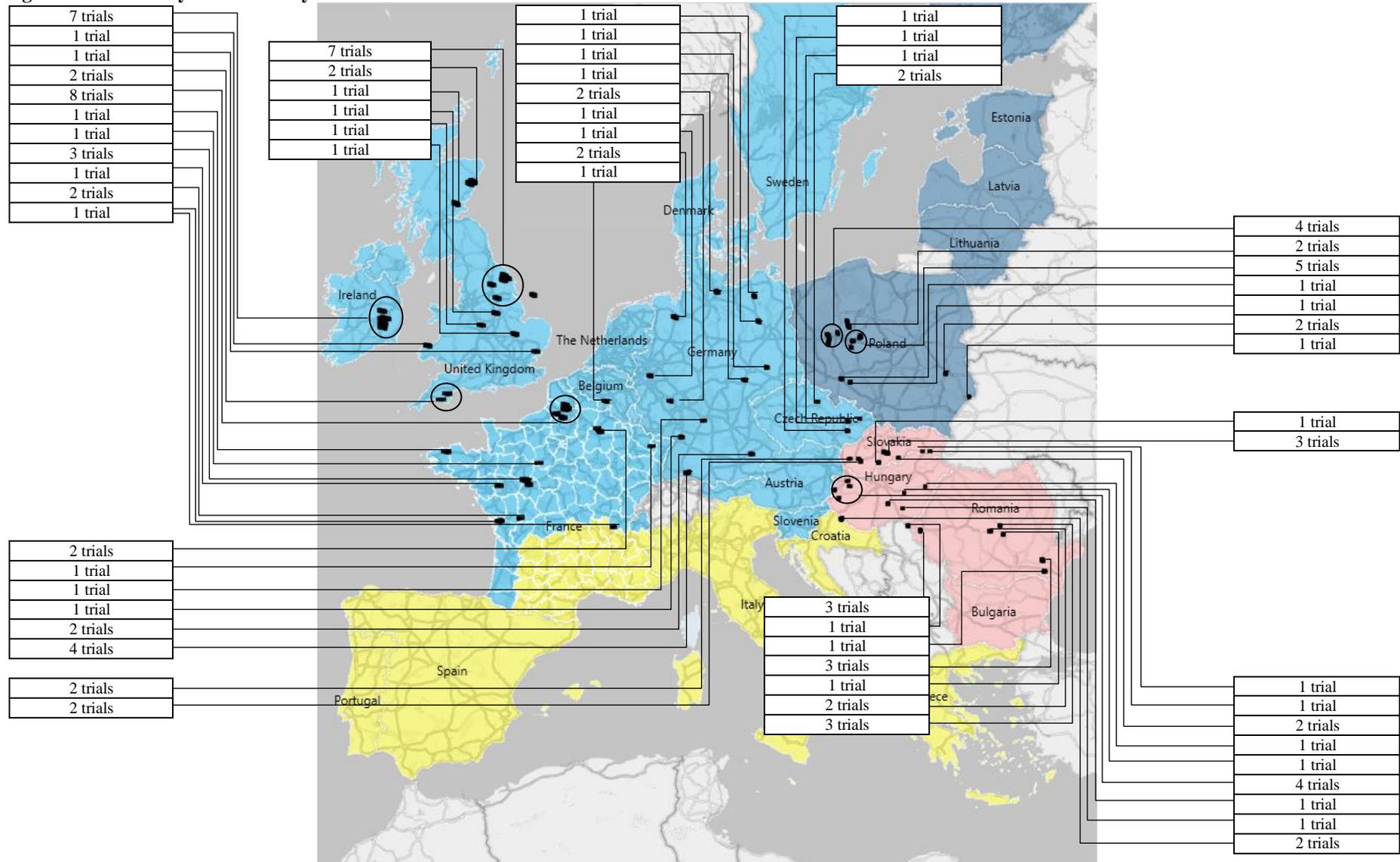


Figure 3.2-3 Efficacy trials - Rye - Location of the trial sites

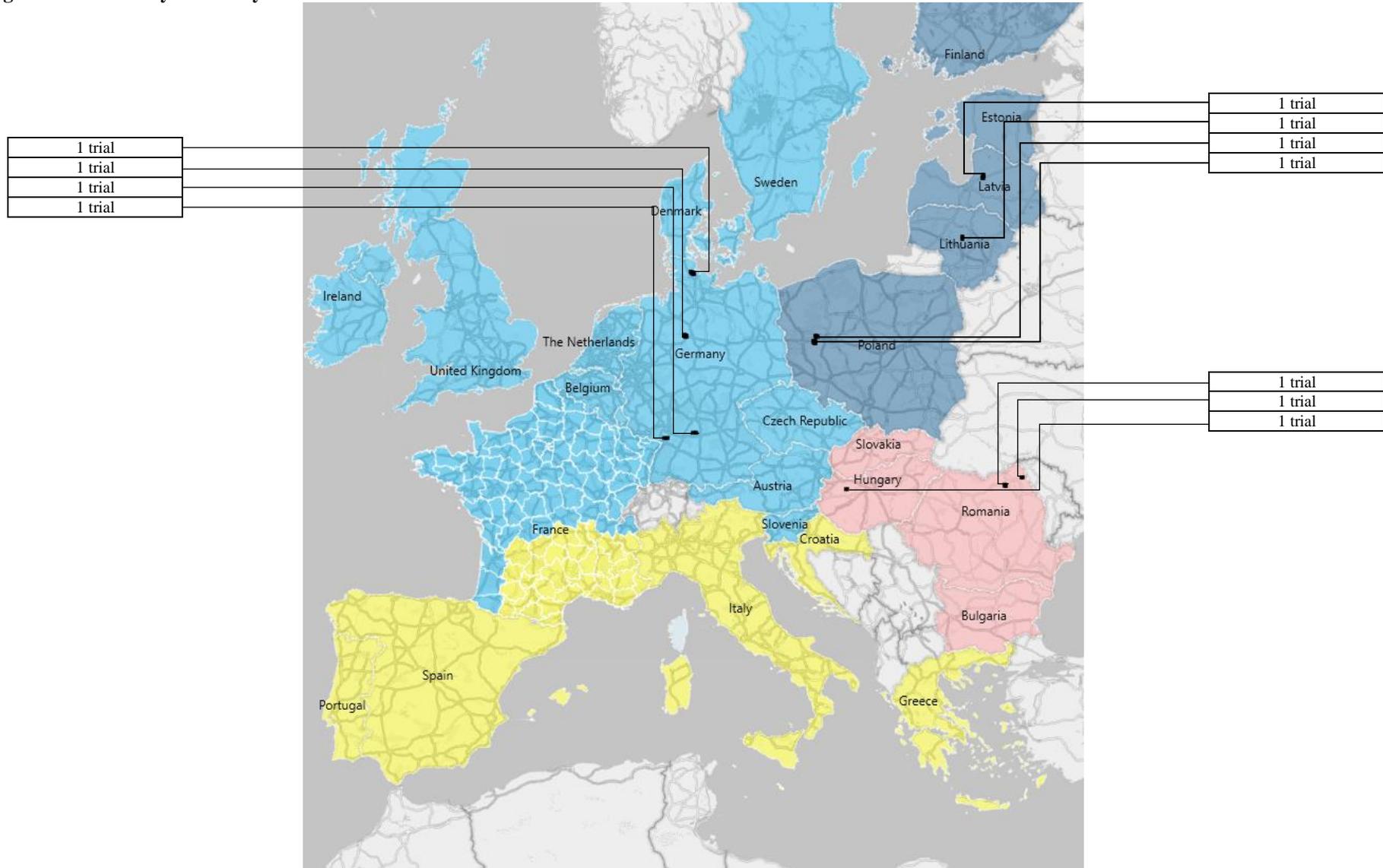


Figure 3.2-4 Efficacy trials - Triticale - Location of the trial sites

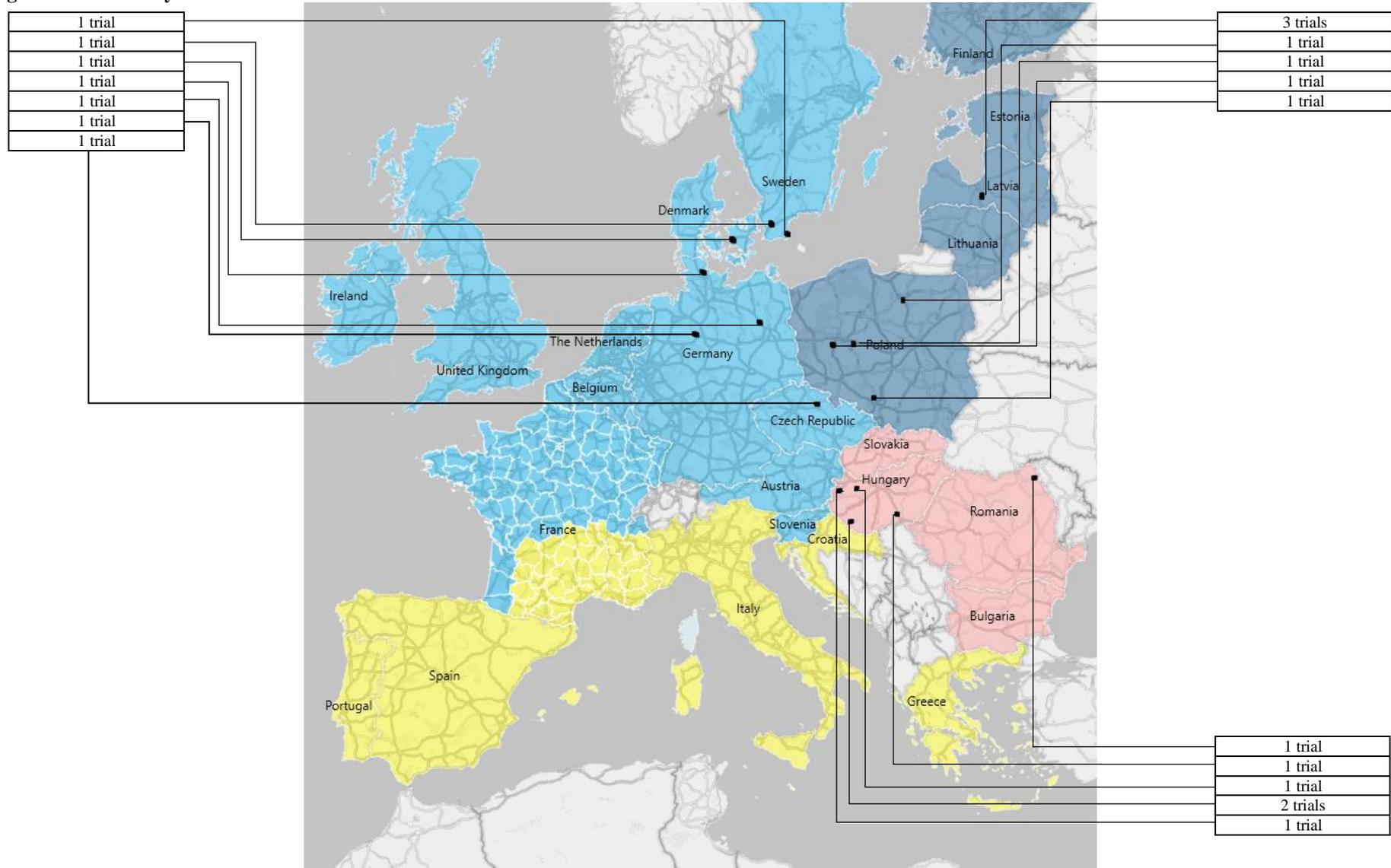


Table 3.2-9: Efficacy trials - Presentation of reference standards - Cereals crops

Crop(s) ⁽¹⁾	Target(s) ⁽¹⁾	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Dose rate in trials (per treatment)	Rate of active substance per ha	Remark ⁽⁴⁾
						Type ⁽²⁾	Concentration of a.s.				
Cereals	All diseases	IMTRES EC	Czech Republic	5448-0	Fluxapyroxad	EC	62.5 g/L	2.0 L/ha	1.5 L/ha	93.75 g a.s./ha	Named IMTRES in this dRR
		IMBRES EC	Germany	026979-00							
		IMTRES XE	The Netherlands	13578							
		IMTRES	Ireland	04965							
		IMTRES	France	2110144							
		IMTRES	United Kingdom	17108							
		IMBRES XE	Poland	R-39/2017 wu							
		IMBRES	Hungary	04.2/1119-1/2013							
		IMTRES	Romania	Not registered							
		IMTRES EC	Slovakia	19-00561-AU							
		PROLINE 250 EC	Czech Republic	4523-1	Prothioconazole	EC	250 g/L	0.8 L/ha	0.75 L/ha	187.5 g a.s./ha	Named PROLINE in this dRR
		PROLINE	Germany	025287-00							
		PROLINE	Belgium	9805P/B							
		PROLINE	The Netherlands	12725							
		PROLINE	Ireland	03786							
		JOAO	France	2060116							
		PROLINE	Poland	R-808/2016b – 01-06-2016							
		PROLINE	Hungary	6300/1205-1/2020							
		PROLINE	Romania	457PC/15 Nov 2018							
		PROLINE 250 EC	Slovakia	06-02-0768							
		PROLINE 275 EC	United Kingdom	14790	Prothioconazole	EC	275 g/L	0.72 L/ha	0.68 L/ha		
		ADEXAR TOP	Austria	3772-0	Fluxapyroxad + Metconazole	EC	62.5 g/L + 45 g/L	2.0 L/ha	2.0 L/ha	125 g a.s./ha + 90 g a.s./ha	Named LIBRAX in this dRR
		LIBRAX	Belgium	10177P/B							
		LIBRAX	Czech Republic	5083-0							
		LIBRAX	Germany	007969-00							
		LIBRAX	The Netherlands	Not registered							
LIBRAX	Ireland	04968									
LIBRAX	France	2140173									
LIBRAX	United Kingdom	17107									
LIBRAX	Poland	R-47/2016									
LIBRAX	Hungary	Not registered									
LIBRAX	Romania	Not registered									
LIBRAX	Slovakia	16-02-1816									

Crop(s) ⁽¹⁾	Target(s) ₍₁₎	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Dose rate in trials (per treatment)	Rate of active substance per ha	Remark ⁽⁴⁾
						Type ₍₂₎	Concentration of a.s.				
Rye Triticale	All diseases	REVYTREX	Lithuania	AS2-97F(2019)	Fluxapyroxad + Mefentrifluconazole	EC	66.7 g/L + 66.7 g/L	1.5 L/ha	1.5 L/ha	100 g a.s./ha + 100 g a.s./ha	Supportive data
			Latvia	0708							
			Denmark	Not registered							
		Sweden	5585								
		REVYSTAR XL	Latvia	0707	Fluxapyroxad + Mefentrifluconazole	EC	100 g/L + 50g/L	1.5 L/ha	1.5 L/ha	150 g a.s./ha + 75 g a.s./ha	

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

⁽²⁾ EC: Emulsifiable concentrate

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

Justification for the use of data from other countries/zones

Data from France (representation from Southern registration zone) and the United Kingdom on all cereals and from Denmark, Sweden, Latvia and Lithuania (representation from Northern registration zone) on triticale and rye crops have been used in this dRR for ADM.3503.F.1.A.

This use has been considered possible by the division of biological data into three regions i.e. North, Central and South Europe based on data comparability between Member states as it is indicated in the Annex III of Directive 93/71/EEC. The following justifications are presented:

Diseases presented are common throughout Europe. Although trials were performed in different countries, sites were selected with known pest populations in order to exert maximum control pressure and to ~~exacerbate~~ widen treatment differences. No difference in disease susceptibility is apparent from the control levels achieved between the efficacy data presented for each country within the zonal regions presented.

Similar trial methodology was used in all countries. Trials were undertaken by official or officially recognized testing facilities in accordance with the relevant EPPO guidelines. Furthermore, identical methods of assessment for efficacy (disease severity, disease incidence) and crop tolerance (visual injury) were employed.

Trials were performed in the major growing areas in each respective country. These areas have been found to be particularly suitable for cereals production due to their innate similarity in terms of soil type and climate.

Data presented shows that soil type has no effect on the level of diseases control achieved with ADM.03503.F.1.A. trials were carried out on different soil types and consistency of control was unaffected.

Data for ADM.03503.F.1.A BAD is summarised by EPPO PP 1/241(1) defined zones. The zones have been defined on the basis of comparable climates in the form of a 'Climatic Justification' paper as approved by EPPO and found within the standard PP 1/241(1), thus the issue of climatic differences need not be addressed within this dossier.

EPPO PP 1/24(1) zones:

- Mediterranean EPPO climatic zone includes the countries or parts of countries around the Mediterranean Sea, together with Jordan, Macedonia and Portugal.

- Maritime EPPO climatic zone is the zone north of the line from the coastal zone of south-west France, through Lyon (France), to the south border of Switzerland and Austria, west of the border between Austria and Hungary, west of the border between Czech Republic and Slovakia, west of the river Oder (between Poland and Germany). This zone also includes Ireland, Sweden and the United Kingdom.

- Northeast EPPO climatic zone is the zone in North-eastern part of Europe: the countries and the regions east of the river Oder (between Poland and Germany), north of the border between Czech Republic and Poland, west of the border between Poland and Ukraine, north of the border between Ukraine and Belarus, Russia north of 50° latitude.

- Southeast EPPO climatic zone includes Bosnia-Herzegovina, Bulgaria, Croatia, Hungary, Moldova, Romania, Russia south of 50° latitude, Slovakia, Slovenia, Serbia and Montenegro, Turkey, Ukraine, except the Mediterranean coastal zones.

In this dRR, additional data 79 trials conducted in Northern France and the United Kingdom, area of Maritime EPPO climatic, are presented to support efficacy claims for ADM.03503.F.1.A against diseases in cereal crops.

Additional data from 67 trials conducted in Denmark (1 trial) and Sweden (2 trials), country of Maritime EPPO climatic, Latvia (24 trials) and Lithuania (1 trial), country of Northeast EPPO climatic, are also presented to support efficacy claims for ADM.3503.F.1.A against diseases on minor cereals, rye and triticale.

Due to comparable agronomic and climatic conditions within the EPPO climatic zone, the presented data is considered to be fully supportive of the label claim of ADM.03503.F.1.A for the Central registration zone.

3.2.1 Preliminary tests (KCP 6.1)

ADM.03503.F.1.A is a new association of two active substances, fluxapyroxad (75 g/L) and prothioconazole (150 g/L) which have been already approved straight or in association on cereals. A complete set of preliminary range finding tests is not reported as their range of activity and efficacy have been widely researched and established through commercial use over many years.

Fluxapyroxad and prothioconazole are existing active substances and their spectrum of activity at the required rate are well known and well documented. The combination of these two active substances is interesting to allow a good protection against foliar diseases.

Based on the benefits with respect to resistance prevention, the knowledge of each active substances, and technical possibilities on formulation, the combination of the active substances of ADM.03503.F.1.A and their rate ratio are justified.

However, in all efficacy trials, ADM.03503.F.1.A at 1.25 L/ha was compared to the same rate applied straight of fluxapyroxad (93.75 g a.s./ha - IMTrex at 1.5 L/ha) and prothioconazole (187.5 g a.s./ha - PROLINE at 0.75 L/ha) to confirm the interest of the association.

Therefore, this part was supported by the data from **99 valid efficacy trials** carried out **between 2019 and 2021** in the Maritime (1 trial in Belgium, 3 trials in Czech Republic, 21 trials in Germany, 7 trials in Ireland, 1 trial in The Netherlands, 9 trials in the United Kingdom and 20 trials in France), the Northeast (12 trials in Poland) and the Southeast (15 trials in Romania, 10 trials in Slovakia) EPPO climatic zones in:

- wheat (38 trials) against SEPTTR (32 trials), PUCCRT (8 trials), PUCST (6 trials), PYRNTR (4 trials) and ERYSGT (1 trial).
- barley (53 trials) RHYNSE (27 trials), PYRNTE (24 trials), PUCCHD (5 trials), RAMUCC (15 trials) and ERYSGH (5 trials).
- rye (8 trials) against RHYNSE (7 trials) and/or PUCCRE (3 trials).

In addition, **10 trials** are also provided to justify the ratio between fluxapyroxad and prothioconazole in ADM.03503.F.1.A.

3.2.1.1 Benefit of the association of fluxapyroxad and prothioconazole for the control of cereals diseases

3.2.1.1.1 Material and Methods

In **99 trials**, ADM.03503.F.1.A applied at 1.25 L/ha (93.75 g a.s./ha fluxapyroxad+187.5 g a.s./ha prothioconazole) was compared to IMTrex at 1.5 L/ha 93.75 g a.s./ha fluxapyroxad) and PROLINE at 0.75 L/ha (187.5 g a.s./ha prothioconazole). These products are presented in Table 3.2-9.

Material and Methods used in these efficacy trials are given within Section 3.2.3.1.

Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar or ears area by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice vs the available data package [available](#) we selected assessments from 4.5% notably to be able to select same number of assessments per trial.

To show the interest of the association, only the last valid assessment after one or* two applications for each trial is presented in the synthesis table. The analysis of the efficacy after the first or* the second application is presented in Section 3.2.2 - Minimum effective dose tests (KCP 6.2) and Section 3.2.3 Efficacy tests (KCP 6.2).

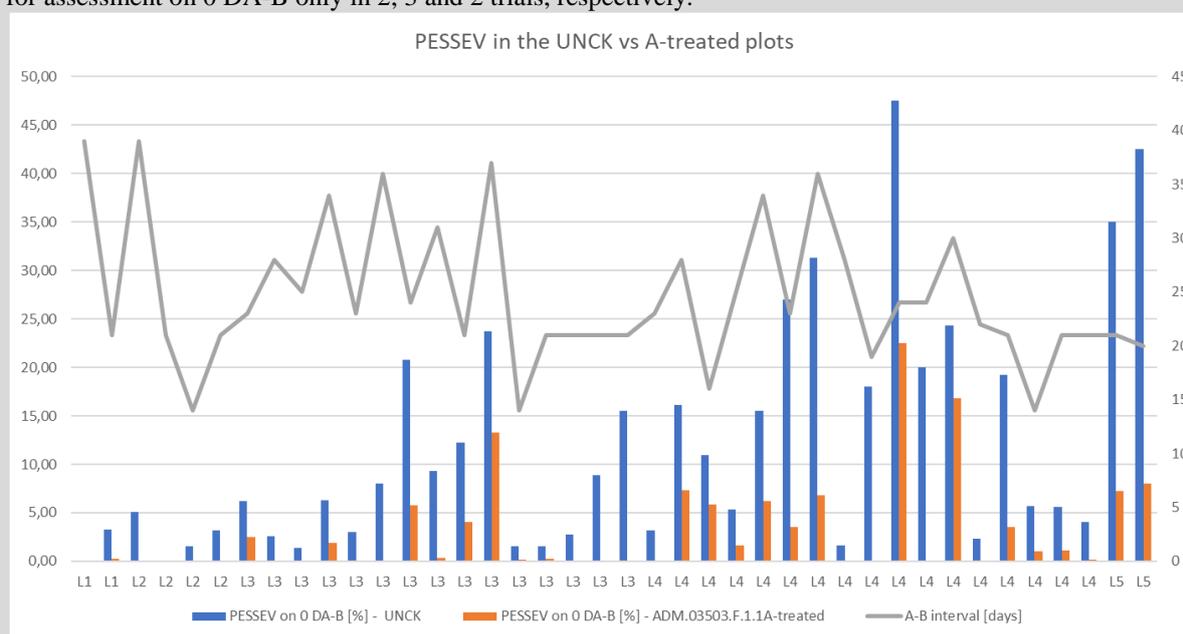
*zRMS comments on the applicant's trial design strategy:

Out of the **318** efficacy trials submitted, **only 70** (ca 22%, or 25% of the 281 valid trials) were carried out consistently with the claimed GAP: using single application of the test item. There are 47 such trials in wheat, 17 - in barley, 2 - in Rye and 3 - in Triticale (Tables 3.2-14 – 3.2-17, BAD). The trialing strategy of the applicant causes repeatedly the unnecessary disturbance to the normal conduct of the evaluation and as such it deserves some attention of both the cMSs and the applicant. The strategy assumed aims probably at reducing infection level on 0 DA-B, in order to challenge the tested product less rather than more, as the efficacy assessment across the entire dossier is based predominantly on the effect of this second application. As can be demonstrated below, the strategy does not work smoothly all the time. Another, much better justification is probably the attempt to

save a trial when facing very low intensity of infection in it, or completely no infection situation, on the day of the application A. In many trials this leads to their exclusion anyway, as mentioned previously by zRMS. The reasons for such exclusions are given by the applicant in the BAD, in Tables 3.2-118, 3.2- 150, 3.2-173 and 3.2-191, for trials in wheat, barley, rye and triticale respectively.

While in the MED and in the Efficacy chapters the efficacy from the scarce single-application trials is demonstrated separately from the majority of double-application data, which enables at least some limited comparison between the efficacy observed in these two situations, the preliminary tests are summarized predominantly based on efficacy after double application, with some single-application data included in the means.

The infection severity in the A-treated plots compared to UNCK, on the day of the application B, may indicate whether the effect of the application A is negligible, it has ceased, or whether it is still lasting, on 0 DA-B. This in turn should be critical in deciding whether efficacy following B can be interpreted as an outcome of a “single” independent treatment, or rather as the one affected by the preceding application A. As an example, the source data on the ADM.03503.F.1.A, used to compile the Table 3.2-10 (based on 29 preliminary trials) have been used to picture the situation. The PESSEV values come from the same leaf strata in the UNCK and in the plots previously treated with the application A. The leaves are L5-L1, but most often L4-L3, with L5, L2 and L1 available for assessment on 0 DA-B only in 2, 3 and 2 trials, respectively.



The table below summarizes PESSEV from all the data points collectively:

	PESSEV (%) UNCK, 0 DA-B	PESSEV (%) in ADM.03503.F.1.A, after application A, 0 DA-B
n	42*	40*
mean	11,9	3,1
median	6,3	0,3
min	0,0	0,0
max	47,5	22,5

*in some trials the same leaves were not assessed in the UNCK and in the treated plots, in such case the respective data are missing and consequently *n* is non-equal

As can be seen, the effect of the application A is neither negligible, nor it has ceased, on the 0 DA-B. Instead, this effect is lasting still on 0 DA-B, making the application B not a separate, single treatment, but one laid over the control effect brought about before, by the application A. Within the individual trials considerable differences can be seen between the efficacy of A and B. However, they testify to the advantage of either A or B application with comparable, **inconclusive** frequency: the efficacy of $A \geq B$ in 22 cases (61%), and that of the application $B > A$ in 14 cases (39%). The table below compares 36 assessments on the same data as the figure above (leaf numbers are not indicated for conciseness):

EFFI applic. A	97,8	99,7	59,7	54,7	46,5	69,8
EFFI applic. B	87,1	85,5	96,3	80,3	78,7	82,1
A-B=	10,7	14,2	-36,6	-25,6	-32,2	-12,3

EFFI applic. A	69,8	60,0	100,0	87,0	100,0	78,3
EFFI applic. B	69,0	59,4	92,7	83,6	100,0	77,0
A-B=	0,8	0,6	7,3	3,4	0,0	1,3
EFFI applic. A	100,0	100,0	52,6	72,3	79,3	100,0
EFFI applic. B	68,9	96,4	87,9	72,5	46,0	81,3
A-B=	31,1	3,6	-35,3	-0,2	33,3	18,7
EFFI applic. A	96,8	30,9	81,2	100,0	67,3	81,8
EFFI applic. B	75,0	91,3	70,0	80,0	100,0	100,0
A-B=	21,8	-60,4	11,2	20,0	-32,7	-18,2
EFFI applic. A	44,2	92,3	82,8	90,5	80,1	85,2
EFFI applic. B	95,8	88,2	84,3	91,9	85,6	91,1
A-B=	-51,6	4,1	-1,5	-1,4	-5,5	-5,9
EFFI applic. A	100,0	96,9	100,0	100,0	99,7	100,0
EFFI applic. B	95,4	88,2	82,3	99,5	98,2	99,1
A-B=	4,6	8,7	17,7	0,5	1,5	0,9

The mean and median efficacy of the two treatments are comparable, when averaged across the whole set of trials discussed:

	Efficacy of application A (Abbott (%))	Efficacy of application B (Abbott (%))
n	37*	36*
mean	82,2	85,0
median	85,2	86,4
min	30,9	46,0
max	100,0	100,0

*one single-application trial is included in the Table 3.2-10 summary

The interval between the A and B applications in the 29 trials summarized in the Table 3.2-10 is between **14** and **39** days, and it appears that there is **no link** between the length of this interval and the final level of PESSEV observed on the 0 DA-B in the A-treated plots. The A-B interval in the remaining 247 double application trials is **11 - 46** days, with only 3 trials showing interval <14 days. In 83 trials the A-B interval is 14-20 days, while 161 trials has it ≥ 21 and up to 46 days, that is long enough to consider the efficacy of B independently, although calculated **relative to the another infection severity level**. It is the zRMS opinion that, despite the protocol that is incongruent with the proposed GAP, the data thus produced may eventually still support the applicant`s claim. They demonstrate comparable efficacy of the test item irrespective of the level of infection being original (prior to application A) or mitigated (prior to application B), thereby suggesting the test item`s applicability within a wide range of the growth stages of cereals and (potentially) within a protection program including other types of fungicides.

Last but not least, and **contrary to what may appear from the above conclusion**, the primary intention of zRMS behind this whole comment is to make it clear that the applicant`s strategy is plainly pointless. The outcome of the present evaluation would be the same (or even more definite) should the appropriate number of single-application trials be submitted.

Apart from being clearly irrelevant to the claimed GAP, this producing of redundant double-application data inflates the individual reports as well as the entire dossier for no good reason: the action undertaken shows finally inconsequential, it has no effect on the concluded efficacy and no effect on the evaluation process, other than adding extra workload to both zRMS **and to the applicant**: the data set must usually be updated by the applicant, through extracting and summarizing of the proper data, those following single application, when the evaluation is still in progress.

While such a conduct may be sometimes acceptable in the preliminary research, when not only the timing but even the number of the applications can still be a matter of debate, the handling of the main efficacy data in the same manner is simply inappropriate and should be avoided.

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3.2.1.1.2 Results on the benefit of the association of fluxapyroxad and prothioconazole for the control of wheat diseases

A total of **38 valid efficacy trials** were carried out to show the interest of the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A. These trials were carried out **from 2019 to 2021** in the Maritime (2 trials in Czech Republic, 7 trials in Germany, 2 trials in Ireland, 1 trial in The Netherlands, 4 trials in the United Kingdom and 9 trials in France), the Northeast (3 trials in Poland) and the Southeast (6 trials in Romania, 4 trials in Slovakia) EPPO climatic zones against SEPTTR (32 trials), PUCCRT (8 trials), PUC CST (6 trials), PYRNTR (4 trials) and ERYSGT (1 trial).
Table 3.2-10 (SEPTTR),

Table 3.2-11 (PUCCRT), Table 3.2-12 (PUC CST),

zRMS comments to Table 3.2-12:

The 6-trial summary is based exclusively on double-application trials.

Table 3.2-13 (PYRNTR), Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-13:

The 4-trial summary is based exclusively on double-application trials.

Table 3.2-14 (ERYSGT) summarise all observations for each disease (efficacy) and Table 3.2-15 synthesises the benefit of the association of fluxapyroxad and prothioconazole contained in ADM.03503.F.1.A against the wheat disease complex.

Table 3.2-10: Benefit of the association of fluxapyroxad and prothioconazole - Wheat - SEPTTR

Target Parameters	Assessment timing	Eppo climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to		
					Untreated			ADM.03503.F.1.A 1.25 L/ha				IMTrex 1.5 L/ha				PROLINE 0.75 L/ha					
					Fluxapyroxad + Prothioconazole			Fluxapyroxad				Prothioconazole									
					93.75+187.5 g a.s./ha			93.75 g a.s./ha				187.5 g a.s./ha									
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTrex 1.5 L/ha	PROLINE 0.75 L/ha		
SEPTTR Disease severity	Last valid assessment	Maritime	FLAGLE	16	20.6	6.6	41.1	87.1	69.0	100.0	8.8	75.9	46.7	99.2	15.4	65.4	26.7	100.0	20.3	4>; 12=; 0<	9>; 7=; 0<
			FLMII	19	44.9	11.3	99.0	76.6	46.0	97.9	13.5	69.1	24.4	95.4	16.4	62.4	21.6	97.3	19.8	2>; 17=; 0<	10>; 9=; 0<
		Northeast	FLAGLE	2	26.9	21.3	32.5	90.0	80.0	100.0	10.0	91.2	82.3	100.0	8.9	91.1	82.1	100.0	9.0	0>; 2=; 0<	0>; 2=; 0<
			FLMII	2	31.8	26.8	36.8	97.9	95.8	100.0	2.1	89.8	79.5	100.0	10.3	99.7	99.4	100.0	0.3	1>; 1=; 0<	0>; 2=; 0<
		Southeast	FLAGLE	5	6.2	5.3	7.0	87.1	78.5	99.1	6.8	78.7	61.4	98.0	12.1	76.7	51.7	97.8	14.7	1>; 4=; 0<	1>; 4=; 0<
			FLMII	8	14.2	5.3	35.2	93.2	82.3	99.5	5.7	85.2	61.3	98.3	13.4	87.4	71.0	98.2	9.4	4>; 4=; 0<	3>; 5=; 0<
		All Eppo climatic zones	FLAGLE	23	18.0	5.3	41.1	87.3	69.0	100.0	8.5	77.8	46.7	100.0	14.9	70.0	26.7	100.0	20.1	5>; 18=; 0<	10>; 13=; 0<
			FLMII	29	35.5	5.3	99.0	82.6	46.0	100.0	14.1	75.0	24.4	100.0	17.3	71.9	21.6	100.0	21.4	7>; 22=; 0<	13>; 16=; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-10:

The 29-trial summary includes only one trial carried out with single application (FR21FETRZAW551C, KCP 6.1-21).

Table 3.2-11: Benefit of the association of fluxapyroxad and prothioconazole - Wheat - PUCCRT

Target Parameters	Assessment timing	EPP0 climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ > ; = ; < to	
								ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha					
								Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole					
								93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha					
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha		
PUCCRT Disease severity	Last valid assessment	Maritime	FLAGLE	5	45.9	6.8	96.4	88.2	55.6	100.0	17.3	86.8	54.3	100.0	18.1	76.8	18.5	100.0	30.6	1> ; 4= ; 0<	2> ; 3= ; 0<
			FLMII	3	65.2	23.4	97.4	94.0	82.1	100.0	8.4	92.8	79.0	100.0	9.7	89.4	76.3	100.0	9.9	0> ; 3= ; 0<	1> ; 2= ; 0<
		Southeast	FLAGLE	3	16.6	9.6	21.9	94.8	88.5	98.1	4.5	93.9	84.4	99.4	6.7	88.2	78.6	97.8	7.8	0> ; 3= ; 0<	1> ; 2= ; 0<
			FLMII	2	9.0	6.7	11.3	99.6	99.1	100.0	0.5	99.2	98.4	100.0	0.8	89.5	81.7	97.3	7.8	0> ; 2= ; 0<	1> ; 1= ; 0<
		All EPP0 climatic zones	FLAGLE	8	34.9	6.8	96.4	90.7	55.6	100.0	14.3	89.4	54.3	100.0	15.3	81.1	18.5	100.0	25.3	1> ; 7= ; 0<	3> ; 5= ; 0<
			FLMII	5	42.7	6.7	97.4	96.2	82.1	100.0	7.1	95.3	79.0	100.0	8.2	89.5	76.3	100.0	9.1	0> ; 5= ; 0<	2> ; 3= ; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-11:

The 8-trial summary includes only one trial carried out with single application (FR19FETRZAX109B, KCP 6.1-17).

Table 3.2-12: Benefit of the association of fluxapyroxad and prothioconazole - Wheat - PUCST

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
								ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha					
								Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole					
								93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha					
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha		
PUCST Disease severity	Last valid assessment	Maritime	FLAGLE	5	39.2	12.8	92.9	98.9	95.8	100.0	1.6	94.6	85.9	100.0	5.3	82.1	60.5	100.0	16.1	1> ; 4= ; 0<	3> ; 2= ; 0<
			FLMII	5	50.3	5.5	99.0	97.5	88.3	100.0	4.6	92.1	70.0	100.0	11.3	87.0	67.0	100.0	13.2	2> ; 3= ; 0<	3> ; 2= ; 0<
		Southeast	FLMII	1	5.5	-	-	88.0	-	-	-	68.0	-	-	-	83.7	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
		All EPPO climatic zones	FLAGLE	5	39.2	12.8	92.9	98.9	95.8	100.0	1.6	94.6	85.9	100.0	5.3	82.1	60.5	100.0	16.1	1> ; 4= ; 0<	3> ; 2= ; 0<
			FLMII	6	42.8	5.5	99.0	95.9	88.0	100.0	5.5	88.1	68.0	100.0	13.7	86.4	67.0	100.0	12.1	3> ; 3= ; 0<	3> ; 3= ; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-12:

The 6-trial summary is based exclusively on double-application trials.

Table 3.2-13: Benefit of the association of fluxapyroxad and prothioconazole – Wheat – PYRNTR

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole									
					93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha									
		Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha				
PYRNTR Disease severity	Last valid assessment	Maritime	FLAGLE	3	7.2	4.5	9.5	83.5	66.7	97.4	12.7	66.2	44.4	84.2	16.5	66.4	51.4	92.1	18.3	1> ; 2= ; 0<	1> ; 2= ; 0<	
			FLMII	3	14.1	8.0	22.5	80.9	60.0	95.2	15.1	59.4	33.3	82.5	20.2	69.5	53.3	80.2	11.6	1> ; 2= ; 0<	0> ; 3= ; 0<	
		Southeast	FLAGLE	1	5.9	-	-	99.0	-	-	-	95.8	-	-	-	85.3	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMII	1	10.1	-	-	87.7	-	-	-	85.2	-	-	-	72.8	-	-	-	-	0> ; 1= ; 0<	1> ; 0= ; 0<
		All EPPO climatic zones	FLAGLE	4	6.9	4.5	9.5	87.4	66.7	99.0	12.9	73.6	44.4	95.8	19.2	71.1	51.4	92.1	17.8	1> ; 3= ; 0<	1> ; 3= ; 0<	
			FLMII	4	13.1	8.0	22.5	82.6	60.0	95.2	13.4	65.9	33.3	85.2	20.8	70.3	53.3	80.2	10.2	1> ; 3= ; 0<	1> ; 3= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-13:

The 4-trial summary is based exclusively on double-application trials.

Table 3.2-14: Benefit of the association of fluxapyroxad and prothioconazole - Wheat - ERYSGT

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
								ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole								
					93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha								
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha		
ERYSGT Disease severity	Last valid assessment after application A	Northeast	FLMI2	1	10.0	-	-	85.0	-	-	-	70.0	-	-	-	77.5	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
	Last valid assessment after application B	Northeast	FLMI1	1	11.3	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI2	1	40.8	-	-	99.4	-	-	-	84.0	-	-	-	98.8	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-14:

PL20FETRZAW060B (KCP 6.1-37) is double-application a trial.

Table 3.2-15: Benefit of the association of fluxapyroxad and prothioconazole - Wheat - All valid efficacy trials

Target	Parts	No. of trials	Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=;< to	
			Untreated			ADM.03503.F.1.A 1.25 L/ha			IMTREX 1.5 L/ha			PROLINE 0.75 L/ha				
			Fluxapyroxad + Prothioconazole			Fluxapyroxad			Prothioconazole							
			93.75+187.5 g a.s./ha			93.75 g a.s./ha			187.5 g a.s./ha							
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha
SEPTTR	FLAGLE	23	18.0	5.3	41.1	87.3	69.0	100.0	77.8	46.7	100.0	70.0	26.7	100.0	5>;18=;0<	10>;13=;0<
	FLMI1	29	35.5	5.3	99.0	82.6	46.0	100.0	75.0	24.4	100.0	71.9	21.6	100.0	7>;22=;0<	13>;16=;0<
PUCCRT	FLAGLE	8	34.9	6.8	96.4	90.7	55.6	100.0	89.4	54.3	100.0	81.1	18.5	100.0	1>;7=;0<	3>;5=;0<
	FLMI1	5	42.7	6.7	97.4	96.2	82.1	100.0	95.3	79.0	100.0	89.5	76.3	100.0	0>;5=;0<	2>;3=;0<
PUCCST	FLAGLE	5	39.2	12.8	92.9	98.9	95.8	100.0	94.6	85.9	100.0	82.1	60.5	100.0	1>;4=;0<	3>;2=;0<
	FLMI1	6	42.8	5.5	99.0	95.9	88.0	100.0	88.1	68.0	100.0	86.4	67.0	100.0	3>;3=;0<	3>;3=;0<
PYRNTTR	FLAGLE	4	6.9	4.5	9.5	87.4	66.7	99.0	73.6	44.4	95.8	71.1	51.4	92.1	1>;3=;0<	1>;3=;0<
	FLMI1	4	13.1	8.0	22.5	82.6	60.0	95.2	65.9	33.3	85.2	70.3	53.3	80.2	1>;3=;0<	1>;3=;0<
ERYSGT	FLMI1	1	11.3	-	-	100.0	-	-	100.0	-	-	100.0	-	-	0>;1=;0<	0>;1=;0<
	FLMI2	1	40.8	-	-	99.4	-	-	84.0	-	-	98.8	-	-	1>;0=;0<	0>;1=;0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-15:

Except for 2 datapoints, this 48-datapoint summary in wheat is based on double-application efficacy data.

The results are summarized by EPPO climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPPO climatic zones presented Table 3.2-15) are discussed hereafter to justify the benefit of the association fluxapyroxad with prothioconazole formulated in ADM.03503.F.1.A. Across 38 efficacy trials carried out in the Maritime, the Northeast and the Southeast EPPO climatic zones, ADM.03503.F.1.A, applied at the proposed label rate of 1.25 L/ha, was compared to straight fluxapyroxad at 93.75 g a.s./ha (IMTREX at 1.5 L/ha) and straight prothioconazole at 187.5 g a.s./ha (PROLINE at 0.75 L/ha).

Against SEPTTR, ADM.03503.F.1.A applied at 1.25 L/ha delivered 87% on FLAGLE and 83% on FLMI1 when IMTREX provided 78% on FLAGLE and 75% on FLMI1 and PROLINE provided 70% on FLAGLE and 72% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in 5 out of 23 trials

on FLAGLE and in 7 out of 29 trials on FLMI1. ADM.03503.F.1.A was also significantly superior to PROLINE in 10 out of 23 trials on FLAGLE and in 13 out of 29 trials on FLMI1.

Against PUCCRT, ADM.03503.F.1.A applied at 1.25 L/ha delivered 91% on FLAGLE and 96% on FLMI1 when IMTREX provided 89% on FLAGLE and 95% on FLMI1 and PROLINE provided 81% on FLAGLE and 90% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in 1 out of 8 trials on FLAGLE. ADM.03503.F.1.A was also significantly superior to PROLINE in 3 out of 8 trials on FLAGLE and in 2 out of 5 trials on FLMI1.

Against PUC CST, ADM.03503.F.1.A applied at 1.25 L/ha delivered 99% on FLAGLE and 96% on FLMI1 when IMTREX provided 95% on FLAGLE and 88% on FLMI1 and PROLINE provided 82% on FLAGLE and 86% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in 1 out of 5 trials on FLAGLE and in 3 out of 6 trials on FLMI1. ADM.03503.F.1.A was also significantly superior to PROLINE in 3 out of 5 trials on FLAGLE and in 3 out of 6 trials on FLMI1.

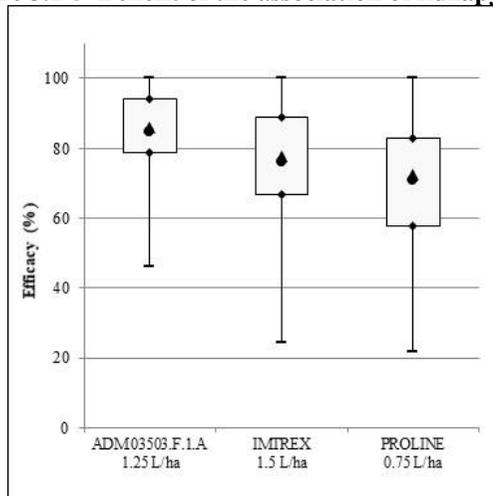
Against PYRNTR, ADM.03503.F.1.A applied at 1.25 L/ha delivered 87% on FLAGLE and 83% on FLMI1 when IMTREX provided 74% on FLAGLE and 66% on FLMI1 and PROLINE provided 71% on FLAGLE and 70% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in 1 out of 4 trials on FLAGLE and FLMI1. ADM.03503.F.1.A was also significantly superior to PROLINE in 1 out of 4 trials on FLAGLE and FLMI1.

Against ERYSGT, ADM.03503.F.1.A applied at 1.25 L/ha delivered 100% on FLMI1 and 99% on FLMI2 when IMTREX provided 100% on FLMI1 and 84% on FLMI2 and PROLINE provided 100% on FLMI1 and 99% on FLMI2. ADM.03503.F.1.A was significantly superior to IMTREX on FLMI2.

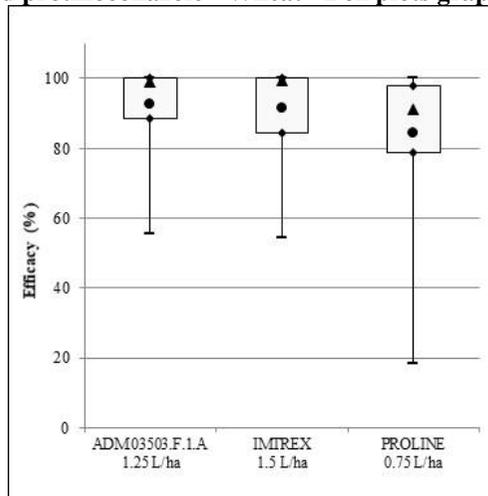
These results confirm that fluxapyroxad and prothioconazole are complementary against the wheat disease complex (SEPTTR, PUC CRT, PUC CST, PYRNTR, and ERYSGT).

For each disease with at least 5 assessments, the interest of the association of fluxapyroxad with prothioconazole can be illustrated by box plot graphics (Figure 3.2-5). Overall, box plot graphics clearly show a better control and homogeneity for ADM.03503.F.1.A than IMTREX or PROLINE according to the disease. Indeed, according to the box plots graphics, the efficacy level and the dispersion between efficacies is less important for ADM.03503.F.1.A than IMTREX or PROLINE.

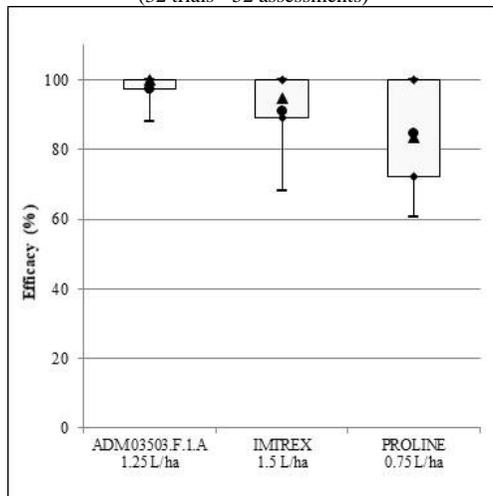
Figure 3.2-5 Benefit of the association of fluxapyroxad and prothioconazole - Wheat - Box plots graphics



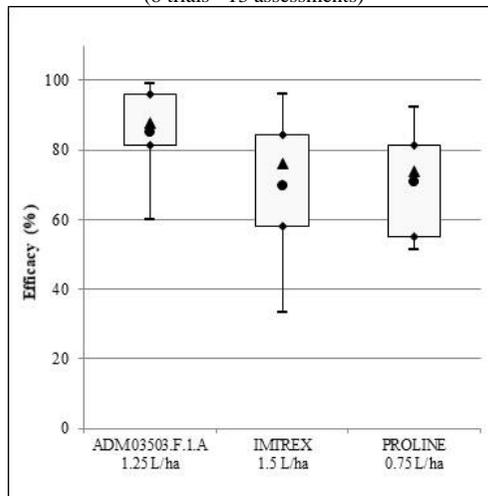
SEPTTR - Last valid assessment
 disease severity on leaves (FLAGLE, FLMI1)
 (32 trials - 52 assessments)



PUCCRT - Last valid assessment
 disease severity on leaves (FLAGLE, FLMI1)
 (8 trials - 13 assessments)



PUC CST - Last valid assessment
 disease severity on leaves (FLAGLE, FLMI1)
 (6 trials - 11 assessments)

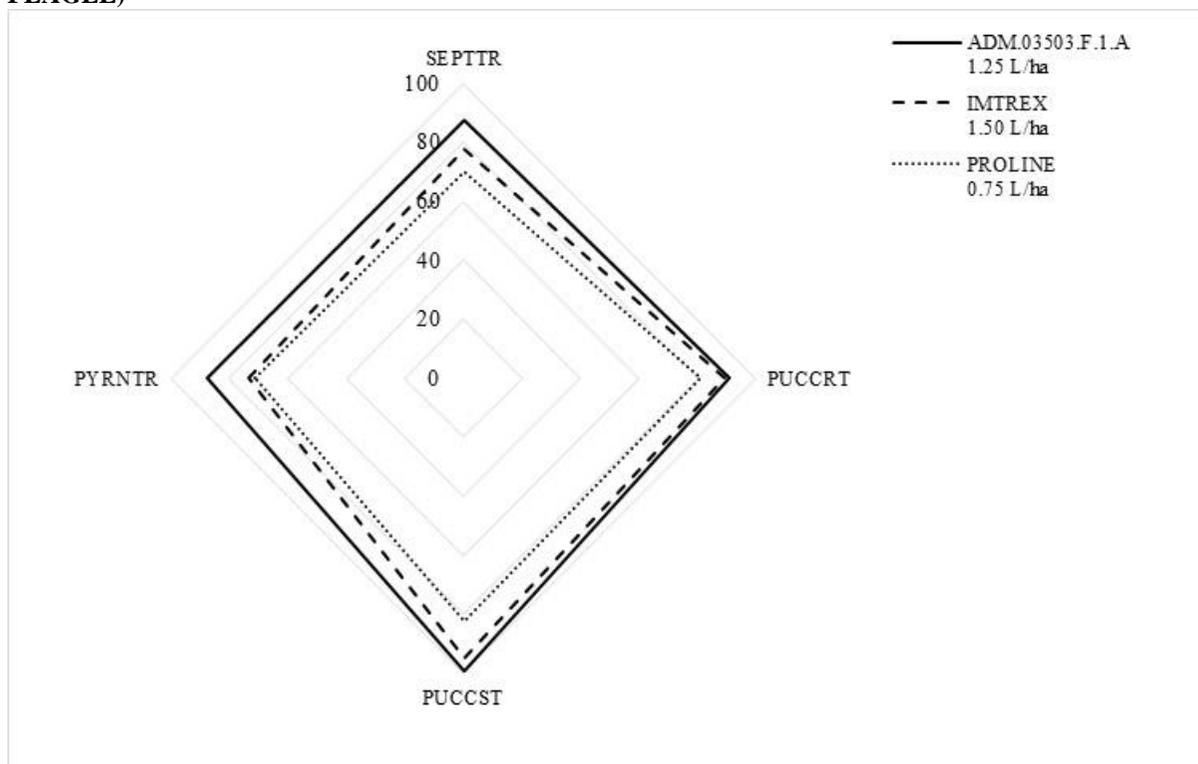


PYRNTR - Last valid assessment
 disease severity on leaves (FLAGLE, FLMI1)
 (4 trials - 8 assessments)

• q1 - Min ▲ Median ● Mean - Max ♦ q3

The interest of the association of fluxapyroxad with prothioconazole against wheat disease complex can be illustrated by graphic from the last valid assessment on FLAGLE (SEPTTR, PUCCRT, PUC CST and PYRNTR) (Figure 3.2-6). According to the efficacy results and as illustrated on the graphic hereafter, the association contained in ADM.03503.F.1.A at 1.25 L/ha is a good association to control the major diseases of wheat.

Figure 3.2-6 Benefit of the association of fluxapyroxad and prothioconazole - Wheat - Disease complex (efficacy against SEPTTR, PUCCRT, PUC CST, PYRNTR on FLAGLE)



To conclude, the benefit of the formulated product ADM.03503.F.1.A over fluxapyroxad or prothioconazole applied straight against the wheat disease complex (SEPTTR, PUC CRT, PUC CST, PYRNTR) is clearly demonstrated.

3.2.1.1.3 Results on the benefit of the association of fluxapyroxad and prothioconazole for the control of barley diseases

A total of 53 valid efficacy trials were carried out to show the interest of the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A. These trials were carried out from 2019 to 2021 in the Maritime (1 trial in Belgium, 1 trial in Czech Republic, 10 trials in Germany, 5 trials in Ireland, 5 trials

in the United Kingdom and 11 trials in France), the Northeast (7 trials in Poland) and the Southeast (7 trials in Romania, 6 trials in Slovakia) EPPO climatic zones against RHYNSE (27 trials), PYRNTE (24 trials), PUCCHD (5 trials), RAMUCC (15 trials) and ERYSGH (5 trials).

Table 3.2-16 (RHYNSE), Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-16:

This 27-trial summary includes only 3 trials with single application data: one in the NE zone (PL) and two in Maritime zone (DE, FR).

Table 3.2-17 (PYRNTE), Table 3.2-18 (PUCCHD), Table 3.2-19 (RAMUCC), Table 3.2-20 (ERYSGH) summarise all observations for each disease (efficacy) and Table 3.2-21 synthesises the benefit of the association of fluxapyroxad and prothioconazole contained in ADM.03503.F.1.A against the barley disease complex.

Table 3.2-16: Benefit of the association of fluxapyroxad and prothioconazole - Barley - RHYNSE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
								ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole								
					93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha								
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha		
RHYNSE Disease severity	Last valid assessment	Maritime	FLAGLE	14	19.4	5.8	88.8	91.2	65.2	100.0	11.0	76.1	32.7	100.0	22.5	84.1	56.5	99.2	13.6	3>; 11=; 0<	2>; 12=; 0<
			FLMII	16	22.7	5.3	100.0	86.4	42.9	100.0	14.9	72.9	32.8	97.7	21.1	81.7	42.9	95.5	14.8	3>; 13=; 0<	1>; 15=; 0<
		Northeast	FLAGLE	4	13.9	5.5	20.6	89.0	80.6	100.0	7.4	63.7	36.9	80.8	16.5	73.6	69.2	81.7	5.0	3>; 1=; 0<	2>; 2=; 0<
			FLMII	4	14.6	7.3	20.0	93.0	86.2	99.3	6.1	76.5	54.7	99.3	15.9	86.9	62.4	99.0	14.3	2>; 2=; 0<	1>; 3=; 0<
		Southeast	FLAGLE	2	22.2	11.3	33.1	100.0	100.0	100.0	0.0	98.9	98.9	98.9	0.0	92.4	84.7	100.0	7.7	0>; 2=; 0<	0>; 2=; 0<
			FLMII	6	16.9	5.5	45.3	94.9	88.9	100.0	4.5	90.2	74.4	100.0	8.3	89.6	80.7	100.0	6.4	2>; 4=; 0<	2>; 4=; 0<
		All EPPO climatic zones	FLAGLE	20	18.6	5.5	88.8	91.6	65.2	100.0	10.2	75.9	32.7	100.0	22.2	82.8	56.5	100.0	12.9	6>; 14=; 0<	4>; 16=; 0<
			FLMII	26	20.1	5.3	100.0	89.4	42.9	100.0	12.7	77.4	32.8	100.0	19.4	84.3	42.9	100.0	13.7	7>; 19=; 0<	4>; 22=; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-16:

This 27-trial summary includes only 3 trials with single application data: one in the NE zone (PL) and two in Maritime zone (DE, FR).

Table 3.2-17: Benefit of the association of fluxapyroxad and prothioconazole - Barley - PYRNTE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad				Prothioconazole										
					93.75+187.5 g a.s./ha			93.75 g a.s./ha				187.5 g a.s./ha										
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha	
PYRNTE Disease severity	Last valid assessment	Maritime	FLAGLE	9	16.0	4.5	48.2	81.3	45.8	100.0	17.4	66.1	30.6	100.0	22.9	71.2	43.1	97.4	15.1	2>; 7=; 0<	2>; 7=; 0<	
			FLMII	12	34.5	4.8	99.0	85.5	61.2	99.0	10.8	57.6	24.5	97.2	21.5	75.4	35.3	98.7	16.6	7>; 5=; 0<	4>; 8=; 0<	
		Northeast	FLAGLE	2	10.6	7.0	14.3	95.5	94.5	96.4	1.0	82.0	81.9	82.1	0.1	81.2	76.6	85.7	4.6	1>; 1=; 0<	1>; 1=; 0<	
			FLMII	2	18.9	13.5	24.3	96.9	95.9	97.9	1.0	81.8	80.3	83.3	1.5	83.0	75.2	90.8	7.8	2>; 0=; 0<	1>; 1=; 0<	
		Southeast	FLAGLE	5	9.1	4.7	16.4	92.5	84.9	100.0	6.0	79.9	48.3	95.9	16.7	83.8	69.7	100.0	9.7	2>; 3=; 0<	2>; 3=; 0<	
			FLMII	8	13.7	6.4	35.3	92.7	83.0	100.0	6.2	83.7	44.7	100.0	17.1	85.6	67.1	100.0	11.9	2>; 6=; 0<	2>; 6=; 0<	
		All EPPO climatic zones	FLAGLE	16	13.2	4.5	48.2	86.6	45.8	100.0	14.8	72.4	30.6	100.0	20.8	76.4	43.1	100.0	14.0	5>; 11=; 0<	5>; 11=; 0<	
			FLMII	22	25.5	4.8	99.0	89.2	61.2	100.0	9.8	69.3	24.5	100.0	22.9	79.8	35.3	100.0	15.2	11>; 11=; 0<	7>; 15=; 0<	

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-17:

This 24-trial summary includes only 4 trials with single application data: one in the SE zone (RO) and three in the Maritime zone (DE, FR, UK).

Table 3.2-18: Benefit of the association of fluxapyroxad and prothioconazole - Barley - PUCCHD

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to		
								ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha						
								Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole						
								93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha						
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha			
PUCCHD Disease severity	Last valid assessment	Maritime	FLAGLE	2	12.3	11.8	12.8	86.3	80.9	91.6	5.4	59.6	31.9	87.2	27.7	74.1	66.0	82.1	8.1	2> ; 0= ; 0<	1> ; 1= ; 0<	
			FLMII	4	31.8	6.0	99.0	91.7	88.7	97.5	3.4	56.4	0.0	95.6	37.4	83.5	71.5	95.2	8.9	2> ; 2= ; 0<	1> ; 3= ; 0<	
		Northeast	FLAGLE	1	6.5	-	-	100.0	-	-	-	84.5	-	-	-	84.5	-	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
			FLMII	1	7.0	-	-	96.9	-	-	-	85.6	-	-	-	88.7	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		All EPPO climatic zones	FLAGLE	3	10.4	6.5	12.8	90.8	80.9	100.0	7.8	67.9	31.9	87.2	25.5	77.5	66.0	84.5	8.2	3> ; 0= ; 0<	2> ; 1= ; 0<	
			FLMII	5	26.8	6.0	99.0	92.7	88.7	97.5	3.7	62.2	0.0	95.6	35.4	84.5	71.5	95.2	8.3	2> ; 3= ; 0<	1> ; 4= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-18:

This 5-trial summary is based exclusively on double-application data.

Table 3.2-19: Benefit of the association of fluxapyroxad and prothioconazole - Barley - RAMUCC

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated		Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to		
							ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha						
							Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole						
							93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha						
		Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha			
RAMUCC Disease severity	Last valid assessment	Maritime	FLAGLE	10	32.3	4.9	89.4	87.5	77.4	98.9	7.6	60.2	28.1	88.6	23.0	79.1	57.9	100.0	13.4	6>; 4=; 0<	1>; 9=; 0<
			FLMI1	12	46.6	5.8	99.0	85.7	70.2	99.7	9.1	62.0	18.7	87.5	19.9	78.5	57.0	100.0	10.7	8>; 4=; 0<	1>; 11=; 0<
		Southeast	FLAGLE	2	84.9	82.9	86.9	99.7	99.4	100.0	0.3	98.6	98.3	98.9	0.3	97.4	94.8	100.0	2.6	0>; 2=; 0<	0>; 2=; 0<
			FLMI1	2	97.8	97.5	98.1	98.3	96.8	99.7	1.5	96.0	95.8	96.2	0.2	95.3	92.6	98.0	2.7	1>; 1=; 0<	1>; 1=; 0<
		All EPPO climatic zones	FLAGLE	12	41.1	4.9	89.4	89.5	77.4	100.0	8.3	66.6	28.1	98.9	25.4	82.2	57.9	100.0	14.0	6>; 6=; 0<	1>; 11=; 0<
			FLMI1	14	53.9	5.8	99.0	87.5	70.2	99.7	9.5	66.8	18.7	96.2	21.9	80.9	57.0	100.0	11.6	9>; 5=; 0<	2>; 12=; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-19:

This 15-trial summary includes only 2 trials with single application data: both in the Maritime zone (DE).

Table 3.2-20: Benefit of the association of fluxapyroxad and prothioconazole - Barley - ERYSGH

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;< to			
					Untreated			ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad				Prothioconazole										
					93.75+187.5 g a.s./ha			93.75 g a.s./ha				187.5 g a.s./ha										
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha	
ERYSGH Disease severity	Last valid assessment	Maritime	FLMI2	3	5.4	4.8	6.3	84.6	57.9	100.0	19.0	77.1	63.2	100.0	16.3	91.6	78.9	100.0	9.2	0> ; 3= ; 0<	0> ; 3= ; 0<	
		Northeast	FLAGLE	1	5.3	-	-	100.0	-	-	-	85.8	-	-	-	100.0	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI1	2	14.8	13.5	16.0	91.8	85.7	97.9	6.1	87.0	85.1	88.9	1.9	87.9	86.9	88.9	1.0	1> ; 1= ; 0<	1> ; 1= ; 0<	
		All EPPO climatic zones	FLMI2	1	16.0	16.0	16.5	96.9	83.1	96.9	-	84.4	83.1	84.4	-	90.6	83.1	90.6	-	1> ; 0= ; 0<	0> ; 4= ; 0<	
			FLMI2	4	16.3	16.0	16.5	90.0	83.1	96.9	-	83.8	83.1	84.4	-	86.9	83.1	90.6	-	1> ; 0= ; 0<	0> ; 4= ; 0<	
		All EPPO climatic zones	FLAGLE	1	5.3	-	-	100.0	-	-	-	85.8	-	-	-	100.0	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI1	2	14.8	13.5	16.0	91.8	85.7	97.9	6.1	87.0	85.1	88.9	1.9	87.9	86.9	88.9	1.0	1> ; 1= ; 0<	1> ; 1= ; 0<	
			FLMI2	4	8.0	4.8	16.0	87.7	57.9	100.0	17.3	78.9	63.2	100.0	14.5	91.4	78.9	100.0	7.9	1> ; 3= ; 0<	0> ; 4= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-20:

This 5-trial summary includes 3 trials with single application data (DE (2), PL).

Table 3.2-21: Benefit of the association of fluxapyroxad and prothioconazole - Barley - All valid efficacy trials

Target	Parts	No. of trials	Untreated			Percentage of efficacy (%)									No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
						ADM.03503.F.1.A 1.25 L/ha			IMTREX 1.5 L/ha			PROLINE 0.75 L/ha				
						Fluxapyroxad + Prothioconazole			Fluxapyroxad			Prothioconazole				
						93.75+187.5 g a.s./ha			93.75 g a.s./ha			187.5 g a.s./ha				
Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha
RHYNSE	FLAGLE	20	18.6	5.5	88.8	91.6	65.2	100.0	75.9	32.7	100.0	82.8	56.5	100.0	6>;14=;0<	4>;16=;0<
	FLMI1	26	20.1	5.3	100.0	89.4	42.9	100.0	77.4	32.8	100.0	84.3	42.9	100.0	7>;19=;0<	4>;22=;0<
PYRNTE	FLAGLE	16	13.2	4.5	48.2	86.6	45.8	100.0	72.4	30.6	100.0	76.4	43.1	100.0	5>;11=;0<	5>;11=;0<
	FLMI1	22	25.5	4.8	99.0	89.2	61.2	100.0	69.3	24.5	100.0	79.8	35.3	100.0	11>;11=;0<	7>;15=;0<
PUCCHD	FLAGLE	3	10.4	6.5	12.8	90.8	80.9	100.0	67.9	31.9	87.2	77.5	66.0	84.5	3>;0=;0<	2>;1=;0<
	FLMI1	5	26.8	6.0	99.0	92.7	88.7	97.5	62.2	0.0	95.6	84.5	71.5	95.2	2>;3=;0<	1>;4=;0<
RAMUCC	FLAGLE	12	41.1	4.9	89.4	89.5	77.4	100.0	66.6	28.1	98.9	82.2	57.9	100.0	6>;6=;0<	1>;11=;0<
	FLMI1	14	53.9	5.8	99.0	87.5	70.2	99.7	66.8	18.7	96.2	80.9	57.0	100.0	9>;5=;0<	2>;12=;0<
ERYSGH	FLAGLE	1	5.3	-	-	100.0	-	-	85.8	-	-	100.0	-	-	0>;1=;0<	0>;1=;0<
	FLMI1	2	14.8	13.5	16.0	91.8	85.7	97.9	87.0	85.1	88.9	87.9	86.9	88.9	1>;1=;0<	1>;1=;0<
	FLMI2	4	8.0	4.8	16.0	87.7	57.9	100.0	78.9	63.2	100.0	91.4	78.9	100.0	1>;3=;0<	0>;4=;0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-21:

Except for 16 datapoints, this 76-datapoint summary in barley is based on double-application efficacy data.

The results are summarized by EPP0 climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPP0 climatic zones presented Table 3.2-21) are discussed hereafter to justify the benefit of the association fluxapyroxad with prothioconazole formulated in ADM.03503.F.1.A

Across 53 efficacy trials carried out in the Maritime, the Northeast and the Southeast EPP0 climatic zones, ADM.03503.F.1.A, applied at the proposed label rate of 1.25 L/ha, was compared to straight fluxapyroxad at 93.75 g a.s./ha (IMTREX at 1.5 L/ha) and straight prothioconazole at 187.5 g a.s./ha (PROLINE at 0.75 L/ha).

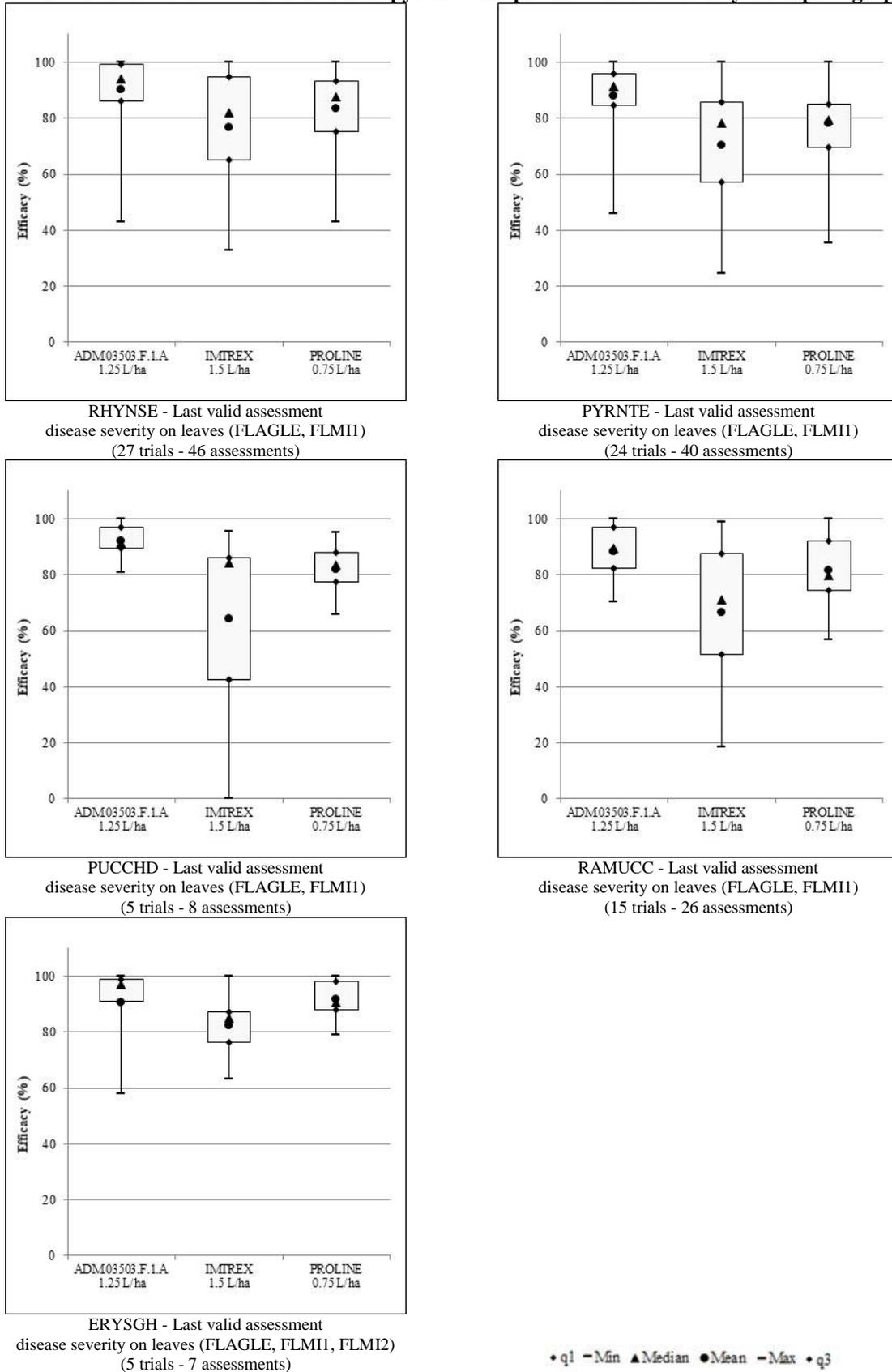
Against RHYNSE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 92% on FLAGLE and 89% on FLMI1 when IMTREX provided 76% on FLAGLE and 77% on FLMI1 and PROLINE provided 83% on FLAGLE and 84% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in 6 out of 20 trials on FLAGLE and in 7 out of 26 trials on FLMI1. ADM.03503.F.1.A was also significantly superior to PROLINE in 4 out of 20 trials on FLAGLE and in 4 out of 26 trials on FLMI1. Against PYRNTE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 87% on FLAGLE and 89% on FLMI1 when IMTREX provided 72% on FLAGLE and 69% on FLMI1 and PROLINE provided 76% on FLAGLE and 80% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in 5 out of 16 trials on FLAGLE and in 11 out of 22 trials on FLMI1. ADM.03503.F.1.A was also significantly superior to PROLINE in 5 out of 16 trials on FLAGLE and in 7 out of 22 trials on FLMI1.

Against PUCCHD, ADM.03503.F.1.A applied at 1.25 L/ha delivered 91% on FLAGLE and 93% on FLMI1 when IMTREX provided 68% on FLAGLE and 62% on FLMI1 and PROLINE provided 78% on FLAGLE and 85% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in the 3 trials on FLAGLE and in 2 out of 5 trials on FLMI1. ADM.03503.F.1.A was also significantly superior to PROLINE in 2 out of 3 trials on FLAGLE and in 1 out of 5 trials on FLMI1.

Against RAMUCC, ADM.03503.F.1.A applied at 1.25 L/ha delivered 90% on FLAGLE and 88% on FLMI1 when IMTREX provided 67% on FLAGLE and FLMI1 and PROLINE provided 82% on FLAGLE and 81% on FLMI1. ADM.03503.F.1.A was significantly superior to IMTREX in 6 out of 12 trials on FLAGLE and in 9 out of 14 trials on FLMI1. ADM.03503.F.1.A was also significantly superior to PROLINE in 1 out of 12 trials on FLAGLE and in 2 out of 14 trials on FLMI1. Against ERYSGH, ADM.03503.F.1.A applied at 1.25 L/ha delivered 100% on FLAGLE, 92% on FLMI1 and 88% on FLMI2 when IMTREX provided 86% on FLAGLE, 87% on FLMI1 and 79% on FLMI2 and PROLINE provided 100% on FLAGLE, 88% on FLMI1 and 91% on FLMI2. ADM.03503.F.1.A was significantly superior to IMTREX in 1 out of 2 trials on FLMI1 and in 1 out of 4 trials on FLMI2. ADM.03503.F.1.A was also significantly superior to PROLINE in 1 out of 2 trials on FLMI1.

These results confirm that fluxapyroxad and prothioconazole are complementary against the barley disease complex (RHYNSE, PYRNTE, PUCCHD, RAMUCC, and ERYSGH). For each disease with at least 5 assessments, the interest of the association of fluxapyroxad with prothioconazole can be illustrated by box plot graphics (Figure 3.2-7). Overall, box plot graphics clearly show a better control and homogeneity for ADM.03503.F.1.A than IMTREX or PROLINE according to the disease. Indeed, according to the box plots graphics, the efficacy level and the dispersion between efficacies is less important for ADM.03503.F.1.A than IMTREX or PROLINE.

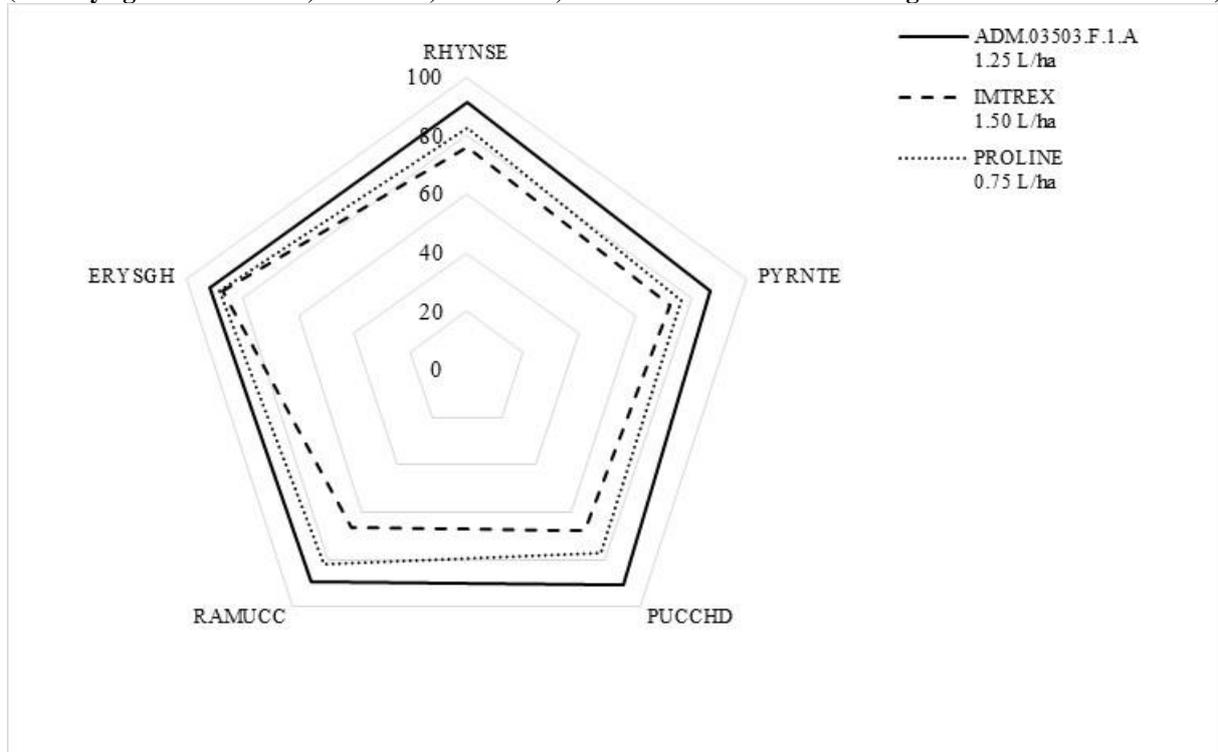
Figure 3.2-7 Benefit of the association of fluxapyroxad and prothioconazole - Barley - Box plots graphics



The interest of the association of fluxapyroxad with prothioconazole against barley disease complex can be illustrated by graphic from the last valid assessment on FLAGLE (RHYNSE, PYRNTE, PUCCHD and RAMUCC) (Figure 3.2-8). According to the efficacy results and as illustrated on the graphic

hereafter, the association contained in ADM.03503.F.1.A at 1.25 L/ha is a good association to control the major diseases of barley.

Figure 3.2-8 Benefit of the association of fluxapyroxad and prothioconazole - Barley - Disease complex (efficacy against RHYNSE, PYRNTE, PUCCHD, RAMUCC on FLAGLE and against ERYSGH on FLMI1)



To conclude, the benefit of the formulated product ADM.03503.F.1.A over fluxapyroxad or prothioconazole applied straight against the barley disease complex (RHYNSE, PYRNTE, PUCCHD, RAMUCC and ERYSGH) is clearly demonstrated.

3.2.1.1.4 Results on the benefit of the association of fluxapyroxad and prothioconazole for the control of rye diseases

A total of **8 valid efficacy trials** were carried out to show the interest of the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A. These trials were carried out **from 2020 to 2021** in the Maritime (4 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (2 trials in Table 3.2-22 (RHYNSE) and

Table 3.2-23 (PUCCRE) summarise all observations for each disease (efficacy) and Table 3.2-24 synthesises the benefit of the association of fluxapyroxad and prothioconazole contained in ADM.03503.F.1.A against the rye disease complex.

Table 3.2-22: Benefit of the association of fluxapyroxad and prothioconazole - Rye - RHYNSE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 1.25 L/ha				IMTREX 1.5 L/ha				PROLINE 0.75 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad				Prothioconazole										
					93.75+187.5 g a.s./ha			93.75 g a.s./ha				187.5 g a.s./ha										
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha	
RHYNSE Disease severity	Last valid assessment	Maritime	FLAGLE	2	25.4	25.0	25.8	84.7	83.0	86.4	1.7	64.5	60.0	68.9	4.5	77.9	72.8	83.0	5.1	1>; 1=; 0<	0>; 2=; 0<	
			FLMI1	3	46.7	7.5	77.5	91.4	86.4	100.0	6.1	76.1	47.7	100.0	21.6	88.1	81.8	100.0	8.4	1>; 2=; 0<	0>; 3=; 0<	
			FLMI2	3	62.3	36.5	99.0	83.1	80.8	85.6	2.0	74.2	65.9	79.5	6.0	77.3	74.0	80.5	2.7	2>; 1=; 0<	2>; 1=; 0<	
		Northeast	FLAGLE	2	14.7	14.4	15.0	84.9	80.9	88.8	4.0	71.1	52.2	90.0	18.9	62.4	56.5	68.3	5.9	1>; 1=; 0<	2>; 0=; 0<	
			FLMI1	1*	11.9	-	-	100.0	-	-	-	76.8	-	-	-	90.0	-	-	-	-	1>; 0=; 0<	1>; 0=; 0<
		Southeast	FLMI2	2	16.9	15.3	18.4	90.8	90.5	91.0	0.3	86.2	77.1	95.3	9.1	71.0	69.8	72.2	1.2	0>; 2=; 0<	2>; 0=; 0<	
			FLAGLE	2	5.1	5.1	5.1	89.9	85.1	94.6	4.8	78.9	76.2	81.5	2.7	85.3	83.0	87.6	2.3	0>; 2=; 0<	0>; 2=; 0<	
			FLMI1	2	8.8	7.3	10.3	85.0	80.1	90.0	5.0	74.1	70.4	77.7	3.7	81.0	76.4	85.5	4.5	1>; 1=; 0<	0>; 2=; 0<	
		All EPPO climatic zones	FLMI2	2	15.4	13.2	17.7	79.4	74.5	84.3	4.9	68.0	64.0	72.1	4.1	76.1	71.0	81.2	5.1	1>; 1=; 0<	0>; 2=; 0<	
			FLAGLE	6	15.1	5.1	25.8	86.5	80.9	94.6	4.4	71.5	52.2	90.0	12.8	75.2	56.5	87.6	10.6	2>; 4=; 0<	2>; 4=; 0<	
			FLMI1	6	28.3	7.3	77.5	90.7	80.1	100.0	7.2	75.6	47.7	100.0	15.5	86.1	76.4	100.0	7.5	3>; 3=; 0<	1>; 5=; 0<	
			FLMI2	7	35.9	13.2	99.0	84.2	74.5	91.0	5.3	75.9	64.0	95.3	9.6	75.2	69.8	81.2	4.2	3>; 4=; 0<	4>; 3=; 0<	

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-22:

This 7-trial summary includes 2 trials with single application data (3 data points) (PL).

* There is still one more data point available but not used by the applicant, in the PL21FESECSS033A trial, from the FLMI1 (L2) leaf layer: efficacy **88.1%**, 91.9% and 68.1%, the **test item**, IMTREX and PROLINE respectively, on the day 26 DA-AA (0 DA-B), with PESSEV UNCK 20.9% making the observation reliable / valid.

Table 3.2-23: Benefit of the association of fluxapyroxad and prothioconazole - Rye - PUCCRE

Target Parameters	Assessment timing	EPP0 climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
								ADM.03503.F.1.A 1.25 L/ha				IMTrex 1.5 L/ha				PROLINE 0.75 L/ha					
								Fluxapyroxad + Prothioconazole				Fluxapyroxad				Prothioconazole					
								93.75+187.5 g a.s./ha				93.75 g a.s./ha				187.5 g a.s./ha					
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	IMTrex 1.5 L/ha	PROLINE 0.75 L/ha		
PUCCRE Disease severity	Last valid assessment	Maritime	FLAGLE	3	6.0	4.5	8.4	82.8	48.5	100.0	24.3	74.9	24.8	100.0	35.5	74.8	54.5	100.0	18.9	0> ; 3= ; 0<	1> ; 2= ; 0<
			FLMI1	3	8.9	4.5	11.6	84.5	53.4	100.0	22.0	81.1	43.4	100.0	26.7	86.1	67.8	100.0	13.5	0> ; 3= ; 0<	1> ; 2= ; 0<
			FLMI2	2	10.4	7.5	13.3	78.6	57.2	100.0	21.4	74.2	48.4	100.0	25.8	84.9	69.8	100.0	15.1	0> ; 2= ; 0<	0> ; 2= ; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-23:

This 3-trial summary is based exclusively on double-application data.

Table 3.2-24: Benefit of the association of fluxapyroxad and prothioconazole - Rye - All valid efficacy trials

Target	Parts	No. of trials	Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
			Untreated			ADM.03503.F.1.A 1.25 L/ha			IMTREX 1.5 L/ha			PROLINE 0.75 L/ha				
			Fluxapyroxad + Prothioconazole			Fluxapyroxad			Prothioconazole							
			93.75+187.5 g a.s./ha			93.75 g a.s./ha			187.5 g a.s./ha							
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	IMTREX 1.5 L/ha	PROLINE 0.75 L/ha
RHYNSE	FLAGLE	6	15.1	5.1	25.8	86.5	80.9	94.6	71.5	52.2	90.0	75.2	56.5	87.6	2> ; 4= ; 0<	2> ; 4= ; 0<
	FLMI1	6	28.3	7.3	77.5	90.7	80.1	100.0	75.6	47.7	100.0	86.1	76.4	100.0	3> ; 3= ; 0<	1> ; 5= ; 0<
	FLMI2	7	35.9	13.2	99.0	84.2	74.5	91.0	75.9	64.0	95.3	75.2	69.8	81.2	3> ; 4= ; 0<	4> ; 3= ; 0<
PUCCRE	FLAGLE	3	6.0	4.5	8.4	82.8	48.5	100.0	74.9	24.8	100.0	74.8	54.5	100.0	0> ; 3= ; 0<	1> ; 2= ; 0<
	FLMI1	3	8.9	4.5	11.6	84.5	53.4	100.0	81.1	43.4	100.0	86.1	67.8	100.0	0> ; 3= ; 0<	1> ; 2= ; 0<
	FLMI2	2	10.4	7.5	13.3	78.6	57.2	100.0	74.2	48.4	100.0	84.9	69.8	100.0	0> ; 2= ; 0<	0> ; 2= ; 0<

(1) Comparison based on statistics carried out in each trial report.

zRMS comments to Table 3.2-24:
 Except for 3 datapoints, this 28-datapoint summary in rye is based on double-application efficacy data.

The results are summarized by EPPO climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPPO climatic zones presented Table 3.2-24) are discussed hereafter to justify the benefit of the association fluxapyroxad with prothioconazole formulated in ADM.03503.F.1.A

Across 8 efficacy trials carried out in the Maritime, the Northeast and the Southeast EPPO climatic zones, ADM.03503.F.1.A, applied at the proposed label rate of 1.25 L/ha, was compared to straight fluxapyroxad at 93.75 g a.s./ha (IMTREX at 1.5 L/ha) and straight prothioconazole at 187.5 g a.s./ha (PROLINE at 0.75 L/ha).

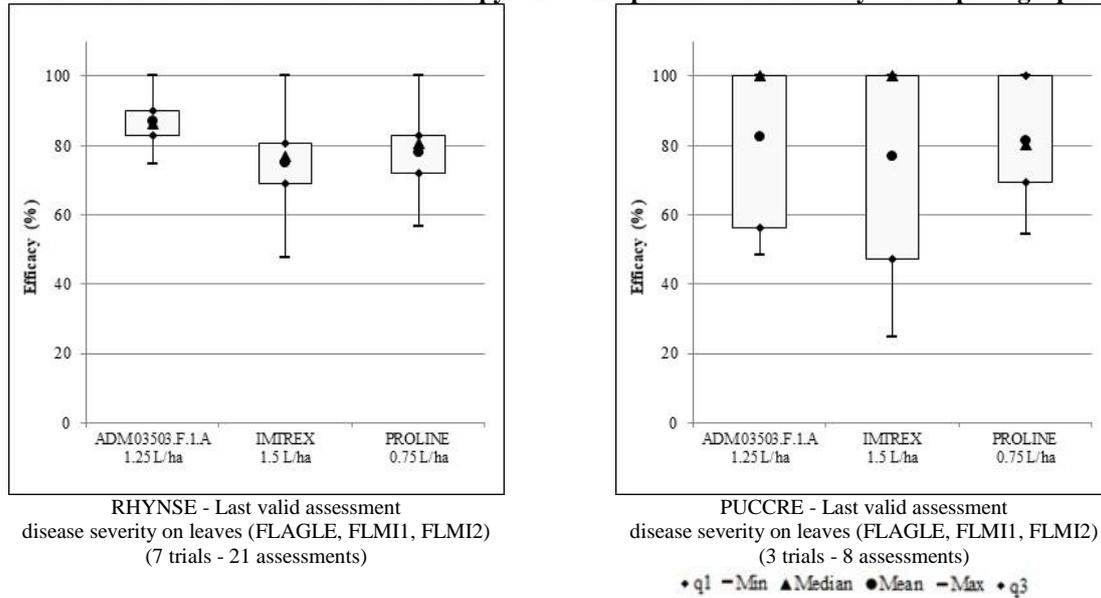
Against RHYNSE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 87% on FLAGLE, 91% on FLMI1 and 84% on FLMI2 when IMTREX provided 72% on FLAGLE, 76% on FLMI1 and FLMI2 and PROLINE provided 75% on FLAGLE, 86% on FLMI1 and 75% on FLMI2. ADM.03503.F.1.A was significantly superior to IMTREX in 2 out of 6 trials on FLAGLE, in 3 out of 6 trials on FLMI1 and in 3 out of 7 trials on FLMI2. ADM.03503.F.1.A was also significantly superior to PROLINE in 2 out of 6 trials on FLAGLE, in 1 out of 6 trials on FLMI1 and in 4 out of 7 trials on FLMI2.

Against PUCCRE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 83% on FLAGLE, 85% on FLMI1 and 79% on FLMI2 when IMTREX provided 75% on FLAGLE, 81% on FLMI1 and 74% on FLMI2 and PROLINE provided 75% on FLAGLE, 86% on FLMI1 and 85% on FLMI2. ADM.03503.F.1.A was significantly superior to PROLINE in 1 out of 3 trials on FLAGLE and in 1 out of 3 trials on FLMI1.

These results confirm that fluxapyroxad and prothioconazole are complementary against the rye disease complex (RHYNSE and PUCCRE).

For each disease with at least 5 assessments, the interest of the association of fluxapyroxad with prothioconazole can be illustrated by box plot graphics (Figure 3.2-9). Overall, box plot graphics clearly show a better control and homogeneity for ADM.03503.F.1.A than IMTREX or PROLINE according to the disease. Indeed, according to the box plots graphics, the efficacy level and the dispersion between efficacies is less important for ADM.03503.F.1.A than IMTREX or PROLINE.

Figure 3.2-9 Benefit of the association of fluxapyroxad and prothioconazole - Rye - Box plots graphics



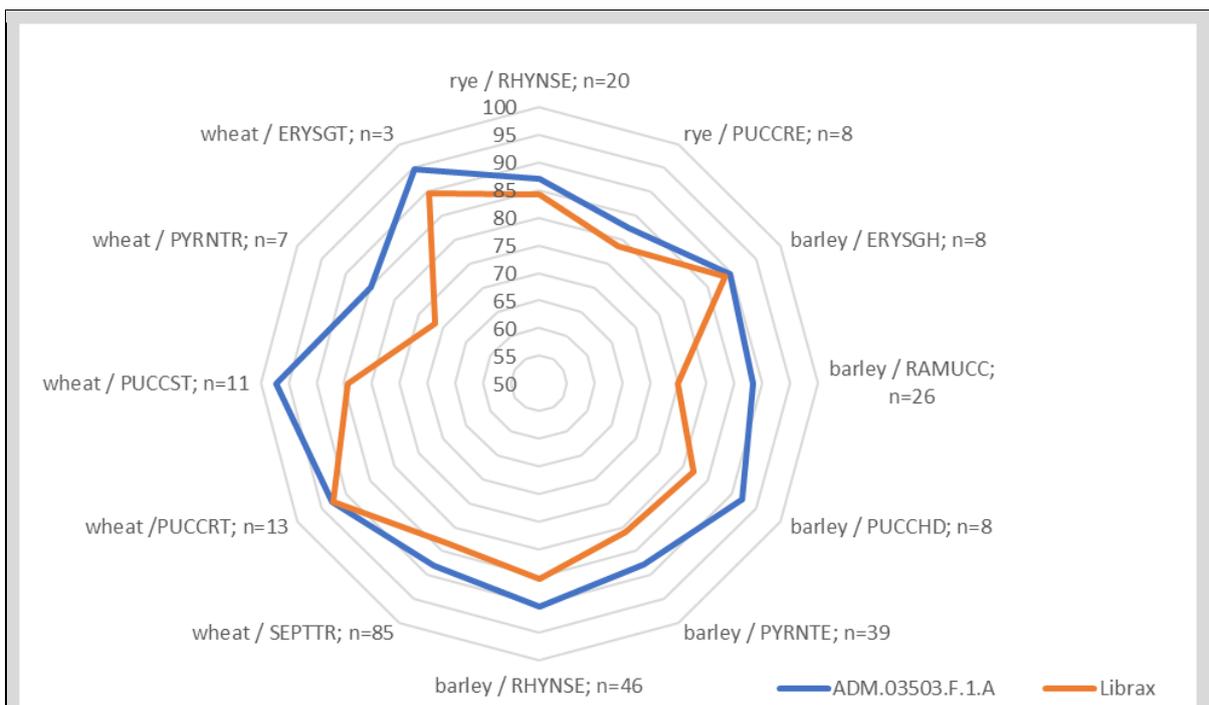
To conclude, the benefit of the formulated product ADM.03503.F.1.A over fluxapyroxad or prothioconazole applied straight against the rye disease complex (RHYNSE, PUCCRE) is clearly demonstrated.

3.2.1.1.5 Summary and conclusion of the interest of the association

On cereals, a total of **99 valid efficacy trials** were carried out to demonstrate the interest of the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A. By and large, in these trials performed **from 2019 to 2021** in the Maritime, the Northeast and the Southeast EPO climatic zones, the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A allowed increasing the control of the disease complex of wheat (SEPTTR, PUCCRT, PUCST, PYRNT, ERYSGT), barley (RHYNSE, PYRNTE, PUCCHD, ERYSGH and RAMUCC) and rye (RHYNSE, PUCCRE) compared to the same rate of fluxapyroxad or prothioconazole applied straight. **Based on the benefits with respect to resistance prevention, the knowledge of each active substances, and technical possibilities on formulation, the combination of the active substances fluxapyroxad + prothioconazole in ADM.03503.F.1.A and their rate ratio are is clearly justified on cereals.**

zRMS comments to the applicant’s general conclusion on co-formulation advantage:

1. Please note, that it is only the **next** chapter, that covers the issue of ratio.
2. The data summarized above come from 3 cereal crops and they represent complex of pathogens in each one of these crops. In each case the applicant’s conclusion is focused on the co-formulation advantage compared to the solo use of the components; most of the time **the results justify the co-formulation.**
3. In addition, data on Librax, a product co-formulating fluxapyroxad with another triazole (metconazole) and therefore used for comparison, have been summarized in the BAD, but were not used by the applicant in this chapter of the dRR. Since the zRMS considered these data useful **here**, for they also include observations on rye, the figure pasted below summarizes them concisely (based on collated data from the leaves L1 and L2), showing average distance in the efficacy between the test item used at the target rate and Librax, product already on the market, for all crops and targets that were tested to this stage.



Please note that the number of datapoints (n) varies considerably between the different crop/target combinations. Nonetheless, as preliminary, these results essentially demonstrate that the co-formulation of the two actives in the test item results in the product that mostly keeps up with the standard applied for comparison.

[Back to Abstract](#)

3.2.1.2 Justification of ratio between fluxapyroxad and prothioconazole in ADM.03503.F.1.A.

3.2.1.2.1 Material and Methods

In **10 trials**, several tank-mixes IMTREX/PROLINE were tested to justify the ratio between both active substances contained in ADM.03503.F.1.A. These products are presented in Table 3.2-9.

Experimental details

All the trials were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines or trial method recommendations published by the French CEB (“Commission des Essais Biologiques”). The “CEB” methods are in accordance with EPPO directives. Main characteristics are summarised in Table 3.2-25.

Table 3.2-25: Details on trial methodology - Ratio trials - Cereals

Guidelines	General guidelines	PP1/135 (4): Phytotoxicity assessment PP1/152 (4): Design and analysis of efficacy evaluation trials PP1/181 (4): Conduct and reporting of efficacy evaluation trials including good experimental practice
	Specific guidelines	PP 1/26(4): “Foliar and ear diseases on cereals” CEB 189: “Efficacy trials method for fungicide products intended to control cereal diseases (treatment of the above - ground crop parts)”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	<u>Winter wheat</u> : From 14 m ² to 30 m ² . <u>Barley</u> : From 18 m ² to 30 m ² .
	Number of replications	4 replications
Crop	Number of trials	10 trials (7 trials in wheat, 3 trials in barley)
Crop	Varieties	<u>Winter wheat</u> : <i>Cubus</i> (1), <i>Dekan</i> (1), <i>MV Kolo</i> (1), <i>Laurier</i> (1), <i>SY Matis</i> (1), <i>Rubisko</i> (1), <i>KWS Santiago</i> (1). <u>Winter barley</u> : <i>Cassia</i> (1), <i>Etincel</i> (1), <i>Fabian</i> (1).
Application	Application timing	<u>Wheat</u> : 1 st application BBCH 31-39 - 2 nd applications BBCH 39-69 <u>Barley</u> : 1 st application BBCH 31-37 - 2 nd applications BBCH 61-69
	Number of applications	2 applications.
	Spray volumes	200 - 300 L/ha.
Assessment	Assessment dates	7-14-day intervals after each application
	Assessment types	Disease severity on leaves (SEPTTR, PUCCRE, PUCST, PYRNTR, RHYNSE, PYRNTE, PUCCHD) Yield (7 trials in wheat, 3 trials in barley)
Results & Analysis	Statistical analysis	ANOVA - Newman - Keuls test (5%)

Treatments and reference standards

Several tank-mixes IMTREX/PROLINE presented in Table 3.2-26 were tested to determine the best ratio between Fluxapyroxad and Prothioconazole. These tank-mixes were applied twice.

Table 3.2-26: Presentation of reference standards used in trials - Efficacy trials - Cereals

Reference standard	Active substance(s)	Formulation		Application rate in trials (per treatment)	Rate of active substance per ha
		Type	Concentration of a.s.		
IMTREX + PROLINE	Fluxapyroxad + Prothioconazole	EC	62.5 g/L	1.50 L/ha + 0.52 L/ha	94+130 g a.s./ha
		EC	250 g/L	1.50 L/ha + 0.60 L/ha 1.50 L/ha + 0.75 L/ha 1.20 L/ha + 0.60 L/ha 1.00 L/ha + 0.75 L/ha 2.00 L/ha + 0.80 L/ha	94+150 g a.s./ha 94+188 g a.s./ha 75+150 g a.s./ha 62.5+188 g a.s./ha 125+200 g a.s./ha

Assessment methods

See Section 3.2.3.1. (i.e. Material and Methods in: *Efficacy Tests*)

Statistical analyses

See Section 3.2.3.1. (*i.e.* Material and Methods in: *Efficacy Tests*)

Results layout

See Section 3.2.3.1.

3.2.1.2.2 Results on the justification of ratio between of fluxapyroxad and prothioconazole for the control of wheat diseases

A total of **7 valid efficacy trials** were carried out to show the interest of the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A. These trials were carried out **in 2019** in the Maritime (2 trials in Germany, 1 trial in the United Kingdom and 3 trials in France), and the Southeast (1 trial in Hungary) EPPO climatic zones against SEPTTR (4 trials), PUCCRT (2 trials), and PUC CST (1 trial). Table 3.2-27 synthesises all tested ratio between fluxapyroxad and prothioconazole.

Table 3.2-27: Justification of ratio between of fluxapyroxad and prothioconazole - Wheat

Target Parameters	Assessment timing	Parts	No. of trials	IMTREX + PROLINE																										
				Fluxapyroxad + Prothioconazole																										
				94+130 g a.s./ha				94+150 g a.s./ha				75+150 g a.s./ha				62.5+188 g a.s./ha				94+188 g a.s./ha				125+200 g a.s./ha						
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.			
Percentage of efficacy (%)																														
SEPTTR Disease severity	Last valid assessment	FLAGLE	3	27.9	19.0	38.8	93.9	85.8	100.0	6.0	97.4	92.3	100.0	3.6	93.4	82.6	100.0	7.7	94.4	84.5	100.0	7.0	96.1	90.3	100.0	4.2	95.6	87.1	100.0	6.0
		FLMI1	4	69.4	45.6	99.0	67.8	48.2	94.5	19.5	71.3	49.5	94.6	20.0	66.1	41.9	91.1	19.3	68.2	47.0	91.0	20.7	70.9	49.5	95.1	18.8	72.7	45.7	96.2	20.9
		FLMI2	3	45.1	27.0	73.1	69.5	46.5	83.2	16.4	69.9	51.3	83.7	13.7	67.7	51.0	81.6	12.7	72.5	58.9	86.2	11.1	76.1	63.6	82.5	8.8	78.7	66.9	86.6	8.5
PUCCRT Disease severity	Last valid assessment	FLAGLE	1	17.9	-	-	96.2	-	-	-	97.6	-	-	-	95.5	-	-	-	95.8	-	-	-	96.9	-	-	-	97.9	-	-	-
		FLMI1	1	8.4	-	-	98.5	-	-	-	99.1	-	-	-	99.4	-	-	-	99.4	-	-	-	99.4	-	-	-	99.7	-	-	-
		FLMI2	1	7.8	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-
PUC CST Disease severity	Last valid assessment	FLAGLE	1	19.9	-	-	95.9	-	-	-	73.1	-	-	-	92.8	-	-	-	93.4	-	-	-	96.0	-	-	-	83.5	-	-	-
		FLMI1	1	94.5	-	-	86.9	-	-	-	81.9	-	-	-	86.1	-	-	-	87.1	-	-	-	87.9	-	-	-	90.4	-	-	-
		FLMI2	1	62.7	-	-	95.2	-	-	-	92.8	-	-	-	95.0	-	-	-	93.8	-	-	-	94.2	-	-	-	96.4	-	-	-
PYRNTR Disease severity	Last valid assessment	FLMI2	1	10.0	-	-	75.0	-	-	-	80.0	-	-	-	60.0	-	-	-	77.5	-	-	-	87.5	-	-	-	87.5	-	-	-
Increase of green leaf area (%)																														
All diseases Green leaf area (%)	Last valid assessment	Leaves	5	22.0	11.5	43.8	34.3	8.2	77.4	27.7	35.4	13.3	73.2	25.1	34.0	13.1	76.6	25.8	35.5	11.9	77.8	26.7	36.9	13.3	81.3	27.9	38.5	17.5	83.6	26.3
Percentage of Untreated (%)																														
Yield (t/ha)	At harvest	Grains	7	9.6	7.8	11.9	114.0	97.9	164.5	21.5	113.2	98.5	157.8	19.1	113.5	98.0	163.6	21.3	113.9	98.1	163.1	20.8	115.6	98.3	163.8	20.8	112.8	98.7	161.5	20.6

zRMS comments to Table 3.2-27:

This 7-trial summary includes 2 trials with SEPTTR, that report efficacy following application A (FR). Otherwise (for other targets) it is based on double application trials.

Across 7 efficacy trials carried out in the Maritime and the Southeast EPPO climatic zones, several tank-mixes IMTREX/PROLINE were tested to determine the best ratio between Fluxapyroxad and Prothioconazole.

To study the prothioconazole rate, 3 rates (130, 150 and 188 g a.s./ha) were tested in tank-mix with 94 g a.s./ha fluxapyroxad.

In 5 trials against SEPTTR, 150 g a.s./ha prothioconazole are necessary to have the best efficacy (97% on FLAGLE, 71% on FLMI1 and 70% on FLMI2) compared to the tank-mix IMTREX/PROLINE bringing 130 g a.s./ha (94% on FLAGLE, 68% on FLMI1 and 70% on FLMI2).

In 2 trials against PUCCRT, no difference was observed between the prothioconazole rates.

In 1 trial against PUCGST, 188 g a.s./ha prothioconazole are necessary to have the best efficacy (96% on FLAGLE, 88% on FLMI1 and 94% on FLMI2) compared to the tank-mix IMTREX/PROLINE bringing 150 g a.s./ha (73% on FLAGLE, 82% on FLMI1 and 93% on FLMI2).

In 1 trial against PYRNTR, 188 g a.s./ha prothioconazole are necessary to have the best efficacy (88% on FLMI2) compared to the tank-mix IMTREX/PROLINE bringing 150 g a.s./ha (80% on FLMI2).

To study the fluxapyroxad rate, 2 rates (62.5 and 94 g a.s./ha) were tested in tank-mix with 188 g a.s./ha prothioconazole.

In 5 trials against SEPTTR, 94 g a.s./ha fluxapyroxad are necessary to have the best efficacy (96% on FLAGLE, 71% on FLMI1 and 76% on FLMI2) compared to the tank-mix IMTREX/PROLINE bringing 62.5 g a.s./ha (94% on FLAGLE, 68% on FLMI1 and 73% on FLMI2).

In 1 trial against PYRNTR, 94 g a.s./ha fluxapyroxad are necessary to have the best efficacy (88% on FLMI2) compared to the tank-mix IMTREX/PROLINE bringing 62.5 g a.s./ha (78% on FLMI2).

In 2 trials against PUCCRT and 1 trial against PUCGST, no difference was observed between the fluxapyroxad rates .

Finally, the tank-mix with the best effect on the yield was IMTREX/PROLINE bringing 94 g a.s./ha fluxapyroxad and 188 g a.s./ha prothioconazole.

The ratio 94 g a.s./ha fluxapyroxad with 188 g a.s./ha prothioconazole seems to be the best association to control SEPTTR, PUCCRT or PUCGST and to have the best positive effect on the yield.

Even if few data are available, the rates fluxapyroxad (93.75 g a.s./ha) and prothioconazole (187.5 g a.s./ha) bringing brought by ADM.03503.F.1.A at 1.25 L/ha against the wheat disease complex (SEPTTR, PUCCRT, PUCGST) can be considered as justified.

3.2.1.2.3 Results on the justification of ratio between of fluxapyroxad and prothioconazole for the control of barley diseases

A total of **3 valid efficacy trials** were carried out to show the interest of the association fluxapyroxad + prothioconazole formulated in ADM.03503.F.1.A. These trials were carried out **in 2019** in the Maritime (2 trials in Germany, 1 trial in the United Kingdom and 3 trials in France), and the Southeast (1 trial in Hungary) EPPO climatic zones against RHYNSE (2 trials), PYRNTE (2 trials), and PUCCHD (1 trial). Table 3.2-28 synthesises all tested ratio between fluxapyroxad and prothioconazole.

Table 3.2-28: Justification of ratio between of fluxapyroxad and prothioconazole - Barley

Target Parameters	Assessment timing	Parts	No. of trials	Untreated			IMTRESX + PROLINE																							
							Fluxapyroxad + Prothioconazole																							
				94+130 g a.s./ha				94+150 g a.s./ha				75+150 g a.s./ha				62.5+188 g a.s./ha				94+188 g a.s./ha				125+200 g a.s./ha						
				Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
RHYNSE Disease severity	Last valid assessment	FLAGLE	2	48.6	26.5	70.6	92.4	91.5	93.2	0.9	96.2	94.2	98.1	2.0	96.6	95.1	98.1	1.5	98.0	95.9	100.0	2.1	96.0	94.8	97.2	1.2	96.0	95.3	96.6	0.6
		FLMI1	2	70.9	43.8	98.0	85.4	84.0	86.7	1.4	89.0	85.4	92.6	3.6	87.7	86.9	88.5	0.8	93.4	93.0	93.7	0.4	91.9	89.5	94.3	2.4	91.3	88.2	94.3	3.1
		FLMI2	2	60.7	57.5	63.8	81.4	70.9	91.9	10.5	86.6	81.7	91.4	4.9	86.8	77.0	96.6	9.8	89.8	81.7	97.9	8.1	88.8	80.0	97.6	8.8	87.7	77.0	98.4	10.7
PYRNTE Disease severity	Last valid assessment	FLAGLE	1	59.8	-	-	95.8	-	-	-	100.0	-	-	-	100.0	-	-	-	95.3	-	-	-	100.0	-	-	-	100.0	-	-	-
		FLMI1	1	37.5	-	-	90.8	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-
		FLMI2	1	52.5	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-
PUCCHD Disease severity	Last valid assessment	FLAGLE	1	40.6	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-
All diseases Green leaf area (%)	Last valid assessment	Leaves		11.8	10.0	13.7	Increase of green leaf area (%)																							
							61.0	33.3	88.7	27.7	64.2	33.3	95.1	30.9	59.8	27.8	91.8	32.0	53.8	11.1	96.6	42.7	64.6	33.3	95.8	31.2	70.2	44.4	95.9	25.8
Yield (t/ha)	At harvest	Grains	3	8.3	5.5	9.9	Percentage of Untreated (%)																							
							122.9	109.9	142.4	14.1	122.8	111.8	143.8	14.9	123.3	112.0	144.8	15.2	123.3	113.9	140.1	11.9	123.8	111.3	145.2	15.2	123.9	111.6	146.2	15.8

zRMS comments to Table 3.2-28:
 This 3-trial summary is based on double application trials.

Across 3 efficacy trials carried out in the Maritime and the Southeast EPPO climatic zones, several tank-mixes IMTREX/PROLINE were tested to determine the best ratio between Fluxapyroxad and Prothioconazole.

To study the prothioconazole rate, 3 rates (130, 150 and 188 g a.s./ha) were tested in tank-mix with 94 g a.s./ha fluxapyroxad.

In 2 trials against RHYNSE, 188 g a.s./ha prothioconazole are necessary to have the best efficacy (96% on FLAGLE, 92% on FLMI1, and 89% on FLMI2) compared to the tank-mix IMTREX/PROLINE bringing 130 g a.s./ha (92% on FLAGLE, 85% on FLMI1, and 81% on FLMI2).

In 2 trials against PYRNTE, 150 g a.s./ha prothioconazole are necessary to have the best efficacy (100% on FLAGLE, 100% on FLMI1, and 100% on FLMI2) compared to the tank-mix IMTREX/PROLINE bringing 130 g a.s./ha (96% on FLAGLE, 91% on FLMI1, and 100% on FLMI2).

In 1 trial against PUCCHD, no difference was observed between the prothioconazole rates .

To study the fluxapyroxad rate, 2 rates (62.5 and 94 g a.s./ha) were tested in tank-mix with 188 g a.s./ha prothioconazole.

However, no difference was observed between the fluxapyroxad rates against RHYNSE, PYRNTE or PUCCHD.

Finally, the tank-mix with the best effect on the yield was IMTREX/PROLINE bringing 94 g a.s./ha fluxapyroxad and 188 g a.s./ha prothioconazole.

The ratio 94 g a.s./ha fluxapyroxad with 188 g a.s./ha prothioconazole seems to be the best association to control RHYNSE, PYRNTE or PUCCHD and to have the best positive effect on the yield.

Even if few data are available, the rates fluxapyroxad (93.75 g a.s./ha) and prothioconazole (187.5 g a.s./ha) bringing brought by ADM.03503.F.1.A at 1.25 L/ha against the barley disease complex (RHYNSE, PYRNTE, PUCCHD) can be considered as justified.

zRMS comments on the actives` ratio:

In both wheat and barley the conclusions are based on > 1 trial for the main pathogens only (SEPTTR, RHYNSE). Values obtained for the other targets are not means but single data points making impossible any conclusions based on data distribution. Similar to the GLA and the yield, these data do not always follow the ratio response observed for SEPTTR and RHYNSE. Nonetheless, taken the importance of the main pathogens of wheat and barley, the justification for the proposed ratio between the prothioconazole and fluxaproxad has been accepted.

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3.2.2 Minimum effective dose tests (KCP 6.2)

The confirmation of required doses of ADM.03503.F.1.A, presented in the GAP table in Table 3.1-1, was supported by the data from **263 valid efficacy trials** carried out **between 2019 and 2021** in the Maritime (2 trials in Austria, 2 trials in Belgium, 11 trials in Czech Republic, 53 trials in Germany, 7 trials in Ireland and 2 trials in The Netherlands, 26 trials in the United Kingdom and 41 trials in France), the Northeast (42 trials in Poland) and the Southeast (15 trials in Hungary, 37 trials in Romania and 25 trials in Slovakia) EPPO climatic zones in:

- wheat (143 trials) against SEPTTR (63 trials), PUCCRT (33 trials), PUC CST (28 trials), ERYSGT (15 trials), PYRNTR (19 trials), FUSASS FUSASP (20 trials) and/or MONGNI (2 trials).
- barley (99 trials) against RHYNSE (31 trials), PYRNTE (35 trials), PUCCHD (27 trials), RAMUCC (20 trials), or ERYSGH (26 trials).
- rye (8 trials) against RHYNSE (7 trials) and/or PUCCRE (3 trials).
- triticale (13 trials) against SEPTTR (1 trial), PUCCRE (8 trials), PUC CST (1 trial), PYRNTR (5 trials) and/or ERYSGR (5 trials).

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3.2.2.1 Material and methods

ADM.03503.F.1.A was tested at 0.70-0.75, 1.00 and 1.25 L/ha and. These rates reflect 56-60%, 80% and 100% (1.25 L/ha, the maximum recommended dose of ADM.03503.F.1.A) in accordance with the EPPO guideline PP 1/225(1) “Minimum effective rate”. Material and Methods used in these efficacy trials are given within Section 3.2.3.1.

Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar or ears area by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice vs the available data package available we selected assessments from 4.5% notably to be able to select same number of assessments per trial.

3.2.2.2 Results of minimum effective dose tests in wheat

A total of **143 valid efficacy trials** were carried out to justify the minimum effective dose of ADM.03503.F.1.A. These trials were carried out **from 2019 to 2021** in the Maritime (2 trials in Austria, 1 trial in Belgium, 6 trials in Czech Republic, 28 trials in Germany, 2 trials in Ireland and 2 trials in The Netherlands, 14 trials in the United Kingdom and 23 trials in France), the Northeast (21 trials in Poland) and the Southeast (9 trials in Hungary, 21 trials in Romania and 14 trials in Slovakia) EPPO climatic zones against SEPTTR (63 trials), PUCCRT (33 trials), PUC CST (28 trials), PYRNTR (15 trials), ERYSGT (19 trials), FUSASS FUSASP (22 trials), or MONGNI (2 trials).

Table 3.2-29 (SEPTTR), Table 3.2-30 (PUCCRT), Table 3.2-31 (PUC CST), Table 3.2-32 (PYRNTR), Table 3.2-33 (ERYSGT), Table 3.2-34 (FUSASS FUSASP) and Table 3.2-35 (MONGNI) summarise all observations for each disease (efficacy) and Table 3.2-36 synthesises the minimum effective dose of ADM.03503.F.1.A against the wheat disease complex.

To estimate the efficacy level after one application, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the first (for trials with 2 applications) or the single application (for trials with 1 application) was considered. This assessment is noted “Last valid assessment after application A” in the synthesis tables.

To estimate the efficacy level after two applications, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the second applications of trials with 2 applications was considered. This assessment is noted “Last valid assessment after application B” in the synthesis tables.

Finally, to estimate the intrinsic efficacy level of ADM.03503.F.1.A, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the single (for trials with 1 application) or the second (for trials with 2 applications) application was considered. This assessment is noted “Last valid assessment” in the synthesis tables.

Table 3.2-29: Minimum effective dose of ADM.03503.F.1.A - Wheat - SEPTTR

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A		
														0.70-0.75 L/ha		1.00 L/ha						
SEPTTR Disease severity	Last valid assessment after application A	Maritime	FLAGLE	3	24.9	6.3	39.7	84.4	75.6	100.0	11.1	85.8	75.9	100.0	10.3	89.8	82.4	100.0	7.5	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	3	14.5	5.1	24.4	87.4	76.1	93.3	8.0	91.0	78.6	97.7	8.8	90.5	73.6	100.0	12.0	0> ; 3= ; 0<	0> ; 3= ; 0<	
		Northeast	1	9.3	-	-	71.0	-	-	-	80.2	-	-	-	84.6	-	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
		Southeast	1	5.6	-	-	50.0	-	-	-	70.1	-	-	-	75.0	-	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<	
		All EPPO climatic zones	FLAGLE	3	24.9	6.3	39.7	84.4	75.6	100.0	11.1	85.8	75.9	100.0	10.3	89.8	82.4	100.0	7.5	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	5	11.7	5.1	24.4	76.7	50.0	93.3	16.0	84.7	70.1	97.7	10.8	86.2	73.6	100.0	11.1	2> ; 3= ; 0<	1> ; 4= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	25	30.2	6.1	96.6	69.2	37.0	100.0	17.3	77.9	37	100	16.4	83.6	43.8	100.0	13.7	7> ; 18= ; 0<	1> ; 24= ; 0<	
			FLMII	33	45.5	6.8	100.0	66.2	36.4	97.5	14.7	74.0	51.5	96.8	12.5	78.4	46.0	97.9	12.4	11> ; 22= ; 0<	3> ; 30= ; 0<	
		Northeast	FLAGLE	3	22.4	13.4	32.5	66.8	54.2	78.7	10	78.2	69.2	91.7	9.7	86.2	78.5	100	9.8	3> ; 0= ; 0<	2> ; 1= ; 0<	
			FLMII	3	44.3	26.8	69.5	64.7	50.7	75.7	10.4	86.9	77.5	98.2	8.6	93.3	84.0	100.0	6.8	3> ; 0= ; 0<	2> ; 1= ; 0<	
		Southeast	FLAGLE	11	11.8	4.6	63.4	81.2	57.8	100	11.5	88.6	71.6	100	9.9	91.9	78.5	100	7.7	4> ; 7= ; 0<	1> ; 10= ; 0<	
			FLMII	17	13.0	5.3	35.2	82.5	59.6	99.0	11.8	89.4	70.4	100.0	9.3	93.5	72.3	100.0	7.4	10> ; 7= ; 0<	3> ; 14= ; 0<	
All EPPO climatic zones	FLAGLE	39	24.4	4.6	96.6	72.4	37.0	100.0	16.3	80.9	37.0	100.0	15.1	86.1	43.8	100.0	12.6	14> ; 25= ; 0<	4> ; 35= ; 0<			
	FLMII	53	35.0	5.3	100.0	71.4	36.4	99.0	15.6	79.7	51.5	100.0	13.5	84.1	46.0	100.0	13.0	24> ; 29= ; 0<	8> ; 45= ; 0<			
SEPTTR Disease severity	Last valid assessment	Maritime	FLAGLE	28	29.6	6.1	96.6	70.8	37.0	100.0	17.4	78.7	37.0	100.0	16.0	84.3	43.8	100.0	13.3	7> ; 21= ; 0<	1> ; 27= ; 0<	
			FLMII	34	44.6	6.8	100.0	66.5	36.4	97.5	14.5	74.1	51.5	96.8	12.4	78.2	46.0	97.9	12.3	11> ; 23= ; 0<	3> ; 31= ; 0<	
		Northeast	FLAGLE	3	22.4	13.4	32.5	66.8	54.2	78.7	10.0	78.2	69.2	91.7	9.7	86.2	78.5	100.0	9.8	3> ; 0= ; 0<	2> ; 1= ; 0<	
			FLMII	4	35.6	9.3	69.5	66.3	50.7	75.7	9.4	85.2	77.5	98.2	8.0	91.1	84.0	100.0	7.0	4> ; 0= ; 0<	2> ; 2= ; 0<	
		Southeast	FLAGLE	11	11.8	4.6	63.4	81.2	57.8	100.0	11.5	88.6	71.6	100.0	9.9	91.9	78.5	100.0	7.7	4> ; 7= ; 0<	1> ; 10= ; 0<	
			FLMII	18	12.6	5.3	35.2	80.7	50.0	99.0	13.6	88.3	70.1	100.0	10.1	92.5	72.3	100.0	8.4	11> ; 7= ; 0<	4> ; 14= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha										
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																		0.70-0.75 L/ha	1.00 L/ha			
		All EPPO climatic zones	FLAGLE	42	24.4	4.6	96.6	73.2	37.0	100.0	16.3	81.3	37.0	100.0	14.9	86.4	43.8	100.0	12.3	14> ; 28= ; 0<	4> ; 38= ; 0<	
			FLMI1	56	33.7	5.3	100.0	71.1	36.4	99.0	15.4	79.5	51.5	100.0	13.2	83.7	46.0	100.0	12.8	26> ; 30= ; 0<	9> ; 47= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-30: Minimum effective dose of ADM.03503.F.1.A - Wheat - PUCCRT

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A	
																			0.70-0.75 L/ha		1.00 L/ha	
PUCCRT Disease severity	Last valid assessment after application A*	Maritime	FLAGLE	3	40.3	8.4	96.4	70.7	39.4	98.7	24.3	80.5	49.8	99.1	21.9	84.4	55.6	99.2	20.4	1> ; 2= ; 0<	0> ; 3= ; 0<	
			FLMII	3	35.8	15.0	74.8	94.6	87.1	99.1	5.3	96.9	94.6	98.9	1.8	98.2	96.8	100.0	1.3	0> ; 3= ; 0<	0> ; 3= ; 0<	
		Northeast	FLAGLE	1	15.0	-	-	60.1	-	-	-	73.0	-	-	-	86.5	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<	
			FLMII	3	10.2	8.5	13.4	68.3	61.9	79.5	7.9	84.8	73.2	93.0	8.4	92.0	87.9	96.7	3.6	3> ; 0= ; 0<	1> ; 2= ; 0<	
		Southeast	FLMII	2	6.1	5.2	6.9	64.6	54.8	74.4	9.8	75.0	70.2	79.8	4.8	84.7	81.3	88.1	3.4	2> ; 0= ; 0<	2> ; 0= ; 0<	
		All EPPO climatic zones	FLAGLE	4	34.0	8.4	96.4	68.1	39.4	98.7	21.6	78.6	49.8	99.1	19.2	85.0	55.6	99.2	17.7	2> ; 2= ; 0<	1> ; 3= ; 0<	
	FLMII		8	18.7	5.2	74.8	77.2	54.8	99.1	15.5	86.9	70.2	98.9	10.4	92.5	81.3	100.0	6.0	5> ; 3= ; 0<	3> ; 5= ; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	11	32.4	6.4	62.5	87.1	45.5	100.0	17.4	94.8	83.4	100.0	6.8	94.5	74.5	100.0	7.8	3> ; 8= ; 0<	0> ; 11= ; 0<	
			FLMII	9	41.4	6.0	97.4	91.1	62.6	100.0	12.5	95.2	81.2	100.0	6.8	96.3	82.1	100.0	6.1	1> ; 8= ; 0<	0> ; 9= ; 0<	
		Northeast	FLAGLE	3	18.5	8.0	26.3	76.4	75.0	78.2	1.3	87.5	85.0	90.6	2.4	95.1	92.1	100.0	3.5	3> ; 0= ; 0<	0> ; 3= ; 0<	
			FLMII	2	13.6	9.0	18.1	86.9	77.5	96.2	9.4	93.5	88.8	98.3	4.8	98.4	96.9	100.0	1.6	1> ; 1= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	8	11.6	6.4	21.9	83.4	75.2	92.4	6.4	89.2	76.8	96.3	6.7	93.2	79.1	99.4	6.4	3> ; 5= ; 0<	1> ; 7= ; 0<	
			FLMII	10	9.4	4.6	28.3	76.9	59.2	96.4	12.3	85.6	74.5	100.0	9.0	91.8	76.2	100.0	7.3	6> ; 4= ; 0<	2> ; 8= ; 0<	
		All EPPO climatic zones	FLAGLE	22	22.9	6.4	62.5	84.3	45.5	100.0	13.4	91.8	76.8	100.0	7.0	94.1	74.5	100.0	6.9	9> ; 13= ; 0<	1> ; 21= ; 0<	
FLMII			21	23.5	4.6	97.4	83.9	59.2	100.0	13.9	90.5	74.5	100.0	9.1	94.3	76.2	100.0	6.9	8> ; 13= ; 0<	2> ; 19= ; 0<		
PUCCRT Disease severity	Last valid assessment	Maritime	FLAGLE	14	34.1	6.8	96.4	83.6	39.4	100.0	20.3	91.8	49.8	100.0	13.2	92.3	55.6	100.0	12.4	4> ; 10= ; 0<	0> ; 14= ; 0<	
			FLMII	12	40.0	6.0	97.4	91.9	62.6	100.0	11.3	95.6	81.2	100.0	6.0	96.8	82.1	100.0	5.4	1> ; 11= ; 0<	0> ; 12= ; 0<	
		Northeast	FLAGLE	4	17.6	8.0	26.3	72.4	60.1	78.2	7.2	83.8	73.0	90.6	6.6	92.9	86.5	100.0	4.8	4> ; 0= ; 0<	1> ; 3= ; 0<	
			FLMII	4	12.3	8.5	18.1	79.2	63.6	96.2	11.6	88.3	73.2	98.3	9.4	95.4	87.9	100.0	4.5	3> ; 1= ; 0<	1> ; 3= ; 0<	
		Southeast	FLAGLE	8	11.6	6.4	21.9	83.4	75.2	92.4	6.4	89.2	76.8	96.3	6.7	93.2	79.1	99.4	6.4	3> ; 5= ; 0<	1> ; 7= ; 0<	
			FLMII	12	8.8	4.6	28.3	74.8	54.8	96.4	12.8	83.8	70.2	100.0	9.4	90.6	76.2	100.0	7.3	8> ; 4= ; 0<	4> ; 8= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																		0.70-0.75 L/ha	1.00 L/ha			
		All EPPO climatic zones	FLAGLE	26	24.6	6.4	96.4	81.8	39.4	100.0	16.1	89.8	49.8	100.0	11.0	92.7	55.6	100.0	10.0	11> ; 15= ; 0<	2> ; 24= ; 0<	
			FLMI1	28	22.7	4.6	97.4	82.8	54.8	100.0	14.4	89.5	70.2	100.0	9.8	93.9	76.2	100.0	6.8	12> ; 16= ; 0<	5> ; 23= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

(2) The summary includes 12 data points from 8 trials overall, following single application

Table 3.2-31: Minimum effective dose of ADM.03503.F.1.A - Wheat - PUCST

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole 52.5-56.25+ 105-112.5 g a.s./ha				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min
PUCST Disease severity	Last valid assessment after application A	Maritime	FLAGLE	4	25.8	14.7	49.0	79.7	48.9	92.6	17.9	86.9	69.8	94.6	10.0	88.0	66.4	97.5	12.6	2> ; 2= ; 0<	0> ; 4= ; 0<	
			FLMII	10	22.9	4.5	81.4	82.2	18.2	100.0	26.7	87.2	31.8	100.0	21.4	89.2	45.5	100.0	17.7	2> ; 7= ; 1<	1> ; 9= ; 0<	
		Northeast	FLAGLE	2	9.7	6.6	12.8	80.0	72.4	87.6	7.6	88.1	84.3	91.8	3.8	92.7	91.0	94.3	1.7	1> ; 1= ; 0<	0> ; 2= ; 0<	
			FLMII	3	9.3	5.5	16.0	63.9	59.5	68.6	3.7	80.8	71.3	88.1	7.0	87.9	82.7	92.3	4.0	3> ; 0= ; 0<	1> ; 2= ; 0<	
		Southeast	FLMII	1	5.0	-	-	87.3	-	-	-	88.7	-	-	-	91.5	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		All EPPO climatic zones	FLAGLE	6	20.4	6.6	49.0	79.8	48.9	92.6	15.2	87.3	69.8	94.6	8.4	89.6	66.4	97.5	10.6	3> ; 3= ; 0<	0> ; 6= ; 0<	
	FLMII		14	18.7	4.5	81.4	78.6	18.2	100.0	24.0	85.9	31.8	100.0	18.6	89.1	45.5	100.0	15.1	5> ; 8= ; 1<	2> ; 12= ; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	17	39.6	5.0	98.8	87.3	54.4	100.0	12.7	90.6	69.6	100.0	10.0	92.7	78.9	100.0	7.8	3> ; 14= ; 0<	1> ; 16= ; 0<	
			FLMII	16	55.3	5.0	99.3	89.6	55.0	100.0	11.1	94.6	86.8	100.0	5.3	96.0	87.2	100.0	4.6	2> ; 14= ; 0<	1> ; 15= ; 0<	
		Northeast	FLAGLE	1	13.5	-	-	60.4	-	-	-	78.3	-	-	-	85.0	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
		Southeast	FLAGLE	3	5.8	4.7	7.2	79.5	68.1	100.0	14.5	90.9	80.6	100.0	8.0	95.3	87.5	100.0	5.6	2> ; 1= ; 0<	0> ; 3= ; 0<	
			FLMII	5	11.3	5.5	27.5	73.6	59.6	100.0	15.4	82.4	73.2	100.0	9.5	89.4	80.7	100.0	6.4	3> ; 2= ; 0<	0> ; 5= ; 0<	
		All EPPO climatic zones	FLAGLE	21	33.5	4.7	98.8	84.9	54.4	100.0	14.1	90.1	69.6	100.0	9.9	92.7	78.9	100.0	7.5	6> ; 15= ; 0<	1> ; 20= ; 0<	
	FLMII		21	44.9	5.0	99.3	85.8	55.0	100.0	14.0	91.7	73.2	100.0	8.3	94.4	80.7	100.0	5.9	5> ; 16= ; 0<	1> ; 20= ; 0<		
PUCST Disease severity	Last valid assessment	Maritime	FLAGLE	18	40.1	5.0	98.8	87.6	54.4	100.0	12.4	90.8	69.6	100.0	9.8	92.9	78.9	100.0	7.6	4> ; 14= ; 0<	1> ; 17= ; 0<	
			FLMII	17	56.9	5.0	99.3	90.0	55.0	100.0	10.8	94.7	86.8	100.0	5.1	96.2	87.2	100.0	4.5	2> ; 15= ; 0<	1> ; 16= ; 0<	
		Northeast	FLAGLE	3	10.9	6.6	13.5	73.5	60.4	87.6	11.1	84.8	78.3	91.8	5.5	90.1	85.0	94.3	3.9	2> ; 1= ; 0<	0> ; 3= ; 0<	
			FLMII	3	9.3	5.5	16.0	63.9	59.5	68.6	3.7	80.8	71.3	88.1	7.0	87.9	82.7	92.3	4.0	3> ; 0= ; 0<	1> ; 2= ; 0<	
		Southeast	FLAGLE	3	5.8	4.7	7.2	79.5	68.1	100.0	14.5	90.9	80.6	100.0	8.0	95.3	87.5	100.0	5.6	2> ; 1= ; 0<	0> ; 3= ; 0<	
			FLMII	6	10.3	5.0	27.5	75.9	59.6	100.0	15.0	83.5	73.2	100.0	8.9	89.7	80.7	100.0	5.9	3> ; 3= ; 0<	0> ; 6= ; 0<	
All EPPO climatic zones	FLAGLE	24	32.2	4.7	98.8	84.9	54.4	100.0	13.5	90.1	69.6	100.0	9.3	92.9	78.9	100.0	7.1	8> ; 16= ; 0<	1> ; 23= ; 0<			

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha										
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																		0.70-0.75 L/ha	1.00 L/ha			
			FLMI1	26	40.6	5.0	99.3	83.7	55.0	100.0	14.7	90.5	71.3	100.0	8.7	93.7	80.7	100.0	5.9	8>; 18=; 0<	2>; 24=; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-32: Minimum effective dose of ADM.03503.F.1.A - Wheat - PYRNTR

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A		
																	0.70-0.75 L/ha	1.00 L/ha				
PYRNTR Disease severity	Last valid assessment after application A*	Maritime	FLAGLE	1	22.5	-	-	63.3	-	-	-	82.2	-	-	-	90.0	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
			FLMII	1	44.0	-	-	67.6	-	-	-	86.9	-	-	-	90.9	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
		Northeast	FLAGLE	1	5.2	-	-	52.1	-	-	-	78.9	-	-	-	89.6	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<	
			FLMII	2	6.6	6.5	6.7	55.1	41.1	69.1	14.0	80.2	75.9	84.5	4.3	86.2	84.5	87.8	1.6	2> ; 0= ; 0<	1> ; 1= ; 0<	
		Southeast	FLAGLE	1	16.0	-	-	94.6	-	-	-	93.9	-	-	-	96.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMII	1	31.6	-	-	90.8	-	-	-	82.6	-	-	-	92.4	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		All EPPO climatic zones	FLAGLE	3	14.6	5.2	22.5	70.0	52.1	94.6	18.0	85.0	78.9	93.9	6.4	92.1	89.6	96.7	3.3	2> ; 1= ; 0<	1> ; 2= ; 0<	
			FLMII	4	22.2	6.5	44.0	67.1	41.1	90.8	17.6	82.5	75.9	86.9	4.1	88.9	84.5	92.4	3.0	3> ; 1= ; 0<	1> ; 3= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	7	9.3	4.5	19.7	68.9	26.6	85.0	18.1	74.7	46.0	89.5	15.8	79.2	48.2	97.4	15.3	2> ; 5= ; 0<	0> ; 7= ; 0<	
			FLMII	7	21.1	8.0	34.7	63.4	18.9	80.9	19.1	76.3	51.1	93.9	14.2	81.7	60.0	95.2	10.4	1> ; 6= ; 0<	0> ; 7= ; 0<	
		Northeast	FLAGLE	2	12.3	9.5	15.0	68.6	63.3	73.9	5.3	78.5	72.5	84.4	6.0	90.4	85.8	95.0	4.6	2> ; 0= ; 0<	2> ; 0= ; 0<	
			FLMII	2	9.8	9.0	10.5	57.6	43.8	71.4	13.8	73.6	66.3	80.9	7.3	89.6	88.8	90.5	0.8	2> ; 0= ; 0<	2> ; 0= ; 0<	
		Southeast	FLAGLE	2	26.1	5.9	46.2	78.0	70.8	85.3	7.2	88.8	79.7	97.9	9.1	93.5	88.1	99.0	5.4	1> ; 1= ; 0<	1> ; 1= ; 0<	
			FLMII	3	26.0	6.6	61.4	74.0	65.8	86.3	8.9	82.5	73.1	93.0	8.2	88.1	80.0	96.5	6.8	3> ; 0= ; 0<	2> ; 1= ; 0<	
		All EPPO climatic zones	FLAGLE	11	12.9	4.5	46.2	70.5	26.6	85.3	15.4	77.9	46.0	97.9	14.5	83.8	48.2	99.0	14.0	5> ; 6= ; 0<	3> ; 8= ; 0<	
			FLMII	12	20.4	6.6	61.4	65.1	18.9	86.3	17.2	77.4	51.1	93.9	12.3	84.6	60.0	96.5	9.3	6> ; 6= ; 0<	4> ; 8= ; 0<	
PYRNTR Disease severity	Last valid assessment	Maritime	FLAGLE	8	10.9	4.5	22.5	68.2	26.6	85.0	17.0	75.6	46.0	89.5	15.0	80.5	48.2	97.4	14.7	3> ; 5= ; 0<	0> ; 8= ; 0<	
			FLMII	8	23.9	8.0	44.0	64.0	18.9	80.9	18.0	77.7	51.1	93.9	13.7	82.8	60.0	95.2	10.2	2> ; 6= ; 0<	0> ; 8= ; 0<	
		Northeast	FLAGLE	3	9.9	5.2	15.0	63.1	52.1	73.9	8.9	78.6	72.5	84.4	4.9	90.1	85.8	95.0	3.8	3> ; 0= ; 0<	3> ; 0= ; 0<	
			FLMII	3	8.7	6.7	10.5	52.1	41.1	71.4	13.7	74.4	66.3	80.9	6.1	89.0	87.8	90.5	1.1	3> ; 0= ; 0<	3> ; 0= ; 0<	
		Southeast	FLAGLE	3	22.7	5.9	46.2	83.6	70.8	94.6	9.8	90.5	79.7	97.9	7.8	94.6	88.1	99.0	4.7	1> ; 2= ; 0<	1> ; 2= ; 0<	
			FLMII	4	27.4	6.6	61.4	78.2	65.8	90.8	10.6	82.6	73.1	93.0	7.1	89.1	80.0	96.5	6.1	3> ; 1= ; 0<	2> ; 2= ; 0<	
		All EPPO climatic zones	FLAGLE	14	13.2	4.5	46.2	70.4	26.6	94.6	16.0	79.5	46.0	97.9	13.5	85.6	48.2	99.0	13.0	7> ; 7= ; 0<	4> ; 10= ; 0<	
			FLMII	15	21.8	6.6	61.4	65.4	18.9	90.8	17.9	78.3	51.1	93.9	11.4	85.8	60.0	96.5	8.7	8> ; 7= ; 0<	5> ; 10= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

(2) The summary includes 7 datapoints from 4 single-application trials

Table 3.2-33: Minimum effective dose of ADM.03503.F.1.A - Wheat - ERYSGT

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.		
ERYSGT Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	5.0	-	-	70.0	-	-	-	70.0	-	-	-	70.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	2	9.3	6.0	12.5	70.4	68.7	72.0	1.7	81.9	80.0	83.8	1.9	83.8	80.0	87.6	3.8	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	3	12.8	8.9	20.0	74.0	61.3	84.2	9.5	89.1	80.0	100.0	8.3	89.3	76.3	100.0	9.8	1> ; 2= ; 0<	0> ; 3= ; 0<	
		Northeast	FLMI1	1	5.3	-	-	61.7	-	-	-	85.8	-	-	-	100.0	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
			FLMI2	5	14.0	7.8	21.0	46.4	20.9	61.8	14.3	74.2	65.6	84.6	6.9	84.7	77.7	90.5	4.2	5> ; 0= ; 0<	2> ; 3= ; 0<	
		All EPPO climatic zones	FLAGLE	1	5.0	-	-	70.0	-	-	-	70.0	-	-	-	70.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	3	7.9	5.3	12.5	67.5	61.7	72.0	4.3	83.2	80.0	85.8	2.4	89.2	80.0	100.0	8.3	1> ; 2= ; 0<	0> ; 3= ; 0<	
			FLMI2	8	13.6	7.8	21.0	56.8	20.9	84.2	18.5	79.8	65.6	100.0	10.4	86.5	76.3	100.0	7.2	6> ; 2= ; 0<	2> ; 6= ; 0<	
		Last valid assessment after application B	Maritime	FLAGLE	3	9.9	5.0	15.0	57.9	16.7	86.9	29.9	79.7	53.3	93.3	18.7	85.8	65.0	96.7	14.7	1> ; 2= ; 0<	0> ; 3= ; 0<
				FLMI1	6	21.9	8.3	51.7	68.5	37.8	87.9	19.9	77.9	46.9	90.5	15.6	84.7	62.5	97.4	13.0	1> ; 5= ; 0<	1> ; 5= ; 0<
				FLMI2	5	34.9	7.9	82.8	77.0	40.0	99.4	21.0	82.5	50.0	99.1	17.4	85.0	45.0	99.7	20.3	2> ; 3= ; 0<	1> ; 4= ; 0<
			Northeast	FLAGLE	2	7.6	5.5	9.7	51.1	19.4	82.7	31.7	75.1	56.1	94.1	19.0	88.2	76.8	99.5	11.4	2> ; 0= ; 0<	0> ; 2= ; 0<
	FLMI1			5	20.4	8.6	38.5	64.7	30.0	84.6	20.2	89.1	82.0	97.7	5.2	96.6	92.7	100.0	2.4	5> ; 0= ; 0<	2> ; 3= ; 0<	
	Southeast		FLMI2	3	44.8	40.8	52.8	66.1	43.1	80.5	16.5	86.1	84.0	89.0	2.1	97.4	95.1	99.4	1.8	3> ; 0= ; 0<	3> ; 0= ; 0<	
			FLAGLE	2	5.6	5.0	6.2	80.3	75.1	85.5	5.2	85.3	83.2	87.5	2.2	93.5	92.1	95.0	1.5	1> ; 1= ; 0<	0> ; 2= ; 0<	
			FLMI1	4	7.3	5.5	8.8	73.3	68.4	78.5	4.2	82.5	77.2	84.4	3.1	88.3	85.8	92.7	2.7	1> ; 3= ; 0<	0> ; 4= ; 0<	
	All EPPO climatic zones		FLMI2	5	7.7	5.6	11.6	76.8	65.9	88.4	7.3	81.7	74.5	90.1	5.4	88.6	82.7	92.2	3.6	2> ; 3= ; 0<	0> ; 5= ; 0<	
			FLAGLE	7	8.0	5.0	15.0	62.3	16.7	86.9	28.6	80.0	53.3	94.1	16.4	88.7	65.0	99.5	11.9	4> ; 3= ; 0<	0> ; 7= ; 0<	
			FLMI1	15	17.5	5.5	51.7	68.5	30.0	87.9	17.6	82.9	46.9	97.7	11.5	89.6	62.5	100.0	9.9	7> ; 8= ; 0<	3> ; 12= ; 0<	
	ERYSGT Disease severity		Last valid assessment	Maritime	FLMI2	13	26.7	5.6	82.8	74.4	40.0	99.4	16.6	83.0	50.0	99.1	11.4	89.3	45.0	99.7	13.6	7> ; 6= ; 0<
		FLAGLE			3	9.9	5.0	15.0	57.9	16.7	86.9	29.9	79.7	53.3	93.3	18.7	85.8	65.0	96.7	14.7	1> ; 2= ; 0<	0> ; 3= ; 0<
		FLMI1			7	19.6	6.0	51.7	68.5	37.8	87.9	18.4	78.7	46.9	90.5	14.6	85.1	62.5	97.4	12.1	1> ; 6= ; 0<	1> ; 6= ; 0<
		Northeast		FLMI2	6	30.6	7.9	82.8	76.9	40.0	99.4	19.2	83.3	50.0	99.1	15.9	86.1	45.0	99.7	18.7	3> ; 3= ; 0<	1> ; 5= ; 0<
				FLAGLE	2	7.6	5.5	9.7	51.1	19.4	82.7	31.7	75.1	56.1	94.1	19.0	88.2	76.8	99.5	11.4	2> ; 0= ; 0<	0> ; 2= ; 0<
FLMI1				6	17.9	5.3	38.5	64.2	30.0	84.6	18.5	88.5	82.0	97.7	4.9	97.1	92.7	100.0	2.6	6> ; 0= ; 0<	2> ; 4= ; 0<	
Southeast		FLMI2		6	29.5	7.8	52.8	56.5	20.9	80.5	20.0	79.6	65.6	89.0	7.7	91.2	77.7	99.4	7.4	6> ; 0= ; 0<	4> ; 2= ; 0<	
		FLAGLE		2	5.6	5.0	6.2	80.3	75.1	85.5	5.2	85.3	83.2	87.5	2.2	93.5	92.1	95.0	1.5	1> ; 1= ; 0<	0> ; 2= ; 0<	
		FLMI1		4	7.3	5.5	8.8	73.3	68.4	78.5	4.2	82.5	77.2	84.4	3.1	88.3	85.8	92.7	2.7	1> ; 3= ; 0<	0> ; 4= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole 52.5-56.25+ 105-112.5 g a.s./ha				Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha									
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max
			FLMI2	5	7.7	5.6	11.6	76.8	65.9	88.4	7.3	81.7	74.5	90.1	5.4	88.6	82.7	92.2	3.6	2> ; 3= ; 0<	0> ; 5= ; 0<	
			FLAGLE	7	8.0	5.0	15.0	62.3	16.7	86.9	28.6	80.0	53.3	94.1	16.4	88.7	65.0	99.5	11.9	4> ; 3= ; 0<	0> ; 7= ; 0<	
		All EPPO climatic zones	FLMI1	17	16.1	5.3	51.7	68.1	30.0	87.9	16.6	83.1	46.9	97.7	10.8	90.1	62.5	100.0	9.6	8> ; 9= ; 0<	3> ; 14= ; 0<	
			FLMI2	17	23.4	5.6	82.8	69.7	20.9	99.4	19.5	81.5	50.0	99.1	11.0	88.7	45.0	99.7	12.3	11> ; 6= ; 0<	5> ; 12= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-34: Minimum effective dose of ADM.03503.F.1.A - Wheat - Ear complex diseases with a majority of FUSASS FUSASP

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A		
																				0.70-0.75 L/ha	1.00 L/ha	
FUSASS FUSASP Disease severity	Last valid assessment	Maritime	Ears	11	46.7	8.1	97.8	57.0	36.1	82.7	13.8	68.0	46.7	91.0	12.1	75.7	58.8	89.3	8.9	5>; 6=; 0<	4>; 7=; 0<	
		Northeast	Ears	4	43.6	23.8	67.5	60.4	34.1	80.5	16.7	70.6	49.8	85.3	12.9	80.4	71.5	87.6	5.9	3>; 1=; 0<	1>; 3=; 0<	
		Southeast	Ears	7	27.1	5.6	50.2	71.5	57.3	93.1	10.8	80.6	70.7	100.0	9.2	86.6	73.6	100.0	8.8	4>; 3=; 0<	0>; 7=; 0<	
		All EPPO climatic zones	Ears	22	39.9	5.6	97.8	62.2	34.1	93.1	15.0	72.5	46.7	100.0	12.7	80.0	58.8	100.0	9.7	12>; 10=; 0<	5>; 17=; 0<	
FUSASS FUSASP Percentage of infected grains	After harvest	Maritime	Grains	8	44.3	7.0	99.8	46.3	16.8	80.5	19.0	54.2	20.7	82.7	19.9	65.1	36.9	94.6	19.1	4>; 4=; 0<	2>; 6=; 0<	
		Northeast	Grains	3	40.7	22.3	61.3	72.3	61.8	88.8	11.8	79.0	64.1	93.3	11.9	83.6	70.4	96.6	10.7	2>; 1=; 0<	0>; 3=; 0<	
		Southeast	Grains	5	16.4	7.1	25.0	57.6	25.0	96.0	26.5	63.6	32.7	100.0	26.1	72.1	46.4	100.0	20.4	3>; 2=; 0<	2>; 3=; 0<	
		All EPPO climatic zones	Grains	16	34.9	7.0	99.8	54.7	16.8	96.0	22.8	61.8	20.7	100.0	22.9	70.8	36.9	100.0	19.5	9>; 7=; 0<	4>; 12=; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-35: Minimum effective dose of ADM.03503.F.1.A - Wheat - Ear complex diseases with a majority of MONGNI

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
				Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A		
																				0.70-0.75 L/ha	1.00 L/ha	
MONGNI Disease severity	Last valid assessment	Maritime	Ears	1	38.2	-	-	30.6	-	-	-	52.6	-	-	-	50.2	-	-	-	0>; 1=; 0<	0>; 1=; 0<	
		Southeast	Ears	1	6.5	-	-	64.3	-	-	-	79.1	-	-	-	81.8	-	-	-	0>; 1=; 0<	0>; 1=; 0<	
		All EPPO climatic zones	Ears	2	22.3	6.5	38.2	47.5	30.6	64.3	16.8	65.8	52.6	79.1	13.3	66.0	50.2	81.8	15.8	0>; 2=; 0<	0>; 2=; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-36: Minimum effective dose of ADM.03503.F.1.A - Wheat - All valid efficacy trials

Target	Parts	No. of trials	Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ > ; = ; < to ADM.03503.F.1.A			
			ADM.03503.F.1.A															
			Fluxapyroxad + Prothioconazole															
			0.70-0.75 L/ha			1.00 L/ha			1.25 L/ha			0.70-0.75 L/ha					1.00 L/ha	
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max			Mean	Min
SEPTTR	FLAGLE	42	24.4	4.6	96.6	73.2	37.0	100.0	81.3	37.0	100.0	86.4	43.8	100.0	14>;28=;0<	4>;38=;0<		
	FLMI1	56	33.7	5.3	100.0	71.1	36.4	99.0	79.5	51.5	100.0	83.7	46.0	100.0	26>;30=;0<	9>;47=;0<		
PUCCRT	FLAGLE	26	24.6	6.4	96.4	81.8	39.4	100.0	89.8	49.8	100.0	92.7	55.6	100.0	11>;15=;0<	2>;24=;0<		
	FLMI1	28	22.7	4.6	97.4	82.8	54.8	100.0	89.5	70.2	100.0	93.9	76.2	100.0	12>;16=;0<	5>;23=;0<		
PUC CST	FLAGLE	24	32.2	4.7	98.8	84.9	54.4	100.0	90.1	69.6	100.0	92.9	78.9	100.0	8>;16=;0<	1>;23=;0<		
	FLMI1	26	40.6	5.0	99.3	83.7	55.0	100.0	90.5	71.3	100.0	93.7	80.7	100.0	8>;18=;0<	2>;24=;0<		
PYRNT R	FLAGLE	14	13.2	4.5	46.2	70.4	26.6	94.6	79.5	46.0	97.9	85.6	48.2	99.0	7>;7=;0<	4>;10=;0<		
	FLMI1	15	21.8	6.6	61.4	65.4	18.9	90.8	78.3	51.1	93.9	85.8	60.0	96.5	8>;7=;0<	5>;10=;0<		
ERYSG T	FLAGLE	7	8.0	5.0	15.0	62.3	16.7	86.9	80.0	53.3	94.1	88.7	65.0	99.5	4>;3=;0<	0>;7=;0<		
	FLMI1	17	16.1	5.3	51.7	68.1	30.0	87.9	83.1	46.9	97.7	90.1	62.5	100.0	8>;9=;0<	3>;14=;0<		
	FLMI2	17	23.4	5.6	82.8	69.7	20.9	99.4	81.5	50.0	99.1	88.7	45.0	99.7	11>;6=;0<	5>;12=;0<		
FUSAS & FUSAS P	Ears	22	39.9	5.6	97.8	62.2	34.1	93.1	72.5	46.7	100.0	80.0	58.8	100.0	12>;10=;0<	5>;17=;0<		
	Grains	16	34.9	7.0	99.8	54.7	16.8	96.0	61.8	20.7	100.0	70.8	36.9	100.0	9>;7=;0<	4>;12=;0<		
MONG NI	Ears	2	22.3	6.5	38.2	47.5	30.6	64.3	65.8	52.6	79.1	66.0	50.2	81.8	0>;2=;0<	0>;2=;0<		

⁽¹⁾ Comparison based on statistics carried out in each trial report.

The results are summarized by Eppo climatic zone in each summary table by disease. Only results for all valid efficacy trials (all Eppo climatic zones presented Table 3.2-36) are discussed hereafter to justify the minimum effective dose of ADM.03503.F.1.A against wheat diseases.

Across 143 efficacy trials carried out in the Maritime, the Northeast and the Southeast Eppo climatic zones, ADM.03503.F.1.A, applied at the proposed label rate of 1.25 L/ha, was compared to ADM.03503.F.1.A at 0.70-75 L/ha (56-60% of maximum recommended dose) and 1.00 L/ha (80% of maximum recommended dose).

Against SEPTTR, ADM.03503.F.1.A applied at 1.25 L/ha delivered 87% on FLAGLE and 84% on FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 73% on FLAGLE and 71% on FLMI1 and ADM.03503.F.1.A at 1.00 L/ha provided 82% on FLAGLE and 80% on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 14 out of 42 trials on FLAGLE and in 26 out of 56 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 4 out of 42 trials on FLAGLE and in 9 out of 56 trials on FLMI1.

Against PUC CRT, ADM.03503.F.1.A applied at 1.25 L/ha delivered 93% on FLAGLE and 94% on FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 82% on FLAGLE and 83% on FLMI1 and ADM.03503.F.1.A at 1.00 L/ha provided 90% on FLAGLE and FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 11 out of 26 trials on FLAGLE and in 12 out of 28 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 2 out of 26 trials on FLAGLE and in 5 out of 23 trials on FLMI1.

Against PUC CST, ADM.03503.F.1.A applied at 1.25 L/ha delivered 93% on FLAGLE and 94% on FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 85% on FLAGLE and 84% on FLMI1 and

ADM.03503.F.1.A at 1.00 L/ha provided 90% on FLAGLE and 91% on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 8 out of 24 trials on FLAGLE and in 8 out of 26 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 24 trials on FLAGLE and in 2 out of 26 trials on FLMI1.

Against PYRNTR, ADM.03503.F.1.A applied at 1.25 L/ha delivered 86% on FLAGLE and FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 70% on FLAGLE and 65% on FLMI1 and ADM.03503.F.1.A at 1.00 L/ha provided 80% on FLAGLE and 78% on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 7 out of 14 trials on FLAGLE and in 7 out of 15 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 4 out of 14 trials on FLAGLE and in 5 out of 15 trials on FLMI1.

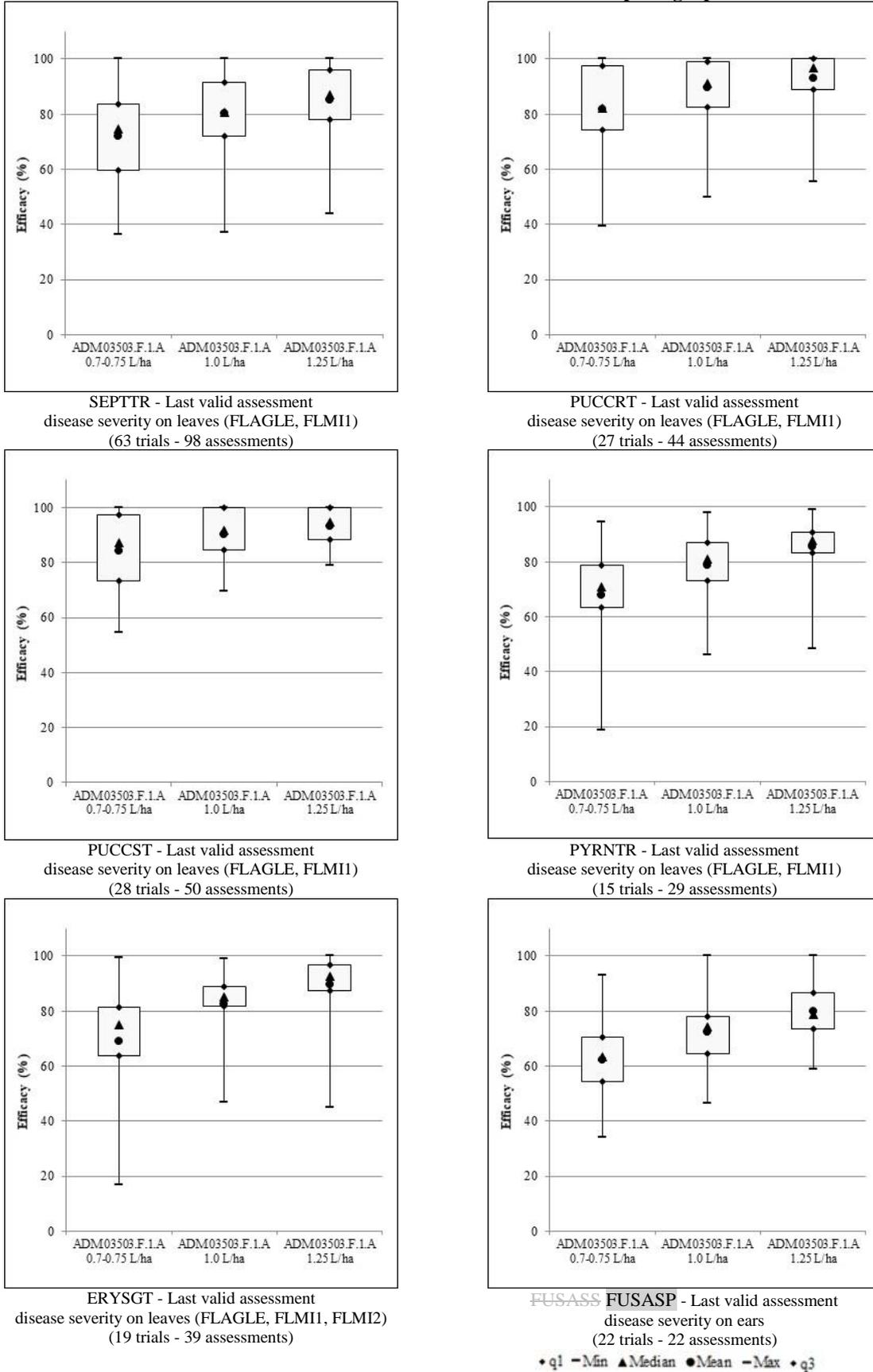
Against ERYSGT, ADM.03503.F.1.A applied at 1.25 L/ha delivered 89% on FLAGLE, 90% on FLMI1 and 89% on FLMI2 when ADM.03503.F.1.A at 0.70-0.75 L/ha 62% on FLAGLE, 68% on FLMI1 and 70% on FLMI2 and ADM.03503.F.1.A at 1.00 L/ha provided 80% on FLAGLE, 83% on FLMI1 and 82% on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 4 out of 7 trials on FLAGLE, in 8 out of 17 trials on FLMI1 and in 11 out of 17 trials on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 3 out of 17 trials on FLMI1 and in 5 out of 17 trials on FLMI2.

Against ~~FUSASS~~ FUSASP, ADM.03503.F.1.A applied at 1.25 L/ha delivered 80% on ears when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 62% and ADM.03503.F.1.A at 1.00 L/ha provided 73%. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 12 out of 22 trials. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 5 out of 22 trials.

After harvest, these results are confirmed with 71% of ~~FUSASS~~ FUSASP on grains when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 55% and ADM.03503.F.1.A at 1.00 L/ha provided 62%. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 9 out of 16 trials. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 4 out of 16 trials.

Against MONGNI, ADM.03503.F.1.A applied at 1.25 L/ha delivered 66% on ears when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 48% and ADM.03503.F.1.A at 1.00 L/ha provided 66%. It can be considered that the choice of 1.25 L/ha as maximum recommended dose rate of ADM.03503.F.1.A is justified against the wheat diseases. Indeed, for each disease with at least 5 assessments, the dose effect is clearly illustrated by box plot graphics (Figure 3.2-10). According to the box plot graphics, the higher the dose of ADM.03503.F.1.A, the lower the dispersion and variation between means. However, the efficacy of ADM.03503.F.1.A at 1.00 L/ha was also acceptable to control wheat disease according to the disease pressure.

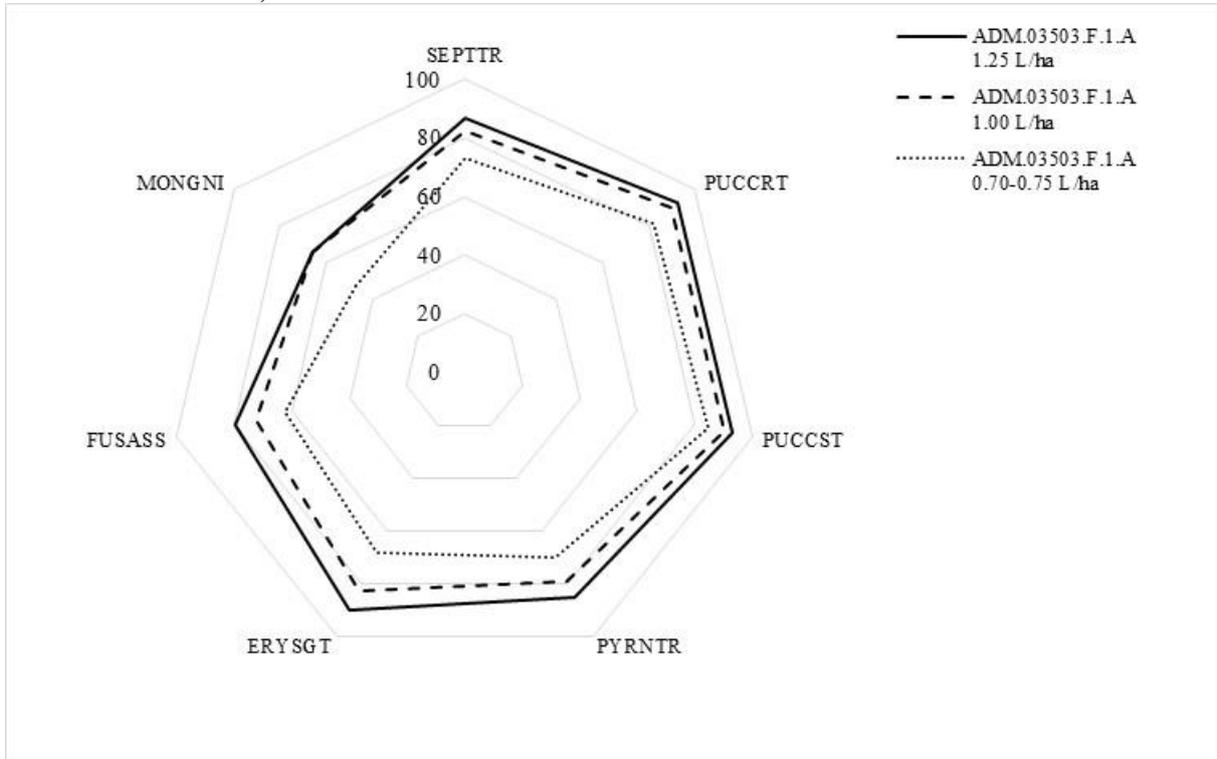
Figure 3.2-10 Minimum effective dose of ADM.03503.F.1.A - Wheat - Box plots graphics



The justification of the minimum effective dose of ADM.03503.F.1.A against wheat disease complex can be illustrated by graphic from the last valid assessment (Figure 3.2-11). According to the efficacy

results and as illustrated on the graphic hereafter, ADM.03503.F.1.A at 1.25 L/ha is the best dose rate to control the major diseases of wheat.

Figure 3.2-11 Minimum effective dose of ADM.03503.F.1.A - Wheat - Disease complex (efficacy against SEPTTR, PUCCRT, PUCST, PYRNTR on FLAGLE, against ERYSGT on FLMI1 and FUSASS FUSASP and MONGNI on ears) after last valid assessment



The wheat data demonstrates the mean efficacy increases for the dose rate of ADM.03503.F.1.A. The maximum proposed dose of 1.25 L/ha attains higher and more consistent control than the lower rates tested. ADM.03503.F.1.A at 1.25 L/ha gives excellent control of all the target diseases, confirming the selection of 1.25 L/ha as the proposed registered dose.

Overall, the efficacy of ADM.03503.F.1.A at 1.0 L/ha was lower than ADM.03503.F.1.A at 1.25 L/ha, however 1.0 L/ha can achieve acceptable control when there is low disease pressure.

zRMS comments:

See the zRMS overall comments at the end of this MED chapter.

3.2.2.3 Results of minimum effective dose tests in barley

A total of **99 valid efficacy trials** were carried out to justify the minimum effective dose of ADM.03503.F.1.A. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Belgium, 4 trials in Czech Republic, 18 trials in Germany, 5 trials in Ireland, 12 trials in the United Kingdom and 18 trials in France), the Northeast (15 trials in Poland) and the Southeast (2 trials in Hungary, 13 trials in Romania and 11 trials in Slovakia) EPPO climatic zones against RHYNSE (31 trials), PYRNTE (35 trials), PUCCHD (27 trials), RAMUCC (20 trials), or ERYSGH (26 trials).

Table 3.2-37 (RHYNSE), Table 3.2-38 (PYRNTE), Table 3.2-39 (PUCCHD), Table 3.2-40 (RAMUCC), and Table 3.2-41 (ERYSGH) summarise all observations for each disease (efficacy) and Table 3.2-42 synthesises the minimum effective dose of ADM.03503.F.1.A against the barley disease complex.

To estimate the efficacy level after one application, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the first (for trials with 2 applications) or the single application (for trials with 1 application) was considered. This assessment is noted “Last valid assessment after application A” in the synthesis tables.

To estimate the efficacy level after two applications, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the second applications of trials with 2 applications was considered. This assessment is noted “Last valid assessment after application B” in the synthesis tables.

Finally, to estimate the intrinsic efficacy level of ADM.03503.F.1.A, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the single (for trials with 1 application) or the second (for trials with 2 applications) application was considered. This assessment is noted “Last valid assessment” in the synthesis tables.

Table 3.2-37: Minimum effective dose of ADM.03503.F.1.A - Barley - RHYNSE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha										
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
						0.70-0.75 L/ha				1.00 L/ha												
RHYNSE Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	5.8	-	-	47.8	-	-	-	47.8	-	-	-	65.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMII	4	7.7	5.3	12.5	69.1	42.9	98.7	19.8	71.8	42.9	99.4	20.4	75.8	42.9	100.0	21.8	0> ; 4= ; 0<	0> ; 4= ; 0<	
		Northeast	FLAGLE	1	9.1	-	-	74.2	-	-	-	79.7	-	-	-	91.2	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<	
			FLMII	2	9.1	6.3	12.0	61.1	51.8	70.4	9.3	77.4	76.2	78.5	1.2	85.8	83.9	87.6	1.8	2> ; 0= ; 0<	1> ; 1= ; 0<	
		All EPPO climatic zones	FLAGLE	2	7.4	5.8	9.1	61.0	47.8	74.2	13.2	63.8	47.8	79.7	16.0	78.2	65.2	91.2	13.0	1> ; 1= ; 0<	1> ; 1= ; 0<	
			FLMII	6	8.2	5.3	12.5	66.4	42.9	98.7	17.5	73.6	42.9	99.4	16.9	79.1	42.9	100.0	18.4	2> ; 4= ; 0<	1> ; 5= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	15	20.3	6.4	88.8	77.9	36.5	97.5	18.7	87.8	51.6	100.0	13.8	91.7	72.9	100.0	9.5	4> ; 11= ; 0<	1> ; 14= ; 0<	
			FLMII	17	22.8	5.5	100.0	72.3	30.0	96.1	20.2	80.2	42.0	98.0	15.3	89.0	68.7	100.0	9.3	4> ; 13= ; 0<	2> ; 15= ; 0<	
		Northeast	FLAGLE	3	15.5	5.5	20.6	55.0	43.1	63.6	8.7	79.3	69.2	90.8	8.9	88.2	80.6	100.0	8.5	3> ; 0= ; 0<	1> ; 2= ; 0<	
			FLMII	3	15.4	7.3	20.0	64.8	58.5	75.1	7.3	86.8	79.5	95.1	6.4	94.8	86.2	99.3	6.1	3> ; 0= ; 0<	0> ; 3= ; 0<	
		Southeast	FLAGLE	2	22.2	11.3	33.1	82.7	67.7	97.7	15.0	97.5	95.5	99.4	2.0	100.0	100.0	100.0	0.0	1> ; 1= ; 0<	0> ; 2= ; 0<	
			FLMII	6	16.9	5.5	45.3	85.0	71.6	97.4	7.9	91.1	78.5	99.6	7.4	94.9	88.9	100.0	4.5	2> ; 4= ; 0<	2> ; 4= ; 0<	
		All EPPO climatic zones	FLAGLE	20	19.8	5.5	88.8	74.9	36.5	97.7	19.2	87.5	51.6	100.0	13.2	92.0	72.9	100.0	9.3	8> ; 12= ; 0<	2> ; 18= ; 0<	
			FLMII	26	20.6	5.5	100.0	74.4	30.0	97.4	18.1	83.5	42.0	99.6	13.9	91.0	68.7	100.0	8.6	9> ; 17= ; 0<	4> ; 22= ; 0<	
RHYNSE Disease severity	Last valid assessment	Maritime	FLAGLE	16	19.4	5.8	88.8	76.0	36.5	97.5	19.5	85.3	47.8	100.0	16.5	90.0	65.2	100.0	11.2	4> ; 12= ; 0<	1> ; 15= ; 0<	
			FLMII	20	20.3	5.3	100.0	71.9	30.0	98.7	20.7	78.6	42.0	99.4	17.1	86.3	42.9	100.0	14.0	4> ; 16= ; 0<	2> ; 18= ; 0<	
		Northeast	FLAGLE	4	13.9	5.5	20.6	59.8	43.1	74.2	11.2	79.4	69.2	90.8	7.7	89.0	80.6	100.0	7.4	4> ; 0= ; 0<	2> ; 2= ; 0<	
			FLMII	4	14.6	7.3	20.0	66.2	58.5	75.1	6.8	84.7	78.5	95.1	6.6	93.0	86.2	99.3	6.1	4> ; 0= ; 0<	1> ; 3= ; 0<	
		Southeast	FLAGLE	2	22.2	11.3	33.1	82.7	67.7	97.7	15.0	97.5	95.5	99.4	2.0	100.0	100.0	100.0	0.0	1> ; 1= ; 0<	0> ; 2= ; 0<	
			FLMII	6	16.9	5.5	45.3	85.0	71.6	97.4	7.9	91.1	78.5	99.6	7.4	94.9	88.9	100.0	4.5	2> ; 4= ; 0<	2> ; 4= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha										
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																		0.70-0.75 L/ha	1.00 L/ha			
		All EPPO climatic zones	FLAGLE	22	18.6	5.5	88.8	73.7	36.5	97.7	19.2	85.4	47.8	100.0	15.1	90.7	65.2	100.0	10.5	9> ; 13= ; 0<	3> ; 19= ; 0<	
			FLMI1	30	18.9	5.3	100.0	73.7	30.0	98.7	18.4	81.9	42.0	99.6	15.4	88.9	42.9	100.0	12.4	10> ; 20= ; 0<	5> ; 25= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-38: Minimum effective dose of ADM.03503.F.1.A - Barley - PYRNTE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	0.70-0.75 L/ha	1.00 L/ha
PYRNTE Disease severity	Last valid assessment after application A	Maritime	FLAGLE	2	7.5	5.0	10.0	82.5	70.0	95.0	12.5	75.0	60.0	90.0	15.0	82.5	70.0	95.0	12.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMII	4	21.3	4.5	46.3	73.8	41.2	88.9	19.4	76.2	41.2	100.0	22.8	82.8	61.2	100.0	13.9	0> ; 4= ; 0<	0> ; 4= ; 0<	
		Northeast	FLAGLE	1	5.0	-	-	59.2	-	-	-	65.4	-	-	-	73.3	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMII	2	7.4	6.3	8.5	55.9	47.5	64.4	8.4	71.9	52.5	91.3	19.4	78.9	60.2	97.5	18.6	1> ; 1= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	1	5.9	-	-	81.0	-	-	-	84.0	-	-	-	86.1	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMII	1	11.4	-	-	80.7	-	-	-	84.9	-	-	-	87.5	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
	All EPPO climatic zones	FLAGLE	4	6.5	5.0	10.0	76.3	59.2	95.0	13.3	74.9	60.0	90.0	12.5	81.1	70.0	95.0	10.0	0> ; 4= ; 0<	0> ; 4= ; 0<		
		FLMII	7	15.9	4.5	46.3	69.7	41.2	88.9	17.8	76.2	41.2	100.0	20.5	82.3	60.2	100.0	14.8	1> ; 6= ; 0<	0> ; 7= ; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	11	16.5	4.5	48.2	65.1	33.3	87.7	17.8	80.0	37.5	96.9	17.3	84.6	45.8	100.0	15.9	6> ; 5= ; 0<	0> ; 11= ; 0<	
			FLMII	16	27.1	4.8	99.0	72.1	45.9	100.0	15.1	84.6	60.0	100.0	12.9	90.4	72.5	100.0	8.7	9> ; 7= ; 0<	1> ; 15= ; 0<	
		Northeast	FLAGLE	3	10.3	7.0	14.3	69.8	64.3	75.3	4.5	86.9	78.6	92.9	6.1	91.0	82.1	96.4	6.4	3> ; 0= ; 0<	0> ; 3= ; 0<	
			FLMII	2	18.9	13.5	24.3	71.7	68.5	75.0	3.3	94.5	94.4	94.7	0.2	96.9	95.9	97.9	1.0	2> ; 0= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	5	8.9	4.7	16.4	77.9	49.7	97.9	16.6	87.4	70.9	100.0	9.5	93.6	84.9	100.0	5.2	3> ; 2= ; 0<	1> ; 4= ; 0<	
			FLMII	12	11.6	6.4	35.3	78.2	47.9	96.0	15.5	87.7	69.5	100.0	9.5	93.7	83.0	100.0	5.1	7> ; 5= ; 0<	3> ; 9= ; 0<	
All EPPO climatic zones		FLAGLE	19	13.5	4.5	48.2	69.2	33.3	97.9	17.0	83.1	37.5	100.0	14.7	88.0	45.8	100.0	13.2	12> ; 7= ; 0<	1> ; 18= ; 0<		
		FLMII	30	20.3	4.8	99.0	74.5	45.9	100.0	15.1	86.5	60.0	100.0	11.5	92.2	72.5	100.0	7.4	18> ; 12= ; 0<	4> ; 26= ; 0<		
PYRNTE Disease severity	Last valid assessment	Maritime	FLAGLE	12	16.0	4.5	48.2	65.5	33.3	87.7	17.1	78.4	37.5	96.9	17.5	83.4	45.8	100.0	15.7	6> ; 6= ; 0<	0> ; 12= ; 0<	
			FLMII	18	27.8	4.8	99.0	71.3	41.2	100.0	16.4	81.4	41.2	100.0	15.9	88.4	61.2	100.0	10.6	9> ; 9= ; 0<	1> ; 17= ; 0<	
		Northeast	FLAGLE	2	10.6	7.0	14.3	69.8	64.3	75.3	5.5	91.1	89.3	92.9	1.8	95.5	94.5	96.4	1.0	2> ; 0= ; 0<	0> ; 2= ; 0<	
			FLMII	2	18.9	13.5	24.3	71.7	68.5	75.0	3.3	94.5	94.4	94.7	0.2	96.9	95.9	97.9	1.0	2> ; 0= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	6	8.4	4.7	16.4	78.4	49.7	97.9	15.2	86.8	70.9	100.0	8.8	92.3	84.9	100.0	5.5	3> ; 3= ; 0<	1> ; 5= ; 0<	
			FLMII	13	11.6	6.4	35.3	78.4	47.9	96.0	14.9	87.5	69.5	100.0	9.1	93.3	83.0	100.0	5.1	7> ; 6= ; 0<	3> ; 10= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha										
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
						0.70-0.75 L/ha				1.00 L/ha												
		All EPPO climatic zones	FLAGLE	20	13.2	4.5	48.2	69.8	33.3	97.9	16.8	82.2	37.5	100.0	15.2	87.3	45.8	100.0	13.4	11> ; 9= ; 0<	1> ; 19= ; 0<	
			FLMI1	33	20.9	4.8	99.0	74.1	41.2	100.0	15.7	84.6	41.2	100.0	13.6	90.8	61.2	100.0	8.9	18> ; 15= ; 0<	4> ; 29= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-39: Minimum effective dose of ADM.03503.F.1.A - Barley - PUCCHD

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min
PUCCHD Disease severity	Last valid assessment after application A	Maritime	FLAGLE	2	11.5	5.5	17.5	97.9	95.7	100.0	2.2	98.6	97.1	100.0	1.5	100.0	100.0	100.0	0.0	0>; 2=; 0<	0>; 2=; 0<	
			FLMII	3	10.1	6.3	15.0	82.2	76.0	90.0	5.8	95.2	88.9	100.0	4.7	99.4	98.3	100.0	0.8	1>; 2=; 0<	0>; 3=; 0<	
		Northeast	FLMII	2	12.8	5.3	20.3	72.0	62.5	81.5	9.5	93.8	92.6	95.0	1.2	98.5	96.9	100.0	1.6	2>; 0=; 0<	0>; 2=; 0<	
		All EPPO climatic zones	FLAGLE	2	11.5	5.5	17.5	97.9	95.7	100.0	2.2	98.6	97.1	100.0	1.5	100.0	100.0	100.0	0.0	0>; 2=; 0<	0>; 2=; 0<	
			FLMII	5	11.2	5.3	20.3	78.1	62.5	90.0	9.0	94.6	88.9	100.0	3.8	99.0	96.9	100.0	1.3	3>; 2=; 0<	0>; 5=; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	10	21.8	9.3	59.2	81.8	46.3	99.2	16.1	87.5	63.6	100.0	12.9	90.7	60.0	100.0	11.9	2>; 8=; 0<	0>; 10=; 0<	
			FLMII	15	28.2	5.0	99.0	84.4	43.0	100.0	17.7	90.8	63.0	100.0	11.7	94.2	76.0	100.0	6.8	5>; 10=; 0<	1>; 14=; 0<	
		Northeast	FLAGLE	4	12.5	5.5	27.2	66.0	55.5	75.9	7.5	84.3	79.0	92.3	5.0	91.3	81.7	100.0	6.5	4>; 0=; 0<	1>; 3=; 0<	
			FLMII	2	9.0	7.0	11.0	76.1	71.1	81.1	5.0	88.0	83.7	92.3	4.3	91.5	86.2	96.9	5.3	1>; 1=; 0<	0>; 2=; 0<	
		Southeast	FLAGLE	1	15.4	-	-	99.2	-	-	-	100.0	-	-	-	100.0	-	-	-	-	0>; 1=; 0<	0>; 1=; 0<
			FLMII	4	8.1	5.0	13.5	87.7	63.2	100.0	14.8	92.7	76.8	100.0	9.5	97.6	91.9	100.0	3.4	1>; 3=; 0<	0>; 4=; 0<	
		All EPPO climatic zones	FLAGLE	15	18.9	5.5	59.2	78.7	46.3	99.2	16.3	87.5	63.6	100.0	11.4	91.5	60.0	100.0	10.5	6>; 9=; 0<	1>; 14=; 0<	
	FLMII		21	22.6	5.0	99.0	84.2	43.0	100.0	16.6	90.9	63.0	100.0	10.9	94.6	76.0	100.0	6.3	7>; 14=; 0<	1>; 20=; 0<		
	PUCCHD Disease severity	Last valid assessment	Maritime	FLAGLE	10	22.4	9.3	59.2	81.8	46.3	99.2	16.1	87.2	63.6	99.7	12.6	90.7	60.0	100.0	11.9	2>; 8=; 0<	0>; 10=; 0<
FLMII				15	28.8	5.0	99.0	84.3	43.0	100.0	17.7	90.9	63.0	100.0	11.8	94.7	76.0	100.0	6.8	5>; 10=; 0<	1>; 14=; 0<	
Northeast			FLAGLE	4	12.5	5.5	27.2	66.0	55.5	75.9	7.5	84.3	79.0	92.3	5.0	91.3	81.7	100.0	6.5	4>; 0=; 0<	1>; 3=; 0<	
			FLMII	4	10.9	5.3	20.3	74.1	62.5	81.5	7.9	90.9	83.7	95.0	4.3	95.0	86.2	100.0	5.2	3>; 1=; 0<	0>; 4=; 0<	
Southeast			FLAGLE	1	15.4	-	-	99.2	-	-	-	100.0	-	-	-	100.0	-	-	-	-	0>; 1=; 0<	0>; 1=; 0<

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																		0.70-0.75 L/ha	1.00 L/ha			
			FLMI1	4	8.1	5.0	13.5	87.7	63.2	100.0	14.8	92.7	76.8	100.0	9.5	97.6	91.9	100.0	3.4	1> ; 3= ; 0<	0> ; 4= ; 0<	
		All EPPO climatic zones	FLAGLE	15	19.3	5.5	59.2	78.7	46.3	99.2	16.3	87.3	63.6	100.0	11.2	91.5	60.0	100.0	10.5	6> ; 9= ; 0<	1> ; 14= ; 0<	
			FLMI1	23	22.1	5.0	99.0	83.1	43.0	100.0	16.5	91.2	63.0	100.0	10.5	95.2	76.0	100.0	6.2	9> ; 14= ; 0<	1> ; 22= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-40: Minimum effective dose of ADM.03503.F.1.A - Barley - RAMUCC

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
					Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	Mea n	Min	Max	S.D.	ADM.03503.F.1.A					
					0.70-0.75 L/ha		1.00 L/ha															
RAMUCC Disease severity	Last valid assessment after application A	Maritime	FLAGLE	3	27.6	10.3	50.0	65.0	44.8	92.0	19.9	73.3	60.4	86.0	10.4	83.7	78.2	91.0	5.4	1> ; 2= ; 0<	0> ; 3= ; 0<	
			FLMII	4	36.4	11.3	69.7	60.9	40.0	90.0	20.7	68.0	44.4	85.0	14.8	80.3	66.7	90.0	9.5	2> ; 2= ; 0<	1> ; 3= ; 0<	
		Northeast	FLAGLE	1	5.0	-	-	55.0	-	-	-	75.0	-	-	-	95.0	-	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
			FLMII	1	5.0	-	-	50.0	-	-	-	70.0	-	-	-	85.0	-	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
		All EPPO climatic zones	FLAGLE	4	22.0	5.0	50.0	62.5	44.8	92.0	17.7	73.7	60.4	86.0	9.1	86.5	78.2	95.0	6.8	2> ; 2= ; 0<	1> ; 3= ; 0<	
			FLMII	5	30.1	5.0	69.7	58.7	40.0	90.0	19.0	68.4	44.4	85.0	13.2	81.2	66.7	90.0	8.7	3> ; 2= ; 0<	1> ; 4= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	10	44.0	4.9	100.0	71.5	53.8	93.5	12.6	78.4	62.2	97.8	11.6	86.8	71.7	98.9	9.1	6> ; 4= ; 0<	4> ; 6= ; 0<	
			FLMII	12	52.4	5.8	100.0	71.6	56.5	99.0	13.0	77.2	57.3	99.7	11.1	85.3	70.2	99.7	9.1	5> ; 7= ; 0<	2> ; 10= ; 0<	
		Northeast	FLAGLE	1	7.8	-	-	57.6	-	-	-	77.2	-	-	-	87.1	-	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
			FLMII	1	8.3	-	-	54.2	-	-	-	75.7	-	-	-	85.1	-	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
		Southeast	FLAGLE	3	75.0	55.3	86.9	91.8	83.8	95.9	5.6	97.2	92.8	100.0	3.2	98.5	96.0	100.0	1.8	1> ; 2= ; 0<	1> ; 2= ; 0<	
			FLMII	3	89.2	71.9	98.1	90.7	84.9	94.3	4.2	95.6	92.1	98.5	2.7	97.1	94.9	99.7	2.0	3> ; 0= ; 0<	1> ; 2= ; 0<	
		All EPPO climatic zones	FLAGLE	14	48.1	4.9	100.0	74.9	53.8	95.9	14.5	82.4	62.2	100.0	12.6	89.3	71.7	100.0	9.1	8> ; 6= ; 0<	5> ; 9= ; 0<	
			FLMII	16	56.5	5.8	100.0	74.1	54.2	99.0	14.5	80.6	57.3	99.7	12.1	87.5	70.2	99.7	9.2	9> ; 7= ; 0<	4> ; 12= ; 0<	
RAMUCC Disease severity	Last valid assessment	Maritime	FLAGLE	13	40.2	4.9	100.0	70.0	44.8	93.5	14.9	77.2	60.4	97.8	11.5	86.1	71.7	98.9	8.5	7> ; 6= ; 0<	4> ; 9= ; 0<	
			FLMII	15	50.8	5.8	100.0	70.8	42.6	99.0	14.6	76.9	57.3	99.7	10.4	85.2	70.2	99.7	8.6	7> ; 8= ; 0<	3> ; 12= ; 0<	
		Northeast	FLAGLE	1	7.8	-	-	57.6	-	-	-	77.2	-	-	-	87.1	-	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
			FLMII	1	8.3	-	-	54.2	-	-	-	75.7	-	-	-	85.1	-	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
		Southeast	FLAGLE	3	75.0	55.3	86.9	91.8	83.8	95.9	5.6	97.2	92.8	100.0	3.2	98.5	96.0	100.0	1.8	1> ; 2= ; 0<	1> ; 2= ; 0<	
			FLMII	3	89.2	71.9	98.1	90.7	84.9	94.3	4.2	95.6	92.1	98.5	2.7	97.1	94.9	99.7	2.0	3> ; 0= ; 0<	1> ; 2= ; 0<	
		All EPPO climatic zones	FLAGLE	17	44.4	4.9	100.0	73.1	44.8	95.9	16.1	80.8	60.4	100.0	12.7	88.3	71.7	100.0	8.8	9> ; 8= ; 0<	5> ; 12= ; 0<	
			FLMII	19	54.7	5.8	100.0	73.1	42.6	99.0	15.6	79.8	57.3	99.7	11.5	87.1	70.2	99.7	8.8	11> ; 8= ; 0<	5> ; 14= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-41: Minimum effective dose of ADM.03503.F.1.A - Barley - ERYSGH

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >; < to			
					Untreated						ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole						Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha						75+150 g a.s./ha				93.75+187.5 g a.s./ha									
																				ADM.03503.F.1.A				
																				0.70-0.75 L/ha		1.00 L/ha		
ERYSGH Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	6.5	-	-	80.8	-	-	-	96.2	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<			
			FLMI2	6	9.9	4.8	23.8	72.0	36.8	100.0	24.6	75.5	54.6	100.0	15.7	83.3	57.9	100.0	16.4	1> ; 5= ; 0<	1> ; 5= ; 0<			
		Northeast	FLAGLE	1	5.0	-	-	90.0	-	-	-	95.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<			
			FLMI1	3	9.0	5.0	13.5	77.7	70.4	83.2	5.4	84.9	73.8	92.8	8.1	91.8	82.9	97.5	6.3	3> ; 0= ; 0<	0> ; 3= ; 0<			
			FLMI2	8	10.8	5.2	19.5	61.8	29.7	78.3	14.9	78.0	51.4	92.3	12.7	87.8	65.0	100.0	10.1	8> ; 0= ; 0<	3> ; 5= ; 0<			
		Southeast	FLMI2	1	5.4	-	-	93.0	-	-	-	96.3	-	-	-	98.6	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<			
		All EPPO climatic zones	FLAGLE	1	5.0	-	-	90.0	-	-	-	95.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<			
			FLMI1	4	8.4	5.0	13.5	78.5	70.4	83.2	4.9	87.7	73.8	96.2	8.6	93.8	82.9	100.0	6.6	3> ; 1= ; 0<	0> ; 4= ; 0<			
			FLMI2	15	10.1	4.8	23.8	67.9	29.7	100.0	20.7	78.2	51.4	100.0	14.4	86.7	57.9	100.0	13.3	9> ; 6= ; 0<	4> ; 11= ; 0<			
		Last valid assessment after application B	Maritime	FLAGLE	3	23.8	10.8	36.9	95.1	85.1	100.0	7.0	94.7	83.9	100.0	7.6	96.9	90.8	100.0	4.4	0> ; 3= ; 0<	0> ; 3= ; 0<		
	FLMI1			8	25.8	4.7	73.8	88.2	61.6	99.1	11.5	91.2	60.8	100.0	12.5	93.9	73.0	100.0	8.7	0> ; 8= ; 0<	0> ; 8= ; 0<			
	FLMI2			7	21.7	5.0	63.6	86.0	52.5	100.0	15.3	92.2	70.3	100.0	11.0	94.0	73.4	100.0	9.5	1> ; 6= ; 0<	0> ; 7= ; 0<			
	Northeast		FLAGLE	3	7.2	5.3	9.7	75.7	66.7	92.9	12.1	86.7	80.0	95.8	6.7	96.9	90.7	100.0	4.4	2> ; 1= ; 0<	1> ; 2= ; 0<			
			FLMI1	7	11.6	5.5	16.0	73.2	63.7	81.7	5.6	85.6	76.5	100.0	8.6	93.6	85.7	100.0	5.3	7> ; 0= ; 0<	3> ; 4= ; 0<			
			FLMI2	5	18.0	13.8	26.5	71.3	65.0	76.4	3.7	86.3	82.9	93.8	3.9	94.6	88.7	100.0	4.0	5> ; 0= ; 0<	2> ; 3= ; 0<			
	Southeast		FLMI1	5	7.0	5.4	11.3	87.9	64.1	100.0	13.3	92.0	78.0	100.0	8.1	95.2	85.3	100.0	5.7	1> ; 4= ; 0<	0> ; 5= ; 0<			
			FLMI2	5	11.3	6.5	15.9	83.5	59.0	98.4	13.3	89.8	71.9	100.0	9.6	93.4	81.0	100.0	6.6	3> ; 2= ; 0<	1> ; 4= ; 0<			
	All EPPO climatic zones		FLAGLE	6	15.5	5.3	36.9	85.4	66.7	100.0	13.8	90.7	80.0	100.0	8.2	96.9	90.7	100.0	4.4	2> ; 4= ; 0<	1> ; 5= ; 0<			
			FLMI1	20	16.1	4.7	73.8	82.9	61.6	100.0	12.6	89.4	60.8	100.0	10.6	94.1	73.0	100.0	6.9	8> ; 12= ; 0<	3> ; 17= ; 0<			

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole 52.5-56.25+ 105-112.5 g a.s./ha				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min
			FLMI2	17	17.5	5.0	63.6	80.9	52.5	100.0	13.8	89.8	70.3	100.0	9.4	94.0	73.4	100.0	7.4	9>; 8=; 0<	3>; 14=; 0<	
ERYSGH Disease severity	Last valid assessment	Maritime	FLAGLE	3	23.8	10.8	36.9	95.1	85.1	100.0	7.0	94.7	83.9	100.0	7.6	96.9	90.8	100.0	4.4	0>; 3=; 0<	0>; 3=; 0<	
			FLMI1	8	25.8	4.7	73.8	88.2	61.6	99.1	11.5	91.2	60.8	100.0	12.5	93.9	73.0	100.0	8.7	0>; 8=; 0<	0>; 8=; 0<	
			FLMI2	11	16.3	4.8	63.6	80.8	36.8	100.0	19.7	85.8	57.9	100.0	13.7	89.9	57.9	100.0	13.8	2>; 9=; 0<	1>; 10=; 0<	
		Northeast	FLAGLE	3	7.2	5.3	9.7	75.7	66.7	92.9	12.1	86.7	80.0	95.8	6.7	96.9	90.7	100.0	4.4	2>; 1=; 0<	1>; 2=; 0<	
			FLMI1	7	11.6	5.5	16.0	73.2	63.7	81.7	5.6	85.6	76.5	100.0	8.6	93.6	85.7	100.0	5.3	7>; 0=; 0<	3>; 4=; 0<	
			FLMI2	6	16.3	8.3	26.5	70.0	63.5	76.4	4.4	85.5	81.6	93.8	4.0	93.4	87.9	100.0	4.4	6>; 0=; 0<	2>; 4=; 0<	
		Southeast	FLMI1	5	7.0	5.4	11.3	87.9	64.1	100.0	13.3	92.0	78.0	100.0	8.1	95.2	85.3	100.0	5.7	1>; 4=; 0<	0>; 5=; 0<	
			FLMI2	5	11.3	6.5	15.9	83.5	59.0	98.4	13.3	89.8	71.9	100.0	9.6	93.4	81.0	100.0	6.6	3>; 2=; 0<	1>; 4=; 0<	
		All EPPO climatic zones	FLAGLE	6	15.5	5.3	36.9	85.4	66.7	100.0	13.8	90.7	80.0	100.0	8.2	96.9	90.7	100.0	4.4	2>; 4=; 0<	1>; 5=; 0<	
			FLMI1	20	16.1	4.7	73.8	82.9	61.6	100.0	12.6	89.4	60.8	100.0	10.6	94.1	73.0	100.0	6.9	8>; 12=; 0<	3>; 17=; 0<	
			FLMI2	22	15.1	4.8	63.6	78.5	36.8	100.0	16.3	86.6	57.9	100.0	11.1	91.6	57.9	100.0	10.6	11>; 11=; 0<	4>; 18=; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-42: Minimum effective dose of ADM.03503.F.1.A - Barley - All valid efficacy trials

Target	Parts	No. of trials	Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >=; < to ADM.03503.F.1.A	
			ADM.03503.F.1.A													
			Fluxapyroxad + Prothioconazole													
			0.70-0.75 L/ha 52.5-56.25+ 105-112.5 g a.s./ha			1.00 L/ha 75+150 g a.s./ha			1.25 L/ha 93.75+187.5 g a.s./ ha							
Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	0.70-0.75 L/ha	1.00 L/ha
RHYNSE	FLAGLE	22	18.6	5.5	88.8	73.7	36.5	97.7	85.4	47.8	100.0	90.7	65.2	100.0	9>;13=;0<	3>;19=;0<
	FLMI1	30	18.9	5.3	100.0	73.7	30.0	98.7	81.9	42.0	99.6	88.9	42.9	100.0	10>;20=;0<	5>;25=;0<
PYRNTE	FLAGLE	20	13.2	4.5	48.2	69.8	33.3	97.9	82.2	37.5	100.0	87.3	45.8	100.0	11>;9=;0<	1>;19=;0<
	FLMI1	33	20.9	4.8	99.0	74.1	41.2	100.0	84.6	41.2	100.0	90.8	61.2	100.0	18>;15=;0<	4>;29=;0<
PUCCHD	FLAGLE	15	19.3	5.5	59.2	78.7	46.3	99.2	87.3	63.6	100.0	91.5	60.0	100.0	6>;9=;0<	1>;14=;0<
	FLMI1	23	22.1	5.0	99.0	83.1	43.0	100.0	91.2	63.0	100.0	95.2	76.0	100.0	9>;14=;0<	1>;22=;0<
RAMUCC	FLAGLE	17	44.4	4.9	100.0	73.1	44.8	95.9	80.8	60.4	100.0	88.3	71.7	100.0	9>;8=;0<	5>;12=;0<
	FLMI1	19	54.7	5.8	100.0	73.1	42.6	99.0	79.8	57.3	99.7	87.1	70.2	99.7	11>;8=;0<	5>;14=;0<
ERYSGH	FLAGLE	6	15.5	5.3	36.9	85.4	66.7	100.0	90.7	80.0	100.0	96.9	90.7	100.0	2>;4=;0<	1>;5=;0<
	FLMI1	20	16.1	4.7	73.8	82.9	61.6	100.0	89.4	60.8	100.0	94.1	73.0	100.0	8>;12=;0<	3>;17=;0<
	FLMI2	22	15.1	4.8	63.6	78.5	36.8	100.0	86.6	57.9	100.0	91.6	57.9	100.0	11>;11=;0<	4>;18=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

The results are summarized by EPP0 climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPP0 climatic zones presented Table 3.2-42) are discussed hereafter to justify the minimum effective dose of ADM.03503.F.1.A against barley diseases.

Across 99 efficacy trials carried out in the Maritime, the Northeast and the Southeast EPP0 climatic zones, ADM.03503.F.1.A, applied at the proposed label rate of 1.25 L/ha, was compared to ADM.03503.F.1.A at 0.70-75 L/ha (56-60% of maximum recommended dose) and 1.00 L/ha (80% of maximum recommended dose).

Against RHYNSE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 91% on FLAGLE and 89% on FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 74% on FLAGLE and FLMI1 and ADM.03503.F.1.A at 1.00 L/ha provided 85% on FLAGLE and 82% on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 9 out of 22 trials on FLAGLE and in 10 out of 30 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 3 out of 22 trials on FLAGLE and in 5 out of 30 trials on FLMI1.

Against PYRNTE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 87% on FLAGLE and 91% on FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 70% on FLAGLE and 74% on FLMI1 and ADM.03503.F.1.A at 1.00 L/ha provided 82% on FLAGLE and 85% on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 11 out of 20 trials on FLAGLE and in 18 out of 33 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 20 trials on FLAGLE and in 4 out of 33 trials on FLMI1.

Against PUCCHD, ADM.03503.F.1.A applied at 1.25 L/ha delivered 92% on FLAGLE and 95% on FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 79% on FLAGLE and 83% on FLMI1 and ADM.03503.F.1.A at 1.00 L/ha provided 87% on FLAGLE and 91% on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 6 out of 15 trials on

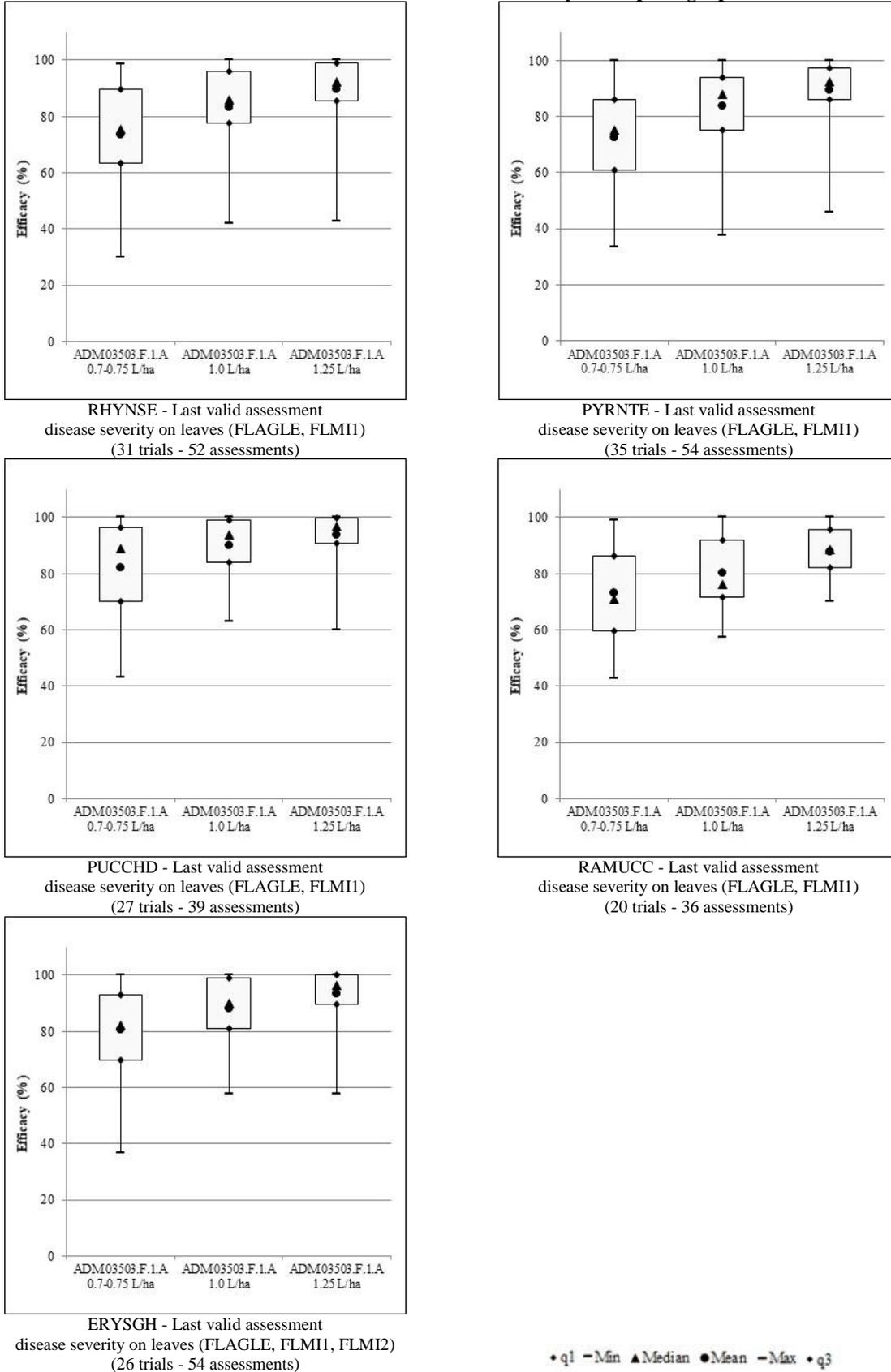
FLAGLE and in 9 out of 23 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 15 trials on FLAGLE and in 1 out of 23 trials on FLMI1.

Against RAMUCC, ADM.03503.F.1.A applied at 1.25 L/ha delivered 88% on FLAGLE and 87% on FLMI1 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 73% on FLAGLE and FLMI1 and ADM.03503.F.1.A at 1.00 L/ha provided 81% on FLAGLE and 80% on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 9 out of 17 trials on FLAGLE and in 11 out of 19 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 5 out of 17 trials on FLAGLE and in 5 out of 19 trials on FLMI1.

Against ERYSGH, ADM.03503.F.1.A applied at 1.25 L/ha delivered 97% on FLAGLE, 94% on FLMI1 and 92% on FLMI2 when ADM.03503.F.1.A at 0.70-0.75 L/ha 85% on FLAGLE, 83% on FLMI1 and 79% on FLMI2 and ADM.03503.F.1.A at 1.00 L/ha provided 91% on FLAGLE, 89% on FLMI1 and 87% on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 2 out of 6 trials on FLAGLE, in 8 out of 20 trials on FLMI1 and in 11 out of 22 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 6 trials on FLAGLE, in 3 out of 20 trials on FLMI1 and in 4 out of 22 trials on FLMI1.

It can be considered that the choice of 1.25 L/ha as maximum recommended dose rate of ADM.03503.F.1.A is justified against the barley diseases. Indeed, for each disease with at least 5 assessments, the dose effect is clearly illustrated by box plot graphics (Figure 3.2-12). According to the box plot graphics, the higher the dose of ADM.03503.F.1.A, the lower the dispersion and variation between means. However, the efficacy of ADM.03503.F.1.A at 1.00 L/ha was also acceptable to control barley disease according to the disease pressure.

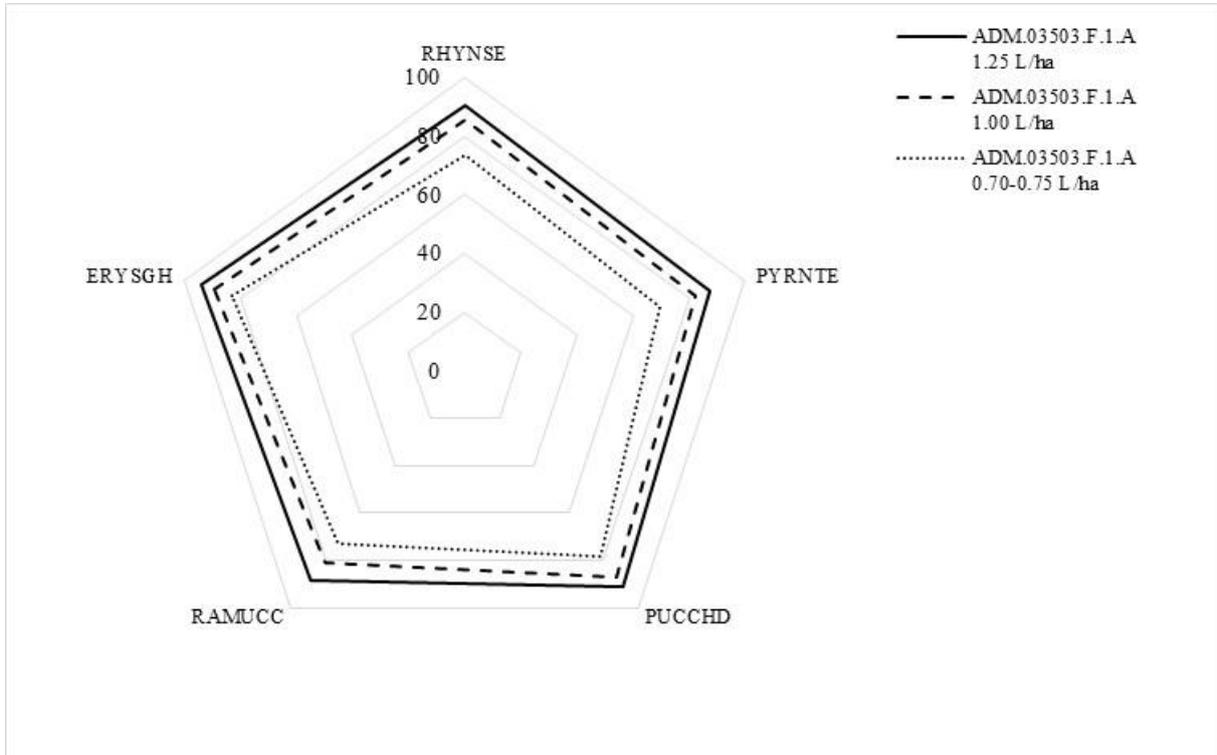
Figure 3.2-12 Minimum effective dose of ADM.03503.F.1.A - Barley - Box plots graphics



The justification of the minimum effective dose of ADM.03503.F.1.A against barley disease complex can be illustrated by graphic from the last valid assessment (Figure 3.2-13). According to the efficacy

results and as illustrated on the graphic hereafter, ADM.03503.F.1.A at 1.25 L/ha is the best dose rate to control the major diseases of barley.

Figure 3.2-13 Minimum effective dose of ADM.03503.F.1.A - Barley - Disease complex (efficacy against RHYNSE, PYRNTE, PUCCHD, RAMUCC on FLAGLE and against ERYSGH on FLMI1) after last valid assessment



The barley data demonstrates the mean efficacy increases for the dose rate of ADM.03503.F.1.A. The maximum proposed dose of 1.25 L/ha attains higher and more consistent control than the lower rates tested. ADM.03503.F.1.A at 1.25 L/ha gives excellent control of all the target diseases, confirming the selection of 1.25 L/ha as the proposed registered dose. Overall, the efficacy of ADM.03503.F.1.A at 1.0 L/ha was lower than ADM.03503.F.1.A at 1.25 L/ha, however 1.0 L/ha can achieve acceptable control when there is low disease pressure.

3.2.2.4 Results of minimum effective dose tests in rye

A total of **8 valid efficacy trials** were carried out to justify the minimum effective dose of ADM.03503.F.1.A. These trials were carried out **from 2020 to 2021** in the Maritime (4 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (2 trials in Romania) EPPO climatic zones against RHYNSE (7 trials) and PUCCRE (3 trials).

Moreover, to complete the data package, **2 efficacy trials** performed **from 2020 to 2021** in the Northeast EPPO climatic zone in Latvia and Lithuania are also provided as supportive data.

Table 3.2-43 (RHYNSE), Table 3.2-44 (RHYNSE - supportive data), Table 3.2-45 (PUCCRE) and Table 3.2-46 (PUCCRE - supportive data) summarise all observations for each disease (efficacy) and Table 3.2-47 synthesises the minimum effective dose of ADM.03503.F.1.A against the rye disease complex.

To estimate the efficacy level after one application, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the first (for trials with 2 applications) or the single application (for trials with 1 application) was considered. This assessment is noted “Last valid assessment after application A” in the synthesis tables.

To estimate the efficacy level after two applications, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the second applications of trials with 2 applications was considered. This assessment is noted “Last valid assessment after application B” in the synthesis tables.

Finally, to estimate the intrinsic efficacy level of ADM.03503.F.1.A, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the single (for trials with 1 application) or the second (for trials with 2 applications) application was considered. This assessment is noted “Last valid assessment” in the synthesis tables.

Table 3.2-43: Minimum effective dose of ADM.03503.F.1.A - Rye - RHYNSE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha				93.75+187.5 g a.s./ha						
																		ADM.03503.F.1.A				
																		0.70-0.75 L/ha	1.00 L/ha			
RHYNSE Disease severity	Last valid assessment after application A	Maritime	FLMI2	1	7.5	-	-	76.7	-	-	-	80.0	-	-	-	86.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		Northeast	FLMI1	1	20.9	-	-	68.7	-	-	-	84.5	-	-	-	88.1	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	16.9	15.3	18.4	63.8	57.1	70.5	6.7	84.9	83.7	86.1	1.2	90.8	90.5	91.0	0.3	2> ; 0= ; 0<	0> ; 2= ; 0<	
		Southeast	FLMI2	1	6.3	-	-	75.2	-	-	-	79.7	-	-	-	83.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		All EPPO climatic zones	FLMI1	1	20.9	-	-	68.7	-	-	-	84.5	-	-	-	88.1	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
	FLMI2		4	11.9	6.3	18.4	69.9	57.1	76.7	7.7	82.4	79.7	86.1	2.7	88.0	83.9	91.0	2.9	2> ; 2= ; 0<	0> ; 4= ; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	2	25.4	25.0	25.8	67.1	59.2	75.0	7.9	78.9	71.8	86.0	7.1	84.7	83.0	86.4	1.7	2> ; 0= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	46.7	7.5	77.5	83.0	73.9	100.0	12.1	87.7	77.3	100.0	9.4	91.4	86.4	100.0	6.1	2> ; 1= ; 0<	1> ; 2= ; 0<	
			FLMI2	3	62.3	36.5	99.0	72.6	69.9	75.6	2.4	78.1	75.3	81.1	2.4	83.1	80.8	85.6	2.0	2> ; 1= ; 0<	1> ; 2= ; 0<	
		Northeast	FLAGLE	2	14.7	14.4	15.0	60.6	58.7	62.5	1.9	75.0	70.4	79.6	4.6	84.9	80.9	88.8	4.0	2> ; 0= ; 0<	0> ; 2= ; 0<	
			FLMI1	1	11.9	-	-	72.6	-	-	-	96.8	-	-	-	100.0	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
		Southeast	FLAGLE	2	5.1	5.1	5.1	81.3	77.3	85.4	4.1	86.6	81.7	91.4	4.9	89.9	85.1	94.6	4.8	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	2	8.8	7.3	10.3	77.2	71.4	83.0	5.8	81.4	76.9	85.8	4.5	85.0	80.1	90.0	5.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	2	15.4	13.2	17.7	71.5	67.1	75.8	4.4	74.6	69.6	79.6	5.0	79.4	74.5	84.3	4.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
		All EPPO climatic zones	FLAGLE	6	15.1	5.1	25.8	69.7	58.7	85.4	10.1	80.2	70.4	91.4	7.4	86.5	80.9	94.6	4.4	4> ; 2= ; 0<	0> ; 6= ; 0<	
	FLMI1		6	28.3	7.3	77.5	79.3	71.4	100.0	10.0	87.1	76.9	100.0	8.8	90.7	80.1	100.0	7.2	3> ; 3= ; 0<	1> ; 5= ; 0<		
	FLMI2		5	43.5	13.2	99.0	72.1	67.1	75.8	3.4	76.7	69.6	81.1	4.0	81.6	74.5	85.6	3.9	2> ; 3= ; 0<	1> ; 4= ; 0<		
	RHYNSE Disease severity	Last valid assessment	Maritime	FLAGLE	2	25.4	25.0	25.8	67.1	59.2	75.0	7.9	78.9	71.8	86.0	7.1	84.7	83.0	86.4	1.7	2> ; 0= ; 0<	0> ; 2= ; 0<
FLMI1				3	46.7	7.5	77.5	83.0	73.9	100.0	12.1	87.7	77.3	100.0	9.4	91.4	86.4	100.0	6.1	2> ; 1= ; 0<	1> ; 2= ; 0<	
Northeast			FLMI2	3	62.3	36.5	99.0	72.6	69.9	75.6	2.4	78.1	75.3	81.1	2.4	83.1	80.8	85.6	2.0	2> ; 1= ; 0<	1> ; 2= ; 0<	
			FLAGLE	2	14.7	14.4	15.0	60.6	58.7	62.5	1.9	75.0	70.4	79.6	4.6	84.9	80.9	88.8	4.0	2> ; 0= ; 0<	0> ; 2= ; 0<	
FLMI1			FLMI1	1	11.9	-	-	72.6	-	-	-	96.8	-	-	-	100.0	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	16.9	15.3	18.4	63.8	57.1	70.5	6.7	84.9	83.7	86.1	1.2	90.8	90.5	91.0	0.3	2> ; 0= ; 0<	0> ; 2= ; 0<	
Southeast			FLAGLE	2	5.1	5.1	5.1	81.3	77.3	85.4	4.1	86.6	81.7	91.4	4.9	89.9	85.1	94.6	4.8	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	2	8.8	7.3	10.3	77.2	71.4	83.0	5.8	81.4	76.9	85.8	4.5	85.0	80.1	90.0	5.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
FLMI2			FLMI2	2	15.4	13.2	17.7	71.5	67.1	75.8	4.4	74.6	69.6	79.6	5.0	79.4	74.5	84.3	4.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
			All EPPO	FLAGLE	6	15.1	5.1	25.8	69.7	58.7	85.4	10.1	80.2	70.4	91.4	7.4	86.5	80.9	94.6	4.4	4> ; 2= ; 0<	0> ; 6= ; 0<

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																		0.70-0.75 L/ha	1.00 L/ha			
		climatic zones	FLMI1	6	28.3	7.3	77.5	79.3	71.4	100.0	10.0	87.1	76.9	100.0	8.8	90.7	80.1	100.0	7.2	3> ; 3= ; 0<	1> ; 5= ; 0<	
			FLMI2	7	35.9	13.2	99.0	69.8	57.1	75.8	5.9	79.1	69.6	86.1	5.1	84.2	74.5	91.0	5.3	4> ; 3= ; 0<	1> ; 6= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-44: Minimum effective dose of ADM.03503.F.1.A - Rye - RHYNSE (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to			
					Untreated				ADM.03503.F.1.A 0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					56.25+112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
			<i>Mea n</i>			<i>Min</i>			<i>Max</i>			<i>S.D.</i>						ADM.03503.F.1.A				
			<i>Mea n</i>			<i>Min</i>			<i>Max</i>			<i>S.D.</i>						0.75 L/ha		1.00 L/ha		
RHYNSE Disease severity	Last valid assessment after application A	Maritime	FLAGLE	2	22.1	12.5	31.6	65.3	63.8	66.8	1.5	64.5	61.7	67.2	2.8	67.8	52.7	82.8	15.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	2	27.8	23.8	31.3	55.1	45.9	64.2	9.2	49.1	30.4	67.8	18.7	52.2	30.2	74.2	22.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	2	17.5	16.2	18.8	52.0	35.7	68.3	16.3	64.9	51.6	78.1	13.3	68.3	59.5	77.0	8.8	0> ; 2= ; 0<	0> ; 2= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-45: Minimum effective dose of ADM.03503.F.1.A - Rye - PUCCRE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to			
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+105-112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha									
			<i>Mea n</i>			<i>Min</i>			<i>Max</i>			<i>S.D.</i>						ADM.03503.F.1.A				
			<i>Mea n</i>			<i>Min</i>			<i>Max</i>			<i>S.D.</i>						0.70-0.75 L/ha		1.00 L/ha		
PUCCRE Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	8.0	-	-	50.0	-	-	-	39.6	-	-	-	45.8	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	1	11.9	-	-	50.8	-	-	-	55.1	-	-	-	52.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	3	6.0	4.5	8.4	70.8	52.5	100.0	20.9	75.9	42.6	100.0	24.3	82.8	48.5	100.0	24.3	1> ; 2= ; 0<	1> ; 2= ; 0<	
			FLMI1	3	8.9	4.5	11.6	79.2	52.0	100.0	20.1	85.4	56.3	100.0	20.6	84.5	53.4	100.0	22.0	1> ; 2= ; 0<	0> ; 3= ; 0<	
			FLMI2	2	10.4	7.5	13.3	78.0	56.0	100.0	22.0	79.9	59.7	100.0	20.2	78.6	57.2	100.0	21.4	0> ; 2= ; 0<	0> ; 2= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-46: Minimum effective dose of ADM.03503.F.1.A - Rye - PUCCRE (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	<i>Untreated</i>			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;< to	
								ADM.03503.F.1.A 0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
								Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole					
								56.25+112.5 g a.s./ha				75+150 g a.s./ha				93.75+187.5 g a.s./ha					
			<i>Mean</i>	<i>Min</i>	<i>Max</i>	<i>Mean</i>	Min	Max	<i>S.D.</i>	<i>Mean</i>	Min	Max	<i>S.D.</i>	<i>Mean</i>	Min	Max	<i>S.D.</i>	ADM.03503.F.1.A			
																			0.75 L/ha	1.00 L/ha	
PUCCRE Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	13.4	-	-	87.9	-	-	-	91.1	-	-	-	93.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMII	1	12.2	-	-	74.1	-	-	-	69.9	-	-	-	72.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-47: Minimum effective dose of ADM.03503.F.1.A - Rye - All valid efficacy trials

Target	Parts	No. of trials	Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to ADM.03503.F.1.A	
			ADM.03503.F.1.A													
			Fluxapyroxad + Prothioconazole													
			0.70-0.75 L/ha			1.00 L/ha			1.25 L/ha							
			52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha			93.75+187.5 g a.s./ha							
Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	0.70-0.75 L/ha	1.00 L/ha
RHYNSE	FLAGLE	6	15.1	5.1	25.8	69.7	58.7	85.4	80.2	70.4	91.4	86.5	80.9	94.6	4>;2=;0<	0>;6=;0<
	FLMI1	6	28.3	7.3	77.5	79.3	71.4	100.0	87.1	76.9	100.0	90.7	80.1	100.0	3>;3=;0<	1>;5=;0<
	FLMI2	7	35.9	13.2	99.0	69.8	57.1	75.8	79.1	69.6	86.1	84.2	74.5	91.0	4>;3=;0<	1>;6=;0<
RHYNSE Supportive data	FLAGLE	2	22.1	12.5	31.6	65.3	63.8	66.8	64.5	61.7	67.2	67.8	52.7	82.8	0>;2=;0<	0>;2=;0<
	FLMI1	2	27.8	23.8	31.3	55.1	45.9	64.2	49.1	30.4	67.8	52.2	30.2	74.2	0>;2=;0<	0>;2=;0<
	FLMI2	2	17.5	16.2	18.8	52.0	35.7	68.3	64.9	51.6	78.1	68.3	59.5	77.0	0>;2=;0<	0>;2=;0<
PUCCRE	FLAGLE	3	6.0	4.5	8.4	70.8	52.5	100.0	75.9	42.6	100.0	82.8	48.5	100.0	1>;2=;0<	1>;2=;0<
	FLMI1	3	8.9	4.5	11.6	79.2	52.0	100.0	85.4	56.3	100.0	84.5	53.4	100.0	1>;2=;0<	0>;3=;0<
	FLMI2	2	10.4	7.5	13.3	78.0	56.0	100.0	79.9	59.7	100.0	78.6	57.2	100.0	0>;2=;0<	0>;2=;0<
PUCCRE Supportive data	FLAGLE	1	13.4	-	-	87.9	-	-	91.1	-	-	93.9	-	-	0>;1=;0<	0>;1=;0<
	FLMI1	1	12.2	-	-	74.1	-	-	69.9	-	-	72.9	-	-	0>;1=;0<	0>;1=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

The results are summarized by EPP0 climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPP0 climatic zones presented Table 3.2-47) are discussed hereafter to justify the minimum effective dose of ADM.03503.F.1.A against rye diseases.

Across 8 efficacy trials carried out in the Maritime, the Northeast and the Southeast EPP0 climatic zones and 2 supportive trials carried out in the Northeast EPP0 climatic zones, ADM.03503.F.1.A, applied at the proposed label rate of 1.25 L/ha, was compared to ADM.03503.F.1.A at 0.70-75 L/ha (56-60% of maximum recommended dose) and 1.00 L/ha (80% of maximum recommended dose).

Against RHYNSE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 87% on FLAGLE, 91% on FLMI1 and 84% on FLMI2 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 70% on FLAGLE, 79% on FLMI1 and 70% on FLMI2 and ADM.03503.F.1.A at 1.00 L/ha provided 80% on FLAGLE, 87% on FLMI1 and 79% on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 4 out of 6 trials on FLAGLE, in 3 out of 6 trials on FLMI1 and in 4 out of 7 trials on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 6 trials on FLMI1 and in 1 out of 7 trials on FLMI2.

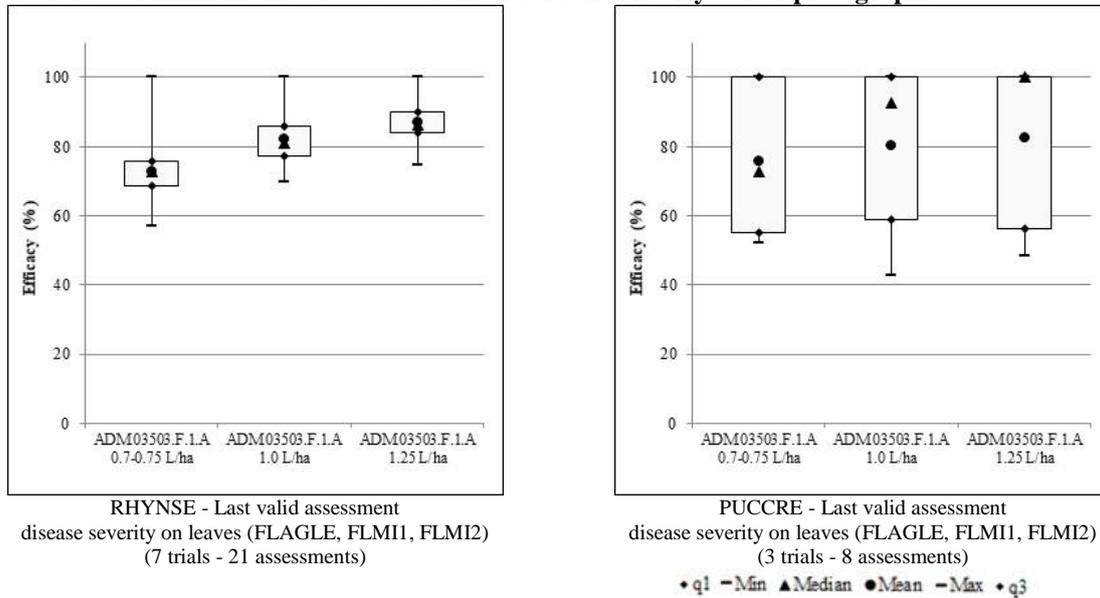
A slight dose effect was also noted in both supportive trials notably on FLMI2 with 68% for ADM.03503.F.1.A applied at 1.25 L/ha, 65% for ADM.03503.F.1.A applied at 1.0 L/ha and 52% for ADM.03503.F.1.A applied at 0.75 L/ha.

Against PUCCRE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 83% on FLAGLE, 85% on FLMI1 and 79% on FLMI2 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 71% on FLAGLE, 79% on FLMI1 and 78% on FLMI2 and ADM.03503.F.1.A at 1.00 L/ha provided 76% on FLAGLE, 85% on FLMI1 and 80% on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 1 out of 3 trials on FLAGLE, and in 1 out of 3 trials on FLMI1. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 3 trials on FLAGLE.

A slight dose effect was also noted in the supportive trial notably on FLAGLE with 94% for ADM.03503.F.1.A applied at 1.25 L/ha, 91% for ADM.03503.F.1.A applied at 1.0 L/ha and 88% for ADM.03503.F.1.A applied at 0.75 L/ha.

It can be considered that the choice of 1.25 L/ha as maximum recommended dose rate of ADM.03503.F.1.A is justified against the rye diseases. Indeed, for each disease with at least 5 assessments, the dose effect is clearly illustrated by box plot graphics (Figure 3.2-14). According to the box plot graphics, the higher the dose of ADM.03503.F.1.A, the lower the dispersion and variation between means. However, the efficacy of ADM.03503.F.1.A at 1.00 L/ha was also acceptable to control rye disease according to the disease pressure.

Figure 3.2-14 Minimum effective dose of ADM.03503.F.1.A - Rye - Box plots graphics



The rye data demonstrates the mean efficacy increases for the dose rate of ADM.03503.F.1.A. The maximum proposed dose of 1.25 L/ha attains higher and more consistent control than the lower rates tested. ADM.03503.F.1.A at 1.25 L/ha gives excellent control of all the target diseases, confirming the selection of 1.25 L/ha as the proposed registered dose. Overall, the efficacy of ADM.03503.F.1.A at 1.0 L/ha was lower than ADM.03503.F.1.A at 1.25 L/ha, however 1.0 L/ha can achieve acceptable control when there is low disease pressure.

3.2.2.5 Results of minimum effective dose tests in triticale

A total of **13 valid efficacy trials** were carried out to justify the minimum effective dose of ADM.03503.F.1.A. These trials were carried out **from 2020 to 2021** in the Maritime (1 trial in Czech Republic and 3 trials in Germany), the Northeast (4 trials in Poland) and the Southeast (4 trials in Hungary and 1 trial in Romania) EPPO climatic zones against SEPTTR (1 trial), PUCCRE (8 trials), PUC CST (1 trial), PYRNTR (6 trials), or ERYSGR (5 trials).

Moreover, to complete the data package, **6 efficacy trials** performed **from 2020 to 2021** in the Maritime and the Northeast EPPO climatic zone in Denmark (1 trial), Sweden (2 trials) and Latvia (3 trials) are also provided as supportive data.

Table 3.2-48 (SEPTTR), Table 3.2-49 (SEPTTR - supportive data), Table 3.2-50 (PUCCRE), Table 3.2-51 (PUC CST), Table 3.2-52 (PUC CST - supportive data), Table 3.2-53 (PYRNTR), Table 3.2-54 (PYRNTR - supportive data), Table 3.2-55 (ERYSGR) and Table 3.2-56 (ERYSGR - supportive data), summarise all observations for each disease (efficacy) and Table 3.2-57 synthesises the minimum effective dose of ADM.03503.F.1.A against the triticale disease complex.

To estimate the efficacy level after one application, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the first (for trials with 2 applications) or the single application (for trials with 1 application) was considered. This assessment is noted “Last valid assessment after application A” in the synthesis tables.

To estimate the efficacy level after two applications, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the second applications of trials with 2 applications was considered. This assessment is noted “Last valid assessment after application B” in the synthesis tables.

Finally, to estimate the intrinsic efficacy level of ADM.03503.F.1.A, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the single (for trials with 1 application) or the second (for trials with 2 applications) application was considered. This assessment is noted “Last valid assessment” in the synthesis tables.

Table 3.2-48: Minimum effective dose of ADM.03503.F.1.A - Triticale - SEPTTR

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to		
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole					
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha									
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A			
						0.70-0.75 L/ha				1.00 L/ha											
SEPTTR Disease severity	Last valid assessment after application A	Maritime	FLMI2	1	5.4	-	-	81.8	-	-	-	88.0	-	-	-	89.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Last valid assessment after application B	Maritime	FLAGLE	1	5.6	-	-	66.4	-	-	-	85.9	-	-	-	88.8	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<
			FLMI1	1	8.6	-	-	69.5	-	-	-	86.0	-	-	-	87.3	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-49: Minimum effective dose of ADM.03503.F.1.A - Triticale - SEPTTR (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to		
					Untreated			ADM.03503.F.1.A 0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole					
					56.25+112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha									
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A			
						0.75 L/ha				1.00 L/ha											
SEPTTR Disease severity	Last valid assessment after application B	Maritime	FLMI2	1	25.0	-	-	92.0	-	-	-	92.0	-	-	-	93.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		Northeast	FLMI1	1	6.6	-	-	90.6	-	-	-	84.6	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-50: Minimum effective dose of ADM.03503.F.1.A - Triticale - PUCCRE

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to			
					Untreated						ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole						Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole									
					52.5-56.25+ 105-112.5 g a.s./ha						75+150 g a.s./ha				93.75+187.5 g a.s./ha									
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																				0.70-0.75 L/ha	1.00 L/ha			
PUCCRE Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	8.8	-	-	68.6	-	-	-	45.7	-	-	-	60.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<			
			FLMI2	1	42.5	-	-	55.9	-	-	-	52.9	-	-	-	55.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<			
		Northeast	FLMI1	1	7.3	-	-	58.5	-	-	-	86.2	-	-	-	86.2	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<			
			FLMI2	1	8.3	-	-	60.4	-	-	-	85.1	-	-	-	91.0	-	-	-	1> ; 0= ; 0<	0> ; 1= ; 0<			
		All EPPO climatic zones	FLMI1	2	8.0	7.3	8.8	63.5	58.5	68.6	5.1	65.9	45.7	86.2	20.2	73.1	60.0	86.2	13.1	1> ; 1= ; 0<	0> ; 2= ; 0<			
			FLMI2	2	25.4	8.3	42.5	58.2	55.9	60.4	2.3	69.0	52.9	85.1	16.1	73.4	55.9	91.0	17.5	1> ; 1= ; 0<	0> ; 2= ; 0<			
	Last valid assessment after application B	Maritime	FLAGLE	3	14.5	5.8	28.8	68.0	39.1	100.0	25.0	77.6	47.8	100.0	21.9	82.5	60.9	100.0	16.2	2> ; 1= ; 0<	0> ; 3= ; 0<			
			FLMI1	2	28.6	9.7	47.5	33.9	15.8	52.0	18.1	55.4	28.9	81.9	26.5	62.1	39.5	84.7	22.6	2> ; 0= ; 0<	0> ; 2= ; 0<			
			FLMI2	1	45.0	-	-	47.2	-	-	-	66.7	-	-	-	75.0	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<			
		Northeast	FLAGLE	2	6.6	5.8	7.5	75.8	73.2	78.3	2.6	93.3	86.6	100.0	6.7	100.0	100.0	100.0	0.0	2> ; 0= ; 0<	1> ; 1= ; 0<			
			FLMI1	2	10.3	9.5	11.0	75.8	72.7	78.9	3.1	86.8	84.1	89.4	2.7	92.1	84.1	100.0	8.0	1> ; 1= ; 0<	1> ; 1= ; 0<			
			FLMI2	1	16.0	-	-	63.8	-	-	-	84.3	-	-	-	98.3	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<			
		Southeast	FLAGLE	2	5.5	5.4	5.6	95.9	91.7	100.0	4.2	100.0	100.0	100.0	0.0	100.0	100.0	100.0	0.0	0> ; 2= ; 0<	0> ; 2= ; 0<			
			FLMI1	3	8.2	7.4	9.3	89.1	80.9	95.9	6.2	94.8	84.3	100.0	7.4	96.7	90.2	100.0	4.7	1> ; 2= ; 0<	0> ; 3= ; 0<			
			FLMI2	3	12.8	8.4	16.3	86.9	73.5	94.6	9.5	92.5	77.4	100.0	10.6	94.5	83.5	100.0	7.8	0> ; 3= ; 0<	0> ; 3= ; 0<			
		All EPPO climatic zones	FLAGLE	7	9.7	5.4	28.8	78.2	39.1	100.0	20.2	88.5	47.8	100.0	17.7	92.5	60.9	100.0	13.7	4> ; 3= ; 0<	1> ; 6= ; 0<			
			FLMI1	7	14.6	7.4	47.5	69.5	15.8	95.9	25.5	81.2	28.9	100.0	22.5	85.5	39.5	100.0	19.9	4> ; 3= ; 0<	1> ; 6= ; 0<			
			FLMI2	5	19.9	8.4	45.0	74.3	47.2	94.6	17.8	85.7	66.7	100.0	13.0	91.4	75.0	100.0	10.3	2> ; 3= ; 0<	2> ; 3= ; 0<			
		PUCCRE Disease severity	Last valid assessment	Maritime	FLAGLE	3	14.5	5.8	28.8	68.0	39.1	100.0	25.0	77.6	47.8	100.0	21.9	82.5	60.9	100.0	16.2	2> ; 1= ; 0<	0> ; 3= ; 0<	
					FLMI1	2	28.6	9.7	47.5	33.9	15.8	52.0	18.1	55.4	28.9	81.9	26.5	62.1	39.5	84.7	22.6	2> ; 0= ; 0<	0> ; 2= ; 0<	
FLMI2	1				45.0	-	-	47.2	-	-	-	66.7	-	-	-	75.0	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<			
Northeast	FLAGLE			2	6.6	5.8	7.5	75.8	73.2	78.3	2.6	93.3	86.6	100.0	6.7	100.0	100.0	100.0	0.0	2> ; 0= ; 0<	1> ; 1= ; 0<			
	FLMI1			2	10.3	9.5	11.0	75.8	72.7	78.9	3.1	86.8	84.1	89.4	2.7	92.1	84.1	100.0	8.0	1> ; 1= ; 0<	1> ; 1= ; 0<			

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated				ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole 52.5-56.25+ 105-112.5 g a.s./ha				Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha									
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A 0.70-0.75 L/ha	ADM.03503.F.1.A 1.00 L/ha
			FLMI2	2	12.1	8.3	16.0	62.1	60.4	63.8	1.7	84.7	84.3	85.1	0.4	94.6	91.0	98.3	3.7	2> ; 0= ; 0<	1> ; 1= ; 0<	
			FLAGLE	2	5.5	5.4	5.6	95.9	91.7	100.0	4.2	100.0	100.0	100.0	0.0	100.0	100.0	100.0	0.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	8.2	7.4	9.3	89.1	80.9	95.9	6.2	94.8	84.3	100.0	7.4	96.7	90.2	100.0	4.7	1> ; 2= ; 0<	0> ; 3= ; 0<	
			FLMI2	3	12.8	8.4	16.3	86.9	73.5	94.6	9.5	92.5	77.4	100.0	10.6	94.5	83.5	100.0	7.8	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLAGLE	7	9.7	5.4	28.8	78.2	39.1	100.0	20.2	88.5	47.8	100.0	17.7	92.5	60.9	100.0	13.7	4> ; 3= ; 0<	1> ; 6= ; 0<	
			FLMI1	7	14.6	7.4	47.5	69.5	15.8	95.9	25.5	81.2	28.9	100.0	22.5	85.5	39.5	100.0	19.9	4> ; 3= ; 0<	1> ; 6= ; 0<	
			FLMI2	6	18.0	8.3	45.0	72.0	47.2	94.6	17.1	85.6	66.7	100.0	11.8	91.3	75.0	100.0	9.4	3> ; 3= ; 0<	2> ; 4= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-51: Minimum effective dose of ADM.03503.F.1.A - Triticale - PUCST

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha										
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
						0.70-0.75 L/ha				1.00 L/ha												
PUCST Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	5.3	-	-	71.4	-	-	-	90.5	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	1	5.3	-	-	71.4	-	-	-	90.5	-	-	-	95.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	1	76.3	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	1	99.0	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	1	99.0	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-52: Minimum effective dose of ADM.03503.F.1.A - Triticale - PUCST (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha										
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
						0.70-0.75 L/ha				1.00 L/ha												
PUCST Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	5.8	-	-	89.0	-	-	-	89.0	-	-	-	89.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	1	51.3	-	-	84.7	-	-	-	89.3	-	-	-	89.1	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	1	68.8	-	-	91.6	-	-	-	95.3	-	-	-	94.6	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
PUCST Disease severity	Last valid assessment	Maritime	FLAGLE	1	51.3	-	-	84.7	-	-	-	89.3	-	-	-	89.1	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	2	37.3	5.8	68.8	90.3	89.0	91.6	1.3	92.2	89.0	95.3	3.2	91.8	89.0	94.6	2.8	0> ; 2= ; 0<	0> ; 2= ; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-53: Minimum effective dose of ADM.03503.F.1.A - Triticale - PYRNTR

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha				93.75+187.5 g a.s./ha						
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																			0.70-0.75 L/ha	1.00 L/ha		
PYRNTR Disease severity	Last valid assessment after application A	Northeast	FLMI1	1	15.5	-	-	40.4	-	-	-	83.9	-	-	-	87.0	-	-	-	1>; 0=; 0<	0>; 1=; 0<	
			FLMI2	1	21.8	-	-	40.2	-	-	-	83.0	-	-	-	89.5	-	-	-	1>; 0=; 0<	0>; 1=; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	2	52.4	5.9	99.0	80.3	71.1	89.4	9.2	87.6	83.6	91.7	4.0	89.4	85.3	93.4	4.1	1>; 1=; 0<	0>; 2=; 0<	
			FLMI1	2	53.2	7.4	99.0	80.6	70.5	90.7	10.1	89.0	83.2	94.7	5.8	90.6	84.2	97.0	6.4	2>; 0=; 0<	0>; 2=; 0<	
			FLMI2	1	99.0	-	-	95.2	-	-	-	-	97.0	-	-	-	98.5	-	-	-	1>; 0=; 0<	0>; 1=; 0<
		Northeast	FLMI1	2	14.5	7.5	21.5	62.5	51.2	73.8	11.3	82.0	80.3	83.7	1.7	89.2	86.6	91.8	2.6	2>; 0=; 0<	1>; 1=; 0<	
			FLMI2	2	21.4	14.0	28.8	65.0	55.6	74.3	9.4	79.2	79.1	79.3	0.1	88.7	86.9	90.5	1.8	2>; 0=; 0<	1>; 1=; 0<	
		Southeast	FLMI2	2	4.9	4.7	5.1	79.7	79.0	80.3	0.7	86.9	84.0	89.7	2.9	94.4	93.6	95.1	0.8	2>; 0=; 0<	1>; 1=; 0<	
		All EPPO climatic zones	FLAGLE	2	52.4	5.9	99.0	80.3	71.1	89.4	9.2	87.6	83.6	91.7	4.0	89.4	85.3	93.4	4.1	1>; 1=; 0<	0>; 2=; 0<	
			FLMI1	4	33.9	7.4	99.0	71.5	51.2	90.7	14.0	85.5	80.3	94.7	5.5	89.9	84.2	97.0	4.9	4>; 0=; 0<	1>; 3=; 0<	
FLMI2	5		30.3	4.7	99.0	76.9	55.6	95.2	12.7	85.8	79.1	97.0	6.8	92.9	86.9	98.5	4.0	5>; 0=; 0<	2>; 3=; 0<			

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-54: Minimum effective dose of ADM.03503.F.1.A - Triticale - PYRNTR (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha				93.75+187.5 g a.s./ha				93.75+187.5 g a.s./ha						
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A				
																			0.70-0.75 L/ha	1.00 L/ha		
PYRNTR Disease severity	Last valid assessment after application B	Northeast	FLMI1	3	12.2	8.8	19.1	59.4	40.0	84.3	18.6	77.6	66.1	100.0	15.8	79.8	59.9	98.6	15.8	0>; 3=; 0<	0>; 3=; 0<	
			FLMI2	1	40.6	-	-	87.4	-	-	-	93.8	-	-	-	94.0	-	-	-	0>; 1=; 0<	0>; 1=; 0<	

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-55: Minimum effective dose of ADM.03503.F.1.A - Triticale - ERYSGR

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to			
					Untreated						ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha					
					Fluxapyroxad + Prothioconazole 52.5-56.25+ 105-112.5 g a.s./ha						Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole					
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A
																		0.70-0.75 L/ha	1.00 L/ha					
ERYSGR Disease severity	Last valid assessment after application A	Northeast	FLMI1	1	4.8	-	-	73.8	-	-	-	100.0	-	-	-	100.0	-	-	-	1>; 0=; 0<	0>; 1=; 0<			
			FLMI2	1	13.5	-	-	59.2	-	-	-	77.7	-	-	-	92.6	-	-	-	1>; 0=; 0<	1>; 0=; 0<			
			FLMI3	2	13.9	8.3	19.5	50.6	42.3	58.9	8.3	77.4	75.7	79.1	1.7	90.1	89.7	90.5	0.4	2>; 0=; 0<	1>; 1=; 0<			
		Southeast	FLMI2	2	7.7	5.3	10.2	66.0	50.4	81.6	15.6	95.5	90.9	100.0	4.6	96.1	92.1	100.0	4.0	2>; 0=; 0<	0>; 2=; 0<			
			FLMI3	2	15.4	10.9	19.9	58.7	48.2	69.1	10.5	87.1	76.9	97.2	10.2	92.4	86.5	98.2	5.9	2>; 0=; 0<	0>; 2=; 0<			
			All EPPO climatic zones	FLMI1	1	4.8	-	-	73.8	-	-	-	100.0	-	-	-	100.0	-	-	-	1>; 0=; 0<	0>; 1=; 0<		
		All EPPO climatic zones	FLMI2	3	9.7	5.3	13.5	63.8	50.4	81.6	13.1	89.5	77.7	100.0	9.2	94.9	92.1	100.0	3.6	3>; 0=; 0<	1>; 2=; 0<			
			FLMI3	4	14.6	8.3	19.9	54.6	42.3	69.1	10.3	82.2	75.7	97.2	8.7	91.2	86.5	98.2	4.3	4>; 0=; 0<	1>; 3=; 0<			
			Maritime	FLMI3	1	6.8	-	-	77.8	-	-	-	77.8	-	-	-	77.8	-	-	-	0>; 1=; 0<	0>; 1=; 0<		
	Last valid assessment after application B	Northeast	FLMI1	1	5.8	-	-	73.3	-	-	-	91.7	-	-	-	100.0	-	-	-	1>; 0=; 0<	0>; 1=; 0<			
			FLMI2	1	16.5	-	-	81.8	-	-	-	92.4	-	-	-	93.9	-	-	-	1>; 0=; 0<	0>; 1=; 0<			
			FLMI3	2	26.8	23.5	30.0	63.8	49.9	77.7	13.9	82.0	80.0	84.0	2.0	94.5	94.2	94.7	0.3	2>; 0=; 0<	2>; 0=; 0<			
		Southeast	FLMI1	1	5.4	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0>; 1=; 0<	0>; 1=; 0<			
			FLMI2	2	11.7	7.4	16.0	63.6	41.3	85.9	22.3	92.6	91.2	93.9	1.4	96.7	93.4	100.0	3.3	2>; 0=; 0<	0>; 2=; 0<			
			FLMI3	1	31.4	-	-	37.6	-	-	-	83.1	-	-	-	89.6	-	-	-	1>; 0=; 0<	0>; 1=; 0<			
		All EPPO climatic zones	FLMI1	2	5.6	5.4	5.8	86.7	73.3	100.0	13.3	95.8	91.7	100.0	4.2	100.0	100.0	100.0	0.0	1>; 1=; 0<	0>; 2=; 0<			
			FLMI2	3	13.3	7.4	16.5	69.7	41.3	85.9	20.1	92.5	91.2	93.9	1.1	95.8	93.4	100.0	3.0	3>; 0=; 0<	0>; 3=; 0<			
			FLMI3	4	22.9	6.8	31.4	60.7	37.6	77.8	17.5	81.2	77.8	84.0	2.5	89.1	77.8	94.7	6.8	3>; 1=; 0<	2>; 2=; 0<			
ERYSGR Disease severity	Last valid assessment	Maritime	FLMI3	1	6.8	-	-	77.8	-	-	-	77.8	-	-	-	77.8	-	-	-	0>; 1=; 0<	0>; 1=; 0<			
		Northeast	FLMI1	1	5.8	-	-	73.3	-	-	-	91.7	-	-	-	100.0	-	-	-	1>; 0=; 0<	0>; 1=; 0<			
			FLMI2	1	16.5	-	-	81.8	-	-	-	92.4	-	-	-	93.9	-	-	-	1>; 0=; 0<	0>; 1=; 0<			
			FLMI3	2	26.8	23.5	30.0	63.8	49.9	77.7	13.9	82.0	80.0	84.0	2.0	94.5	94.2	94.7	0.3	2>; 0=; 0<	2>; 0=; 0<			
		Southeast	FLMI1	1	5.4	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0>; 1=; 0<	0>; 1=; 0<			

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole 52.5-56.25+ 105-112.5 g a.s./ha			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max
																				0.70-0.75 L/ha	1.00 L/ha	
			FLMI2	2	11.7	7.4	16.0	63.6	41.3	85.9	22.3	92.6	91.2	93.9	1.4	96.7	93.4	100.0	3.3	2> ; 0= ; 0<	0> ; 2= ; 0<	
			FLMI3	2	21.1	10.9	31.4	53.4	37.6	69.1	15.8	90.2	83.1	97.2	7.1	93.9	89.6	98.2	4.3	2> ; 0= ; 0<	0> ; 2= ; 0<	
		All EPPO climatic zones	FLMI1	2	5.6	5.4	5.8	86.7	73.3	100.0	13.3	95.8	91.7	100.0	4.2	100.0	100.0	100.0	0.0	1> ; 1= ; 0<	0> ; 2= ; 0<	
			FLMI2	3	13.3	7.4	16.5	69.7	41.3	85.9	20.1	92.5	91.2	93.9	1.1	95.8	93.4	100.0	3.0	3> ; 0= ; 0<	0> ; 3= ; 0<	
			FLMI3	5	20.5	6.8	31.4	62.4	37.6	77.8	16.0	84.4	77.8	97.2	6.8	90.9	77.8	98.2	7.1	4> ; 1= ; 0<	2> ; 3= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-56: Minimum effective dose of ADM.03503.F.1.A - Triticale - ERYSGR (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to	
					Untreated			ADM.03503.F.1.A 0.70-0.75 L/ha				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha						
					Fluxapyroxad + Prothioconazole 52.5-56.25+ 105-112.5 g a.s./ha			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole						
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max
																			0.70-0.75 L/ha	1.00 L/ha		
ERYSGR Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	5.5	-	-	88.0	-	-	-	64.0	-	-	-	75.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	1	22.5	-	-	83.0	-	-	-	69.0	-	-	-	81.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	13.3	6.6	20.0	88.0	87.9	88.0	0.0	86.3	87.5	85.0	1.3	91.6	89.1	94.0	2.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
	Last valid assessment after application B	Northeast	FLAGLE	2	11.8	7.6	15.9	64.4	37.2	91.5	27.2	79.7	61.4	98.0	18.3	78.4	61.3	95.4	17.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	23.6	17.5	31.3	61.8	33.1	93.6	24.8	74.7	54.9	100.0	18.8	79.6	56.6	99.3	17.6	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI2	3	42.7	24.1	63.4	82.1	71.9	91.2	7.9	93.2	88.4	100.0	4.9	92.3	86.6	100.0	5.7	0> ; 3= ; 0<	0> ; 3= ; 0<	
ERYSGR Disease severity	Last valid assessment	Maritime	FLAGLE	1	5.5	-	-	88.0	-	-	-	64.0	-	-	-	75.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	1	22.5	-	-	83.0	-	-	-	69.0	-	-	-	81.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	13.3	6.6	20.0	88.0	87.9	88.0	0.0	86.3	87.5	85.0	1.3	91.6	89.1	94.0	2.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Northeast	FLAGLE	2	11.8	7.6	15.9	64.4	37.2	91.5	27.2	79.7	61.4	98.0	18.3	78.4	61.3	95.4	17.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	23.6	17.5	31.3	61.8	33.1	93.6	24.8	74.7	54.9	100.0	18.8	79.6	56.6	99.3	17.6	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI2	3	42.7	24.1	63.4	82.1	71.9	91.2	7.9	93.2	88.4	100.0	4.9	92.3	86.6	100.0	5.7	0> ; 3= ; 0<	0> ; 3= ; 0<	
		All EPPO climatic zones	FLAGLE	3	9.7	5.5	15.9	72.2	37.2	91.5	24.8	74.5	61.4	98.0	16.7	77.2	61.3	95.4	14.0	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI1	4	23.3	17.5	31.3	67.1	33.1	93.6	23.3	73.3	54.9	100.0	16.5	79.9	56.6	99.3	15.2	0> ; 4= ; 0<	0> ; 4= ; 0<	
			FLMI2	5	30.9	6.6	63.4	84.4	71.9	91.2	6.8	90.4	85.0	100.0	5.2	92.0	86.6	100.0	4.7	0> ; 5= ; 0<	0> ; 5= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-57: Minimum effective dose of ADM.03503.F.1.A - Triticale - All valid efficacy trials

Target	Parts	No. of trials	Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A 1.25 L/ha is significantly ⁽¹⁾ >;=< to ADM.03503.F.1.A	
			ADM.03503.F.1.A													
			Fluxapyroxad + Prothioconazole													
			0.70-0.75 L/ha			1.00 L/ha			1.25 L/ha							
			52.5-56.25+ 105-112.5 g a.s./ha			75+150 g a.s./ha			93.75+187.5 g a.s./ha							
			Me an	Min	Max	Mea n	Min	Max	Mea n	Min	Max	Mea n	Min	Max	0.70- 0.75 L/ha	1.00 L/ha
SEPTT R	FLAGL E	1	5.6	-	-	66.4	-	-	85.9	-	-	88.8	-	-	1>;0=;0<	0>;1=;0<
	FLMI1	1	8.6	-	-	69.5	-	-	86.0	-	-	87.3	-	-	1>;0=;0<	0>;1=;0<
	FLMI2	1	5.4	-	-	81.8	-	-	88.0	-	-	89.2	-	-	0>;1=;0<	0>;1=;0<
SEPTT R Supporti ve data	FLMI1	1	6.6	-	-	90.6	-	-	84.6	-	-	100. 0	-	-	0>;1=;0<	0>;1=;0<
	FLMI2	1	25.0	-	-	92.0	-	-	92.0	-	-	93.0	-	-	0>;1=;0<	0>;1=;0<
PUCCR E	FLAGL E	7	9.7	5.4	28.8	78.2	39.1	100. 0	88.5	47.8	100. 0	92.5	60.9	100. 0	4>;3=;0<	1>;6=;0<
	FLMI1	7	14.6	7.4	47.5	69.5	15.8	95.9	81.2	28.9	100. 0	85.5	39.5	100. 0	4>;3=;0<	1>;6=;0<
	FLMI2	6	18.0	8.3	45.0	72.0	47.2	94.6	85.6	66.7	100. 0	91.3	75.0	100. 0	3>;3=;0<	2>;4=;0<
PUCCS T	FLAGL E	1	76.3	-	-	100. 0	-	-	100. 0	-	-	100. 0	-	-	0>;1=;0<	0>;1=;0<
	FLMI1	1	99.0	-	-	100. 0	-	-	100. 0	-	-	100. 0	-	-	0>;1=;0<	0>;1=;0<
	FLMI2	1	99.0	-	-	100. 0	-	-	100. 0	-	-	100. 0	-	-	0>;1=;0<	0>;1=;0<
PUCCS T Supporti ve data	FLAGL E	1	51.3	-	-	84.7	-	-	89.3	-	-	89.1	-	-	0>;1=;0<	0>;1=;0<
	FLMI1	2	37.3	5.8	68.8	90.3	89.0	91.6	92.2	89.0	95.3	91.8	89.0	94.6	0>;2=;0<	0>;2=;0<
PYRNT R	FLAGL E	2	52.4	5.9	99.0	80.3	71.1	89.4	87.6	83.6	91.7	89.4	85.3	93.4	1>;1=;0<	0>;2=;0<
	FLMI1	4	33.9	7.4	99.0	71.5	51.2	90.7	85.5	80.3	94.7	89.9	84.2	97.0	4>;0=;0<	1>;3=;0<
	FLMI2	5	30.3	4.7	99.0	76.9	55.6	95.2	85.8	79.1	97.0	92.9	86.9	98.5	5>;0=;0<	2>;3=;0<
PYRNT R Supporti ve data	FLMI1	3	12.2	8.8	19.1	59.4	40.0	84.3	77.6	66.1	100. 0	79.8	59.9	98.6	0>;3=;0<	0>;3=;0<
	FLMI2	1	40.6	-	-	87.4	-	-	93.8	-	-	94.0	-	-	0>;1=;0<	0>;1=;0<
ERYSG R	FLMI1	2	5.6	5.4	5.8	86.7	73.3	100. 0	95.8	91.7	100. 0	100. 0	100. 0	100. 0	1>;1=;0<	0>;2=;0<
	FLMI2	3	13.3	7.4	16.5	69.7	41.3	85.9	92.5	91.2	93.9	95.8	93.4	100. 0	3>;0=;0<	0>;3=;0<
	FLMI3	5	20.5	6.8	31.4	62.4	37.6	77.8	84.4	77.8	97.2	90.9	77.8	98.2	4>;1=;0<	2>;3=;0<
ERYSG R Supporti ve data	FLAGL E	3	9.7	5.5	15.9	72.2	37.2	91.5	74.5	61.4	98.0	77.2	61.3	95.4	0>;3=;0<	0>;3=;0<
	FLMI1	4	23.3	17.5	31.3	67.1	33.1	93.6	73.3	54.9	100. 0	79.9	[56. 6	99.3	0>;4=;0<	0>;4=;0<
	FLMI2	5	30.9	6.6	63.4	84.4	71.9	91.2	90.4	85.0	100. 0	92.0	86.6	100. 0	0>;5=;0<	0>;5=;0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

The results are summarized by EPP0 climatic zone in each summary table by disease. Only results for all valid efficacy trials (all EPP0 climatic zones presented Table 3.2-57) are discussed hereafter to justify the minimum effective dose of ADM.03503.F.1.A against triticale diseases.

Across 13 efficacy trials carried out in the Maritime, the Northeast and the Southeast EPP0 climatic zones, ADM.03503.F.1.A, applied at the proposed label rate of 1.25 L/ha, was compared to ADM.03503.F.1.A at 0.70-75 L/ha (56-60% of maximum recommended dose) and 1.00 L/ha (80% of maximum recommended dose).

Against SEPTTR, ADM.03503.F.1.A applied at 1.25 L/ha delivered 89% on FLAGLE, 87% on FLMI1 and 89% on FLMI2 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 66% on FLAGLE, 70% on FLMI1 and 82% on FLMI2 and ADM.03503.F.1.A at 1.00 L/ha provided 86% on FLAGLE, 86% on FLMI1 and 88% on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in the trial on FLAGLE and FLMI1.

A slight dose effect was also noted in one out of 2 supportive trials on FLMI1 with 100% for ADM.03503.F.1.A applied at 1.25 L/ha, 85% for ADM.03503.F.1.A applied at 1.0 L/ha and 91% for ADM.03503.F.1.A applied at 0.75 L/ha.

Against PUCCRE, ADM.03503.F.1.A applied at 1.25 L/ha delivered 93% on FLAGLE, 86% on FLMI1 and 91% on FLMI2 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 78% on FLAGLE, 70% on FLMI1 and 72% on FLMI2 and ADM.03503.F.1.A at 1.00 L/ha provided 89% on FLAGLE, 81% on FLMI1 and 86% on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 4 out of 7 trials on FLAGLE, in 4 out of 7 trials on FLMI1 and in 3 out of 6 trials on FLMI2. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 7 trials on FLAGLE and FLMI1 and in 2 out of 6 trials on FLMI2.

Against PUCST, ADM.03503.F.1.A applied at 1.25 L/ha delivered 100% on FLAGLE, FLMI1 and FLMI2 like ADM.03503.F.1.A at 0.70-0.75 L/ha and ADM.03503.F.1.A at 1.00 L/ha. No dose effect was also noted in both supportive trials.

Against PYRNTR, ADM.03503.F.1.A applied at 1.25 L/ha delivered 89% on FLAGLE, 90% on FLMI1 and 93% on FLMI2 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 80% on FLAGLE, 72% on FLMI1 and 77% on FLMI2 and ADM.03503.F.1.A at 1.00 L/ha provided 88% on FLAGLE, 86% on FLMI1 and FLMI2. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 1 out of 2 trials on FLAGLE and in all trials on FLMI1 and FLMI2. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 1 out of 4 trials on FLMI1 and in 2 out of 5 trials on FLMI2.

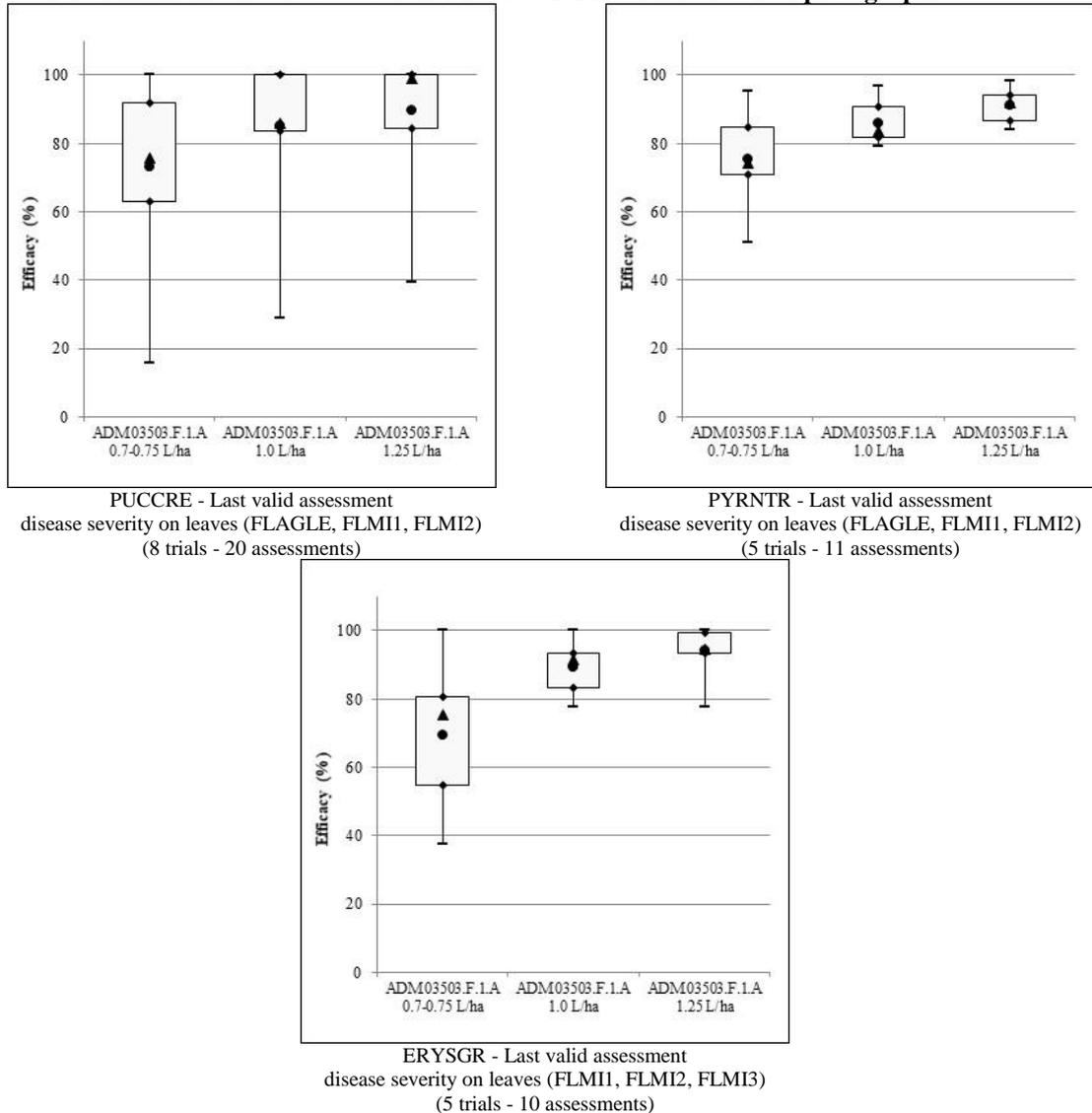
A slight dose effect was also noted in the supportive trials on FLMI1 with 80% for ADM.03503.F.1.A applied at 1.25 L/ha, 78% for ADM.03503.F.1.A applied at 1.0 L/ha and 59% for ADM.03503.F.1.A applied at 0.75 L/ha.

Against ERYSGR, ADM.03503.F.1.A applied at 1.25 L/ha delivered 100% on FLMI1, 96% on FLMI2 and 91% on FLMI3 when ADM.03503.F.1.A at 0.70-0.75 L/ha provided 87% on FLMI1, 70% on FLMI2 and 62% on FLMI3 and ADM.03503.F.1.A at 1.00 L/ha provided 96% on FLMI1, 93% on FLMI2 and 84% on FLMI3. ADM.03503.F.1.A at 1.25 L/ha was significantly superior to ADM.03503.F.1.A at 0.70-0.75 L/ha in 1 out of 2 trials on FLMI1, in all trials on FLMI2 and in 4 out of 5 trials on FLMI3. ADM.03503.F.1.A at 1.25 L/ha was also significantly superior to ADM.03503.F.1.A at 1.00 L/ha in 2 out of 5 trials on FLMI3.

A dose effect was also noted in the supportive trials on FLAGLE with 77% for ADM.03503.F.1.A applied at 1.25 L/ha, 75% for ADM.03503.F.1.A applied at 1.0 L/ha and 72% for ADM.03503.F.1.A applied at 0.75 L/ha, on FLMI1 with 80% for ADM.03503.F.1.A applied at 1.25 L/ha, 73% for ADM.03503.F.1.A applied at 1.0 L/ha and 67% for ADM.03503.F.1.A applied at 0.75 L/ha and on FLMI2 with 92% for ADM.03503.F.1.A applied at 1.25 L/ha, 90% for ADM.03503.F.1.A applied at 1.0 L/ha and 84% for ADM.03503.F.1.A applied at 0.75 L/ha.

It can be considered that the choice of 1.25 L/ha as maximum recommended dose rate of ADM.03503.F.1.A is justified against the triticale diseases. Indeed, for each disease with at least 5 assessments, the dose effect is clearly illustrated by box plot graphics (Figure 3.2-15). According to the box plot graphics, the higher the dose of ADM.03503.F.1.A, the lower the dispersion and variation between means. However, the efficacy of ADM.03503.F.1.A at 1.00 L/ha was also acceptable to control triticale disease according to the disease pressure.

Figure 3.2-15 Minimum effective dose of ADM.03503.F.1.A - Triticale - Box plots graphics



The triticale data demonstrates the mean efficacy increases for the dose rate of ADM.03503.F.1.A. The maximum proposed dose of 1.25 L/ha attains higher and more consistent control than the lower rates tested. ADM.03503.F.1.A at 1.25 L/ha gives excellent control of all the target diseases, confirming the selection of 1.25 L/ha as the proposed registered dose.

Overall, the efficacy of ADM.03503.F.1.A at 1.0 L/ha was lower than ADM.03503.F.1.A at 1.25 L/ha, however 1.0 L/ha can achieve acceptable control when there is low disease pressure.

zRMS comments on the Minimum Effective Dose:

The trials submitted allow for a very clear conclusion that the dose rate of 1.25L/ha is the minimum effective dose for majority of the target pathogens in all the crops to which the submission pertains.

For the main pathogens of **wheat**, SEPTTR and ERYSGT, for most of the time the proposed target dose rate 1.25 L/ha merely allows to exceed 90% efficacy compared to lower dose rates.

It can be noticed in **barley** that the test item at 1.25L/ha deals well with PUCCHD and ERYSGH, but the same cannot be said about RAMUCC, for which the 1.25 dose rate is definitely the MED. In the figures presented, taken their scale and graduation, e.g. the Figure 3.2-13, the efficacy distance between 1.0 and 1.25 L/ha is clearly underestimated.

In **rye** and in **triticale** the 1.25 L/ha dose rate should be definitely considered as the MED, with no exceptions for any particular pathogen targets.

Notwithstanding, the 1.00-1.25 L/ha **dose range** is claimed, for Poland, Hungary, Slovenia and Slovakia, which, to the opinion of zRMS, is daring, considered both the end user`s perception of efficacy, and the resistance issues.

According to the submitted data, the efficacy margin, between the 1.00 and 1.25 L/ha dose rates, is as follows (where not indicated otherwise, the available data from HU, PL and SK are used, while the dossier does not include any Slovenian data):

in wheat:

target	Effi _{1,25L/ha} – Effi _{1,00L/ha} [%]	min	max	n
SEPTTR	3.8	0.0	10.8	26
PUCCRT	5.7	0.0	14.7	24
PUCST	4.5	0.0	11.4	9
PYRNTR	8.4	0.0	22.5	14
ERYSGT ¹	9.8	-1.2	20.7	17
FUSASP PESSEV ears	8.4	2.3	21.7	8
FUSASP PESINC grains	8.7	3.3	16.1	5

¹PL and SK data only

in barley:

target	Effi _{1,25L/ha} – Effi _{1,00L/ha} [%]	min	max	n
RHYNSE ¹	6.4	0.4	14.8	14
PYRNTE	4.4	0.0	18.9	17
PUCCHD ¹	3.7	0.0	13.7	10
RAMUCC ¹	6.3	0.0	20.0	10
ERYSGH	4.0	0.0	11.0	14

¹PL and SK data only

in rye:

target	Effi _{1,25L/ha} – Effi _{1,00L/ha} [%]	min	max	n
RHYNSE ¹	6.4	3.2	10.5	6
RHYNSE ²	3.3	-9.0	15.6	6
PUCCRE ²	2.9	2.8	3.0	2
PUCCRE ³	1.9	-2.9	15.0	10

¹PL data only

²LT+LT, supporting North zone data

³DE data only

in triticale:

target	Effi _{1,25L/ha} – Effi _{1,00L/ha} [%]	min	max	n
SEPTTR ¹	1.8	1.2	2.9	3
SEPTTR ²	8.2	1.0	15.4	2
PUCCRE ³	3.4	0.0	14.0	13
PUCST ⁴	2.8	0.0	9.5	5 ⁴
PUCST ⁵	-0.3	0.0	-0.7	3 ⁵
PYRNTR ³	7.25	2.9	11.5	8
PYRNTR ⁶	1.7	-6.2	14.1	4
ERYSGR ⁷	3.6	-4.6	13.5	12

¹Czech Republic data only

²DK+LV, supporting North zone data

³HU and PL data

⁴DE data only: 1 trial, 2 assessment dates, 3 leaf strata

⁵DK+SE, supporting North zone data

⁷LV+SE, supporting North zone data

To the opinion of zRMS the efficacy margin between the dose rates proposed by the applicant for the dose range, is too wide, in both wheat and barley, particularly when min. and max. values are considered. Allowing dose range use may result in the exposure of inoculum to the rates of sub-optimal efficacy, triggering sensitivity shifts in populations of pathogens, which would be particularly unwelcome for the RAMUCC in barley. That might

be contrary to anti-resistance strategy (see the [respective section](#) in the Resistance comm. box). On the other hand, it should be noted that in many cases the (mean) difference in question is approximately the magnitude of the distance between the ADM.03503.F.1.A and the standard coded as LIBRAX, the one used in co-formulation trials – compare the figure within the [co-formulation](#) commenting box. Therefore, and taking into account that the applicant postulates dose diversification according to the observed intensity of infection, the zRMS has concluded that **the dose range can be authorized**, in Poland, Hungary, Slovenia and Slovakia, but on this *sine qua non* condition that the dose rates < 1.25 L/ha are used exclusively in circumstances when the intensity of infection is monitored and low infection level is observed.

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3.2.3 Efficacy tests (KCP 6.2)

3.2.3.1 Material and Methods

Experimental details

All the trials were carried out by officially recognised organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed following EPPO guidelines or trial method recommendations published by the French CEB (“Commission des Essais Biologiques”). The “CEB” methods are in accordance with EPPO directives.

Main characteristics are summarised in Table 3.2-58.

Table 3.2-58: Details on trial methodology - Efficacy trials - Cereals

Guidelines	General guidelines	PP1/135 (4): Phytotoxicity assessment PP1/152 (4): Design and analysis of efficacy evaluation trials PP1/181 (4): Conduct and reporting of efficacy evaluation trials including good experimental practice
	Specific guidelines	PP 1/26(4): “Foliar and ear diseases on cereals” CEB 189: “Efficacy trials method for fungicide products intended to control cereal diseases (treatment of the above - ground crop parts)”
Experimental design	Plot design	Randomized Complete Block (RCB)
	Plot size	<u>Winter wheat</u> : From 10 m ² to 36 m ² . <u>Barley</u> : From 10 m ² to 36 m ² . <u>Rye</u> : From 18 m ² to 30 m ² . <u>Triticale</u> : From 18 m ² to 30 m ² .
	Number of replications	4 replications
Crop	Number of trials	Interest of the association: 99 trials (38 trials in wheat, 53 trials in barley, 8 trials in rye) Minimum effective dose trials: 263 trials (143 trials in wheat, 99 trials in barley, 8 trials in rye, 13 trials in triticale) Valid efficacy trials: 262 trials (143 trials in wheat, 98 trials in barley, 8 trials in rye, 13 trials in triticale) Not valid efficacy trials only used for phytotoxicity assessment: 37 trials (16 trials in wheat, 19 trials in barley, 1 trial in rye and 1 trial in triticale)

Crop	Varieties	<p><u>Winter wheat</u> Akteur (3), Alixan (1), Amandus (2), Amboise (1), Amicus (1), Anapurna (1), Antonius (1), Apache (3), Apostel (1), Ariesan (4), Arkadia (4), Arkeos (1), Asano (1), Attraktion (1), Aurelius (1), Avenue (1), Belissa (1), Benchmark (2), Bennington (1), Bermude (2), Bernstein (1), Bilans (3), Bussard (2), Capo (1), Cellule (1), Chevron (2), Claire (1), Costello (2), Creek (3), Crusoe (2), Cubus (2), Dekan (2), Delavar (2), Depot (1), Dickens (1), Dinosaur (1), Discus (1), Elation (2), Etana (1), Evina (1), Exotic (1), Fairplay (1), Federer (1), Fidelius (1), Genius (4), GK Bago (1), GK Bekes (5), GK Körös (1), GK Petur (1), Glosa (2), Hardy (2), Hyfi (1), Illustrious (2), IS Carnea (1), JB Diego (1), Judita (1), Julie (1), Julius (1), Kashmir (1), Kometus (1), Kws Extase (1), KWS Kerrin (1), KWS Santiago (1), Leeds (1), LG Mocca (1), Linus (1), Lukullus (3), Madejka (1), Matrix (1), Medalistka (1), Miranda (1), Montana (1), Monte Cristo (1), Mutic (2), MV Kolompos (2), MV Menrot (1), MV Nador (3), Nemo (3), Oregrain (2), Ostroga (1), Pamir (1), Pannonikus (1), Porthus (1), Princeps (3), Providence (1), PS Kvalitas (1), RGT Reform (1), Rubisko (2), Sheriff (1), Siskin (1), Skagen (3), Skyscraper (1), Smaragd (1), Sorial (5), Svitava (1), Talent (1), Terroir (1), Tobak (7), Tonacja (1), Tytanica (1).</p> <p><u>Barley</u> <u>Winter barley</u> Amistar (1), Antonella (2), Astaire (1), Atlantic (3), Azrah (1), Bazooka (1), California (1), Calypso (3), Cardinal (1), Carmina (1), Casanova (1), Cassia (5), Etinzel (7), Funky (1), Gerlach (4), GK Judy (1), Gloria (2), Hawking (1), Higgins (1), Hirondella (1), Jaguar (2), Jakubus (1), Jalon (1), Jule (1), Jup (4), Kosmos (3), KWS Faro (2), KWS Higgins (1), KWS Jaguar (1), KWS Joy (1), KWS Keeper (2), KWS Orwell (5), KWS Scala (1), Laverda (1), LG Castings (1), LG Triumph (2), Lomerit (2), Margaux (1), Memento (2), Metaksa (2), Pixel (5), Rosita (1), Sandra (5), Scala (2), Seduction (2), SU Ellen (2), SU Jule (1), SU Vireni (1), Titus (2), Tower (2), Valerie (1), Vanessa (1), Wintmalt (3), Wotan (1), Zebra (1), Zenek (1), Zita (1), Zophia (1).</p> <p><u>Spring barley</u> Concerto (1), Explorer (1), Francin (1), Grace (1), Kangoo (1), Laudis 550 (1), Malz (3), Tungsten (1).</p> <p><u>Rye</u> Dankowskie Diament (1), Dukato (1), Helltop (1), Jethro (1), KWS Binntto (1), Poznańskie (2), Suceveana (2).</p> <p><u>Triticale</u> Cedrico (1), GK Maros (1), GK Szemes (1), Grenado (1), Lanetto (1), Leontino (3), Lombardo (1), Orinoko (1), Rotondo (1), Tarzan (1), Temuco (1), Trapero (1).</p>
Application	Application timing	<p><u>Wheat:</u> 1st application BBCH 30-69 - 2nd applications BBCH 39-71 <u>Barley:</u> 1st application BBCH 30-56 - 2nd applications BBCH 39-71 <u>Rye:</u> 1st application BBCH 31-39 - 2nd applications BBCH 45-69 <u>Triticale:</u> 1st application BBCH 32-69 - 2nd applications BBCH 39-67</p>
	Number of applications	<p><u>Winter wheat:</u> 1 application (47 trials), 2 applications (112 trials). <u>Barley:</u> 1 application (23 trials), 2 applications (133 trials). <u>Rye:</u> 1 application (1 trial), 2 applications (8 trials). <u>Triticale:</u> 1 application (1 trial), 2 applications (13 trials).</p>
	Spray volumes	<p><u>Winter wheat:</u> 125-400 L/ha. <u>Barley:</u> 125-400 L/ha. <u>Rye:</u> 200-230 L/ha. <u>Triticale:</u> 200-300 L/ha.</p>
Assessment	Assessment dates	7-14-day intervals after each application
	Assessment types	<p>Disease severity on leaves (ERYSGT, ERYSGH, SEPTTR, PUCCRE, PUC CST, PYRNTR, PYRNTE, RHYNSE) Disease severity on ears (<u>FUSASS</u> <u>FUSASP</u>, MONGNI) Yield (155 trials in wheat, 110 trials in barley, 9 trials in rye, 14 trials in triticale) Quality parameters: Moist content (155 trials in wheat, 110 trials in barley, 9 trials in rye, 14 trials in triticale). Thousand grain weight (132 trials in wheat, 88 trials in barley, 9 trials in rye, 14 trials in triticale). Specific weight (154 trials in wheat, 105 trials in barley, 9 trials in rye, 14 trials in triticale).</p>
Results & Analysis	Statistical analysis	ANOVA - Newman - Keuls test (5%)

Treatments and reference standards

ADM.03503.F.1.A was tested at 0.70 L/ha, 0.75 L/ha, 1.00 L/ha and 1.25 L/ha and compared with different reference standards presented in Table 3.2-59. According to the disease pressure, ADM.03503.F.1.A was applied once or twice. *

~~**The dose rate of 0.70 L/ha was applied in 2019 while the dose rate of 0.75L/ha was applied in 2020-2021. To simplify the study of the minimum effective dose and with only a difference of 6.6%, the results of these two dose rates are merged in the synthesis table.~~

Table 3.2-59: Presentation of reference standards used in trials - Efficacy trials - Cereals

Reference standard	Active substance(s)	Formulation		Application rate in trials (per treatment)	Rate of active substance per ha
		Type	Concentration of a.s.		
ADM.03503.F.1.A	Fluxapyroxad Prothioconazole	EC	75 g/L 150 g/L	0.70 L/ha 0.75 L/ha 1.00 L/ha 1.25 L/ha	52.5+105 g a.s./ha 56.25+112.5 g a.s./ha 75+150 g a.s./ha 93.75+187.5 g a.s./ha
IMTREX	Fluxapyroxad	EC	62.5 g/L	1.50 L/ha	93.75 g a.s./ha
PROLINE	Prothioconazole	EC	250 g/L	0.75 L/ha	187.50 g a.s./ha
LIBRAX	Fluxapyroxad Metconazole	EC	62.5 g/L + 45 g/L	2.00 L/ha	125+90 g a.s./ha

zRMS comments:

*This statement of the applicant is certainly misleading when confronted with the GAP claim of a single application per growth season. The applicant is **not seeking authorization for single or double application depending on the infection severity**. Conversely, the second treatment (B) was usually applied in (majority of) trials in which the infection level on 0 DA-A and on the following dates was too low for reliable efficacy assessment, and not too high to be contained by a single application.

What is in fact a double application regime, has been accepted by zRMS in the context of the present submission only as an exception. The acceptance is based on the analysis of a sample-set of 29 preliminary trials, revealing irrelevance of the number of applications for the efficacy assessment results, if the efficacy is assessed each time relative to the infection severity (UNCK) preceding directly the respective application. The issue is being discussed by the zRMS in more detail in the commenting [box](#) preceding the Preliminary tests chapter.

~~**The struck through and faded text above the Table 3.2-59 refers to the MED tests, while the efficacy results of the 0.70-0.75 L/ha dose rate are not summarized in the present chapter.~~

Assessment methods

In accordance with the CEB and EPPO guidelines, the symptoms were assessed in general on 25 leaves (at least on 15 leaves) by leaf level as percentage of area affected by diseases, from appearance of the first symptoms in the untreated (disease severity expressed in percentage) and at 7-14-day intervals. The efficacy is calculated from the disease severity data, according to ABBOTT formula.

$$Efficacy (\%) = \frac{(Disease\ severity_{Untreated\ control}) - (Disease\ severity_{Treatment})}{(Disease\ severity_{Untreated\ control})} \times 100$$

The potential effect on the green leaf area was also analysed in some efficacy trials. This assessment was expressed in Increase (%) of the green leaf area (corresponding to the reduction of the necrosis leaf area) compared to the untreated plot.

$$GLA\ Increasing (\%) = \frac{(100 - GLA_{Untreated\ control}) - (100 - GLA_{Treatment})}{(100 - GLA_{Untreated\ control})} \times 100$$

GLA = Percentage of green area on the leaves

Moreover, the potential effects on the yield and the yield parameters (thousand grain weight and/or specific weight) were also analysed in some efficacy trials. This assessment was expressed in percentage of the value in untreated plot.

$$\text{Percentage of Untreated control (\%)} = \frac{(Y_{\text{Treatment}})}{(Y_{\text{Untreated control}})} \times 100$$

Y: Yield or yield parameters

The yield results are considered as part of the assessment of the product's effectiveness when the target disease is observed. The results are reported in Section 3.2.3.2.8 (wheat), 3.2.3.3.7 (barley), 3.2.3.4.4 (rye) and 0 (triticale).

In some trials against *Fusarium* species, mycotoxins analyses were performed. The level of Deoxynivalenol mycotoxin (DON) in harvested grains was measured and the effect on the DON reduction is presented in the efficacy part about *Fusarium* species.

Phytotoxicity assessments

In efficacy trials, phytotoxicity was also assessed. Phytotoxicity assessments were carried out in accordance with EPPO guideline PP1/135 ("*Phytotoxicity assessment*"). Assessments were carried out at various intervals post application by recording visual percentage injury (0% = no injury, 100% = complete expression of injury symptom). Crop safety results are presented in Section 3.4.1.

Statistical analyses

Observed or calculated variables are subjected to an analysis of variance (ANOVA) after or not a transformation depending of the variability of the raw data.

When the result of the analysis is significant, a multiple comparison of treatments is performed. The averages are classified using the Dunnett or Newman and Keuls tests and divided into homogeneous groups (a, b, c, ...). Treatment means with no letter in common are significantly different in accordance with the test conducted at a 95% confidence level.

Results layout

The tabulated data presented in this section 3 only represent the means of efficacies of selected treatments, without raw data. However, the statistics presented in conjunction with these data are derived from all data points from all treatments within the assessment. Tables of data comprising all treatments means are presented in the individual trial report summaries.

Only the trials and assessments with a sufficient infestation level in the untreated plot (thresholds of 5% coverage of foliar or ears area by the disease) and where the level of efficacy of the reference standards were as expected are considered in this synthesis. In practice, assessments from 4.5% were selected in the available data package notably to be able to select same number of assessments per trial.

According to PP 1/181, disease severity should be as high as possible. Therefore, assessments are presented according to each application date (first and second application). To group the trials, data are classified per plant levels (Flag leaf (FLAGLE), Flag leaf minus 1 (FLMI1), Flag leaf minus 2 (FLMI2), ears) and only the last observation is considered except when the standard efficacy was not as expected and normal or when the infestation level was very high. Indeed, near 100% attacked area, it is difficult to distinguish the diseases and the leaf senescence.

On foliar disease on wheat and barley, only last leaves (Flag leaf and flag leaf minus 1) are considered in this synthesis. Indeed, these leaves contribute the most to the yield. However, in rye and triticale, to extend the data package, flag leaf minus 2 was also considered.

Powdery mildew is a disease which attacks earlier in the cereal development. Thus, observations on FLMI2 and FLMI3 (only for triticale) are important and conserved. Figure 3.2-16 summarises these choices.

An evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

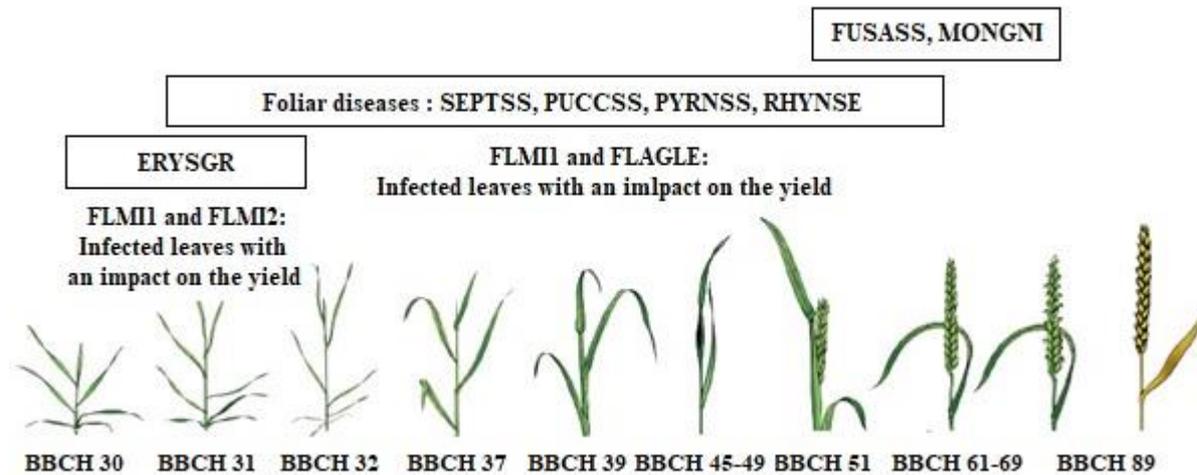
To estimate the efficacy level after one application, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the first (for trials with 2 applications) or the single application (for trials with 1 application) was considered. This assessment is noted "Last valid assessment after application A" in the synthesis tables.

To estimate the efficacy level after two applications, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the second applications of trials with 2 applications was considered. This assessment is noted “Last valid assessment after application B” in the synthesis tables.

Finally, to estimate the intrinsic efficacy level of ADM.03503.F.1.A, an evaluation including the last valid assessment on the last foliar levels (FLAGLE and FLMI1) after the single (for trials with 1 application) or the second (for trials with 2 applications) application was considered. This assessment is noted “Last valid assessment” in the synthesis tables.

About the assessment of the increasing of green leaf area, only the trials where an effect is observed in the reference standards are considered in this synthesis. In practice, assessments from 10% of increasing of GLA for the reference standard LIBRAX at 2.00 L/ha were selected.

Figure 3.2-16 Development cycle, diseases and observations in cereal crops



In barley crops, the trials carried out in winter and spring barley have been merged in the synthesis. Indeed, the efficacy level against one disease performed in winter and spring barley was very close and the extrapolation between both types of cereals (winter and spring) can be considered as valid.

3.2.3.2 Efficacy trials results for the control of wheat diseases

A total of **122 efficacy trials** were carried out in the Central registration zone to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2019 to 2021** in the Maritime (2 trials in Austria, 1 trial in Belgium, 6 trials in Czech Republic, 28 trials in Germany, 3 trials in Ireland and 2 trials in The Netherlands), the Northeast (24 trials in Poland) and the Southeast (20 trials in Hungary, 22 trials in Romania and 14 trials in Slovakia) EPPO climatic zones.

In addition, **37 efficacy trials** carried out in countries belonging to the Maritime EPPO climatic zone, but outside the Central registration zone are also provided to complete the data package. These trials were carried out **from 2019 to 2021** in France (23 trials) and the United Kingdom (14 trials).

Sixteen out of 159 trials are not taken into account in the efficacy analysis below due to a low pest pressure conditions or an abnormal level of efficacy of the reference standards. Thus, these trials are excluded from the analysis of efficacy. However, the potential crop phytotoxicity symptoms observed in this trial is analysed in Section 3.4.1.

Therefore, a total of **143 valid efficacy trials** in the Maritime (78 trials), the Northeast (21 trials) and the Southeast (44 trials) EPPO climatic zone were available to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of wheat diseases.

3.2.3.2.1 Leaf spot of wheat (*Zymoseptoria tritici* - SEPTTR)

A total of **63 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of SEPTTR. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Belgium, 3 trials in Czech Republic, 20 trials in Germany, 2 trials in Ireland, 5 trials in the United Kingdom and 8 trials in France), the Northeast (5 trials in Poland) and the Southeast (3 trials in Hungary, 6 trials in Romania and 10 trials in Slovakia) EPPO climatic zones in winter wheat. Table 3.2-60 summarises the efficacy of ADM.03503.F.1.A against SEPTTR.

Table 3.2-60: Efficacy of ADM.03503.F.1.A - Wheat - SEPTTR - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max
SEPTTR Disease severity	Last valid assessment after application A	Maritime	FLAGLE	3	24.9	6.3	39.7	85.8	75.9	100.0	10.3	89.8	82.4	100.0	7.5	82.5	69.8	100.0	12.8	0> ; 3= ; 0<	1> ; 2= ; 0<	
			FLMII	3	14.5	5.1	24.4	91.0	78.6	97.7	8.8	90.5	73.6	100.0	12.0	91.5	86.6	97.8	4.7	0> ; 3= ; 0<	1> ; 2= ; 0<	
		Northeast	FLMII	1	9.3	-	-	80.2	-	-	-	84.6	-	-	-	79.7	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMII	1	5.6	-	-	70.1	-	-	-	75.0	-	-	-	70.1	-	-	-	-	0> ; 1= ; 0<	1> ; 0= ; 0<
		All EPPO climatic zones	FLAGLE	3	24.9	6.3	39.7	85.8	75.9	100.0	10.3	89.8	82.4	100.0	7.5	82.5	69.8	100.0	12.8	0> ; 3= ; 0<	1> ; 2= ; 0<	
			FLMII	5	11.7	5.1	24.4	84.7	70.1	97.7	10.8	86.2	73.6	100.0	11.1	84.8	70.1	97.8	9.4	0> ; 5= ; 0<	2> ; 3= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	25	30.2	6.1	96.6	77.9	37	100	16.4	83.6	43.8	100.0	13.7	81.3	36.4	100	16.1	1> ; 22= ; 2<	2> ; 23= ; 0<	
			FLMII	33	45.5	6.8	100.0	74.0	51.5	96.8	12.5	78.4	46.0	97.9	12.4	75.6	40.0	100.0	16.3	0> ; 31= ; 2<	4> ; 29= ; 0<	
		Northeast	FLAGLE	3	22.4	13.4	32.5	78.2	69.2	91.7	9.7	86.2	78.5	100	9.8	83.8	75.7	98.9	10.7	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	3	44.3	26.8	69.5	86.9	77.5	98.2	8.6	93.3	84.0	100.0	6.8	93.8	84.4	98.6	6.6	0> ; 1= ; 2<	0> ; 3= ; 0<	
		Southeast	FLAGLE	11	11.8	4.6	63.4	88.6	71.6	100	9.9	91.9	78.5	100	7.7	90.4	77.6	100	8.2	1> ; 9= ; 1<	1> ; 9= ; 1<	
			FLMII	17	13.0	5.3	35.2	89.4	70.4	100.0	9.3	93.5	72.3	100.0	7.4	90.9	60.0	100.0	10.5	1> ; 15= ; 1<	2> ; 14= ; 1<	
		All EPPO climatic zones	FLAGLE	39	24.4	4.6	96.6	80.9	37.0	100.0	15.1	86.1	43.8	100.0	12.6	84.0	36.4	100.0	14.5	2> ; 34= ; 3<	3> ; 35= ; 1<	
			FLMII	53	35.0	5.3	100.0	79.7	51.5	100.0	13.5	84.1	46.0	100.0	13.0	81.5	40.0	100.0	16.2	1> ; 47= ; 5<	6> ; 46= ; 1<	
SEPTTR Disease severity	Last valid assessment	Maritime	FLAGLE	28	29.6	6.1	96.6	78.7	37.0	100.0	16.0	84.3	43.8	100.0	13.3	81.4	36.4	100.0	15.8	1> ; 25= ; 2<	3> ; 25= ; 0<	
			FLMII	34	44.6	6.8	100.0	74.1	51.5	96.8	12.4	78.2	46.0	97.9	12.3	75.9	40.0	100.0	16.2	0> ; 32= ; 4<	4> ; 30= ; 0<	
		Northeast	FLAGLE	3	22.4	13.4	32.5	78.2	69.2	91.7	9.7	86.2	78.5	100.0	9.8	83.8	75.7	98.9	10.7	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	4	35.6	9.3	69.5	85.2	77.5	98.2	8.0	91.1	84.0	100.0	7.0	90.2	79.7	98.6	8.4	0> ; 2= ; 2<	0> ; 4= ; 0<	
		Southeast	FLAGLE	11	11.8	4.6	63.4	88.6	71.6	100.0	9.9	91.9	78.5	100.0	7.7	90.4	77.6	100.0	8.2	1> ; 9= ; 1<	1> ; 9= ; 1<	
			FLMII	18	12.6	5.3	35.2	88.3	70.1	100.0	10.1	92.5	72.3	100.0	8.4	89.7	60.0	100.0	11.3	1> ; 16= ; 1<	3> ; 14= ; 1<	
		All EPPO climatic zones	FLAGLE	42	24.4	4.6	96.6	81.3	37.0	100.0	14.9	86.4	43.8	100.0	12.3	83.9	36.4	100.0	14.4	2> ; 37= ; 3<	4> ; 37= ; 1<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)													No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX			
					Untreated			ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha			Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A	
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
FLMI1	56	33.7	5.3	100.0	79.5	51.5	100.0	13.2	83.7	46.0	100.0	12.8	81.4	40.0	100.0	15.8	1> ; 50= ; 5<	7> ; 48= ; 1<			

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Sixty-three trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 6% to 40% of the flag leaves (FLAGLE) area and from 5% to 24% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 5% to 97% of the flag leaves (FLAGLE) area and from 5% to 100% of the flag leaves minus 1 (FLMI1) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of SEPTTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (84% in 28 trials on FLAGLE and 78% in 34 trials on FLMI1) was similar to LIBRAX (81% on FLAGLE and 76% on FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (79% in 28 trials on FLAGLE and 74% in 34 trials on FLMI1) was similar to LIBRAX (81% on FLAGLE and 76% on FLMI1). No significant difference was at least noted in 58 out of 62 assessments on FLAGLE and FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (86% in 3 trials on FLAGLE and 91% in 4 trials on FLMI1) was similar to LIBRAX (84% on FLAGLE and 90% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (78% in 3 trials on FLAGLE and 85% in 4 trials on FLMI1) was inferior to LIBRAX (84% on FLAGLE and 90% on FLMI1). However, no significant difference was noted in 5 out of 7 assessments on FLAGLE and FLMI1.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (92% in 11 trials on FLAGLE and 93% in 18 trials on FLMI1) was similar to LIBRAX (90% on FLAGLE and 90% on FLMI1). No significant difference was at least noted in 27 out of 29 assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (89% in 11 trials on FLAGLE and 88% in 18 trials on FLMI1) was similar to LIBRAX (90% on FLAGLE and 90% on FLMI1). No significant difference was at least noted in 27 out of 29 assessments on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 63 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat against SEPTTR.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of SEPTTR.

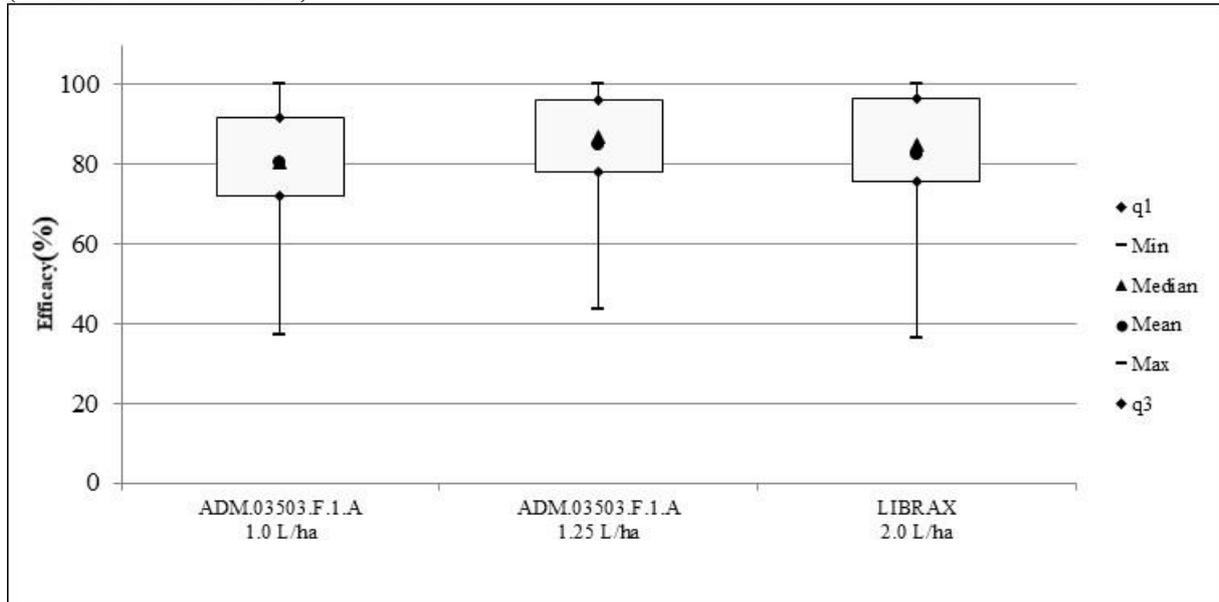
The efficacy of ADM.03503.F.1.A at 1.25 L/ha (86% in 42 trials on FLAGLE and 84% in 56 trials on FLMI1) was similar to LIBRAX (84% on FLAGLE and 81% on FLMI1). No significant difference was at least noted in 96 out of 98 assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (81% in 42 trials on FLAGLE and 80% in 56 trials on FLMI1) was similar to LIBRAX (84% on FLAGLE and 81% on FLMI1). No significant difference was at least noted in 90 out of 98 assessments on FLAGLE and FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-17). Overall, ADM.03503.F.1.A at 1.25 L/ha had at least the same level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-17 Efficacy of ADM.03503.F.1.A - Wheat - SEPTTR - Last valid assessment - Box Plot graphic (63 trials - 98 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of SEPTTR in wheat crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a moderate to good control of leaf spot of wheat similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control leaf spot according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of leaf spot of wheat (*Zymoseptoria tritici* - SEPTTR).

Even if only 5 valid trials are available in the Northeast EPPO climatic zone, the results of trials border countries can be considered as supportive data. Therefore, 23 trials (3 trials in Czech Republic, 20 trials in Germany) support also the request of registration of ADM.03503.F.1.A in Poland.

3.2.3.2.2 Brown rust of wheat (*Puccinia recondita* - PUCCRT)

A total of **33 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PUCCRT. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Austria, 3 trials in Czech Republic, 3 trials in Germany, 2 trials in the United Kingdom and 6 trials in France), the Northeast (4 trials in Poland) and the Southeast (3 trials in Hungary, 4 trials in Romania and 7 trials in Slovakia) EPPO climatic zones in winter wheat.

Table 3.2-61 summarises the efficacy of ADM.03503.F.1.A against PUCCRT.

Table 3.2-61: Efficacy of ADM.03503.F.1.A - Wheat - PUCCRT - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
								Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha					
								Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
PUCCRT Disease severity	Last valid assessment after application A	Maritime	FLAGLE	3	40.3	8.4	96.4	80.5	49.8	99.1	21.9	84.4	55.6	99.2	20.4	84.1	54.6	99.1	20.8	0> ; 3= ; 0<	0> ; 3= ; 0<
			FLMI1	3	35.8	15.0	74.8	96.9	94.6	98.9	1.8	98.2	96.8	100.0	1.3	97.3	95.0	99.9	2.0	0> ; 3= ; 0<	0> ; 3= ; 0<
		Northeast	FLAGLE	1	15.0	-	-	73.0	-	-	-	86.5	-	-	-	89.7	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<
			FLMI1	3	10.2	8.5	13.4	84.8	73.2	93.0	8.4	92.0	87.9	96.7	3.6	93.6	85.0	100.0	6.3	0> ; 2= ; 1<	0> ; 3= ; 0<
		Southeast	FLMI1	2	6.1	5.2	6.9	75.0	70.2	79.8	4.8	84.7	81.3	88.1	3.4	83.2	80.8	85.6	2.4	0> ; 0= ; 2<	0> ; 2= ; 0<
		All EPPO climatic zones	FLAGLE	4	34.0	8.4	96.4	78.6	49.8	99.1	19.2	85.0	55.6	99.2	17.7	85.5	54.6	99.1	18.2	0> ; 3= ; 1<	0> ; 4= ; 0<
	FLMI1	8	18.7	5.2	74.8	86.9	70.2	98.9	10.4	92.5	81.3	100.0	6.0	92.4	80.8	100.0	7.0	0> ; 5= ; 3<	0> ; 8= ; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	11	32.4	6.4	62.5	94.8	83.4	100.0	6.8	94.5	74.5	100.0	7.8	94.7	80.8	100.0	7.5	0> ; 11= ; 0<	0> ; 11= ; 0<
			FLMI1	9	41.4	6.0	97.4	95.2	81.2	100.0	6.8	96.3	82.1	100.0	6.1	95.6	80.0	100.0	6.9	0> ; 9= ; 0<	0> ; 9= ; 0<
		Northeast	FLAGLE	3	18.5	8.0	26.3	87.5	85.0	90.6	2.4	95.1	92.1	100.0	3.5	94.5	91.8	96.9	2.1	0> ; 3= ; 0<	0> ; 3= ; 0<
			FLMI1	2	13.6	9.0	18.1	93.5	88.8	98.3	4.8	98.4	96.9	100.0	1.6	98.8	97.5	100.0	1.3	0> ; 2= ; 0<	0> ; 2= ; 0<
		Southeast	FLAGLE	8	11.6	6.4	21.9	89.2	76.8	96.3	6.7	93.2	79.1	99.4	6.4	93.2	78.3	100.0	6.5	0> ; 6= ; 2<	0> ; 8= ; 0<
			FLMI1	10	9.4	4.6	28.3	85.6	74.5	100.0	9.0	91.8	76.2	100.0	7.3	89.0	73.4	100.0	10.2	0> ; 8= ; 2<	1> ; 8= ; 1<
		All EPPO climatic zones	FLAGLE	22	22.9	6.4	62.5	91.8	76.8	100.0	7.0	94.1	74.5	100.0	6.9	94.1	78.3	100.0	6.7	0> ; 20= ; 2<	0> ; 22= ; 0<
FLMI1		21	23.5	4.6	97.4	90.5	74.5	100.0	9.1	94.3	76.2	100.0	6.9	92.8	73.4	100.0	9.2	0> ; 19= ; 2<	1> ; 19= ; 1<		
PUCCRT Disease severity	Last valid assessment	Maritime	FLAGLE	14	34.1	6.8	96.4	91.8	49.8	100.0	13.2	92.3	55.6	100.0	12.4	92.5	54.6	100.0	12.5	0> ; 14= ; 0<	0> ; 14= ; 0<
			FLMI1	12	40.0	6.0	97.4	95.6	81.2	100.0	6.0	96.8	82.1	100.0	5.4	96.1	80.0	100.0	6.1	0> ; 12= ; 0<	0> ; 12= ; 0<
		Northeast	FLAGLE	4	17.6	8.0	26.3	83.8	73.0	90.6	6.6	92.9	86.5	100.0	4.8	93.3	89.7	96.9	2.8	0> ; 3= ; 1<	0> ; 4= ; 0<
			FLMI1	4	12.3	8.5	18.1	88.3	73.2	98.3	9.4	95.4	87.9	100.0	4.5	98.3	95.8	100.0	1.8	0> ; 3= ; 1<	0> ; 4= ; 0<
		Southeast	FLAGLE	8	11.6	6.4	21.9	89.2	76.8	96.3	6.7	93.2	79.1	99.4	6.4	93.2	78.3	100.0	6.5	0> ; 6= ; 2<	0> ; 8= ; 0<
			FLMI1	12	8.8	4.6	28.3	83.8	70.2	100.0	9.4	90.6	76.2	100.0	7.3	88.0	73.4	100.0	9.6	0> ; 8= ; 4<	1> ; 10= ; 1<

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ > ; = ; < to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
		All EPPO climatic zones	FLAGLE	26	24.6	6.4	96.4	89.8	49.8	100.0	11.0	92.7	55.6	100.0	10.0	92.8	54.6	100.0	9.9	0> ; 23= ; 3<	0> ; 26= ; 0<
			FLMII	28	22.7	4.6	97.4	89.5	70.2	100.0	9.8	93.9	76.2	100.0	6.8	92.9	73.4	100.0	8.7	0> ; 23= ; 5<	1> ; 26= ; 1<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Thirty-three trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 8% to 96% of the flag leaves (FLAGLE) area and from 5% to 75% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 6% to 22% of the flag leaves (FLAGLE) area and from 5% to 28% of the flag leaves minus 1 (FLMI1) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCCRT. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (92% in 14 trials on FLAGLE and 97% in 12 trials on FLMI1) was similar to LIBRAX (93% on FLAGLE and 96% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PUCCRT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (92% in 14 trials on FLAGLE and 96% in 12 trials on FLMI1) was similar to LIBRAX (93% on FLAGLE and 96% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCCRT. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% in 4 trials on FLAGLE and 95% in 4 trials on FLMI1) was similar to LIBRAX (93% on FLAGLE and 98% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of PUCCRT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (84% in 4 trials on FLAGLE and 88% in 4 trials on FLMI1) was inferior to LIBRAX (93% on FLAGLE and 98% on FLMI1). However, no significant difference was noted in 6 out of 8 assessments on FLAGLE and FLMI1.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCCRT. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% in 8 trials on FLAGLE and 91% in 12 trials on FLMI1) was similar to LIBRAX (93% on FLAGLE and 88% on FLMI1). No significant difference was at least noted in 19 out of 20 assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of PUCCRT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (90% in 8 trials on FLAGLE and 90% in 12 trials on FLMI1) was slightly inferior on FLAGLE to LIBRAX (93%) but similar on FLMI1 (88%). No significant difference was noted in 14 out of 20 assessments on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 33 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat against PUCCRT.

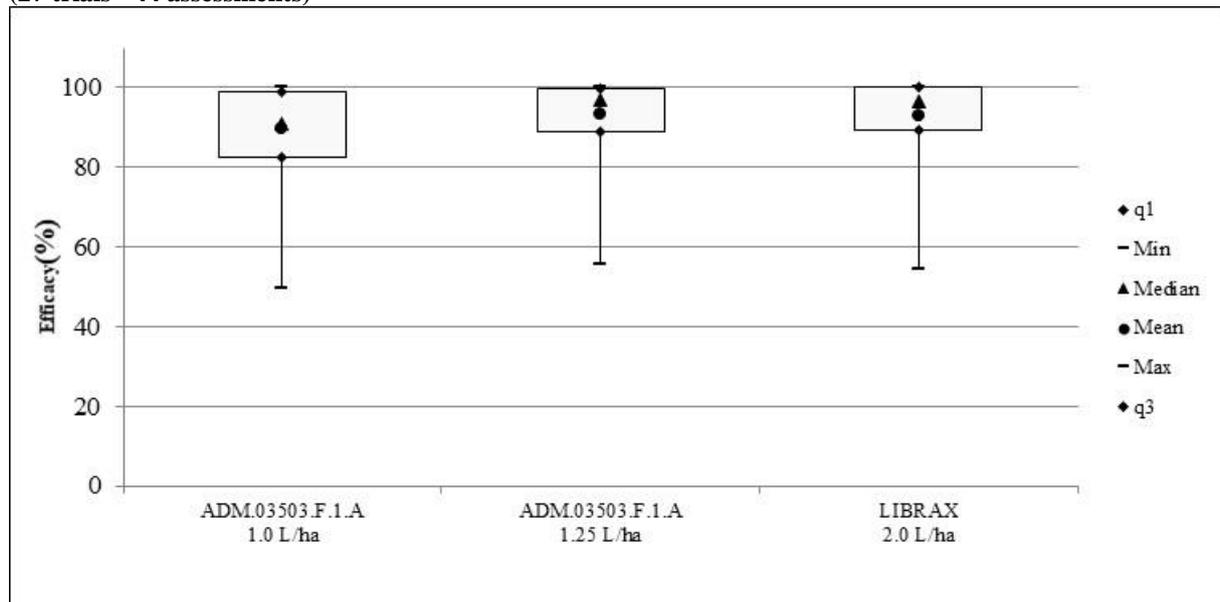
At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of Puccinia recondita (PuccRT). The efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% in 26 trials on FLAGLE and 94% in 28 trials on FLMI1) was similar to LIBRAX (93% on FLAGLE and 93% on FLMI1). No significant difference was at least noted in 53 out of 54 assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PuccRT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (90% in 26 trials on FLAGLE and 90% in 28 trials on FLMI1) was slightly inferior to LIBRAX (93% on FLAGLE and 93% on FLMI1). However, no significant difference was at least noted in 46 out of 54 assessments on FLAGLE and FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-18). Overall, ADM.03503.F.1.A at 1.25 L/ha had at least the same level of efficacy and the same dispersion and variation between means than LIBRAX.

Figure 3.2-18 Efficacy of ADM.03503.F.1.A - Wheat - PuccRT - Last valid assessment - Box Plot graphic (27 trials - 44 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PuccRT in wheat crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a very good control of brown rust of wheat similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control brown rust according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of brown rust of wheat (*Puccinia recondita* - PuccRT).

Even if only 4 valid trials are available in the Northeast EPPO climatic zone, the results of trials border countries can be considered as supportive data. Therefore, 6 trials (3 trials in Czech Republic, 3 trials in Germany) support also the request of registration of ADM.03503.F.1.A in Poland.

3.2.3.2.3 Yellow rust of wheat (*Puccinia striiformis* - PuccST)

A total of **28 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PuccST. These trials were carried out **from 2019 to 2021** in the Maritime (7 trials in Germany, 2 trials in the Netherlands, 4 trials in the United Kingdom and 5 trials in France), the Northeast (4 trials in Poland) and the Southeast (1 trial in Hungary, 4 trials in Romania and 1 trial in Slovakia) EPPO climatic zones in winter wheat.

Table 3.2-62 summarises the efficacy of ADM.03503.F.1.A against PuccST.

Table 3.2-62: Efficacy of ADM.03503.F.1.A - Wheat - PUCST - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max
PUCST Disease severity	Last valid assessment after application A	Maritime	FLAGLE	4	25.8	14.7	49.0	86.9	69.8	94.6	10.0	88.0	66.4	97.5	12.6	87.5	76.6	98.3	9.3	0> ; 4= ; 0<	0> ; 4= ; 0<	
			FLMII	10	22.9	4.5	81.4	87.2	31.8	100.0	21.4	89.2	45.5	100.0	17.7	88.1	22.7	100.0	22.7	0> ; 10= ; 0<	1> ; 9= ; 0<	
		Northeast	FLAGLE	2	9.7	6.6	12.8	88.1	84.3	91.8	3.8	92.7	91.0	94.3	1.7	89.7	88.2	91.1	1.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMII	3	9.3	5.5	16.0	80.8	71.3	88.1	7.0	87.9	82.7	92.3	4.0	85.6	82.7	88.1	2.2	0> ; 2= ; 1<	0> ; 3= ; 0<	
		Southeast	FLAGLE	1	5.0	-	-	88.7	-	-	-	91.5	-	-	-	92.0	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMII	1	5.0	-	-	88.7	-	-	-	91.5	-	-	-	92.0	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	All EPPO climatic zones	FLAGLE	6	20.4	6.6	49.0	87.3	69.8	94.6	8.4	89.6	66.4	97.5	10.6	88.2	76.6	98.3	7.7	0> ; 6= ; 0<	0> ; 6= ; 0<		
		FLMII	14	18.7	4.5	81.4	85.9	31.8	100.0	18.6	89.1	45.5	100.0	15.1	87.8	22.7	100.0	19.3	0> ; 13= ; 1<	1> ; 13= ; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	17	39.6	5.0	98.8	90.6	69.6	100.0	10.0	92.7	78.9	100.0	7.8	93.4	80.0	100.0	6.4	0> ; 16= ; 1<	0> ; 17= ; 0<	
			FLMII	16	55.3	5.0	99.3	94.6	86.8	100.0	5.3	96.0	87.2	100.0	4.6	94.9	81.8	100.0	5.5	1> ; 14= ; 1<	1> ; 15= ; 0<	
		Northeast	FLAGLE	1	13.5	-	-	78.3	-	-	-	85.0	-	-	-	81.3	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMII	1	13.5	-	-	78.3	-	-	-	85.0	-	-	-	81.3	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		Southeast	FLAGLE	3	5.8	4.7	7.2	90.9	80.6	100.0	8.0	95.3	87.5	100.0	5.6	89.3	80.2	100.0	8.2	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	5	11.3	5.5	27.5	82.4	73.2	100.0	9.5	89.4	80.7	100.0	6.4	82.4	71.4	100.0	10.4	0> ; 5= ; 0<	1> ; 4= ; 0<	
All EPPO climatic zones	FLAGLE	21	33.5	4.7	98.8	90.1	69.6	100.0	9.9	92.7	78.9	100.0	7.5	92.2	80.0	100.0	7.1	0> ; 20= ; 1<	0> ; 21= ; 0<			
	FLMII	21	44.9	5.0	99.3	91.7	73.2	100.0	8.3	94.4	80.7	100.0	5.9	91.9	71.4	100.0	8.8	1> ; 19= ; 1<	2> ; 19= ; 0<			
PUCST Disease severity	Last valid assessment	Maritime	FLAGLE	18	40.1	5.0	98.8	90.8	69.6	100.0	9.8	92.9	78.9	100.0	7.6	93.7	80.0	100.0	6.3	0> ; 17= ; 1<	0> ; 18= ; 0<	
			FLMII	17	56.9	5.0	99.3	94.7	86.8	100.0	5.1	96.2	87.2	100.0	4.5	95.1	81.8	100.0	5.4	1> ; 15= ; 1<	1> ; 16= ; 0<	
		Northeast	FLAGLE	3	10.9	6.6	13.5	84.8	78.3	91.8	5.5	90.1	85.0	94.3	3.9	86.9	81.3	91.1	4.1	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	3	9.3	5.5	16.0	80.8	71.3	88.1	7.0	87.9	82.7	92.3	4.0	85.6	82.7	88.1	2.2	0> ; 2= ; 1<	0> ; 3= ; 0<	
		Southeast	FLAGLE	3	5.8	4.7	7.2	90.9	80.6	100.0	8.0	95.3	87.5	100.0	5.6	89.3	80.2	100.0	8.2	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	6	10.3	5.0	27.5	83.5	73.2	100.0	8.9	89.7	80.7	100.0	5.9	84.0	71.4	100.0	10.1	0> ; 6= ; 0<	1> ; 5= ; 0<	
All EPPO climatic zones	FLAGLE	24	32.2	4.7	98.8	90.1	69.6	100.0	9.3	92.9	78.9	100.0	7.1	92.3	80.0	100.0	6.8	0> ; 23= ; 1<	0> ; 24= ; 0<			
	FLMII	26	40.6	5.0	99.3	90.5	71.3	100.0	8.7	93.7	80.7	100.0	5.9	91.5	71.4	100.0	8.3	1> ; 23= ; 2<	2> ; 24= ; 0<			

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Twenty-eight trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 7% to 49% of the flag leaves (FLAGLE) area and from 7% to 57% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 5% to 46% of the flag leaves (FLAGLE) area and from 8% to 81% of the flag leaves minus 1 (FLMI1) area. In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCGST. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% in 18 trials on FLAGLE and 94% in 17 trials on FLMI1) was similar to LIBRAX (94% on FLAGLE and 95% on FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PUCGST.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (91% in 18 trials on FLAGLE and 95% in 17 trials on FLMI1) was similar to LIBRAX (94% on FLAGLE and 95% on FLMI1). No significant difference was at least noted in 33 out of 35 assessments on FLAGLE and FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCGST. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% in 3 trials on FLAGLE and 96% in 3 trials on FLMI1) was similar to LIBRAX (94% on FLAGLE and 95% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PUCGST.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (91% in 3 trials on FLAGLE and 95% in 3 trials on FLMI1) was similar to LIBRAX (94% on FLAGLE and 95% on FLMI1). No significant difference was noted in 5 out of 6 assessments on FLAGLE and FLMI1.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCGST. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (95% in 3 trials on FLAGLE and 90% in 6 trials on FLMI1) was superior to LIBRAX (89% on FLAGLE and 84% on FLMI1). This difference was significant in 1 out of 6 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PUCGST.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (91% in 3 trials on FLAGLE and 84% in 6 trials on FLMI1) was similar to LIBRAX (89% on FLAGLE and 84% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 28 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat against PUCGST.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCGST.

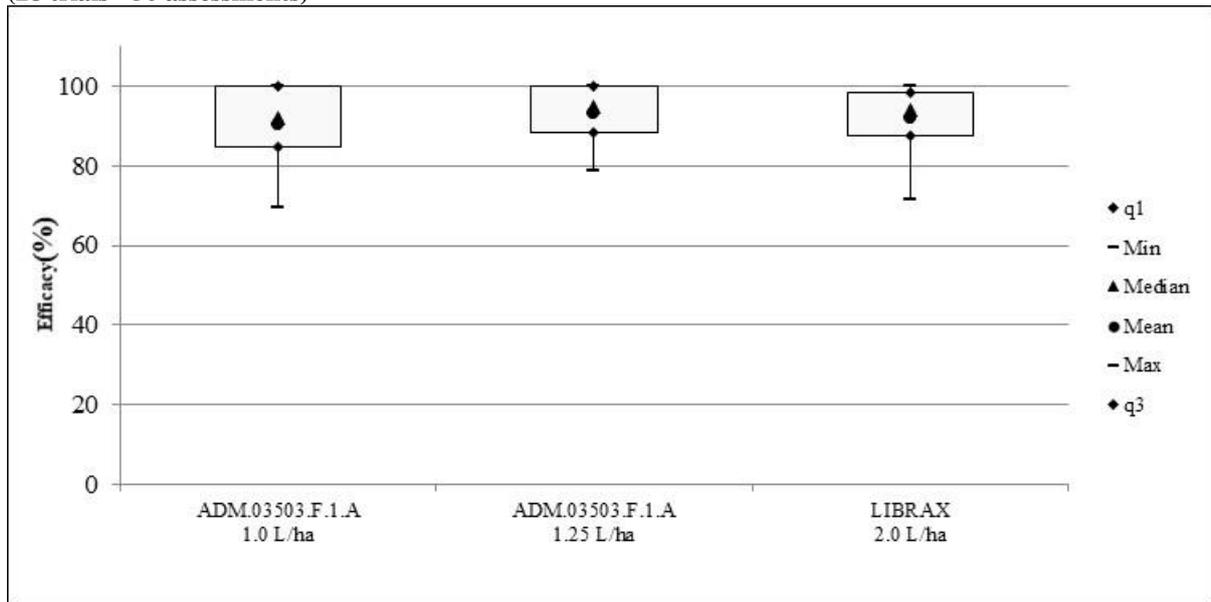
The efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% in 24 trials on FLAGLE and 94% in 26 trials on FLMI1) was similar to LIBRAX (92% on FLAGLE and 92% on FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PUCGST.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (90% in 24 trials on FLAGLE and 91% in 26 trials on FLMI1) was similar to LIBRAX (92% on FLAGLE and 92% on FLMI1). No significant difference was at least noted in 47 out of 50 assessments on FLAGLE and FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-19). Overall, ADM.03503.F.1.A at 1.25 L/ha had at least the same level of efficacy and the same dispersion and variation between means than LIBRAX.

Figure 3.2-19 Efficacy of ADM.03503.F.1.A - Wheat - PuccST - Last valid assessment - Box Plot graphic (28 trials - 50 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PuccST in wheat crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a very good control of yellow rust of wheat similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control yellow rust according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of yellow rust of wheat (*Puccinia striiformis* - PuccST).

3.2.3.2.4 Tan spot of wheat (*Pyrenophora tritici-repentis* - PYRNTR)

A total of **15 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PYRNTR. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Austria, 1 trial in Czech Republic, and 6 trials in Germany), the Northeast (3 trials in Poland) and the Southeast (2 trials in Hungary and 2 trials in Slovakia) EPPO climatic zones in winter wheat.

Table 3.2-63 summarises the efficacy of ADM.03503.F.1.A against PYRNTR.

Table 3.2-63: Efficacy of ADM.03503.F.1.A - Wheat - PYRNTR - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha									
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
PYRNTR Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	22.5	-	-	82.2	-	-	-	90.0	-	-	-	86.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMII	1	44.0	-	-	86.9	-	-	-	90.9	-	-	-	88.6	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		Northeast	FLAGLE	1	5.2	-	-	78.9	-	-	-	89.6	-	-	-	88.3	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<	
			FLMII	2	6.6	6.5	6.7	80.2	75.9	84.5	4.3	86.2	84.5	87.8	1.6	83.9	83.4	84.5	0.6	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	1	16.0	-	-	93.9	-	-	-	96.7	-	-	-	99.3	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMII	1	31.6	-	-	82.6	-	-	-	92.4	-	-	-	95.1	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		All EPPO climatic zones	FLAGLE	3	14.6	5.2	22.5	85.0	78.9	93.9	6.4	92.1	89.6	96.7	3.3	91.4	86.7	99.3	5.6	0> ; 2= ; 1<	0> ; 3= ; 0<	
			FLMII	4	22.2	6.5	44.0	82.5	75.9	86.9	4.1	88.9	84.5	92.4	3.0	87.9	83.4	95.1	4.6	0> ; 4= ; 0<	0> ; 4= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	7	9.3	4.5	19.7	74.7	46.0	89.5	15.8	79.2	48.2	97.4	15.3	74.7	44.4	92.2	18.4	0> ; 7= ; 0<	0> ; 7= ; 0<	
			FLMII	7	21.1	8.0	34.7	76.3	51.1	93.9	14.2	81.7	60.0	95.2	10.4	69.8	47.8	88.6	16.3	1> ; 6= ; 0<	2> ; 5= ; 0<	
		Northeast	FLAGLE	2	12.3	9.5	15.0	78.5	72.5	84.4	6.0	90.4	85.8	95.0	4.6	84.7	84.4	85.0	0.3	0> ; 1= ; 1<	1> ; 1= ; 0<	
			FLMII	2	9.8	9.0	10.5	73.6	66.3	80.9	7.3	89.6	88.8	90.5	0.8	84.9	80.9	88.8	4.0	0> ; 1= ; 1<	1> ; 1= ; 0<	
		Southeast	FLAGLE	2	26.1	5.9	46.2	88.8	79.7	97.9	9.1	93.5	88.1	99.0	5.4	90.1	87.6	92.6	2.5	0> ; 1= ; 1<	0> ; 2= ; 0<	
			FLMII	3	26.0	6.6	61.4	82.5	73.1	93.0	8.2	88.1	80.0	96.5	6.8	88.5	79.2	97.3	7.4	0> ; 1= ; 2<	0> ; 3= ; 0<	
		All EPPO climatic zones	FLAGLE	11	12.9	4.5	46.2	77.9	46.0	97.9	14.5	83.8	48.2	99.0	14.0	79.4	44.4	92.6	16.0	0> ; 9= ; 2<	1> ; 10= ; 0<	
			FLMII	12	20.4	6.6	61.4	77.4	51.1	93.9	12.3	84.6	60.0	96.5	9.3	77.0	47.8	97.3	15.6	1> ; 8= ; 3<	3> ; 9= ; 0<	
PYRNTR Disease severity	Last valid assessment	Maritime	FLAGLE	8	10.9	4.5	22.5	75.6	46.0	89.5	15.0	80.5	48.2	97.4	14.7	76.2	44.4	92.2	17.7	0> ; 8= ; 0<	0> ; 8= ; 0<	
			FLMII	8	23.9	8.0	44.0	77.7	51.1	93.9	13.7	82.8	60.0	95.2	10.2	72.2	47.8	88.6	16.4	1> ; 7= ; 0<	2> ; 6= ; 0<	
		Northeast	FLAGLE	3	9.9	5.2	15.0	78.6	72.5	84.4	4.9	90.1	85.8	95.0	3.8	85.9	84.4	88.3	1.7	0> ; 1= ; 2<	1> ; 2= ; 0<	
			FLMII	3	8.7	6.7	10.5	74.4	66.3	80.9	6.1	89.0	87.8	90.5	1.1	84.4	80.9	88.8	3.3	0> ; 2= ; 1<	1> ; 2= ; 0<	
		Southeast	FLAGLE	3	22.7	5.9	46.2	90.5	79.7	97.9	7.8	94.6	88.1	99.0	4.7	93.2	87.6	99.3	4.8	0> ; 2= ; 1<	0> ; 3= ; 0<	
			FLMII	4	27.4	6.6	61.4	82.6	73.1	93.0	7.1	89.1	80.0	96.5	6.1	90.1	79.2	97.3	7.0	0> ; 2= ; 2<	0> ; 4= ; 0<	
		All EPPO climatic zones	FLAGLE	14	13.2	4.5	46.2	79.5	46.0	97.9	13.5	85.6	48.2	99.0	13.0	81.9	44.4	99.3	15.3	0> ; 11= ; 3<	1> ; 13= ; 0<	
			FLMII	15	21.8	6.6	61.4	78.3	51.1	93.9	11.4	85.8	60.0	96.5	8.7	79.4	47.8	97.3	14.9	1> ; 11= ; 3<	3> ; 12= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Fifteen trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 5% to 23% of the flag leaves (FLAGLE) area and from 7% to 57% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 5% to 46% of the flag leaves (FLAGLE) area and from 7% to 61% of the flag leaves minus 1 (FLMI1) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of PYRNTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (81% in 8 trials on FLAGLE and 83% in 8 trials on FLMI1) was superior to LIBRAX (76% on FLAGLE and 72% on FLMI1). This difference was significant in 2 out of 8 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (76% in 8 trials on FLAGLE and 78% in 8 trials on FLMI1) was similar or even superior to LIBRAX (76% on FLAGLE and 72% on FLMI1). This difference was significant in 1 out of 8 trials on FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PYRNTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (90% in 3 trials on FLAGLE and 89% in 3 trials on FLMI1) was slightly superior to LIBRAX (86% on FLAGLE and 84% on FLMI1). This difference was significant in 1 out of 3 trials on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (79% in 3 trials on FLAGLE and 74% in 3 trials on FLMI1) was inferior to LIBRAX (86% on FLAGLE and 84% on FLMI1). However, no significant difference was noted in 3 out of 6 assessments on FLAGLE and FLMI1.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PYRNTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (95% in 3 trials on FLAGLE and 89% in 4 trials on FLMI1) was similar to LIBRAX (93% on FLAGLE and 90% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (91% in 3 trials on FLAGLE and 83% in 4 trials on FLMI1) was slightly inferior to LIBRAX (93% on FLAGLE and 90% on FLMI1). However, no significant difference was noted in 4 out of 7 assessments on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 15 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat against PYRNTR.

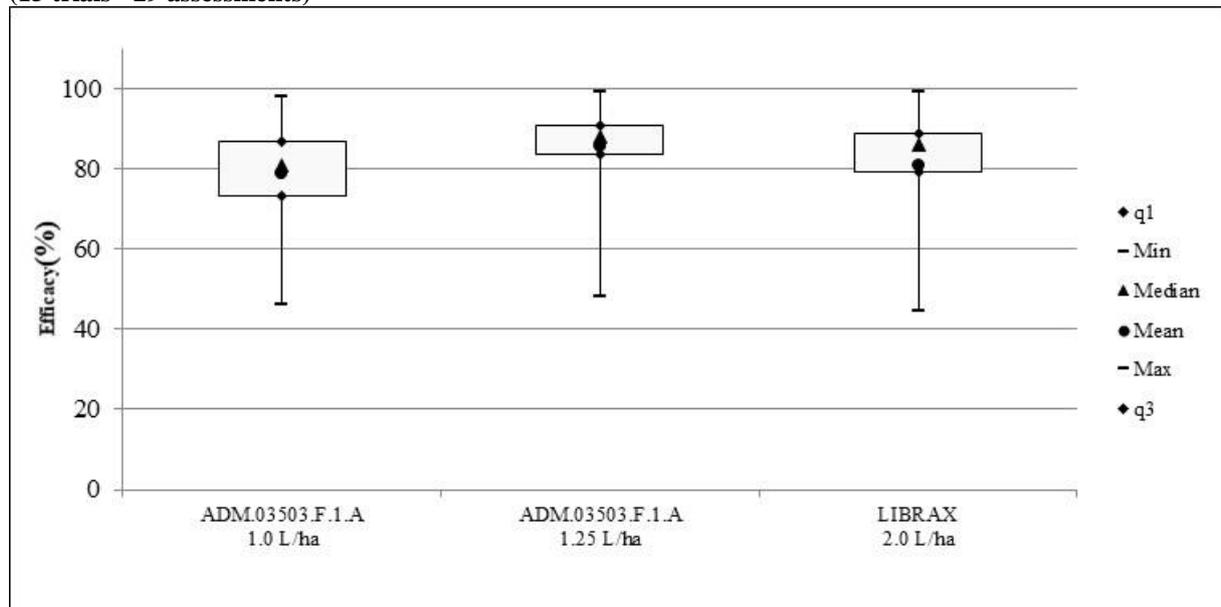
At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of PYRNTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (86% in 14 trials on FLAGLE and 86% in 15 trials on FLMI1) was slightly superior to LIBRAX (82% on FLAGLE and 79% on FLMI1). This difference was significant in 1 out of 14 trials on FLAGLE and in 3 out of 15 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (80% in 14 trials on FLAGLE and 78% in 15 trials on FLMI1) was similar to LIBRAX (82% on FLAGLE and 79% on FLMI1). No significant difference was at least noted in 23 out of 29 assessments on FLAGLE and FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-20). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-20 Efficacy of ADM.03503.F.1.A - Wheat - PYRNTR - Last valid assessment - Box Plot graphic (15 trials - 29 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PYRNTR in wheat crops superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha also showed a moderate control of tan spot of wheat similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control tan spot according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of tan spot of wheat (*Pyrenophora tritici-repentis* - PYRNTR).

Even if only 3 valid trials are available in the Northeast EPPO climatic zone, the results of trials border countries can be considered as supportive data. Therefore, 7 trials (1 trial in Czech Republic and 6 trials in Germany) support also the request of registration of ADM.03503.F.1.A in Poland.

3.2.3.2.5 Powdery mildew of wheat (*Blumeria graminis* - ERYSGT)

A total of **19 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of ERYSGT. These trials were carried out **from 2020 to 2021** in the Maritime (3 trials in Germany, 2 trials in the United Kingdom and 3 trials in France), the Northeast (6 trials in Poland) and the Southeast (4 trials in Romania and 1 trial in Slovakia) EPPO climatic zones in winter wheat.

Table 3.2-64 summarises the efficacy of ADM.03503.F.1.A against ERYSGT.

Table 3.2-64: Efficacy of ADM.03503.F.1.A - Wheat - ERYSGT - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX			
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha	
ERYSGT Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	5.0	-	-	70.0	-	-	-	70.0	-	-	-	50.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	2	9.3	6.0	12.5	81.9	80.0	83.8	1.9	83.8	80.0	87.6	3.8	72.5	54.0	91.0	18.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	3	12.8	8.9	20.0	89.1	80.0	100.0	8.3	89.3	76.3	100.0	9.8	84.0	61.3	97.4	16.1	0> ; 3= ; 0<	0> ; 3= ; 0<	
		Northeast	FLMI1	1	5.3	-	-	85.8	-	-	-	100.0	-	-	-	95.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	5	14.0	7.8	21.0	74.2	65.6	84.6	6.9	84.7	77.7	90.5	4.2	80.5	70.0	94.3	8.2	0> ; 5= ; 0<	2> ; 3= ; 0<	
		All EPPO climatic zones	FLAGLE	1	5.0	-	-	70.0	-	-	-	70.0	-	-	-	50.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	3	7.9	5.3	12.5	83.2	80.0	85.8	2.4	89.2	80.0	100.0	8.3	80.0	54.0	95.0	18.5	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI2	8	13.6	7.8	21.0	79.8	65.6	100.0	10.4	86.5	76.3	100.0	7.2	81.8	61.3	97.4	11.9	0> ; 8= ; 0<	2> ; 6= ; 0<	
		Last valid assessment after application B	Maritime	FLAGLE	3	9.9	5.0	15.0	79.7	53.3	93.3	18.7	85.8	65.0	96.7	14.7	77.4	53.3	93.9	17.4	0> ; 3= ; 0<	0> ; 3= ; 0<
				FLMI1	6	21.9	8.3	51.7	77.9	46.9	90.5	15.6	84.7	62.5	97.4	13.0	77.8	43.8	94.9	16.7	0> ; 6= ; 0<	1> ; 5= ; 0<
				FLMI2	5	34.9	7.9	82.8	82.5	50.0	99.1	17.4	85.0	45.0	99.7	20.3	74.2	35.0	97.9	24.8	1> ; 4= ; 0<	2> ; 3= ; 0<
			Northeast	FLAGLE	2	7.6	5.5	9.7	75.1	56.1	94.1	19.0	88.2	76.8	99.5	11.4	83.4	76.8	90.0	6.6	0> ; 2= ; 0<	1> ; 1= ; 0<
	FLMI1			5	20.4	8.6	38.5	89.1	82.0	97.7	5.2	96.6	92.7	100.0	2.4	94.1	87.2	100.0	4.7	0> ; 4= ; 1<	0> ; 5= ; 0<	
	Southeast		FLMI2	3	44.8	40.8	52.8	86.1	84.0	89.0	2.1	97.4	95.1	99.4	1.8	96.1	91.5	98.8	3.3	0> ; 1= ; 2<	0> ; 3= ; 0<	
			FLAGLE	2	5.6	5.0	6.2	85.3	83.2	87.5	2.2	93.5	92.1	95.0	1.5	85.4	81.3	89.5	4.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	4	7.3	5.5	8.8	82.5	77.2	84.4	3.1	88.3	85.8	92.7	2.7	83.6	76.1	88.5	4.6	0> ; 4= ; 0<	0> ; 4= ; 0<	
	All EPPO climatic zones		FLMI2	5	7.7	5.6	11.6	81.7	74.5	90.1	5.4	88.6	82.7	92.2	3.6	84.2	73.2	89.7	6.0	0> ; 5= ; 0<	0> ; 5= ; 0<	
			FLAGLE	7	8.0	5.0	15.0	80.0	53.3	94.1	16.4	88.7	65.0	99.5	11.9	81.4	53.3	93.9	12.7	0> ; 7= ; 0<	1> ; 6= ; 0<	
			FLMI1	15	17.5	5.5	51.7	82.9	46.9	97.7	11.5	89.6	62.5	100.0	9.9	84.8	43.8	100.0	13.2	0> ; 14= ; 1<	1> ; 14= ; 0<	
	ERYSGT Disease severity		Last valid assessment	Maritime	FLMI2	13	26.7	5.6	82.8	83.0	50.0	99.1	11.4	89.3	45.0	99.7	13.6	83.1	35.0	98.8	18.0	1> ; 10= ; 2<
		FLAGLE			3	9.9	5.0	15.0	79.7	53.3	93.3	18.7	85.8	65.0	96.7	14.7	77.4	53.3	93.9	17.4	0> ; 3= ; 0<	0> ; 3= ; 0<
		FLMI1			7	19.6	6.0	51.7	78.7	46.9	90.5	14.6	85.1	62.5	97.4	12.1	79.6	43.8	94.9	16.1	0> ; 7= ; 0<	1> ; 6= ; 0<
		Northeast		FLMI2	6	30.6	7.9	82.8	83.3	50.0	99.1	15.9	86.1	45.0	99.7	18.7	77.3	35.0	97.9	23.7	1> ; 5= ; 0<	2> ; 4= ; 0<
				FLAGLE	2	7.6	5.5	9.7	75.1	56.1	94.1	19.0	88.2	76.8	99.5	11.4	83.4	76.8	90.0	6.6	0> ; 2= ; 0<	1> ; 1= ; 0<
Southeast		FLMI1		6	17.9	5.3	38.5	88.5	82.0	97.7	4.9	97.1	92.7	100.0	2.6	94.3	87.2	100.0	4.3	0> ; 5= ; 1<	0> ; 6= ; 0<	
		FLMI2		6	29.5	7.8	52.8	79.6	65.6	89.0	7.7	91.2	77.7	99.4	7.4	87.8	75.8	98.8	9.0	0> ; 4= ; 2<	1> ; 5= ; 0<	
		FLAGLE		2	5.6	5.0	6.2	85.3	83.2	87.5	2.2	93.5	92.1	95.0	1.5	85.4	81.3	89.5	4.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
All EPPO		FLMI1		4	7.3	5.5	8.8	82.5	77.2	84.4	3.1	88.3	85.8	92.7	2.7	83.6	76.1	88.5	4.6	0> ; 4= ; 0<	0> ; 4= ; 0<	
		FLMI2		5	7.7	5.6	11.6	81.7	74.5	90.1	5.4	88.6	82.7	92.2	3.6	84.2	73.2	89.7	6.0	0> ; 5= ; 0<	0> ; 5= ; 0<	
		FLAGLE		7	8.0	5.0	15.0	80.0	53.3	94.1	16.4	88.7	65.0	99.5	11.9	81.4	53.3	93.9	12.7	0> ; 7= ; 0<	1> ; 6= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
		climatic zones	FLMI1	17	16.1	5.3	51.7	83.1	46.9	97.7	10.8	90.1	62.5	100.0	9.6	85.7	43.8	100.0	12.7	0> ; 16= ; 1<	1> ; 16= ; 0<
			FLMI2	17	23.4	5.6	82.8	81.5	50.0	99.1	11.0	88.7	45.0	99.7	12.3	83.1	35.0	98.8	16.1	1> ; 14= ; 2<	3> ; 14= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Nineteen trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 5% of the flag leaves (FLAGLE) area, from 5% to 13% of the flag leaves minus 1 (FLMI1) area and from 8% to 21% of the flag leaves minus 2 (FLMI2). After the second application, the disease in the untreated plot attacked from 5% to 15% of the flag leaves (FLAGLE) area, from 6% to 51% of the flag leaves minus 1 (FLMI1) area and from 6% to 83% of the flag leaves minus 2 (FLMI2).

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of ERYSGT. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (86% in 3 trials on FLAGLE, 85% in 7 trials on FLMI1, and 86% in 6 trials on FLMI2) was superior to LIBRAX (77% on FLAGLE, 80% on FLMI1 and 77% on FLMI1). This difference was significant in 1 out of 7 trials on FLMI1 and in 2 out of 6 trials on FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of ERYSGT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (80% in 3 trials on FLAGLE, 79% in 7 trials on FLMI1, and 83% in 6 trials on FLMI2) was similar to LIBRAX (77% on FLAGLE, 80% on FLMI1 and 77% on FLMI1). No significant difference was at least noted in all assessments.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of ERYSGT.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (88% in 2 trials on FLAGLE, 97% in 6 trials on FLMI1, and 91% in 6 trials on FLMI2) was similar or even superior to LIBRAX (83% on FLAGLE, 94% on FLMI1 and 88% on FLMI1). No significant difference was at least noted in all assessments.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of ERYSGT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (75% in 2 trials on FLAGLE, 89% in 6 trials on FLMI1, and 80% in 6 trials on FLMI2) was inferior to LIBRAX (83% on FLAGLE, 94% on FLMI1 and 88% on FLMI1). However, no significant difference was at least noted in 11 out of 14 assessments.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of ERYSGT.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (94% in 2 trials on FLAGLE, 88% in 4 trials on FLMI1, and 88% in 5 trials on FLMI2) was superior to LIBRAX (85% on FLAGLE, 84% on FLMI1 and 84% on FLMI1) even if no significant difference was noted in all assessments.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of ERYSGT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (85% in 2 trials on FLAGLE, 83% in 4 trials on FLMI1, and 82% in 5 trials on FLMI2) was similar to LIBRAX (85% on FLAGLE, 84% on FLMI1 and 84% on FLMI1). No significant difference was noted in all assessments.

Central registration zone

Finally, a total of 19 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat against ERYSGT.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of ERYSGT.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (89% in 7 trials on FLAGLE, 90% in 17 trials on FLMI1, and 89% in 17 trials on FLMI2) was superior to LIBRAX (81% on FLAGLE, 86% on FLMI1 and 83% on FLMI1). This difference was significant in 1 out of 7 trials on FLAGLE, 1 out of 16 trials on FLMI1 and in 3 out of 14 trials on FLMI2.

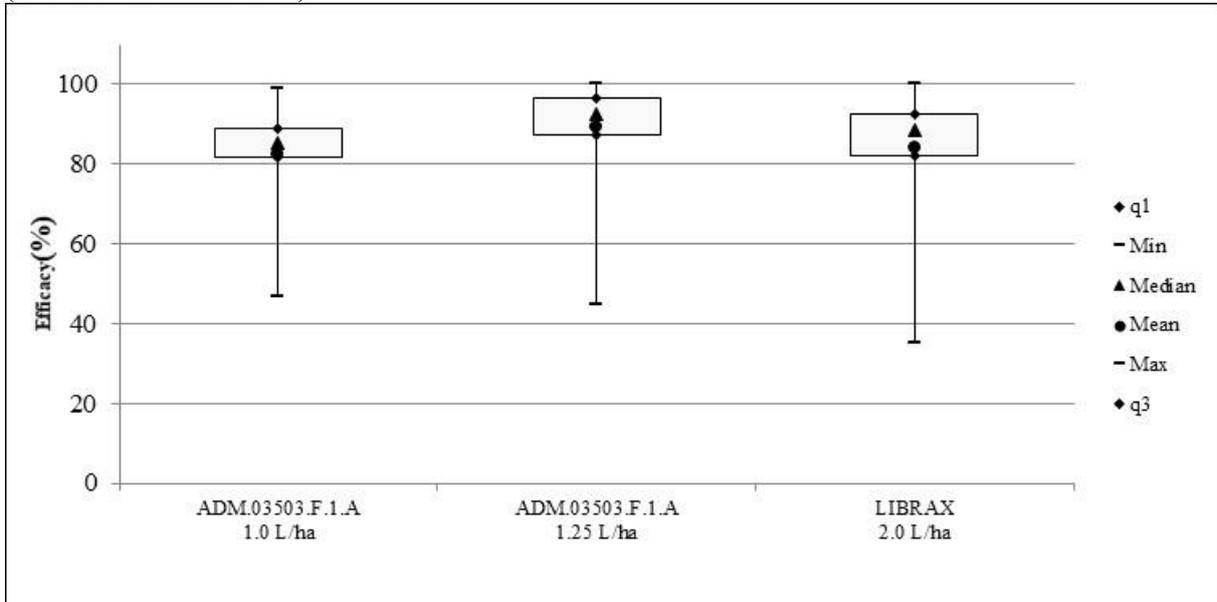
ADM.03503.F.1.A at 1.00 L/ha showed a very good control of ERYSGT.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (80% in 7 trials on FLAGLE, 83% in 17 trials on FLMI1, and 82% in 17 trials on FLMI2) was similar to LIBRAX (81% on FLAGLE, 86% on FLMI1

and 83% on FLMI1). No significant difference was at least noted in 38 out of 41 trials on FLAGLE, FLMI1 and FLMI2.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE, FLMI1 and FLMI2) (Figure 3.2-21). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-21 Efficacy of ADM.03503.F.1.A - Wheat - ERYSGT - Last valid assessment - Box Plot graphic (19 trials - 39 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of ERYSGT in wheat crops superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha also showed a moderate control of powdery mildew of wheat similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control powdery mildew according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of powdery mildew of wheat (*Blumeria graminis* - ERYSGT).

3.2.3.2.6 Head blight of wheat

A total of **24 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of head blight of wheat. These trials were carried out **from 2020 to 2021** in the Maritime (2 trials in Czech Republic, 4 trials in Germany, 3 in the United Kingdom and 3 trials in France), the Northeast (4 trials in Poland) and the Southeast (3 trials in Hungary, 3 trials in Romania, 2 trials in Slovakia) EPPO climatic zones in winter wheat against FUSACU (4 trials), FUSARO (1 trial), GIBBZE (1 trial) and ~~FUSASS~~ FUSASP (16 trials) merged under ~~FUSASS~~ FUSASP and against MONGNI (2 trials).

Table 3.2-65 and Table 3.2-66 summarise the efficacy of ADM.03503.F.1.A against ~~FUSASS~~ FUSASP. Table 3.2-67 summarises the efficacy of ADM.03503.F.1.A against MONGNI.

Table 3.2-65: Efficacy of ADM.03503.F.1.A - Wheat - Ear complex diseases with a majority of FUSASS FUSASP

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
FUSASS FUSASP Disease severity	Last valid assessment	Maritime	Ears	11	46.7	8.1	97.8	68.0	46.7	91.0	12.1	75.7	58.8	89.3	8.9	69.1	54.2	85.8	9.2	1> ; 9= ; 1<	3> ; 8= ; 0<
		Northeast	Ears	4	43.6	23.8	67.5	70.6	49.8	85.3	12.9	80.4	71.5	87.6	5.9	82.5	74.1	87.4	5.1	0> ; 3= ; 1<	0> ; 3= ; 1<
		Southeast	Ears	7	27.1	5.6	50.2	80.6	70.7	100.0	9.2	86.6	73.6	100.0	8.8	78.0	44.5	100.0	16.9	1> ; 6= ; 0<	1> ; 6= ; 0<
		All EPPO climatic zones	Ears	22	39.9	5.6	97.8	72.5	46.7	100.0	12.7	80.0	58.8	100.0	9.7	74.4	44.5	100.0	13.0	2> ; 18= ; 2<	4> ; 17= ; 1<
FUSASS FUSASP Percentage of infected grains	After harvest	Maritime	Grains	8	44.3	7.0	99.8	54.2	20.7	82.7	19.9	65.1	36.9	94.6	19.1	56.1	27.1	89.9	18.1	1> ; 6= ; 1<	1> ; 7= ; 0<
		Northeast	Grains	3	40.7	22.3	61.3	79.0	64.1	93.3	11.9	83.6	70.4	96.6	10.7	81.0	76.4	83.7	3.3	1> ; 1= ; 1<	1> ; 2= ; 0<
		Southeast	Grains	5	16.4	7.1	25.0	63.6	32.7	100.0	26.1	72.1	46.4	100.0	20.4	69.9	36.8	100.0	23.0	0> ; 4= ; 1<	0> ; 5= ; 0<
		All EPPO climatic zones	Grains	16	34.9	7.0	99.8	61.8	20.7	100.0	22.9	70.8	36.9	100.0	19.5	65.1	27.1	100.0	20.7	2> ; 11= ; 3<	2> ; 14= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-66: Efficacy of ADM.03503.F.1.A - Wheat - Ear complex diseases with a majority of FUSASS FUSASP - DON analysis

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of Untreated (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
FUSASS FUSASP DON rate	After harvest	Maritime	Grains	7	1196.4	0.2	7968.0	58.1	21.0	100.0	26.3	51.9	13.0	100.0	28.4	57.1	6.3	100.0	34.9	2> ; 0= ; 3<	2> ; 0= ; 3<
		Northeast	Grains	3	611.5	0.1	1815.0	38.6	0.0	75.8	31.0	29.2	0.0	48.3	21.0	28.7	18.4	38.8	8.3	-	-
		Southeast	Grains	1	0.5	-	-	78.7	-	-	-	70.2	-	-	-	48.9	-	-	-	-	-
		All EPPO climatic zones	Grains	11	928.2	0.1	7968.0	54.6	0.0	100.0	28.8	47.4	0.0	100.0	28.0	48.6	6.3	100.0	30.8	2> ; 0= ; 3<	2> ; 0= ; 3<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-67: Efficacy of ADM.03503.F.1.A - Wheat - Ear complex diseases with a majority of MONGNI

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ > ; = ; < to LIBRAX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
MONGNI Disease severity	Last valid assessment	Maritime	Ears	1	38.2	-	-	52.6	-	-	-	50.2	-	-	-	17.5	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<
		Southeast	Ears	1	6.5	-	-	79.1	-	-	-	81.8	-	-	-	86.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		All EPPO climatic zones	Ears	2	22.3	6.5	38.2	65.8	52.6	79.1	13.3	66.0	50.2	81.8	15.8	51.8	17.5	86.0	34.2	1> ; 1= ; 0<	1> ; 1= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Twenty-two trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone against FUSASS FUSASP. After one application, the disease in the untreated plot attacked from 5% to 98% of the ears area. After harvest, the disease in the untreated plot attacked from 7% to 100% of the grains.

Maritime EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a moderate control of FUSASS FUSASP on ears (78% in 11 trials), superior to LIBRAX (69%). This difference was significant in 3 out of 11 trials.

ADM.03503.F.1.A at 1.25 L/ha showed a moderate control of FUSASS FUSASP on the percentage of *Fusarium* damaged grains after harvest (65% in 8 trials), superior to LIBRAX (56%). This difference was significant in 1 out of 8 trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.25 L/ha allowed reducing of 48 points the DON level in harvested grains (in 7 trials), better than LIBRAX (43 points).

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of FUSASS FUSASP on ears (68% in 11 trials), similar to LIBRAX (69%). No significant difference was at least noted in 10 out of 11 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of FUSASS FUSASP on the percentage of *Fusarium* damaged grains after harvest (54% in 8 trials), similar to LIBRAX (56%). No significant difference was at least noted in 7 out of 8 trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.00 L/ha allowed reducing of 42 points the DON level in harvested grains (in 7 trials), similar to LIBRAX (43 points).

Northeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a good control of FUSASS FUSASP on ears (80% in 4 trials), similar to LIBRAX (83%). No significant difference was noted in 3 out of 4 trials.

ADM.03503.F.1.A at 1.25 L/ha showed a good control of FUSASS FUSASP on the percentage of *Fusarium* damaged grains after harvest (84% in 3 trials), similar to LIBRAX (81%). No significant difference was at least noted in all trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.25 L/ha allowed reducing of 71 points the DON level in harvested grains (in 3 trials), similar to LIBRAX (71 points).

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of FUSASS FUSASP on ears (70% in 4 trials), inferior to LIBRAX (83%). However, no significant difference was at least noted in 3 out of 4 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of FUSASS FUSASP on the percentage of *Fusarium* damaged grains after harvest (79% in 3 trials), similar to LIBRAX (81%). No significant difference was at least noted in 2 out of 3 trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.00 L/ha allowed reducing of 61 points the DON level in harvested grains (in 3 trials), lower than LIBRAX (43 points).

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a good control of FUSASS FUSASP on ears (87% in 7 trials), superior to LIBRAX (78%). This difference was significant in 1 out of 7 trials.

ADM.03503.F.1.A at 1.25 L/ha showed a moderate control of FUSASS FUSASP on the percentage of *Fusarium* damaged grains after harvest (72% in 5 trials), similar to LIBRAX (70%). No significant difference was noted in all trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.25 L/ha allowed reducing of 30 points the DON level in harvested grains (in 1 trial), lower than LIBRAX (51 points).

ADM.03503.F.1.A at 1.00 L/ha showed a good control of FUSASS FUSASP on ears (81% in 7 trials), similar to LIBRAX (78%). No significant difference was at least noted in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of FUSASS FUSASP on the percentage of *Fusarium* damaged grains after harvest (64% in 5 trials), inferior to LIBRAX (70%). However, no significant difference was noted in 4 out of 5 trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.00 L/ha allowed reducing of 21 points the DON level in harvested grains (in 1 trial), lower than LIBRAX (51 points).

Central registration zone

Finally, a total of 22 efficacy trials across Eppo climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat against *FUSASS* *FUSASP*.

ADM.03503.F.1.A at 1.25 L/ha showed a good control of *FUSASS* *FUSASP* on ears (80% in 22 trials), superior to LIBRAX (74%). This difference was significant in 4 out of 22 trials.

ADM.03503.F.1.A at 1.25 L/ha showed a moderate control of *FUSASS* *FUSASP* on the percentage of *Fusarium* damaged grains after harvest (71% in 16 trials), superior to LIBRAX (65%). This difference was significant in 2 out of 16 trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.25 L/ha allowed reducing of 53 points the DON level in harvested grains (in 11 trials) compared to the untreated, similar to LIBRAX (51 points). If only high infestations are considered (>10 ppm), ADM.03503.F.1.A at 1.25 L/ha allowed reducing of 59 points the DON level in harvested grains (in 7 trials) compared to the untreated.

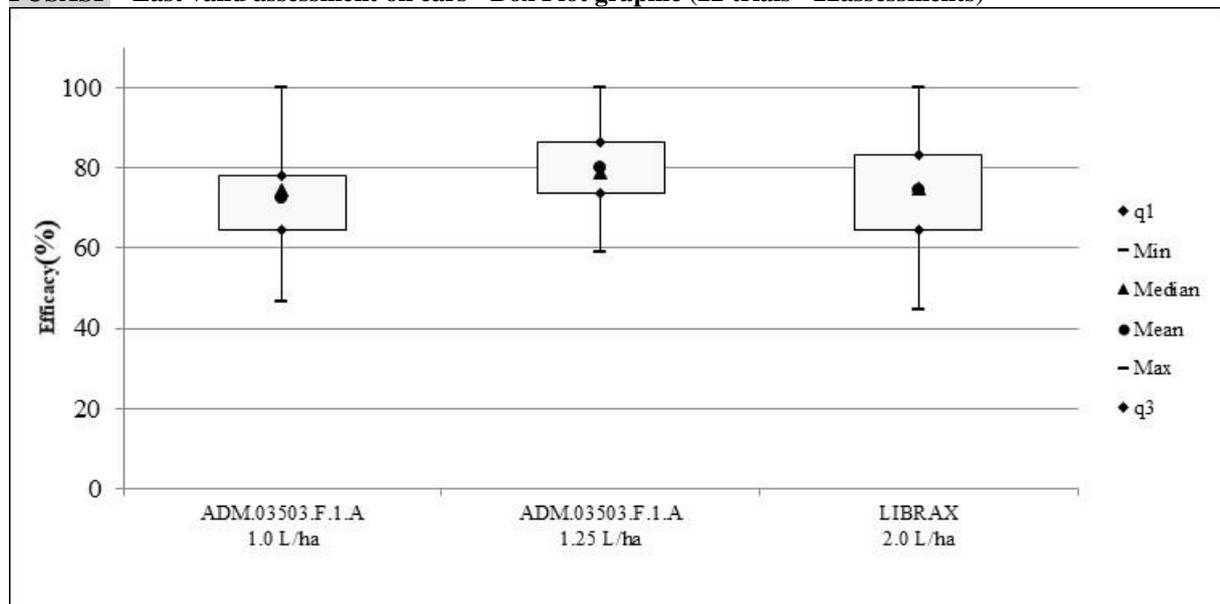
ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of *FUSASS* *FUSASP* on ears (73% in 22 trials), similar to LIBRAX (74%). No significant difference was at least noted in 20 out of 22 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of *FUSASS* *FUSASP* on the percentage of *Fusarium* damaged grains after harvest (62% in 16 trials), similar to LIBRAX (65%). No significant difference was at least noted in 13 out of 16 trials.

About the reduction of mycotoxin rate, ADM.03503.F.1.A at 1.25 L/ha allowed reducing of 45 points the DON level in harvested grains (in 11 trials) compared to the untreated, slightly lower than LIBRAX (51 points). If only high infestations are considered (>10 ppm), ADM.03503.F.1.A at 1.25 L/ha allowed reducing of 51 points the DON level in harvested grains (in 7 trials) compared to the untreated.

The difference between the reference standards can be illustrated by box plot graphic on ears (Figure 3.2-22). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-22 Efficacy of ADM.03503.F.1.A - Wheat - Ear complex diseases with a majority of *FUSASS* *FUSASP* - Last valid assessment on ears - Box Plot graphic (22 trials - 22 assessments)



Two trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone against MONGNI. After one application, the disease in the untreated plot attacked from 7% to 38% of the ears area.

Maritime Eppo climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a moderate control of MONGNI on ears (50% in 1 trial), superior to LIBRAX (18%). This difference was significant.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of MONGNI on ears (53% in 1 trial), superior to LIBRAX (18%). This difference was significant.

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a good control of MONGNI on ears (82% in 1 trial), similar to LIBRAX (86%). No significant difference was noted.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of MONGNI on ears (80% in 1 trial), slightly inferior to LIBRAX (86%). However, no significant difference was noted.

Central registration zone

Finally, 2 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat against MONGNI.

ADM.03503.F.1.A at 1.25 L/ha showed a moderate control of MONGNI on ears (66%), superior to LIBRAX (52%). This difference was significant in 1 out of 2 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of MONGNI on ears (66%), superior to LIBRAX (52%). This difference was significant in 1 out of 2 trials.

To conclude, in the efficacy trials with majority of *FUSASS FUSASP*, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of *FUSASS FUSASP* in wheat crops similar or even superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of *Fusarium* of wheat similar or even superior to LIBRAX. The efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control *Fusarium* according to the disease pressure.

In the efficacy trials with majority of MONGNI, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of MONGNI in wheat crops superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of *Microdochium* of wheat superior to LIBRAX. The efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control *Microdochium* according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of head blight of wheat with a majority of *Fusarium* (*Fusarium* sp.- *FUSASS FUSASP*) or *Microdochium* (*Microdochium nivale* - MONGNI).

3.2.3.2.7 Control of disease complex - Green leaf area

Attacks by pathogens reduce green leaf area and thus grain yield. Thus, the green area is a good indicator of the level of efficacy of one product. Therefore, a total of **101 valid efficacy trials** were carried out to confirm the effect of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha on the green leaf area. These trials were carried out **from 2019 to 2021** in the Maritime (2 trials in Austria, 6 trials in Czech Republic, 18 trials in Germany, 2 trials in the Netherlands, 11 trials in the United Kingdom and 17 trials in France), the Northeast (13 trials in Poland) and the Southeast (5 trials in Hungary, 18 trials in Romania and 9 trials in Slovakia) EPPO climatic zones in winter wheat.

Table 3.2-68 summarises the effect on the increase of the green leaf area after an application of ADM.03503.F.1.A in wheat crops.

Table 3.2-68: Effect of ADM.03503.F.1.A on the green leaf area - Wheat - Increase of green leaf area (%)

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	Increase of green leaf area (%)															
					Untreated Green leaf area (%)				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha			
									Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha			
					Mean	Min	Max		Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.
All diseases Green leaf area (%)	Last valid assessment	Maritime	Leaves	56	24.3	0.0	91.3	42.0	5.8	89.7	20.7	46.6	0.0	94.1	23.0	44.1	10.4	92.4	21.9	
		Northeast	Leaves	13	27.0	13.8	66.0	22.1	7.4	64.1	16.7	28.3	7.4	71.1	20.4	30.5	10.3	84.8	22.4	
		Southeast	Leaves	32	41.5	17.5	67.5	34.8	6.9	86.4	21.2	44.3	10.3	88.0	21.5	37.4	10.3	81.2	18.8	
		All EPPO climatic zones	Leaves	101	30.1	0.0	91.3	37.1	5.8	89.7	21.5	43.5	0.0	94.1	23.0	40.2	10.3	92.4	21.6	

101 trials are available to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The green leaf area in the untreated plot covered from 0% to 91%.

Maritime EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 47% of green leaf area (in 56 trials), similar to LIBRAX (44%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 42% of green leaf area (in 56 trials), similar to LIBRAX (44%).

Northeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 28% of green leaf area (in 13 trials), similar to LIBRAX (31%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 22% of green leaf area (in 13 trials), slightly inferior to LIBRAX (31%).

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 44% of green leaf area (in 32 trials), superior to LIBRAX (37%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 35% of green leaf area (in 32 trials), similar to LIBRAX (37%).

Central registration zone

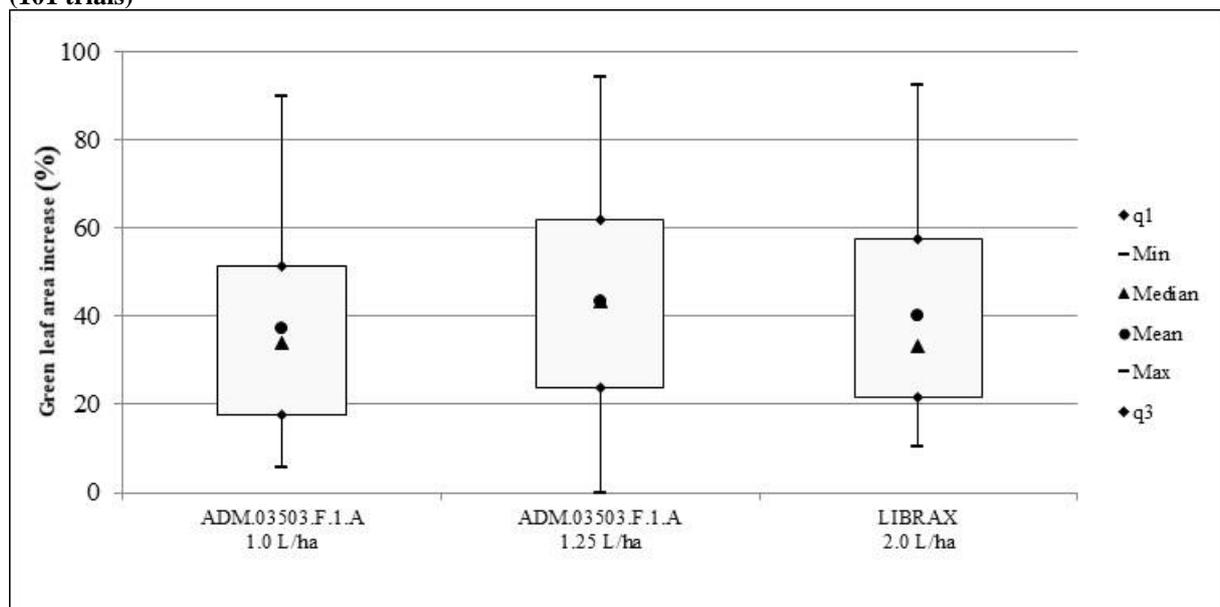
Finally, a total of 101 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat crops.

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 44% of green leaf area, similar or even slightly superior to LIBRAX (40%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 37% of green leaf area, similar to LIBRAX (40%).

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-23). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same (or even better) effect on the increasing green leaf area and the same dispersion and variation between means than LIBRAX.

Figure 3.2-23 Effect of ADM.03503.F.1.A on the green leaf area- Wheat - Increase of the green leaf area (101 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the green leaf area in wheat crops at least like the reference standard LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the green leaf area in wheat crops like LIBRAX.

3.2.3.2.8 Positive effect on the yield in efficacy trials

A total of **139 valid efficacy trials** with sufficient disease pressure were harvested to confirm the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2019 to 2021** in the Maritime (2 trials in Austria, 1 trial in Belgium, 6 trials in Czech Republic, 28 trials in Germany, 2 trials in Ireland, 2 trials in the Netherlands, 13 trials in the United Kingdom and 20 trials in France), the Northeast (21 trials in Poland) and the Southeast (9 trials in Hungary, 21 trials in Romania and 14 trials in Slovakia) EPPO climatic zones in winter wheat.

Table 3.2-69 summarises the positive effect on the yield and yield parameters (TGW and HLW) of ADM.03503.F.1.A in wheat crops with sufficient disease pressure (SEPTTR, PUCCRT, PUCST, PYRNTR, ERYSGT, ~~FUSASS~~ FUSASP and/or MONGNI).

Table 3.2-69: Positive effect on the yield of ADM.03503.F.1.A - Wheat - Yield parameters

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
All diseases	Yield (t/ha)	Maritime	Grains	74	7.9	3.0	11.4	118.7	95.7	229.4	19.9	121.1	97.6	245.3	21.8	118.7	99.0	224.4	20.3	1>; 69=; 4<	5>; 67=; 2<
		Northeast	Grains	21	6.4	3.2	8.8	113.5	104.1	140.6	9.3	115.2	103.6	137.5	8.6	114.9	103.9	150.0	10.5	0>; 21=; 0<	1>; 20=; 0<
		Southeast	Grains	44	5.8	3.8	8.9	106.2	99.4	125.2	4.8	108.1	98.3	123.2	4.6	106.9	98.4	122.8	4.5	2>; 32=; 10<	5>; 39=; 0<
		All EPPO climatic zones	Grains	139	7.0	3.0	11.4	114.0	95.7	229.4	16.2	116.1	97.6	245.3	17.4	114.4	98.4	224.4	16.5	3>; 122=; 14<	11>; 126=; 2<
	TGW (g)	Maritime	Grains	51	38.3	24.4	50.0	109.0	98.7	132.5	7.6	109.5	97.8	134.4	8.4	108.5	93.0	132.7	8.2	2>; 47=; 1<	4>; 45=; 1<
		Northeast	Grains	21	41.7	36.8	48.4	103.6	99.4	110.1	2.8	103.9	99.8	111.5	3.0	103.4	99.8	111.9	3.0	0>; 21=; 0<	0>; 21=; 0<
		Southeast	Grains	44	41.9	27.9	54.7	102.2	97.9	121.6	3.3	102.6	96.7	120.3	3.5	102.3	94.5	117.7	3.3	2>; 38=; 4<	4>; 40=; 0<
		All EPPO climatic zones	Grains	116	40.3	24.4	54.7	105.4	97.9	132.5	6.4	105.9	96.7	134.4	6.9	105.2	93.0	132.7	6.6	4>; 106=; 5<	8>; 106=; 1<
	HLW (kg)	Maritime	Grains	73	73.9	44.9	84.2	103.8	97.3	145.3	6.0	104.0	98.1	147.3	6.3	103.6	98.0	144.6	5.9	2>; 71=; 0<	5>; 68=; 0<
		Northeast	Grains	21	71.8	56.2	82.8	102.0	99.1	107.6	2.4	102.1	99.7	111.3	2.7	101.8	99.3	107.8	2.1	0>; 21=; 0<	0>; 21=; 0<
		Southeast	Grains	44	74.6	61.1	84.8	100.5	95.4	104.8	1.4	100.9	98.4	103.7	1.0	100.9	99.4	103.7	0.9	0>; 43=; 1<	5>; 39=; 0<
		All EPPO climatic zones	Grains	138	73.8	44.9	84.8	102.5	95.4	145.3	4.8	102.7	98.1	147.3	4.9	102.4	98.0	144.6	4.6	2>; 135=; 1<	10>; 128=; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

139 trials are available to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The yield in the untreated plot was from 3.0 to 11.4 t/ha.

Maritime EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 21 points compared to Untreated in 74 trials similar or even slightly superior to LIBRAX (119%). This difference was significant in 5 out of 74 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 19 points compared to Untreated in 74 trials similar to LIBRAX (119%). No significant difference was at least noted with LIBRAX in 70 out of 74 trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 9-10 points or HLW with a positive effect of 3-4 points even if the differences on these yield parameters are less pronounced.

Northeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 15 points compared to Untreated in 21 trials similar to LIBRAX (115%). No significant difference was at least noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 14 points compared to Untreated in 21 trials similar to LIBRAX (115%). No significant difference was at least noted with LIBRAX in all trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 4 points or HLW with a positive effect of 2 points even if the differences on these yield parameters are less pronounced.

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 8 points compared to Untreated in 44 trials similar or even slightly superior to LIBRAX (107%). This difference was significant in 5 out of 44 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 6 points compared to Untreated in 44 trials similar to LIBRAX (107%). No significant difference was at least noted with LIBRAX in 34 out of 44 trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 2-3 points or HLW with a positive effect of 1 point even if the differences on these yield parameters are less pronounced.

Central registration zone

Finally, a total of 139 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in wheat crops.

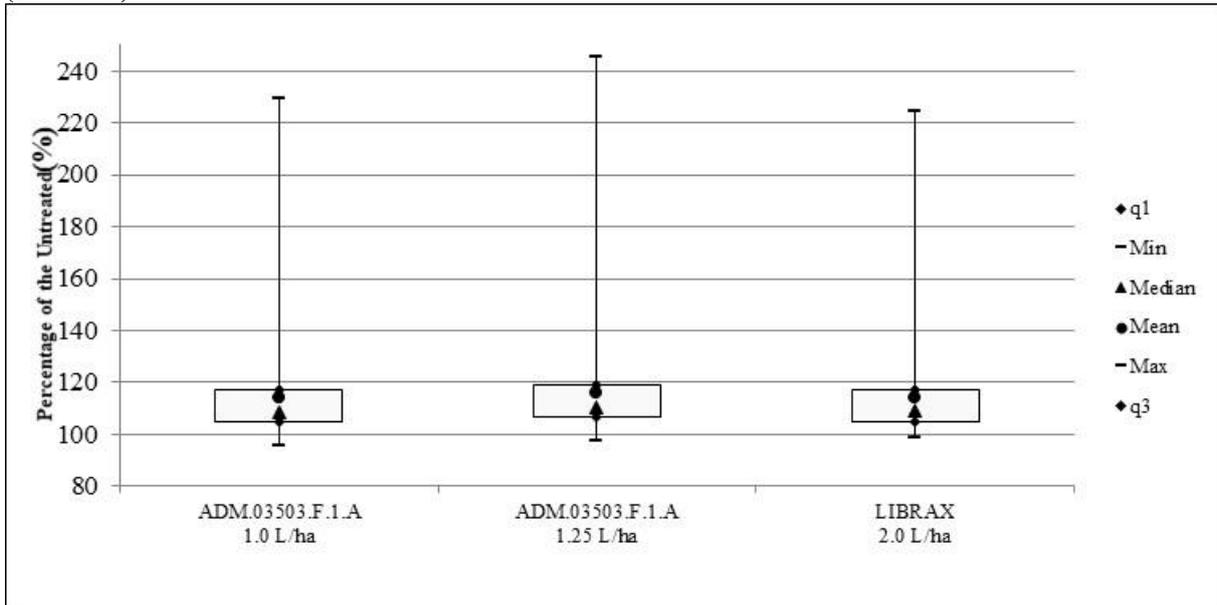
ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 16 points compared to Untreated in 139 trials similar or even slightly superior to LIBRAX (114%). This difference was significant in 11 out of 139 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 14 points compared to Untreated in 139 trials similar to LIBRAX (114%). No significant difference was at least noted with LIBRAX in 125 out of 139 trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 5-6 points or HLW with a positive effect of 3 points even if the differences on these yield parameters are less pronounced.

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-24). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same effect on the yield and the same dispersion and variation between means than LIBRAX.

Figure 3.2-24 Positive effect of ADM.03503.F.1.A on the yield - Wheat - Percentage of the untreated (139 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the yield in wheat crops like or even better than the reference standard LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the yield in wheat crops like LIBRAX.

3.2.3.2.9 Zonal conclusion on efficacy of test product against wheat diseases

A total of **143 valid efficacy trials** carried out **from 2019 to 2021** are provided to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone in wheat crops.

Table 3.2-70 summarises the efficacy of ADM.03503.F.1.A to control wheat disease complex from all valid efficacy trials.

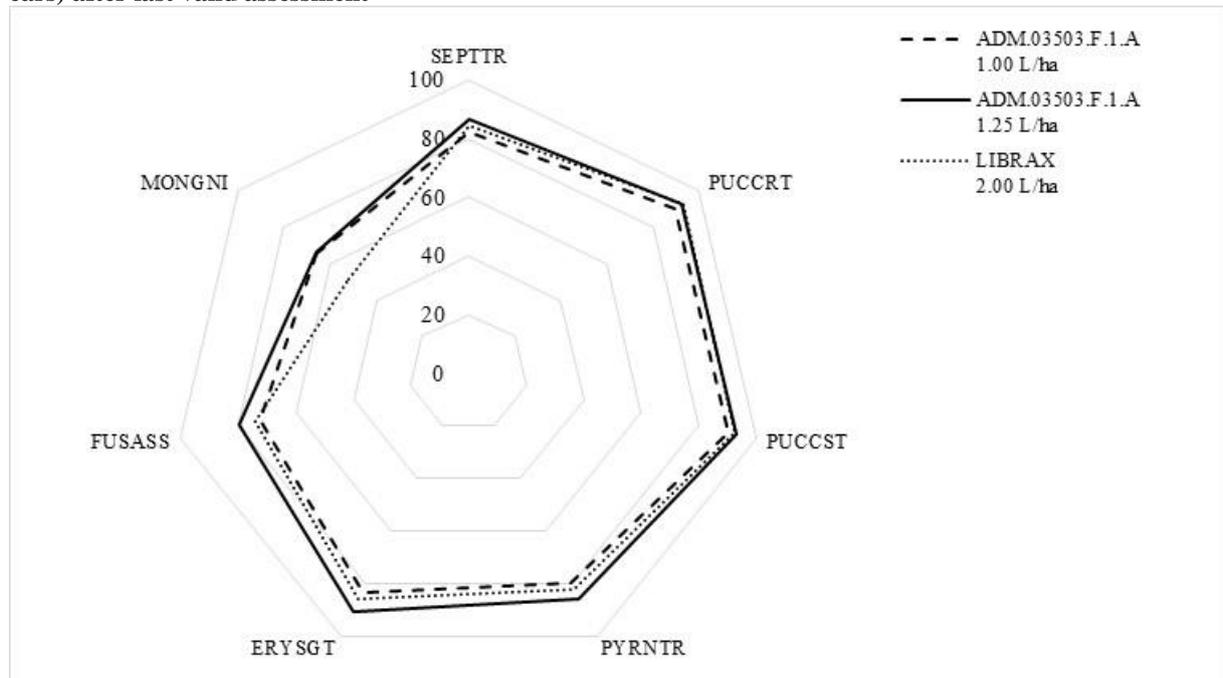
Table 3.2-70: Efficacy of ADM.03503.F.1.A - Wheat - All valid efficacy trials

Target Parameters	Parts	No. of trials	<i>Untreated</i>			Percentage of efficacy (%)								
						ADM.03503.F.1.A 1.00 L/ha			ADM.03503.F.1.A 1.25 L/ha			LIBRAX 2.00 L/ha		
						Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole			Fluxapyroxad + Metconazole		
						75+150 g a.s./ha			93.75+187.5 g a.s./ha			125+90 g a.s./ha		
			<i>Mean</i>	<i>Min</i>	<i>Max</i>	<i>Mean</i>	<i>Min</i>	<i>Max</i>	<i>Mean</i>	<i>Min</i>	<i>Max</i>	<i>Mean</i>	<i>Min</i>	<i>Max</i>
SEPTTR	FLAGLE	42	24.4	4.6	96.6	81.3	37.0	100.0	86.4	43.8	100.0	83.9	36.4	100.0
	FLMI1	56	33.7	5.3	100.0	79.5	51.5	100.0	83.7	46.0	100.0	81.4	40.0	100.0
PUCCRT	FLAGLE	26	24.6	6.4	96.4	89.8	49.8	100.0	92.7	55.6	100.0	92.8	54.6	100.0
	FLMI1	28	22.7	4.6	97.4	89.5	70.2	100.0	93.9	76.2	100.0	92.9	73.4	100.0
PUC CST	FLAGLE	24	32.2	4.7	98.8	90.1	69.6	100.0	92.9	78.9	100.0	92.3	80.0	100.0
	FLMI1	26	40.6	5.0	99.3	90.5	71.3	100.0	93.7	80.7	100.0	91.5	71.4	100.0
PYRNTR	FLAGLE	14	13.2	4.5	46.2	79.5	46.0	97.9	85.6	48.2	99.0	81.9	44.4	99.3
	FLMI1	15	21.8	6.6	61.4	78.3	51.1	93.9	85.8	60.0	96.5	79.4	47.8	97.3
ERYSGT	FLAGLE	7	8.0	5.0	15.0	80.0	53.3	94.1	88.7	65.0	99.5	81.4	53.3	93.9
	FLMI1	17	16.1	5.3	51.7	83.1	46.9	97.7	90.1	62.5	100.0	85.7	43.8	100.0
	FLMI2	17	23.4	5.6	82.8	81.5	50.0	99.1	88.7	45.0	99.7	83.1	35.0	98.8
FUSASS	Ears	22	39.9	5.6	97.8	72.5	46.7	100.0	80.0	58.8	100.0	74.4	44.5	100.0
FUSASP	Grains	16	34.9	7.0	99.8	61.8	20.7	100.0	70.8	36.9	100.0	65.1	27.1	100.0
MONGNI	Ears	2	22.3	6.5	38.2	65.8	52.6	79.1	66.0	50.2	81.8	51.8	17.5	86.0

⁽¹⁾ Comparison based on statistics carried out in each trial report.

The efficacy of ADM.03503.F.1.A against wheat disease complex can be illustrated by graphic from the last valid assessment (SEPTTR, PUC CRT, PUC CST, PYRNTR, ERYSGT, FUSASS FUSASP and/or MONGNI) (Figure 3.2-25). According to the efficacy results and as illustrated on the graphic hereafter, ADM.03503.F.1.A at 1.25 L/ha controlled all diseases of wheat with a level of efficacy similar or even superior to the reference standard LIBRAX. Overall, the efficacy of ADM.03503.F.1.A at 1.00 L/ha was also acceptable to control wheat disease complex.

Figure 3.2-25 Efficacy of ADM.03503.F.1.A - Wheat - Disease complex (efficacy against SEPTTR, PUC CRT, PUC CST, PYRNTR on FLAGLE, against ERYSGT on FLMI1 and FUSASS FUSASP and MONGNI on ears) after last valid assessment



Therefore, provided data are sufficient to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha to control wheat disease complex.

zRMS comments on efficacy in wheat:

The numbers of efficacy trials, the efficacy levels reported and the effect on yield observed, both as stand-alone results as well as relative to the standard reference products, allow for the authorization of the ADM.03503.F.1.A in wheat, in the Member States of the Central zone concerned with this submission.

In the Maritime zone ADM.03503.F.1.A can be authorized for a single application per growth season within the BBCH 30-69, at the dose rate of 1.25 L/ha, in control of SEPTTR, PUCCRT, PUC CST, PYRNTR and ERYSGT in winter and spring wheat. The use against FUSASP should be confirmed by the Member States of the Maritime zone, as only 5 trials covering this use were carried out in that zone: 3 in Germany and 2 in the Czech Republic. Four additional trials were carried out in Poland, the MS neighbouring both CZ and DE.

As already explained while commenting the MED chapter, **in the South-Eastern zone** (Hungary, Slovakia and Slovenia), the **dose range** of 1.00-1.25 L/ha can be authorized in control of the target pathogens SEPTTR, PUC CRT, PUC CST and ERYSGT in winter and spring wheat, by a single application per growth season within the BBCH 30-69.

For the SE zone only 4 trials testing for PYRNTR and 4 trials in control of FUSASP have been submitted. A single trial with PYRNTR is available from the Czech Republic, as well as 4 PL trials and 2 trials from the Czech Republic – all 6 trials testing efficacy against FUSASP. The concerned Member states Hungary and Slovakia are kindly requested to take their individual decision whether They can authorize these uses based on the data from their neighbouring zones.

In Poland, **the North-Eastern zone**, the **dose range** of 1.00-1.25 L/ha can be authorized in control of the target pathogens SEPTTR, PUC CRT, PUC CST, PYRNTR and ERYSGT in winter wheat only, for the extrapolation to spring form is not possible in the absence of trials in TRZAS.

The sub-critical number of trials testing efficacy against SEPTTR, PUC CRT, PUC CST, PYRNTR in the NE zone (Poland) has been accepted by zRMS based on the presence of trials from the neighbouring Czech Republic, Slovakia and Germany (23 trials for SEPTTR, 6 - for PUC CRT, 8 - for PUC CST, 9 for PYRNTR), testing for the same targets and providing comparable results. Only 4 trials have been submitted testing for FUSASP in wheat in the NE zone, but 2 more trials tested for this target in the Czech Republic, 3 – in Germany and 1 – in Slovakia. Based on these 10 trials overall this use has been accepted for Poland either.

Unfortunately, only 2 trials have been delivered that test the efficacy against *Microdochium nivale* (MONGNI), one from SK and one from the Maritime part of FR. This use cannot be authorised, for ADM.03503.F.1.A is the new product and the minimum number of 6 trials should have been submitted.

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3.2.3.3 Efficacy trials results for the control of barley diseases

A total of **82 efficacy trials** were carried out in the Central registration zone to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Belgium, 4 trials in Czech Republic, 18 trials in Germany and 7 trials in Ireland), the Northeast (16 trials in Poland) and the Southeast (10 trials in Hungary, 14 trials in Romania and 12 trials in Slovakia) EPPO climatic zones.

In addition, **36 efficacy trials** carried out in countries belonging to the Maritime EPPO climatic zone, but outside the Central registration zone are also provided to complete the data package. These trials were carried out **from 2019 to 2021** in France (20 trials) and the United Kingdom (16 trials).

Nineteen out of 118 trials are not taken into account in the efficacy analysis below due to a low pest pressure conditions or an abnormal level of efficacy of the reference standards. Thus, these trials are excluded from the analysis of efficacy. However, the potential crop phytotoxicity symptoms observed in this trial is analysed in Section 3.4.1.

Therefore, a total of **99 valid efficacy trials** in the Maritime (58 trials), the Northeast (15 trials) and the Southeast (26 trials) EPPO climatic zone were available to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of barley diseases.

3.2.3.3.1 Leaf blotch of barley (*Rhynchosporium secalis* - RHYNSE)

A total of **31 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of RHYNSE. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Belgium, 4 trials in Germany, 3 trials in Ireland, 5 trials in the United Kingdom and 8 trials in France), the Northeast (4 trials in Poland) and the Southeast (3 trials in Romania and 3 trials in Slovakia) EPPO climatic zones in winter barley (30 trials) and spring barley (1 trial).

Table 3.2-71 summarises the efficacy of ADM.03503.F.1.A against RHYNSE.

Table 3.2-71: Efficacy of ADM.03503.F.1.A - Barley - RHYNSE - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha									
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
RHYNSE Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	5.8	-	-	47.8	-	-	-	65.2	-	-	-	47.8	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMII	4	7.7	5.3	12.5	71.8	42.9	99.4	20.4	75.8	42.9	100.0	21.8	71.3	42.9	99.1	20.8	0> ; 4= ; 0<	0> ; 4= ; 0<	
		Northeast	FLAGLE	1	9.1	-	-	79.7	-	-	-	91.2	-	-	-	93.3	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<	
			FLMII	2	9.1	6.3	12.0	77.4	76.2	78.5	1.2	85.8	83.9	87.6	1.8	92.4	89.0	95.8	3.4	0> ; 0= ; 2<	0> ; 2= ; 0<	
		All EPPO climatic zones	FLAGLE	2	7.4	5.8	9.1	63.8	47.8	79.7	16.0	78.2	65.2	91.2	13.0	70.6	47.8	93.3	22.8	0> ; 1= ; 1<	0> ; 2= ; 0<	
			FLMII	6	8.2	5.3	12.5	73.6	42.9	99.4	16.9	79.1	42.9	100.0	18.4	78.3	42.9	99.1	19.8	0> ; 4= ; 2<	0> ; 6= ; 0<	
		Last valid assessment after application B	Maritime	FLAGLE	15	20.3	6.4	88.8	87.8	51.6	100.0	13.8	91.7	72.9	100.0	9.5	82.5	38.9	100.0	17.3	2> ; 13= ; 0<	3> ; 12= ; 0<
				FLMII	17	22.8	5.5	100.0	80.2	42.0	98.0	15.3	89.0	68.7	100.0	9.3	78.9	43.6	99.0	15.5	1> ; 16= ; 0<	2> ; 15= ; 0<
	Northeast		FLAGLE	3	15.5	5.5	20.6	79.3	69.2	90.8	8.9	88.2	80.6	100.0	8.5	90.6	80.6	100.0	7.9	0> ; 2= ; 1<	0> ; 3= ; 0<	
			FLMII	3	15.4	7.3	20.0	86.8	79.5	95.1	6.4	94.8	86.2	99.3	6.1	98.7	96.4	100.0	1.6	0> ; 2= ; 1<	0> ; 3= ; 0<	
	Southeast		FLAGLE	2	22.2	11.3	33.1	97.5	95.5	99.4	2.0	100.0	100.0	100.0	0.0	99.6	99.1	100.0	0.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMII	6	16.9	5.5	45.3	91.1	78.5	99.6	7.4	94.9	88.9	100.0	4.5	93.5	84.5	100.0	5.8	0> ; 5= ; 1<	0> ; 6= ; 0<	
	All EPPO climatic zones		FLAGLE	20	19.8	5.5	88.8	87.5	51.6	100.0	13.2	92.0	72.9	100.0	9.3	85.4	38.9	100.0	16.2	2> ; 17= ; 1<	3> ; 17= ; 0<	
			FLMII	26	20.6	5.5	100.0	83.5	42.0	99.6	13.9	91.0	68.7	100.0	8.6	84.6	43.6	100.0	15.1	1> ; 23= ; 2<	2> ; 24= ; 0<	
	RHYNSE Disease severity	Last valid assessment	Maritime	FLAGLE	16	19.4	5.8	88.8	85.3	47.8	100.0	16.5	90.0	65.2	100.0	11.2	80.3	38.9	100.0	18.7	2> ; 14= ; 0<	3> ; 13= ; 0<
				FLMII	20	20.3	5.3	100.0	78.6	42.0	99.4	17.1	86.3	42.9	100.0	14.0	77.3	42.9	99.1	17.3	1> ; 19= ; 0<	2> ; 18= ; 0<
Northeast			FLAGLE	4	13.9	5.5	20.6	79.4	69.2	90.8	7.7	89.0	80.6	100.0	7.4	91.3	80.6	100.0	7.0	0> ; 2= ; 2<	0> ; 4= ; 0<	
			FLMII	4	14.6	7.3	20.0	84.7	78.5	95.1	6.6	93.0	86.2	99.3	6.1	96.3	89.0	100.0	4.4	0> ; 2= ; 2<	0> ; 4= ; 0<	
Southeast			FLAGLE	2	22.2	11.3	33.1	97.5	95.5	99.4	2.0	100.0	100.0	100.0	0.0	99.6	99.1	100.0	0.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMII	6	16.9	5.5	45.3	91.1	78.5	99.6	7.4	94.9	88.9	100.0	4.5	93.5	84.5	100.0	5.8	0> ; 5= ; 1<	0> ; 6= ; 0<	
All EPPO climatic zones			FLAGLE	22	18.6	5.5	88.8	85.4	47.8	100.0	15.1	90.7	65.2	100.0	10.5	84.0	38.9	100.0	17.5	2> ; 18= ; 2<	3> ; 19= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)													No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX				
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Prothioconazole 125+90 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A	
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
FLMI1	30	18.9	5.3	100.0	81.9	42.0	99.6	15.4	88.9	42.9	100.0	12.4	83.1	42.9	100.0	16.6	1> ; 26= ; 3<	2> ; 28= ; 0<				

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Thirty-one trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 6% to 9% of the flag leaves (FLAGLE) area and from 5% to 13% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 6% to 89% of the flag leaves (FLAGLE) area and from 6% to 100% of the flag leaves minus 1 (FLMI1) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (90% in 16 trials on FLAGLE and 86% in 20 trials on FLMI1) was superior to LIBRAX (80% on FLAGLE and 77% on FLMI1). This difference was significant in 3 out of 16 trials on FLAGLE and in 2 out of 20 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (85% in 16 trials on FLAGLE and 79% in 20 trials on FLMI1) was similar or even superior to LIBRAX (80% on FLAGLE and 78% on FLMI1). This difference was significant in 2 out of 16 trials on FLAGLE and in 1 out of 20 trials on FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good to very good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (89% in 4 trials on FLAGLE and 93% in 4 trials on FLMI1) was similar to LIBRAX (91% on FLAGLE and 96% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (79% in 4 trials on FLAGLE and 85% in 4 trials on FLMI1) was inferior to LIBRAX (91% on FLAGLE and 96% on FLMI1). However, no significant difference was noted in 4 out of 8 assessments on FLAGLE and FLMI1.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a high control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% in 2 trials on FLAGLE and 95% in 6 trials on FLMI1) was similar to LIBRAX (100% on FLAGLE and 94% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (98% in 2 trials on FLAGLE and 91% in 6 trials on FLMI1) was similar to LIBRAX (100% on FLAGLE and 94% on FLMI1). No significant difference was noted in 7 out of 8 assessments on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 31 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in barley against RHYNSE.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of RHYNSE.

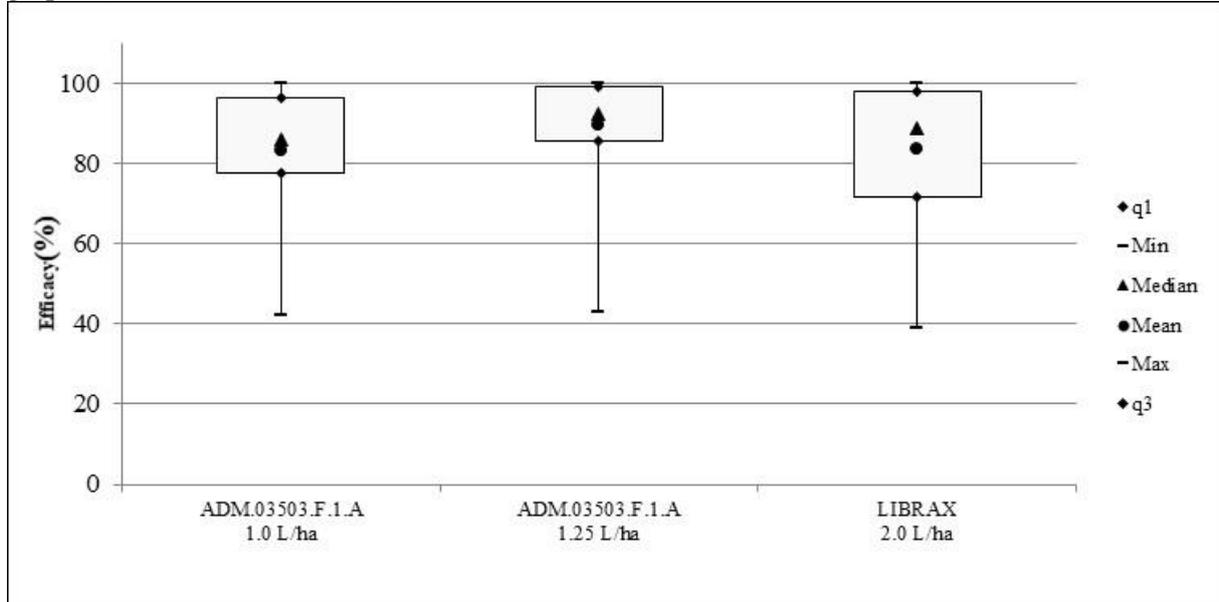
The efficacy of ADM.03503.F.1.A at 1.25 L/ha (91% in 22 trials on FLAGLE and 89% in 30 trials on FLMI1) was similar or even superior to LIBRAX (84% on FLAGLE and 83% on FLMI1). This difference was significant in 3 out of 22 trials on FLAGLE and in 2 out of 29 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (85% in 22 trials on FLAGLE and 82% in 30 trials on FLMI1) was similar to LIBRAX (84% on FLAGLE and 83% on FLMI1). No significant difference was at least noted in 49 out of 51 assessments on FLAGLE and FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-26). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-26 Efficacy of ADM.03503.F.1.A - Barley - RHYNSE - Last valid assessment - Box Plot graphic (31 trials - 52 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of RHYNSE in barley crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a good control of leaf blotch of barley similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control leaf blotch according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of leaf blotch of barley (*Rhynchosporium secalis* - RHYNSE).

Even if only 4 valid trials are available in the Northeast EPPO climatic zone, the results of trials border countries can be considered as supportive data. Therefore, 7 trials (4 trials in Germany and 3 trials in Slovakia) support also the request of registration of ADM.03503.F.1.A in Poland.

3.2.3.3.2 Net blotch of barley (*Pyrenophora teres* - PYRNTE)

A total of **35 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PYRNTE. These trials were carried out **from 2019 to 2021** in the Maritime (3 trials in Czech Republic, 7 trials in Germany, 3 trials in the United Kingdom and 6 trials in France), the Northeast (3 trials in Poland) and the Southeast (1 trial in Hungary, 6 trials in Romania and 6 trials in Slovakia) EPPO climatic zones in winter barley (31 trials) and spring barley (4 trials).

Table 3.2-72 summarises the efficacy of ADM.03503.F.1.A against PYRNTE.

Table 3.2-72: Efficacy of ADM.03503.F.1.A - Barley - PYRNTE - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
PYRNTE Disease severity	Last valid assessment after application A	Maritime	FLAGLE	2	7.5	5.0	10.0	75.0	60.0	90.0	15.0	82.5	70.0	95.0	12.5	75.0	55.0	95.0	20.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMII	4	21.3	4.5	46.3	76.2	41.2	100.0	22.8	82.8	61.2	100.0	13.9	71.8	57.7	100.0	16.5	0> ; 4= ; 0<	0> ; 4= ; 0<	
		Northeast	FLAGLE	1	5.0	-	-	65.4	-	-	-	73.3	-	-	-	60.0	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMII	2	7.4	6.3	8.5	71.9	52.5	91.3	19.4	78.9	60.2	97.5	18.6	69.1	47.5	90.6	21.6	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	1	5.9	-	-	84.0	-	-	-	86.1	-	-	-	84.8	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMII	1	11.4	-	-	84.9	-	-	-	87.5	-	-	-	85.8	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	All EPPO climatic zones	FLAGLE	4	6.5	5.0	10.0	74.9	60.0	90.0	12.5	81.1	70.0	95.0	10.0	73.7	55.0	95.0	16.7	0> ; 4= ; 0<	0> ; 4= ; 0<		
		FLMII	7	15.9	4.5	46.3	76.2	41.2	100.0	20.5	82.3	60.2	100.0	14.8	73.0	47.5	100.0	17.8	0> ; 7= ; 0<	0> ; 7= ; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	11	16.5	4.5	48.2	80.0	37.5	96.9	17.3	84.6	45.8	100.0	15.9	81.4	51.4	100.0	16.5	0> ; 11= ; 0<	0> ; 11= ; 0<	
			FLMII	16	27.1	4.8	99.0	84.6	60.0	100.0	12.9	90.4	72.5	100.0	8.7	78.7	28.7	100.0	20.8	1> ; 14= ; 1<	5> ; 11= ; 0<	
		Northeast	FLAGLE	3	10.3	7.0	14.3	86.9	78.6	92.9	6.1	91.0	82.1	96.4	6.4	88.1	82.1	92.9	4.5	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	2	18.9	13.5	24.3	94.5	94.4	94.7	0.2	96.9	95.9	97.9	1.0	94.2	92.6	95.9	1.7	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	5	8.9	4.7	16.4	87.4	70.9	100.0	9.5	93.6	84.9	100.0	5.2	92.1	81.7	100.0	6.2	0> ; 4= ; 1<	0> ; 5= ; 0<	
			FLMII	12	11.6	6.4	35.3	87.7	69.5	100.0	9.5	93.7	83.0	100.0	5.1	91.1	80.1	100.0	6.0	0> ; 10= ; 2<	1> ; 11= ; 0<	
		All EPPO climatic zones	FLAGLE	19	13.5	4.5	48.2	83.1	37.5	100.0	14.7	88.0	45.8	100.0	13.2	85.3	51.4	100.0	13.9	0> ; 18= ; 1<	0> ; 19= ; 0<	
			FLMII	30	20.3	4.8	99.0	86.5	60.0	100.0	11.5	92.2	72.5	100.0	7.4	84.7	28.7	100.0	16.9	1> ; 26= ; 3<	6> ; 24= ; 0<	
	PYRNTE Disease severity	Last valid assessment	Maritime	FLAGLE	12	16.0	4.5	48.2	78.4	37.5	96.9	17.5	83.4	45.8	100.0	15.7	79.2	51.4	100.0	17.4	0> ; 12= ; 0<	0> ; 12= ; 0<
				FLMII	18	27.8	4.8	99.0	81.4	41.2	100.0	15.9	88.4	61.2	100.0	10.6	77.1	28.7	100.0	20.1	1> ; 16= ; 1<	5> ; 13= ; 0<
Northeast			FLAGLE	2	10.6	7.0	14.3	91.1	89.3	92.9	1.8	95.5	94.5	96.4	1.0	91.1	89.3	92.9	1.8	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMII	2	18.9	13.5	24.3	94.5	94.4	94.7	0.2	96.9	95.9	97.9	1.0	94.2	92.6	95.9	1.7	0> ; 2= ; 0<	0> ; 2= ; 0<	
Southeast			FLAGLE	6	8.4	4.7	16.4	86.8	70.9	100.0	8.8	92.3	84.9	100.0	5.5	90.9	81.7	100.0	6.3	0> ; 5= ; 1<	0> ; 6= ; 0<	
			FLMII	13	11.6	6.4	35.3	87.5	69.5	100.0	9.1	93.3	83.0	100.0	5.1	90.7	80.1	100.0	5.9	0> ; 11= ; 2<	1> ; 12= ; 0<	
All EPPO climatic zones			FLAGLE	20	13.2	4.5	48.2	82.2	37.5	100.0	15.2	87.3	45.8	100.0	13.4	83.9	51.4	100.0	15.1	0> ; 19= ; 1<	0> ; 20= ; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX			
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Prothioconazole 125+90 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A	
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
FLMI1	33	20.9	4.8	99.0	84.6	41.2	100.0	13.6	90.8	61.2	100.0	8.9	83.5	28.7	100.0	16.8	1> ; 29= ; 3<	6> ; 27= ; 0<				

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Thirty-five trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 5% to 10% of the flag leaves (FLAGLE) area and from 5% to 46% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 5% to 48% of the flag leaves (FLAGLE) area and from 5% to 99% of the flag leaves minus 1 (FLMI1) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of PYRNTE. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (83% in 12 trials on FLAGLE and 88% in 18 trials on FLMI1) was superior to LIBRAX (79% on FLAGLE and 77% on FLMI1). This difference was significant in 5 out of 18 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of PYRNTE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (78% in 12 trials on FLAGLE and 81% in 18 trials on FLMI1) was similar to LIBRAX (79% on FLAGLE and 77% on FLMI1). No significant difference was noted in 29 out of 30 trials assessments on FLAGLE and FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a high control of PYRNTE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (96% in 2 trials on FLAGLE and 97% in 2 trials on FLMI1) was similar to LIBRAX (91% on FLAGLE and 94% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PYRNTE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (91% in 2 trials on FLAGLE and 95% in 2 trials on FLMI1) was similar to LIBRAX (91% on FLAGLE and 94% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PYRNTE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (92% in 6 trials on FLAGLE and 93% in 13 trials on FLMI1) was similar to LIBRAX (91% on FLAGLE and FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of PYRNTE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (87% in 6 trials on FLAGLE and 88% in 13 trials on FLMI1) was similar to LIBRAX (91% on FLAGLE and FLMI1). No significant difference was noted in 16 out of 19 assessments on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 35 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in barley against PYRNTE.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good to very good control of PYRNTE.

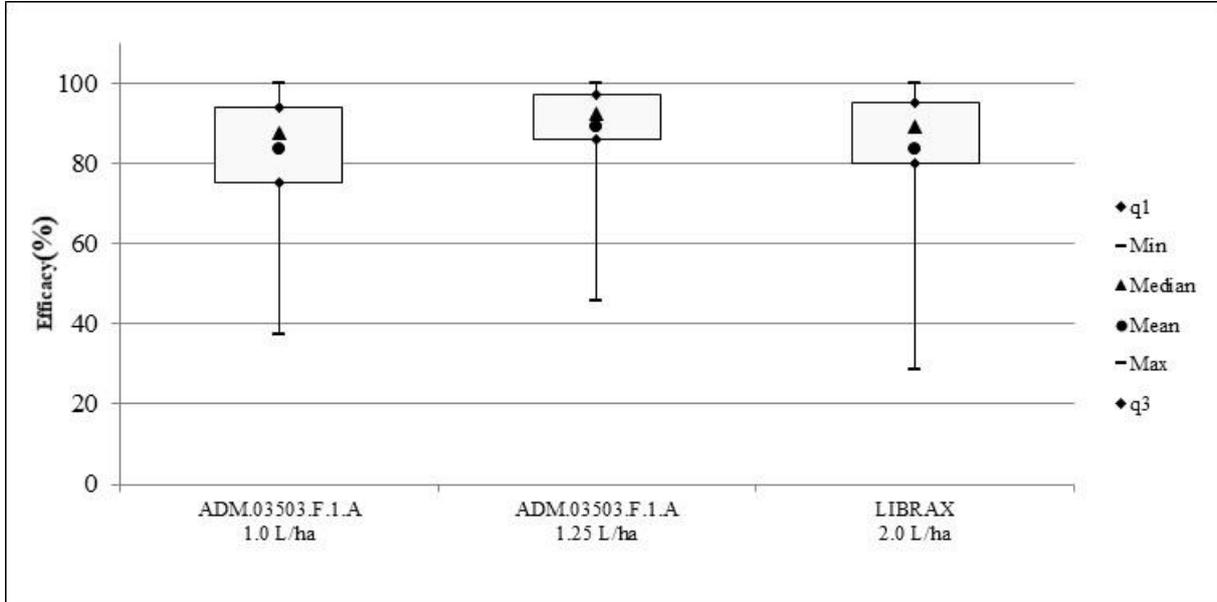
The efficacy of ADM.03503.F.1.A at 1.25 L/ha (87% in 20 trials on FLAGLE and 91% in 33 trials on FLMI1) was similar or even superior to LIBRAX (84% on FLAGLE and 84% on FLMI1). This difference was significant in 6 out of 33 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PYRNTE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (82% in 20 trials on FLAGLE and 85% in 33 trials on FLMI1) was similar to LIBRAX (84% on FLAGLE and 84% on FLMI1). No significant difference was at least noted in 49 out of 53 assessments on FLAGLE and FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-27). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-27 Efficacy of ADM.03503.F.1.A - Barley - PYRNTE - Last valid assessment - Box Plot graphic (35 trials - 54 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PYRNTE in barley crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a very good control of net blotch of barley similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control net blotch according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of net blotch of barley (*Pyrenophora teres* - PYRNTE).

Even if only 3 valid trials are available in the Northeast EPPO climatic zone, the results of trials border countries can be considered as supportive data. Therefore, 16 trials (3 trials in Czech Republic, 7 trials in Germany and 6 trials in Slovakia) support also the request of registration of ADM.03503.F.1.A in Poland.

3.2.3.3.3 Brown rust of barley (*Puccinia hordei* - PUCCHD)

A total of **27 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PUCCHD. These trials were carried out **from 2020 to 2021** in the Maritime (1 trial in Belgium, 3 trials Czech Republic, 7 trials in Germany, 2 trials in the United Kingdom and 4 trials in France), the Northeast (6 trials in Poland) and the Southeast (2 trials in Romania and 2 trials in Slovakia) EPPO climatic zones in winter barley (23 trials) and spring barley (4 trials).

Table 3.2-73 summarises the efficacy of ADM.03503.F.1.A against PUCCHD.

Table 3.2-73: Efficacy of ADM.03503.F.1.A - Barley - PUCCHD - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX		
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha						
								Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha						
								Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha	
PUCCHD Disease severity	Last valid assessment after application A	Maritime	FLAGLE	2	11.5	5.5	17.5	98.6	97.1	100.0	1.5	100.0	100.0	100.0	0.0	97.2	94.3	100.0	2.9	0>; 2=; 0<	0>; 2=; 0<	
			FLMI1	3	10.1	6.3	15.0	95.2	88.9	100.0	4.7	99.4	98.3	100.0	0.8	81.6	76.0	88.3	5.1	0>; 3=; 0<	1>; 2=; 0<	
		Northeast	FLMI1	2	12.8	5.3	20.3	93.8	92.6	95.0	1.2	98.5	96.9	100.0	1.6	96.4	95.0	97.8	1.4	0>; 2=; 0<	0>; 2=; 0<	
		All EPPO climatic zones	FLAGLE	2	11.5	5.5	17.5	98.6	97.1	100.0	1.5	100.0	100.0	100.0	0.0	97.2	94.3	100.0	2.9	0>; 2=; 0<	0>; 2=; 0<	
	FLMI1		5	11.2	5.3	20.3	94.6	88.9	100.0	3.8	99.0	96.9	100.0	1.3	87.5	76.0	97.8	8.3	0>; 5=; 0<	1>; 4=; 0<		
	Last valid assessment after application B	Maritime	FLAGLE	10	21.8	9.3	59.2	87.5	63.6	100.0	12.9	90.7	60.0	100.0	11.9	86.8	56.4	100.0	16.1	0>; 10=; 0<	0>; 10=; 0<	
			FLMI1	15	28.2	5.0	99.0	90.8	63.0	100.0	11.7	94.2	76.0	100.0	6.8	88.8	55.0	100.0	13.7	0>; 15=; 0<	2>; 13=; 0<	
		Northeast	FLAGLE	4	12.5	5.5	27.2	84.3	79.0	92.3	5.0	91.3	81.7	100.0	6.5	91.5	81.7	96.8	5.9	0>; 3=; 1<	0>; 4=; 0<	
			FLMI1	2	9.0	7.0	11.0	88.0	83.7	92.3	4.3	91.5	86.2	96.9	5.3	87.2	81.5	92.9	5.7	0>; 2=; 0<	0>; 2=; 0<	
		Southeast	FLAGLE	1	15.4	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	-	0>; 1=; 0<	0>; 1=; 0<
			FLMI1	4	8.1	5.0	13.5	92.7	76.8	100.0	9.5	97.6	91.9	100.0	3.4	95.5	89.8	100.0	4.6	0>; 4=; 0<	0>; 4=; 0<	
		All EPPO climatic zones	FLAGLE	15	18.9	5.5	59.2	87.5	63.6	100.0	11.4	91.5	60.0	100.0	10.5	89.0	56.4	100.0	14.0	0>; 14=; 1<	0>; 15=; 0<	
			FLMI1	21	22.6	5.0	99.0	90.9	63.0	100.0	10.9	94.6	76.0	100.0	6.3	89.9	55.0	100.0	12.2	0>; 21=; 0<	2>; 19=; 0<	
	PUCCHD Disease severity	Last valid assessment	Maritime	FLAGLE	10	22.4	9.3	59.2	87.2	63.6	99.7	12.6	90.7	60.0	100.0	11.9	86.3	56.4	100.0	15.8	0>; 10=; 0<	0>; 10=; 0<
FLMI1				15	28.8	5.0	99.0	90.9	63.0	100.0	11.8	94.7	76.0	100.0	6.8	88.3	55.0	100.0	13.6	0>; 15=; 0<	2>; 13=; 0<	
Northeast			FLAGLE	4	12.5	5.5	27.2	84.3	79.0	92.3	5.0	91.3	81.7	100.0	6.5	91.5	81.7	96.8	5.9	0>; 3=; 1<	0>; 4=; 0<	
			FLMI1	4	10.9	5.3	20.3	90.9	83.7	95.0	4.3	95.0	86.2	100.0	5.2	91.8	81.5	97.8	6.2	0>; 4=; 0<	0>; 4=; 0<	
Southeast			FLAGLE	1	15.4	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	-	0>; 1=; 0<	0>; 1=; 0<
			FLMI1	4	8.1	5.0	13.5	92.7	76.8	100.0	9.5	97.6	91.9	100.0	3.4	95.5	89.8	100.0	4.6	0>; 4=; 0<	0>; 4=; 0<	

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ > ; = ; < to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
		All EPPO climatic zones	FLAGLE	15	19.3	5.5	59.2	87.3	63.6	100.0	11.2	91.5	60.0	100.0	10.5	88.6	56.4	100.0	13.8	0> ; 14= ; 1<	0> ; 15= ; 0<
			FLMII	23	22.1	5.0	99.0	91.2	63.0	100.0	10.5	95.2	76.0	100.0	6.2	90.1	55.0	100.0	11.7	0> ; 23= ; 0<	2> ; 21= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Twenty-seven trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 5% to 18% of the flag leaves (FLAGLE) area and from 5% to 20% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 6% to 59% of the flag leaves (FLAGLE) area and from 5% to 99% of the flag leaves minus 1 (FLMI1) area. In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCCHD. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (91% in 10 trials on FLAGLE and 95% in 15 trials on FLMI1) was superior to LIBRAX (86% on FLAGLE and 88% on FLMI1). This difference was significant in 2 out of 15 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good to very good control of PUCCHD.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (87% in 10 trials on FLAGLE and 91% in 15 trials on FLMI1) was similar to LIBRAX (86% on FLAGLE and 88% on FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCCHD. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (91% in 4 trials on FLAGLE and 95% in 4 trials on FLMI1) was similar to LIBRAX (92% on FLAGLE and FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good to very good control of PUCCHD.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (84% in 4 trials on FLAGLE and 91% in 4 trials on FLMI1) was slightly inferior to LIBRAX (92% on FLAGLE and FLMI1). However, no significant difference was noted in 7 out of 8 assessments on FLAGLE and FLMI1.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a high control of PUCCHD.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% in 1 trial on FLAGLE and 98% in 4 trials on FLMI1) was similar to LIBRAX (100% on FLAGLE and 96% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of PUCCHD.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (100% in 1 trial on FLAGLE and 93% in 4 trials on FLMI1) was similar to LIBRAX (100% on FLAGLE and 96% on FLMI1). No significant difference was noted in all assessments on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 27 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in barley against PUCCHD.

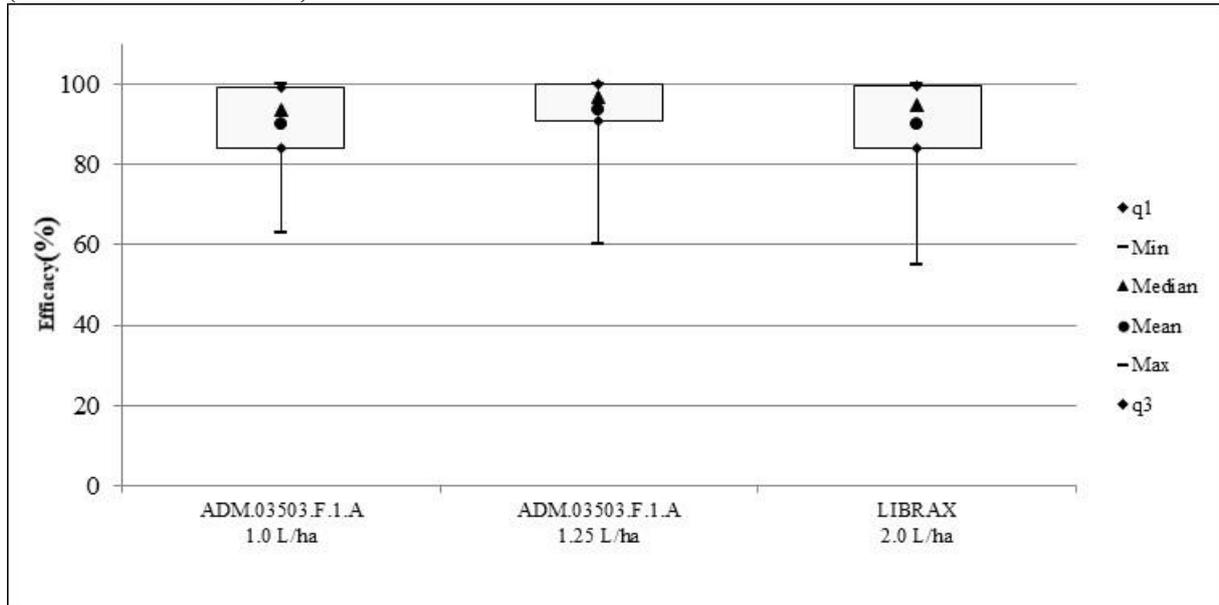
At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PUCCHD. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (92% in 15 trials on FLAGLE and 95% in 23 trials on FLMI1) was similar to LIBRAX (89% on FLAGLE and 90% on FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good to very good control of PUCCHD.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (87% in 15 trials on FLAGLE and 91% in 23 trials on FLMI1) was similar to LIBRAX (89% on FLAGLE and 90% on FLMI1). No significant difference was at least noted in 27 out of 28 assessments on FLAGLE and FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-28). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-28 Efficacy of ADM.03503.F.1.A - Barley - PUCCHD - Last valid assessment - Box Plot graphic (27 trials - 39 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PUCCHD in barley crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a very good control of brown rust of barley similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control brown rust according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of yellow rust of barley (*Puccinia hordei* - PUCCHD).

Even if only 6 valid trials are available in the Northeast EPPO climatic zone, the results of trials border countries can be considered as supportive data. Therefore, 12 trials (3 trials in Czech Republic, 7 trials in Germany and 2 trials in Slovakia) support also the request of registration of ADM.03503.F.1.A in Poland.

3.2.3.3.4 Ramularia leaf spot of barley (*Ramularia collo-cygni* - RAMUCC)

A total of **20 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of RAMUCC. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Czech Republic, 10 trials in Germany, 3 trials in Ireland, 1 trial in the United Kingdom and 1 trial in France), the Northeast (1 trial in Poland) and the Southeast (3 trials in Slovakia) EPPO climatic zones in winter barley (19 trials) and spring barley (1 trial).

Table 3.2-74 summarises the efficacy of ADM.03503.F.1.A against RAMUCC.

Table 3.2-74: Efficacy of ADM.03503.F.1.A - Barley - RAMUCC - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
RAMUCC Disease severity	Last valid assessment after application A	Maritime	FLAGLE	3	27.6	10.3	50.0	73.3	60.4	86.0	10.4	83.7	78.2	91.0	5.4	69.0	49.8	91.0	17.0	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMII	4	36.4	11.3	69.7	68.0	44.4	85.0	14.8	80.3	66.7	90.0	9.5	66.6	42.6	90.0	16.8	0> ; 3= ; 1<	2> ; 2= ; 0<	
		Northeast	FLAGLE	1	5.0	-	-	75.0	-	-	-	95.0	-	-	-	95.0	-	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<
			FLMII	1	5.0	-	-	70.0	-	-	-	85.0	-	-	-	90.0	-	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		All EPPO climatic zones	FLAGLE	4	22.0	5.0	50.0	73.7	60.4	86.0	9.1	86.5	78.2	95.0	6.8	75.5	49.8	95.0	18.5	0> ; 3= ; 1<	0> ; 4= ; 0<	
			FLMII	5	30.1	5.0	69.7	68.4	44.4	85.0	13.2	81.2	66.7	90.0	8.7	71.3	42.6	90.0	17.7	0> ; 4= ; 1<	2> ; 3= ; 0<	
		Last valid assessment after application B	Maritime	FLAGLE	10	44.0	4.9	100.0	78.4	62.2	97.8	11.6	86.8	71.7	98.9	9.1	67.6	44.0	97.1	19.6	3> ; 6= ; 1<	4> ; 6= ; 0<
				FLMII	12	52.4	5.8	100.0	77.2	57.3	99.7	11.1	85.3	70.2	99.7	9.1	72.2	48.3	90.2	14.7	3> ; 9= ; 0<	4> ; 8= ; 0<
	Northeast		FLAGLE	1	7.8	-	-	77.2	-	-	-	87.1	-	-	-	93.3	-	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<
			FLMII	1	8.3	-	-	75.7	-	-	-	85.1	-	-	-	90.6	-	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<
	Southeast		FLAGLE	3	75.0	55.3	86.9	97.2	92.8	100.0	3.2	98.5	96.0	100.0	1.8	94.6	84.4	100.0	7.2	1> ; 2= ; 0<	1> ; 2= ; 0<	
			FLMII	3	89.2	71.9	98.1	95.6	92.1	98.5	2.7	97.1	94.9	99.7	2.0	93.8	85.2	98.5	6.1	1> ; 2= ; 0<	1> ; 2= ; 0<	
	All EPPO climatic zones		FLAGLE	14	48.1	4.9	100.0	82.4	62.2	100.0	12.6	89.3	71.7	100.0	9.1	75.2	44.0	100.0	20.8	4> ; 8= ; 2<	5> ; 9= ; 0<	
			FLMII	16	56.5	5.8	100.0	80.6	57.3	99.7	12.1	87.5	70.2	99.7	9.2	77.4	48.3	98.5	15.9	4> ; 11= ; 1<	5> ; 11= ; 0<	
	RAMUCC Disease severity	Last valid assessment	Maritime	FLAGLE	13	40.2	4.9	100.0	77.2	60.4	97.8	11.5	86.1	71.7	98.9	8.5	67.9	44.0	97.1	19.1	3> ; 9= ; 1<	4> ; 9= ; 0<
				FLMII	15	50.8	5.8	100.0	76.9	57.3	99.7	10.4	85.2	70.2	99.7	8.6	71.1	42.6	90.2	15.9	3> ; 12= ; 0<	6> ; 9= ; 0<
Northeast			FLAGLE	1	7.8	-	-	77.2	-	-	-	87.1	-	-	-	93.3	-	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<
			FLMII	1	8.3	-	-	75.7	-	-	-	85.1	-	-	-	90.6	-	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<
Southeast			FLAGLE	3	75.0	55.3	86.9	97.2	92.8	100.0	3.2	98.5	96.0	100.0	1.8	94.6	84.4	100.0	7.2	1> ; 2= ; 0<	1> ; 2= ; 0<	
			FLMII	3	89.2	71.9	98.1	95.6	92.1	98.5	2.7	97.1	94.9	99.7	2.0	93.8	85.2	98.5	6.1	1> ; 2= ; 0<	1> ; 2= ; 0<	
All EPPO climatic zones			FLAGLE	17	44.4	4.9	100.0	80.8	60.4	100.0	12.7	88.3	71.7	100.0	8.8	74.1	44.0	100.0	20.3	4> ; 11= ; 2<	5> ; 12= ; 0<	
			FLMII	19	54.7	5.8	100.0	79.8	57.3	99.7	11.5	87.1	70.2	99.7	8.8	75.7	42.6	98.5	16.9	4> ; 14= ; 1<	7> ; 12= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Twenty trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 5% to 50% of the flag leaves (FLAGLE) area and from 5% to 70% of the flag leaves minus 1 (FLMI1) area. After the second application, the disease in the untreated plot attacked from 5% to 100% of the flag leaves (FLAGLE) area and from 6% to 100% of the flag leaves minus 1 (FLMI1) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of RAMUCC.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (86% in 13 trials on FLAGLE and 85% in 15 trials on FLMI1) was superior to LIBRAX (68% on FLAGLE and 71% on FLMI1). This difference was significant in 4 out of 13 trials on FLAGLE and in 6 out of 15 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of RAMUCC.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (77% in 13 trials on FLAGLE and 77% in 15 trials on FLMI1) was superior to LIBRAX (68% on FLAGLE and 71% on FLMI1). This difference was significant in 3 out of 13 trials on FLAGLE and in 3 out of 15 trials on FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of RAMUCC.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (87% in 1 trial on FLAGLE and 85% in 1 trial on FLMI1) was slightly inferior to LIBRAX (93% on FLAGLE and 91% on FLMI1). However, no significant difference was noted in this trial.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of RAMUCC.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (77% in 1 trial on FLAGLE and 76% in 1 trial on FLMI1) was inferior to LIBRAX (93% on FLAGLE and 91% on FLMI1).

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a high control of RAMUCC.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (99% in 3 trials on FLAGLE and 97% in 3 trials on FLMI1) was similar or even superior to LIBRAX (95% on FLAGLE and 94% on FLMI1). This difference was significant in 1 out of 3 trials on FLAGLE and FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a high control of RAMUCC.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (97% in 3 trials on FLAGLE and 96% in 3 trials on FLMI1) was similar or even superior to LIBRAX (95% on FLAGLE and 94% on FLMI1). This difference was significant in 1 out of 3 trials on FLAGLE and FLMI1.

Central registration zone

Finally, a total of 20 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in barley against RAMUCC.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of RAMUCC.

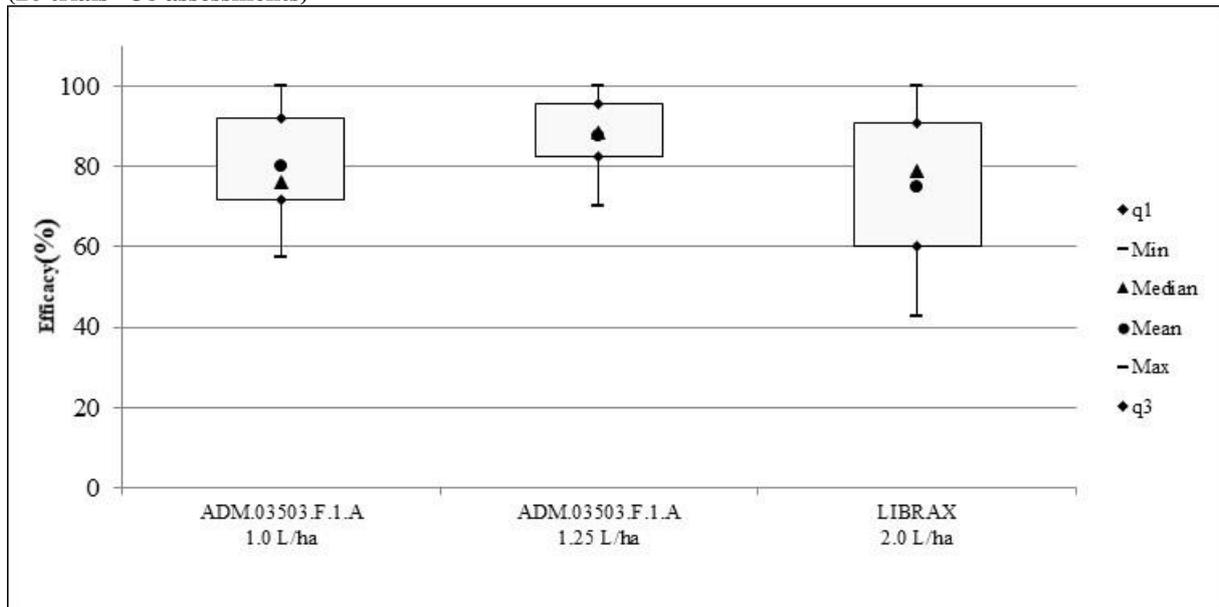
The efficacy of ADM.03503.F.1.A at 1.25 L/ha (88% in 17 trials on FLAGLE and 87% in 19 trials on FLMI1) was superior to LIBRAX (74% on FLAGLE and 76% on FLMI1). This difference was significant in 5 out of 17 trials on FLAGLE and in 7 out of 19 trials on FLMI1.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of RAMUCC.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (81% in 17 trials on FLAGLE and 80% in 19 trials on FLMI1) was slightly superior to LIBRAX (74% on FLAGLE and 76% on FLMI1). This difference was significant in 4 out of 17 trials on FLAGLE and in 4 out of 19 trials on FLMI1.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-29). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-29 Efficacy of ADM.03503.F.1.A - Barley - RAMUCC - Last valid assessment - Box Plot graphic (20 trials - 36 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of RAMUCC in barley crops superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha also showed a good control of *Ramularia* leaf spot of barley similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control *Ramularia* leaf spot according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of *Ramularia* leaf spot of barley (*Ramularia collo-cygni* - RAMUCC).

Even if only 31 valid trials* are available in the Northeast EPPO climatic zone, the results of trials border countries can be considered as supportive data. Therefore, 14 trials (1 trial in Czech Republic, 10 trials in Germany and 3 trials in Slovakia) support also the request of registration of ADM.03503.F.1.A in Poland.

*Comments of zRMS: Only a single trial in control of RAMUCC is available in the NE EPPO zone.

3.2.3.3.5 Powdery mildew of barley (*Blumeria graminis*- ERYSGH)

A total of **26 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of ERYSGH. These trials were carried out **from 2020 to 2021** in the Maritime (4 trials in Germany, 5 trials in the United Kingdom and 3 trials in France), the Northeast (8 trials in Poland) and the Southeast (1 trial in Hungary, 2 trials in Romania and 3 trials in Slovakia) EPPO climatic zones in winter barley (22 trials) and spring barley (4 trials).

Table 3.2-75 summarises the efficacy of ADM.03503.F.1.A against ERYSGH.

Table 3.2-75: Efficacy of ADM.03503.F.1.A - Barley - ERYSGH - Disease severity on leaves

Target Parameters	Assessment timing	EPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
ERYSGH Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	6.5	-	-	96.2	-	-	-	100.0	-	-	-	100.0	-	-	-	0>; 1=; 0<	0>; 1=; 0<
			FLMI2	6	9.9	4.8	23.8	75.5	54.6	100.0	15.7	83.3	57.9	100.0	16.4	82.5	63.2	100.0	14.4	0>; 5=; 1<	0>; 6=; 0<
		Northeast	FLAGLE	1	5.0	-	-	95.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0>; 1=; 0<	0>; 1=; 0<
			FLMI1	3	9.0	5.0	13.5	84.9	73.8	92.8	8.1	91.8	82.9	97.5	6.3	92.7	90.4	96.9	3.0	0>; 2=; 1<	0>; 3=; 0<
			FLMI2	8	10.8	5.2	19.5	78.0	51.4	92.3	12.7	87.8	65.0	100.0	10.1	86.3	67.5	93.5	7.4	0>; 5=; 3<	1>; 7=; 0<
		Southeast	FLMI2	1	5.4	-	-	96.3	-	-	-	98.6	-	-	-	90.7	-	-	-	0>; 1=; 0<	0>; 1=; 0<
		All EPO climatic zones	FLAGLE	1	5.0	-	-	95.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0>; 1=; 0<	0>; 1=; 0<
			FLMI1	4	8.4	5.0	13.5	87.7	73.8	96.2	8.6	93.8	82.9	100.0	6.6	94.6	90.4	100.0	4.1	0>; 3=; 1<	0>; 4=; 0<
			FLMI2	15	10.1	4.8	23.8	78.2	51.4	100.0	14.4	86.7	57.9	100.0	13.3	85.1	63.2	100.0	10.9	0>; 11=; 4<	1>; 14=; 0<
		Last valid assessment after application B	Maritime	FLAGLE	3	23.8	10.8	36.9	94.7	83.9	100.0	7.6	96.9	90.8	100.0	4.4	94.3	82.8	100.0	8.1	0>; 3=; 0<
	FLMI1			8	25.8	4.7	73.8	91.2	60.8	100.0	12.5	93.9	73.0	100.0	8.7	94.8	83.4	100.0	6.5	0>; 7=; 1<	0>; 7=; 1<
	FLMI2			7	21.7	5.0	63.6	92.2	70.3	100.0	11.0	94.0	73.4	100.0	9.5	90.5	73.2	100.0	10.2	1>; 6=; 0<	1>; 6=; 0<
	Northeast		FLAGLE	3	7.2	5.3	9.7	86.7	80.0	95.8	6.7	96.9	90.7	100.0	4.4	96.2	88.6	100.0	5.4	0>; 2=; 1<	0>; 3=; 0<
			FLMI1	7	11.6	5.5	16.0	85.6	76.5	100.0	8.6	93.6	85.7	100.0	5.3	92.6	84.4	100.0	5.7	0>; 4=; 3<	1>; 6=; 0<
			FLMI2	5	18.0	13.8	26.5	86.3	82.9	93.8	3.9	94.6	88.7	100.0	4.0	93.2	87.9	100.0	4.2	0>; 3=; 2<	0>; 5=; 0<
	Southeast		FLMI1	5	7.0	5.4	11.3	92.0	78.0	100.0	8.1	95.2	85.3	100.0	5.7	91.2	76.5	100.0	8.1	0>; 5=; 0<	0>; 5=; 0<
			FLMI2	5	11.3	6.5	15.9	89.8	71.9	100.0	9.6	93.4	81.0	100.0	6.6	84.3	71.3	94.4	8.8	2>; 3=; 0<	2>; 3=; 0<
	All EPO climatic zones		FLAGLE	6	15.5	5.3	36.9	90.7	80.0	100.0	8.2	96.9	90.7	100.0	4.4	95.2	82.8	100.0	7.0	0>; 5=; 1<	0>; 6=; 0<
			FLMI1	20	16.1	4.7	73.8	89.4	60.8	100.0	10.6	94.1	73.0	100.0	6.9	93.1	76.5	100.0	6.9	0>; 16=; 4<	1>; 18=; 1<
		FLMI2	17	17.5	5.0	63.6	89.8	70.3	100.0	9.4	94.0	73.4	100.0	7.4	89.5	71.3	100.0	9.1	3>; 12=; 2<	3>; 14=; 0<	

Target Parameters	Assessment timing	EPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX		
					Untreated			ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha			Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha			ADM.03503.F.1.A		
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min
ERYSGH Disease severity	Last valid assessment	Maritime	FLAGLE	3	23.8	10.8	36.9	94.7	83.9	100.0	7.6	96.9	90.8	100.0	4.4	94.3	82.8	100.0	8.1	0> ; 3= ; 0<	0> ; 3= ; 0<
			FLMI1	8	25.8	4.7	73.8	91.2	60.8	100.0	12.5	93.9	73.0	100.0	8.7	94.8	83.4	100.0	6.5	0> ; 7= ; 1<	0> ; 7= ; 1<
			FLMI2	11	16.3	4.8	63.6	85.8	57.9	100.0	13.7	89.9	57.9	100.0	13.8	87.1	63.2	100.0	12.6	0> ; 9= ; 2<	1> ; 10= ; 0<
		Northeast	FLAGLE	3	7.2	5.3	9.7	86.7	80.0	95.8	6.7	96.9	90.7	100.0	4.4	96.2	88.6	100.0	5.4	0> ; 2= ; 1<	0> ; 3= ; 0<
			FLMI1	7	11.6	5.5	16.0	85.6	76.5	100.0	8.6	93.6	85.7	100.0	5.3	92.6	84.4	100.0	5.7	0> ; 4= ; 3<	1> ; 6= ; 0<
			FLMI2	6	16.3	8.3	26.5	85.5	81.6	93.8	4.0	93.4	87.9	100.0	4.4	92.3	87.9	100.0	4.4	0> ; 4= ; 2<	0> ; 6= ; 0<
		Southeast	FLMI1	5	7.0	5.4	11.3	92.0	78.0	100.0	8.1	95.2	85.3	100.0	5.7	91.2	76.5	100.0	8.1	0> ; 5= ; 0<	0> ; 5= ; 0<
			FLMI2	5	11.3	6.5	15.9	89.8	71.9	100.0	9.6	93.4	81.0	100.0	6.6	84.3	71.3	94.4	8.8	2> ; 3= ; 0<	2> ; 3= ; 0<
		All EPO climatic zones	FLAGLE	6	15.5	5.3	36.9	90.7	80.0	100.0	8.2	96.9	90.7	100.0	4.4	95.2	82.8	100.0	7.0	0> ; 5= ; 1<	0> ; 6= ; 0<
			FLMI1	20	16.1	4.7	73.8	89.4	60.8	100.0	10.6	94.1	73.0	100.0	6.9	93.1	76.5	100.0	6.9	0 ; 16= ; 4<	1> ; 18= ; 1<
			FLMI2	22	15.1	4.8	63.6	86.6	57.9	100.0	11.1	91.6	57.9	100.0	10.6	87.9	63.2	100.0	10.5	2> ; 16= ; 4<	3> ; 19= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Twenty-six trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 5% of the flag leaves (FLAGLE) area, from 5% to 14% of the flag leaves minus 1 (FLMI1) area and from 5% to 24% of the flag leaves minus 2 (FLMI2). After the second application, the disease in the untreated plot attacked from 5% to 37% of the flag leaves (FLAGLE) area, from 5% to 74% of the flag leaves minus 1 (FLMI1) area and from 5% to 64% of the flag leaves minus 2 (FLMI2).

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of ERYSGH. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (97% in 3 trials on FLAGLE, 94% in 8 trials on FLMI1, and 90% in 11 trials on FLMI2) was similar to LIBRAX (94% on FLAGLE, 95% on FLMI1 and 87% on FLMI1). No significant difference was at least noted in 21 out of 22 assessments

ADM.03503.F.1.A at 1.00 L/ha showed a good to very good control of ERYSGH.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (95% in 3 trials on FLAGLE, 91% in 8 trials on FLMI1, and 86% in 11 trials on FLMI2) was similar to LIBRAX (94% on FLAGLE, 95% on FLMI1 and 87% on FLMI1). No significant difference was at least noted in 21 out of 22 assessments.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of ERYSGH. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (97% in 3 trials on FLAGLE, 94% in 7 trials on FLMI1, and 90% in 6 trials on FLMI2) was similar to LIBRAX (96% on FLAGLE, 93% on FLMI1 and 92% on FLMI1). No significant difference was at least noted in all assessments.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of ERYSGH.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (87% in 3 trials on FLAGLE, 86% in 7 trials on FLMI1, and 86% in 6 trials on FLMI2) was inferior to LIBRAX (96% on FLAGLE, 93% on FLMI1 and 92% on FLMI1). However, no significant difference was at least noted in 10 out of 16 assessments.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of ERYSGH. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (95% in 5 trials on FLMI1, and 93% in 5 trials on FLMI2) was superior to LIBRAX (91% on FLMI1 and 84% on FLMI1). This difference was significant in 2 out of 5 trials on FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of ERYSGH.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (92% in 5 trials on FLMI1, and 90% in 5 trials on FLMI2) was similar or even superior to LIBRAX (91% on FLMI1 and 84% on FLMI1). This difference was significant in 2 out of 5 trials on FLMI2.

Central registration zone

Finally, a total of 26 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in barley against ERYSGH.

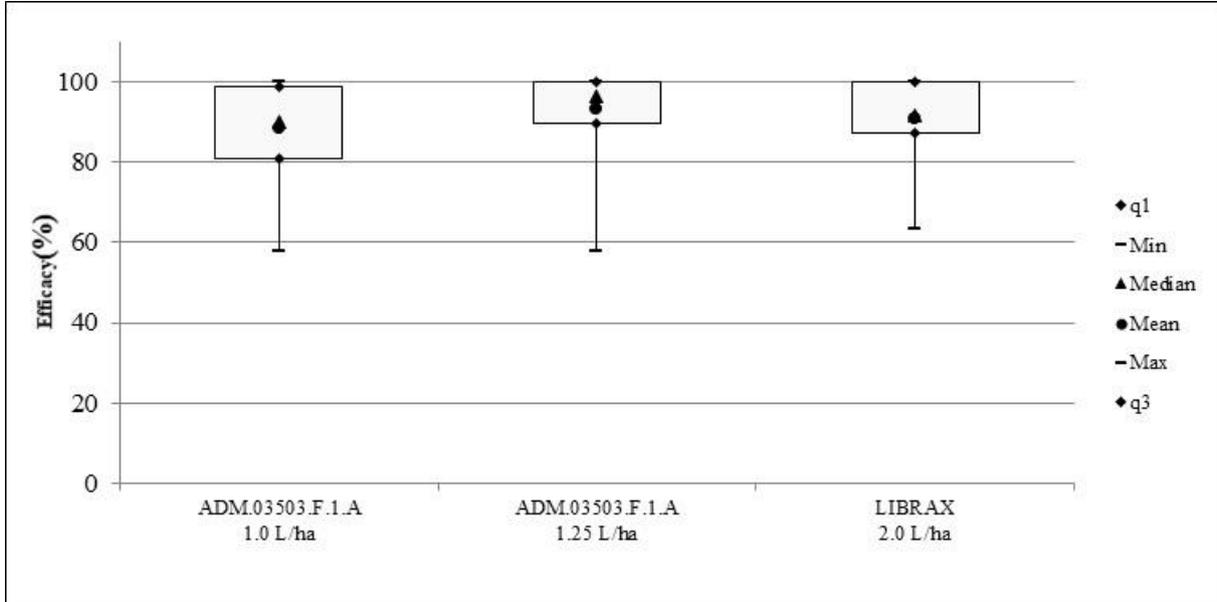
At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of ERYSGH. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (97% in 6 trials on FLAGLE, 94% in 20 trials on FLMI1, and 92% in 22 trials on FLMI2) was similar or even superior to LIBRAX (95% on FLAGLE, 93% on FLMI1 and 88% on FLMI1). This difference was significant in 1 out of 20 trials on FLMI1 and in 3 out of 22 trials on FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of ERYSGH.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (91% in 6 trials on FLAGLE, 89% in 20 trials on FLMI1, and 87% in 22 trials on FLMI2) was similar to LIBRAX (95% on FLAGLE, 93% on FLMI1 and 88% on FLMI1). No significant difference was at least noted in 39 out of 48 trials on FLAGLE, FLMI1 and FLMI2.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE, FLMI1 and FLMI2) (Figure 3.2-30). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-30 Efficacy of ADM.03503.F.1.A - Barley - ERYSGH - Last valid assessment - Box Plot graphic (26 trials - 54 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of ERYSGH in barley crops superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha also showed a good control of powdery mildew of barley similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control powdery mildew according to the disease pressure.

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of powdery mildew of barley (*Blumeria graminis* - ERYSGH).

3.2.3.3.6 Control of disease complex - Green leaf area

Attacks by pathogens reduce green leaf area and thus grain yield. Thus, the green area is a good indicator of the level of efficacy of one product. Therefore, a total of **75 valid efficacy trials** were carried out to confirm the effect of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha on the green leaf area. These trials were carried out **from 2019 to 2021** in the Maritime (4 trials in Czech Republic, 12 trials in Germany, 1 trial in Ireland, 8 trials in the United Kingdom and 10 trials in France), the Northeast (15 trials in Poland) and the Southeast (2 trials in Hungary, 13 trials in Romania and 10 trials in Slovakia) EPPO climatic zones in winter barley.

Table 3.2-76 summarises the effect on the increase of the green leaf area after an application of ADM.03503.F.1.A in barley crops.

Table 3.2-76: Effect of ADM.03503.F.1.A on the green leaf area - Barley - Increase of green leaf area (%)

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	Increase of green leaf area (%)															
					Untreated Green leaf area (%)				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha			
									Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Metconazole			
									75+150 g a.s./ha				93.75+187.5 g a.s./ha				125+90 g a.s./ha			
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.			
All diseases Green leaf area (%)	Last valid assessment	Maritime	Leaves	35	30.0	0.0	86.8	46.7	11.1	100.0	26.4	52.2	14.5	100.0	25.9	44.4	11.8	100.0	23.0	
		Northeast	Leaves	15	30.0	5.0	71.3	22.4	8.4	53.9	13.6	28.4	13.7	59.2	13.6	26.9	10.5	69.3	15.3	
		Southeast	Leaves	25	32.8	0.0	58.3	46.2	18.8	86.8	18.2	53.3	17.7	88.0	18.8	49.7	18.8	88.1	18.6	
		All EPPO climatic zones	Leaves	75	30.9	0.0	86.8	41.7	8.4	100.0	23.7	47.8	13.7	100.0	23.7	42.7	10.5	100.0	21.8	

75 trials are available to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The green leaf area in the untreated plot covered from 0% to 87%.

Maritime EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 52% of green leaf area (in 35 trials), superior to LIBRAX (44%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 47% of green leaf area (in 35 trials), similar to LIBRAX (44%).

Northeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 28% of green leaf area (in 15 trials), similar to LIBRAX (27%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 22% of green leaf area (in 15 trials), slightly inferior to LIBRAX (27%).

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 53% of green leaf area (in 25 trials), similar to LIBRAX (50%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 46% of green leaf area (in 25 trials), similar to LIBRAX (50%).

Central registration zone

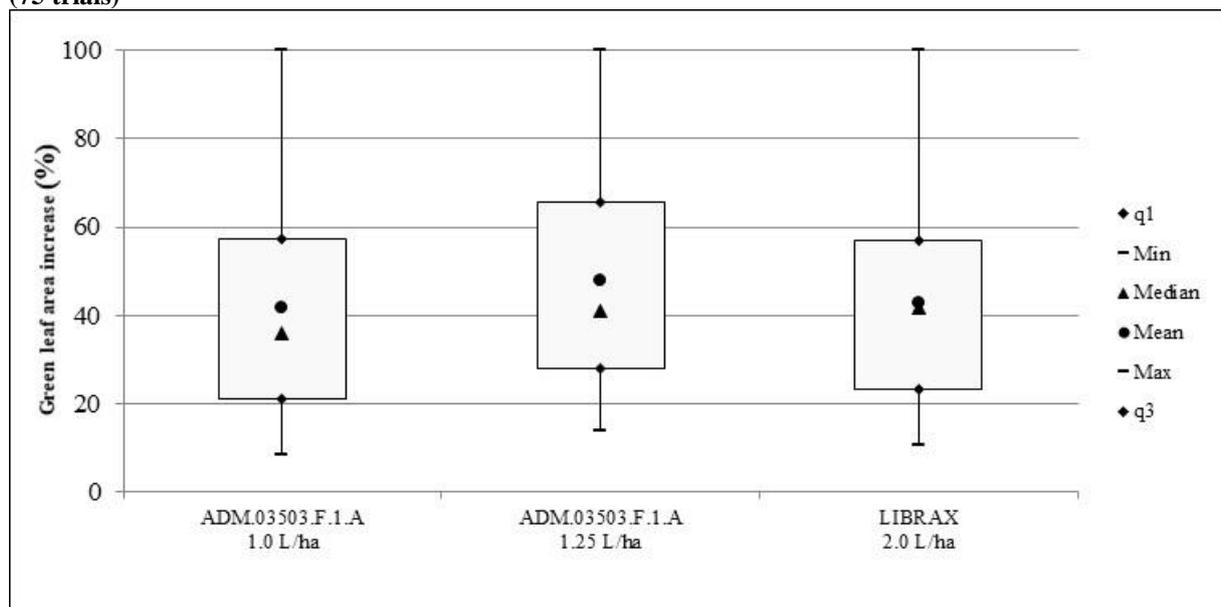
Finally, a total of 75 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in barley crops.

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 48% of green leaf area, similar or even slightly superior to LIBRAX (43%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 42% of green leaf area, similar to LIBRAX (43%).

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-31). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same (or even better) effect on the increasing green leaf area and the same dispersion and variation between means than LIBRAX.

Figure 3.2-31 Effect of ADM.03503.F.1.A on the green leaf area- Barley - Increase of the green leaf area (75 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the green leaf area in barley crops at least like the reference standard LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the green leaf area in barley crops like LIBRAX.

3.2.3.3.7 Positive effect on the yield in efficacy trials

A total of **94 valid efficacy trials** with sufficient disease pressure were harvested to confirm the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2019 to 2021** in the Maritime (1 trial in Belgium, 4 trials in Czech Republic, 17 trials in Germany, 5 trials in Ireland, 12 trials in the United Kingdom and 14 trials in France), the Northeast (15 trials in Poland) and the Southeast (2 trials in Hungary, 13 trials in Romania and 11 trials in Slovakia) EPP0 climatic zones in winter barley.

Table 3.2-77 summarises the positive effect on the yield and yield parameters (TGW and HLW) of ADM.03503.F.1.A in barley crops with sufficient disease pressure (RHYNSE, PYRNTE, PUCCHD, RAMUCC and/or ERYSGH).

Table 3.2-77: Positive effect on the yield of ADM.03503.F.1.A - Barley - Yield parameters

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to LIBRAX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
All diseases	Yield (t/ha)	Maritime	Grains	53	14.4	3.5	105.7	112.0	96.2	132.6	7.3	113.4	95.8	137.2	8.9	110.0	88.9	131.5	7.9	3>; 50=; 0<	6>; 47=; 0<
		Northeast	Grains	15	6.8	4.1	10.0	112.1	100.8	137.9	9.3	115.8	101.8	140.9	11.7	116.0	100.1	146.0	13.0	0>; 13=; 2<	0>; 15=; 0<
		Southeast	Grains	26	5.5	3.3	7.8	107.6	102.0	115.0	3.5	108.7	104.2	118.8	3.2	106.3	94.7	115.9	3.9	2>; 18=; 6<	3>; 23=; 0<
		All EPPO climatic zones	Grains	94	10.7	3.3	105.7	110.8	96.2	137.9	7.2	112.5	95.8	140.9	8.7	109.9	88.9	146.0	8.7	5>; 81=; 8<	9>; 85=; 0<
	TGW (g)	Maritime	Grains	32	44.8	29.1	56.0	105.9	91.1	116.6	5.0	105.9	94.4	116.5	4.6	105.0	97.7	111.3	3.4	3>; 27=; 1<	3>; 26=; 2<
		Northeast	Grains	15	43.4	38.0	51.9	102.7	100.3	113.3	3.5	102.4	100.0	109.4	2.8	102.3	99.8	109.4	2.6	0>; 13=; 2<	0>; 15=; 0<
		Southeast	Grains	26	44.7	33.7	56.1	101.7	84.5	106.3	3.8	102.0	89.1	106.9	3.4	102.4	93.6	110.1	3.1	0>; 24=; 2<	2>; 23=; 1<
		All EPPO climatic zones	Grains	73	44.5	29.1	56.1	103.7	84.5	116.6	4.7	103.8	89.1	116.5	4.3	103.5	93.6	111.3	3.4	3>; 64=; 5<	5>; 64=; 3<
	HLW (kg)	Maritime	Grains	49	62.5	52.7	76.6	102.2	98.7	112.9	2.7	102.6	98.3	113.8	2.9	101.9	98.9	113.9	2.8	0>; 48=; 0<	2>; 46=; 0<
		Northeast	Grains	15	61.5	51.0	69.4	101.2	97.2	104.3	1.7	101.3	99.9	103.3	1.0	101.4	99.7	104.0	1.3	1>; 11=; 3<	0>; 15=; 0<
		Southeast	Grains	26	64.4	53.9	75.9	101.7	95.4	123.1	4.7	101.8	94.4	124.8	5.1	102.0	96.8	124.6	4.9	0>; 23=; 3<	2>; 22=; 2<
		All EPPO climatic zones	Grains	90	62.9	51.0	76.6	101.9	95.4	123.1	3.3	102.1	94.4	124.8	3.5	101.8	96.8	124.6	3.4	1>; 82=; 6<	4>; 83=; 2<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

93 trials are available to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The yield in the untreated plot was from 3.3 to 11.7 t/ha.

Maritime Eppo climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 13 points compared to Untreated in 53 trials similar or even slightly superior to LIBRAX (110%). This difference was significant in 6 out of 53 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 12 points compared to Untreated in 53 trials similar to LIBRAX (110%). No significant difference was at least noted with LIBRAX in all trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 6 points or HLW with a positive effect of 2-3 points even if the differences on these yield parameters are less pronounced.

Northeast Eppo climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 16 points compared to Untreated in 15 trials similar to LIBRAX (116%). No significant difference was at least noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 12 points compared to Untreated in 15 trials similar to LIBRAX (116%). No significant difference was at least noted with LIBRAX in 13 out of 15 trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 2-3 points or HLW with a positive effect of 1 point even if the differences on these yield parameters are less pronounced.

Southeast Eppo climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 9 points compared to Untreated in 26 trials similar or even slightly superior to LIBRAX (106%). This difference was significant in 3 out of 26 trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 8 points compared to Untreated in 26 trials similar to LIBRAX (106%). No significant difference was at least noted with LIBRAX in 20 out of 26 trials.

Overall, the same conclusion can be noted with the other yield parameters TGW or HLW with a positive effect of 2 points even if the differences on these yield parameters are less pronounced.

Central registration zone

Finally, a total of 93 efficacy trials across Eppo climatic zones concerned in the Central registration zone are summarised to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in barley crops.

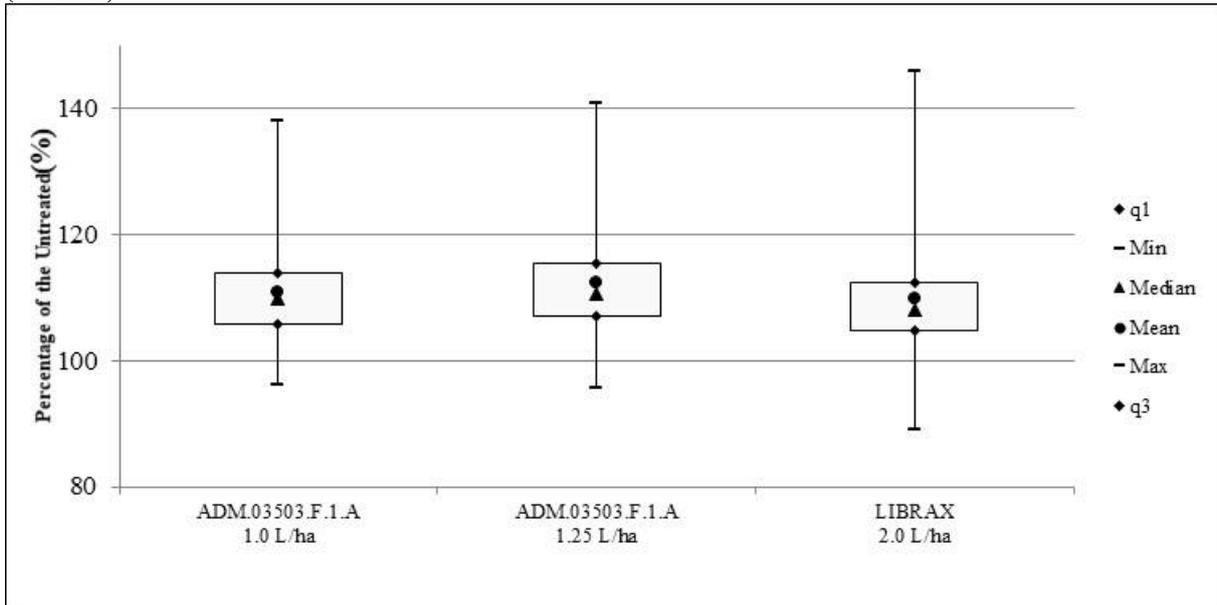
ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 13 points compared to Untreated similar or even slightly superior to LIBRAX (110%). significant difference was at least noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 11 points compared to Untreated similar to LIBRAX (110%). No significant difference was at least noted with LIBRAX in 85 out of 94 trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 4 points or HLW with a positive effect of 2 points even if the differences on these yield parameters are less pronounced.

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-32). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same effect on the yield and the same dispersion and variation between means than LIBRAX.

Figure 3.2-32 Positive effect of ADM.03503.F.1.A on the yield - Barley - Percentage of the untreated (94 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the yield in barley crops like or even better than the reference standard LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the yield in barley crops like LIBRAX.

3.2.3.3.8 Zonal conclusion on efficacy of test product against barley diseases

A total of **98 valid efficacy trials** carried out **from 2019 to 2021** are provided to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone in barley crops.

Table 3.2-78 summarises the efficacy of ADM.03503.F.1.A to control barley disease complex from all valid efficacy trials.

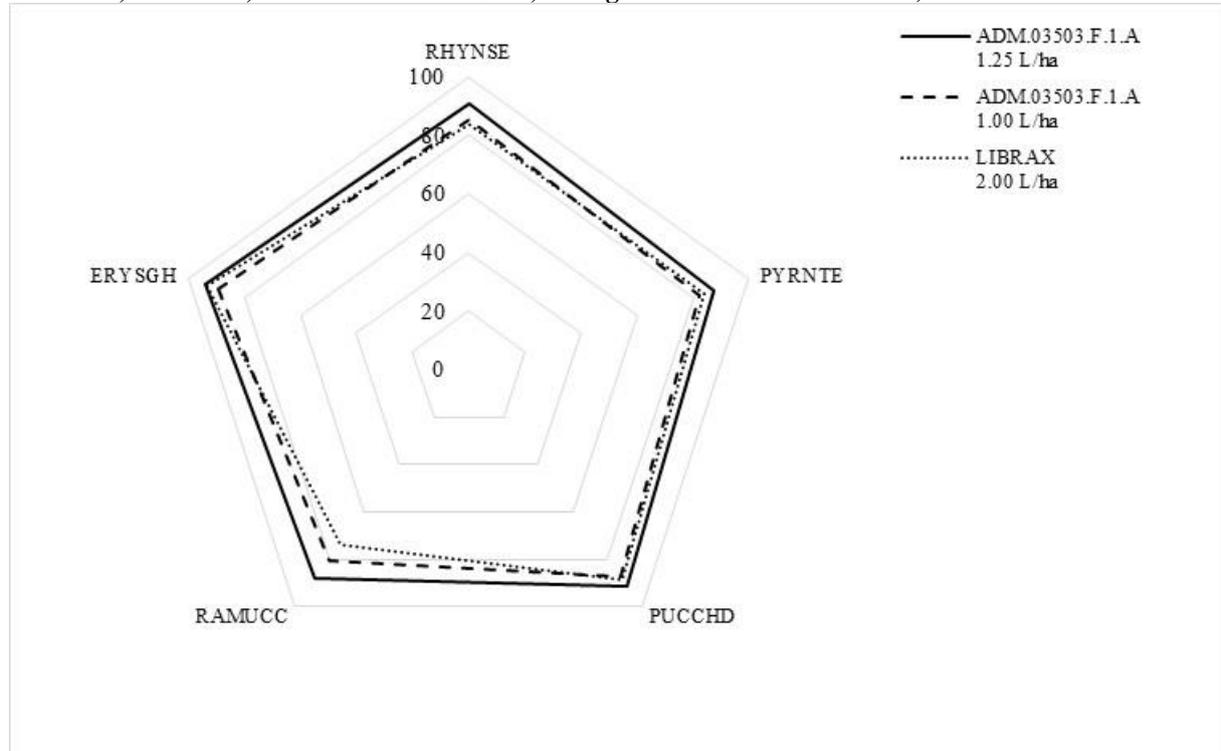
Table 3.2-78: Efficacy of ADM.03503.F.1.A - Barley - All valid efficacy trials

Target Parameters	Parts	No. of trials	Untreated			Percentage of efficacy (%)								
						ADM.03503.F.1.A 1.00 L/ha			ADM.03503.F.1.A 1.25 L/ha			LIBRAX 2.00 L/ha		
			Fluxapyroxad + Prothioconazole 75+150 g a.s./ha			Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha			Fluxapyroxad + Metconazole 125+90 g a.s./ha					
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
RHYNSE	FLAGLE	22	18.6	5.5	88.8	85.4	47.8	100.0	90.7	65.2	100.0	84.0	38.9	100.0
	FLMI1	29	19.3	5.3	100.0	82.1	42.0	99.6	89.3	42.9	100.0	83.6	42.9	100.0
PYRNTE	FLAGLE	20	13.2	4.5	48.2	82.2	37.5	100.0	87.3	45.8	100.0	83.9	51.4	100.0
	FLMI1	33	20.9	4.8	99.0	84.6	41.2	100.0	90.8	61.2	100.0	83.5	28.7	100.0
PUCCHD	FLAGLE	15	19.3	5.5	59.2	87.3	63.6	100.0	91.5	60.0	100.0	88.6	56.4	100.0
	FLMI1	23	22.1	5.0	99.0	91.2	63.0	100.0	95.2	76.0	100.0	90.1	55.0	100.0
RAMUCC	FLAGLE	17	44.4	4.9	100.0	80.8	60.4	100.0	88.3	71.7	100.0	74.1	44.0	100.0
	FLMI1	19	54.7	5.8	100.0	79.8	57.3	99.7	87.1	70.2	99.7	75.7	42.6	98.5
ERYSGH	FLAGLE	6	15.5	5.3	36.9	90.7	80.0	100.0	96.9	90.7	100.0	95.2	82.8	100.0
	FLMI1	20	16.1	4.7	73.8	89.4	60.8	100.0	94.1	73.0	100.0	93.1	76.5	100.0
	FLMI2	22	15.1	4.8	63.6	86.6	57.9	100.0	91.6	57.9	100.0	87.9	63.2	100.0

⁽¹⁾ Comparison based on statistics carried out in each trial report.

The efficacy of ADM.03503.F.1.A against barley disease complex can be illustrated by graphic from the last valid assessment (RHYNSE, PYRNTE, PUCCHD, RAMUCC, and/or ERYSGH) (Figure 3.2-33). According to the efficacy results and as illustrated on the graphic hereafter, ADM.03503.F.1.A at 1.25 L/ha controlled all diseases of barley with a level of efficacy similar or even superior to the reference standard LIBRAX. Overall, the efficacy of ADM.03503.F.1.A at 1.00 L/ha was also acceptable to control barley disease complex.

Figure 3.2-33 Efficacy of ADM.03503.F.1.A - Barley - Disease complex (efficacy against RHYNSE, PYRNTE, PUCCHD, RAMUCC on FLAGLE, and against ERYSGH on FLMI1) after last valid assessment



Therefore, provided data are sufficient to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha to control barley disease complex.

zRMS comments on efficacy in Barley:

The numbers of efficacy trials, the efficacy levels reported and the effect on yield observed, both as stand-alone results as well as relative to the standard reference products, allow for the authorization of the ADM.03503.F.1.A in barley, in the Member States of the Central zone concerned with this submission.

In the Maritime zone the ADM.03503.F.1.A can be authorized for a single application per growth season within the BBCH 30-65, at the dose rate of 1.25 L/ha, in control of RHYNSE, PYRNTE, PUCCHD, RAMUCC, ERYSHG, in winter and spring barley.

In the South-Eastern zone (Hungary, Slovakia and Slovenia), the **dose range** of 1.00-1.25 L/ha can be authorized in control of the target pathogens RHYNSE, PYRNTE, ERYSGH, in winter and spring barley, by a single application per growth season within the BBCH 30-65.

For the SE zone only 4 trials testing control of PUCCHD have been submitted (RO - 2, SK - 2). zRMS is kindly suggesting that the concerned Member states Hungary and Slovakia may possibly consider authorization for this use as supported additionally by 3 available trials from the Maritime zone (CZ), carried out on the spring barley.

In Poland, **the North-Eastern zone**, the **dose range** of 1.00-1.25 L/ha can be authorized in control of the target pathogens RHYNSE, **in winter barley alone** (no trials have been submitted in spring form with control of RHYNSE and the extrapolation to spring form is not possible in the complete absence of trials in HORVS) and in control of PYRNTE, PUCCHD, ERYSGH, in winter **and spring** barley, based on the 3 available CZ trials and 2 SK trials, carried out on spring barley, which support efficacy in control of PYRNTE and PUCCHD, and ERYSGH, respectively.

The sub-critical number of trials testing efficacy against RHYNSE and PYRNTE in the NE zone (Poland) has been accepted by zRMS based on the presence of trials from the neighbouring Slovakia and Germany (7 additional trials for RHYNSE, 16 trials for PYRNTE), testing for the same targets and providing comparable results.

The use in control of RAMUCC cannot be authorized in the North-Eastern nor in the South-Eastern zone. For these zones only 4 trials have been submitted: the single trial from Poland and 3 trials from Slovakia. None of these represent a stand-alone data set, enabling zonal authorization, while the supportive using of data from the neighbouring countries is, to the opinion of zRMS, problematic. Even with support of data from the Czech Republic, Germany and Slovakia, a single trial in the NE zone is still not enough for authorization of, any indeed, use of the **new product**. With respect to the South-Eastern zone: only two trials qualify as data from the neighbouring states, those of CZ and PL thus making the overall number of **five** trials, while Germany do not border with any SE zone Member State.

Therefore the zRMS does not recommend authorization of this use in the SE EPPO zone, but does not exclude the possibility that the concerned Member States will decide otherwise. For the cMSs knowledge, the efficacy in control of RAMUCC averaged for the 5 trials in SK, CZ and PL is 91.1%, the efficacy summarized across all the 16 Maritime zone trials is 85.0%, and that across the 10 DE trials alone is 86.1%.

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3.2.3.4 Efficacy trials results for the control of rye diseases

A total of **9 efficacy trials** were carried out in the Central registration zone to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2020 to 2021** in the Maritime (4 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (1 trial in Hungary, and 2 trials in Romania) EPPO climatic zones.

One out of 9 trials ~~are~~ **is** not taken into account in the efficacy analysis below due to a low pest pressure conditions. Thus, this trial is excluded from the analysis of efficacy. However, the potential crop phytotoxicity symptoms observed in this trial is analysed in Section 3.4.1.

Therefore, a total of **8 valid efficacy trials** in the Maritime (4 trials), the Northeast (2 trials) and the Southeast (2 trials) EPPO climatic zone were available to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of rye diseases.

Moreover, to complete the data package, **2 efficacy trials** performed **from 2020 to 2021** in the Northeast EPPO climatic zone in Lithuania and Latvia are also provided as supportive data.

3.2.3.4.1 Leaf blotch of rye (*Rhynchosporium secalis* - RHYNSE)

A total of **7 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of RHYNSE. These trials were carried out **from 2020 to 2021** in the Maritime (3 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (2 trials in Romania) EPPO climatic zones in winter rye.

Moreover, to complete the data package, **2 efficacy trials** performed **from 2020 to 2021** in the Northeast EPPO climatic zone in Lithuania and Latvia are also provided as supportive data.

Table 3.2-79 and Table 3.2-80 summarise the efficacy of ADM.03503.F.1.A against RHYNSE.

Table 3.2-79: Efficacy of ADM.03503.F.1.A - Rye - RHYNSE - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha									
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
RHYNSE Disease severity	Last valid assessment after application A	Maritime	FLMI2	1	7.5	-	-	80.0	-	-	-	86.7	-	-	-	86.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		Northeast	FLMI1	1	20.9	-	-	84.5	-	-	-	88.1	-	-	-	90.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	16.9	15.3	18.4	84.9	83.7	86.1	1.2	90.8	90.5	91.0	0.3	92.9	91.8	93.9	1.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Southeast	FLMI2	1	6.3	-	-	79.7	-	-	-	83.9	-	-	-	85.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
	Last valid assessment after application B	All EPPO climatic zones	FLMI1	1	20.9	-	-	84.5	-	-	-	88.1	-	-	-	90.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	4	11.9	6.3	18.4	82.4	79.7	86.1	2.7	88.0	83.9	91.0	2.9	89.4	85.2	93.9	3.6	0> ; 4= ; 0<	0> ; 4= ; 0<	
			FLAGLE	2	25.4	25.0	25.8	78.9	71.8	86.0	7.1	84.7	83.0	86.4	1.7	72.5	65.1	80.0	7.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Maritime	FLMI1	3	46.7	7.5	77.5	87.7	77.3	100.0	9.4	91.4	86.4	100.0	6.1	84.9	75.0	100.0	10.9	0> ; 3= ; 0<	1> ; 2= ; 0<	
			FLMI2	3	62.3	36.5	99.0	78.1	75.3	81.1	2.4	83.1	80.8	85.6	2.0	78.8	75.6	83.6	3.5	0> ; 2= ; 1<	1> ; 2= ; 0<	
		Northeast	FLAGLE	2	14.7	14.4	15.0	75.0	70.4	79.6	4.6	84.9	80.9	88.8	4.0	87.0	82.6	91.3	4.4	0> ; 1= ; 1<	0> ; 2= ; 0<	
			FLMI1	1	11.9	-	-	96.8	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		Southeast	FLAGLE	2	5.1	5.1	5.1	86.6	81.7	91.4	4.9	89.9	85.1	94.6	4.8	86.9	85.6	88.1	1.3	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	2	8.8	7.3	10.3	81.4	76.9	85.8	4.5	85.0	80.1	90.0	5.0	82.2	79.6	84.8	2.6	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	2	15.4	13.2	17.7	74.6	69.6	79.6	5.0	79.4	74.5	84.3	4.9	78.4	75.3	81.5	3.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
		All EPPO climatic zones	FLAGLE	6	15.1	5.1	25.8	80.2	70.4	91.4	7.4	86.5	80.9	94.6	4.4	82.1	65.1	91.3	8.5	0> ; 5= ; 1<	0> ; 6= ; 0<	
			FLMI1	6	28.3	7.3	77.5	87.1	76.9	100.0	8.8	90.7	80.1	100.0	7.2	86.5	75.0	100.0	10.0	0> ; 6= ; 0<	1> ; 5= ; 0<	
	FLMI2	5	43.5	13.2	99.0	76.7	69.6	81.1	4.0	81.6	74.5	85.6	3.9	78.7	75.3	83.6	3.3	0> ; 4= ; 1<	1> ; 4= ; 0<			
RHYNSE Disease severity	Last valid assessment	Maritime	FLAGLE	2	25.4	25.0	25.8	78.9	71.8	86.0	7.1	84.7	83.0	86.4	1.7	72.5	65.1	80.0	7.5	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	46.7	7.5	77.5	87.7	77.3	100.0	9.4	91.4	86.4	100.0	6.1	84.9	75.0	100.0	10.9	0> ; 3= ; 0<	1> ; 2= ; 0<	
			FLMI2	3	62.3	36.5	99.0	78.1	75.3	81.1	2.4	83.1	80.8	85.6	2.0	78.8	75.6	83.6	3.5	0> ; 2= ; 1<	1> ; 2= ; 0<	
		Northeast	FLAGLE	2	14.7	14.4	15.0	75.0	70.4	79.6	4.6	84.9	80.9	88.8	4.0	87.0	82.6	91.3	4.4	0> ; 1= ; 1<	0> ; 2= ; 0<	
			FLMI1	1	11.9	-	-	96.8	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	16.9	15.3	18.4	84.9	83.7	86.1	1.2	90.8	90.5	91.0	0.3	92.9	91.8	93.9	1.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Southeast	FLAGLE	2	5.1	5.1	5.1	86.6	81.7	91.4	4.9	89.9	85.1	94.6	4.8	86.9	85.6	88.1	1.3	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	2	8.8	7.3	10.3	81.4	76.9	85.8	4.5	85.0	80.1	90.0	5.0	82.2	79.6	84.8	2.6	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	2	15.4	13.2	17.7	74.6	69.6	79.6	5.0	79.4	74.5	84.3	4.9	78.4	75.3	81.5	3.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
		All EPPO climatic zones	FLAGLE	6	15.1	5.1	25.8	80.2	70.4	91.4	7.4	86.5	80.9	94.6	4.4	82.1	65.1	91.3	8.5	0> ; 5= ; 1<	0> ; 6= ; 0<	
	FLMI1	6	28.3	7.3	77.5	87.1	76.9	100.0	8.8	90.7	80.1	100.0	7.2	86.5	75.0	100.0	10.0	0> ; 6= ; 0<	1> ; 5= ; 0<			
	FLMI2	7	35.9	13.2	99.0	79.1	69.6	86.1	5.1	84.2	74.5	91.0	5.3	82.7	75.3	93.9	7.0	0> ; 6= ; 1<	1> ; 6= ; 0<			

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-80: Efficacy of ADM.03503.F.1.A - Rye - RHYNSE - Disease severity on leaves (Supportive data; trials LT20FESECSS517A and LV21FESECSS460A)

Target Parameters	Assessment timing	EPO climatic zone	Parts	No. of trials	<i>Untreated</i>		Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ > ; = ; < to REVYTREX REVYSTAR XL						
							ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				REVYTREX REVYSTAR XL 1.5 L/ha										
							Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Mefentrifluconazole										
							75+150 g a.s./ha				93.75+187.5 g a.s./ha				100+100 g a.s./ha 150+75 g a.s./ha										
						<i>Mean</i>		<i>Min</i>		<i>Max</i>		<i>S.D.</i>		<i>Mean</i>		<i>Min</i>		<i>Max</i>		<i>S.D.</i>		ADM.03503.F.1.A			
																						1.00 L/ha		1.25 L/ha	
RHYNSE Disease severity	Last valid assessment after application A	Maritime North-East	FLAGLE	2	22.1	12.5	31.6	64.5	61.7	67.2	2.8	67.8	52.7	82.8	15.1	61.2	60.0	62.4	1.2	0> ; 2= ; 0<	0> ; 2= ; 0<				
			FLMI1	2	27.8	23.8	31.3	49.1	30.4	67.8	18.7	52.2	30.2	74.2	22.0	47.9	25.4	70.3	22.5	0> ; 2= ; 0<	0> ; 2= ; 0<				
			FLMI2	2	17.5	16.2	18.8	64.9	51.6	78.1	13.3	68.3	59.5	77.0	8.8	63.0	49.6	76.4	13.4	0> ; 2= ; 0<	0> ; 2= ; 0<				

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Seven trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked 21% of the flag leaves minus 1 (FLMI1) area and from 6% to 18% of the flag leaves minus 2 (FLMI2) area. After the second application, the disease in the untreated plot attacked from 5% to 26% of the flag leaves (FLAGLE) area, from 7% to 78% of the flag leaves minus 1 (FLMI1) area and from 13% to 99% of the flag leaves minus 2 (FLMI2) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime Eppo climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good to very good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (85% in 2 trials on FLAGLE, 91% in 3 trials on FLMI1 and 83% in 3 trials on FLMI2) was superior to LIBRAX (73% on FLAGLE, 85% on FLMI1 and 79% on FLMI2). This difference was significant in 1 out of 3 trials on FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (79% in 2 trials on FLAGLE, 88% in 3 trials on FLMI1 and 78% in 3 trials on FLMI2) was similar to LIBRAX (73% on FLAGLE, 85% on FLMI1 and 79% on FLMI2). No significant difference was noted in 7 out of 8 assessments on FLAGLE, FLMI1 and FLMI2.

Northeast Eppo climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good to very good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (85% in 2 trials on FLAGLE, 100% in 1 trial on FLMI1 and 91% in 2 trials on FLMI2) was similar to LIBRAX (87% on FLAGLE, 100% on FLMI1 and 93% on FLMI2). No significant difference was at least noted in all assessments on FLAGLE, FLMI1 and FLMI2.

In both supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (68% in 2 trials on FLAGLE, 52% in 2 trials on FLMI1 and 68% in 2 trials on FLMI2) was similar to REVYTREX/REVYSTAR XL (61% on FLAGLE, 48% on FLMI1 and 63% on FLMI2). No significant difference was at least noted in all assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (75% in 2 trials on FLAGLE, 97% in 1 trial on FLMI1 and 85% in 2 trials on FLMI2) was similar to LIBRAX (87% on FLAGLE, 100% on FLMI1 and 93% on FLMI2). No significant difference was noted in 4 out of 5 assessments on FLAGLE, FLMI1 and FLMI2.

In both supportive trials, the efficacy of ADM.03503.F.1.A at 1.00 L/ha (65% in 2 trials on FLAGLE, 49% in 2 trials on FLMI1 and 65% in 2 trials on FLMI2) was similar to REVYTREX/REVYSTAR XL (61% on FLAGLE, 48% on FLMI1 and 63% on FLMI2). No significant difference was at least noted in all assessments on FLAGLE, FLMI1 and FLMI2.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of RHYNSE. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (90% in 2 trials on FLAGLE, 85% in 2 trials on FLMI1 and 79% in 2 trials on FLMI2) was similar to LIBRAX (87% on FLAGLE, 82% on FLMI1 and 78% on FLMI2). No significant difference was at least noted in all assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of RHYNSE. The efficacy of ADM.03503.F.1.A at 1.00L/ha (87% in 2 trials on FLAGLE, 81% in 2 trials on FLMI1 and 75% in 2 trials on FLMI2) was similar to LIBRAX (87% on FLAGLE, 82% on FLMI1 and 78% on FLMI2). No significant difference was noted in all assessments on FLAGLE, FLMI1 and FLMI2.

Central registration zone

Finally, a total of 7 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in rye against RHYNSE.

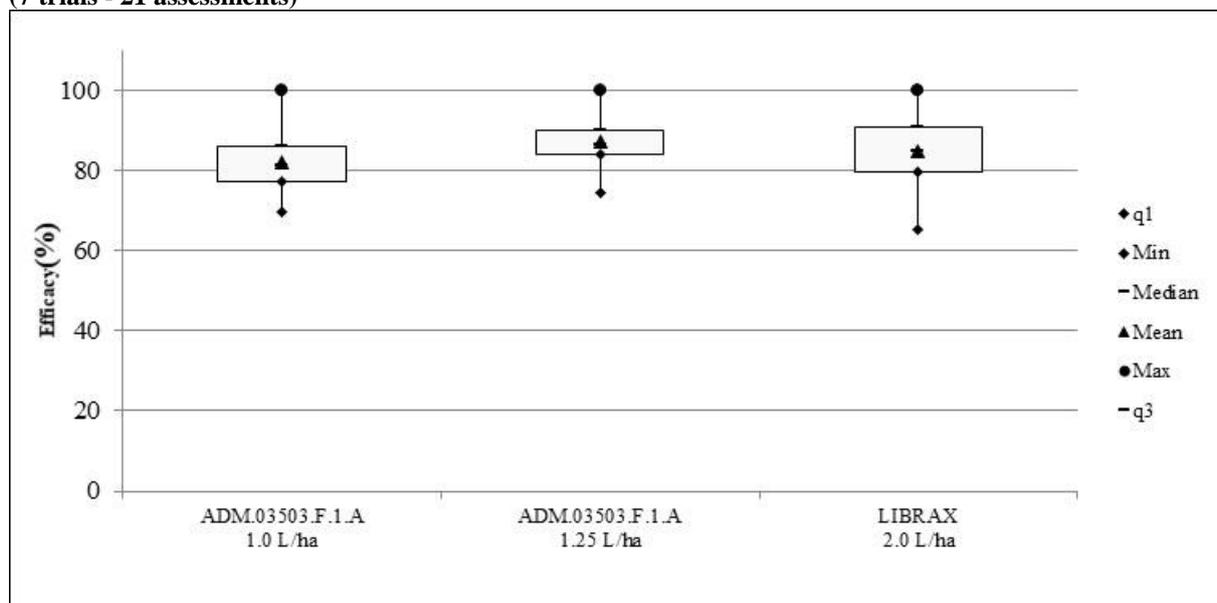
At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good to very good control of RHYNSE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (87% in 6 trials on FLAGLE, 91% in 6 trials on FLMI1 and 84% in 7 trials on FLMI1) was similar to LIBRAX (82% on FLAGLE, 87% on FLMI1 and 83% on FLMI2). No significant difference was at least noted in all assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of RHYNSE. The efficacy of ADM.03503.F.1.A at 1.00 L/ha (80% in 6 trials on FLAGLE, 87% in 6 trials on FLMI1 and 79% in 7 trials on FLMI1) was similar to LIBRAX (82% on FLAGLE, 87% on FLMI1 and 83% on FLMI2). No significant difference was at least noted in 17 out of 19 assessments on FLAGLE, FLMI1 and FLMI2.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE and FLMI1) (Figure 3.2-17). Overall, ADM.03503.F.1.A at 1.25 L/ha had at least the same level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-34 Efficacy of ADM.03503.F.1.A - Rye - RHYNSE - Last valid assessment - Box Plot graphic (7 trials - 21 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of RHYNSE in rye crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a good control of leaf blotch of rye similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control leaf blotch according to the disease pressure.

The authorisation of a rye crop fungicide versus the disease *Rhynchosporium*, can be also granted based on extrapolated data generated in barley *Rhynchosporium* trials. In the BAD, a total of 38 trials are presented to support this use.

This includes 7 supportive trials in rye (presented above) and 31 barley supportive trials (relevant by extrapolation). These additional trials are presented above in Section 3.2.3.3.1 Leaf blotch of barley (*Rhynchosporium secalis* - RHYNSE).

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L /ha for the control of leaf blotch of rye (*Rhynchosporium secalis* - RHYNSE).

3.2.3.4.2 Brown rust of rye (*Puccinia recondita* - PUCCRE)

A total of **3 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PUCCRE. These trials were carried out **from 2020 to 2021** in the Maritime EPPO climatic zone (3 trials in Germany in winter rye).

Moreover, to complete the data package, **1 efficacy trial** performed **in 2021** in the Northeast EPPO climatic zone in Latvia is also provided as supportive data.

Table 3.2-81 and Table 3.2-82 summarise the efficacy of ADM.03503.F.1.A against PUCCRE.

Table 3.2-81: Efficacy of ADM.03503.F.1.A - Rye - PUCCRE - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
PUCCRE Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	8.0	-	-	39.6	-	-	-	45.8	-	-	-	25.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI2	1	11.9	-	-	55.1	-	-	-	52.2	-	-	-	46.6	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Last valid assessment after application B	Maritime	FLAGLE	3	6.0	4.5	8.4	75.9	42.6	100.0	24.3	82.8	48.5	100.0	24.3	76.2	28.7	100.0	33.6	0> ; 2= ; 1<	0> ; 3= ; 0<
			FLMI1	3	8.9	4.5	11.6	85.4	56.3	100.0	20.6	84.5	53.4	100.0	22.0	82.8	48.4	100.0	24.3	0> ; 3= ; 0<	0> ; 3= ; 0<
			FLMI2	2	10.4	7.5	13.3	79.9	59.7	100.0	20.2	78.6	57.2	100.0	21.4	76.1	52.2	100.0	23.9	0> ; 2= ; 0<	0> ; 2= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-82: Efficacy of ADM.03503.F.1.A - Rye - PUCCRE - Disease severity on leaves (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to REVYSTAR XL		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				REVYSTAR XL 1.5 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Mefentrifluconazole 150+75 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
PUCCRE Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	13.4	-	-	91.1	-	-	-	93.9	-	-	-	92.5	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI1	1	12.2	-	-	69.9	-	-	-	72.9	-	-	-	81.1	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Three trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked of 8% of the flag leaves minus 1 (FLMI1) area and 12% of the flag leaves minus 2 (FLMI2) area. After the second application, the disease in the untreated plot attacked from 5% to 8% of the flag leaves (FLAGLE) area, from 5% to 12% of the flag leaves minus 1 (FLMI1) area and from 8% to 13% of the flag leaves minus 2 (FLMI2).

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of PUCCRE. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (83% in 3 trials on FLAGLE, 85% in 3 trials on FLMI1 and 79% in 2 trials on FLMI2) was similar to LIBRAX (76% on FLAGLE, 83% on FLMI1 and 76% on FLMI2). No significant difference was noted in all assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (76% in 3 trials on FLAGLE, 85% in 3 trials on FLMI1 and 80% in 2 trials on FLMI2) was similar to LIBRAX (76% on FLAGLE, 83% on FLMI1 and 76% on FLMI2). No significant difference was noted in 7 out of 8 assessments on FLAGLE, FLMI1 and FLMI2.

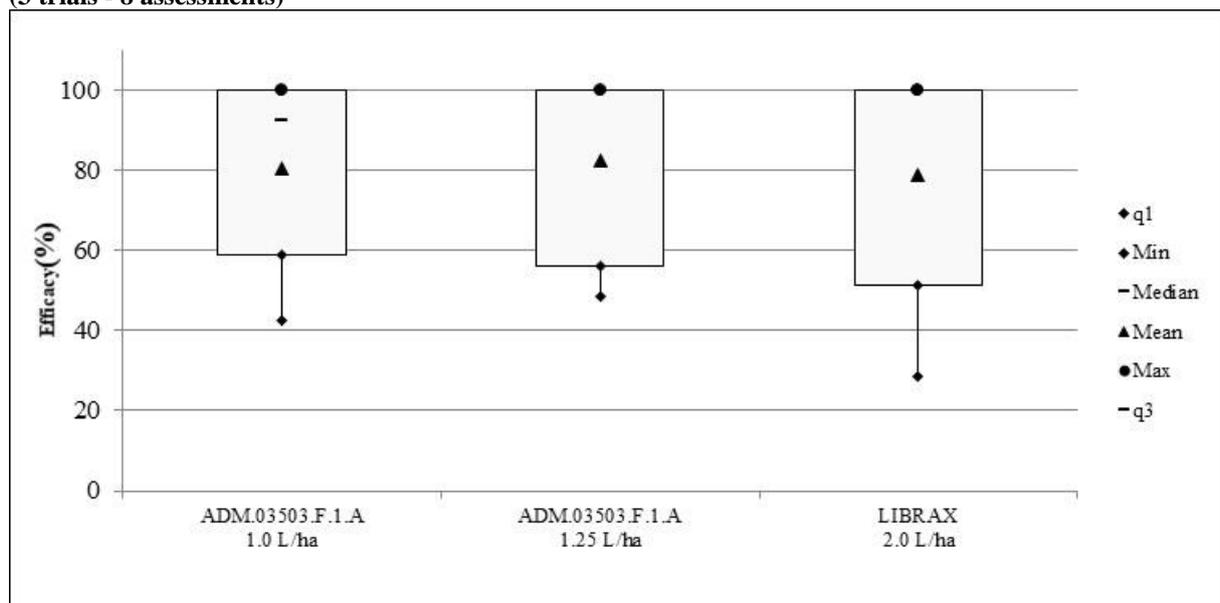
Northeast EPPO climatic zone

In one supportive trial, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (94% on FLAGLE and 73% on FLMI1) was similar to REVYTREX/REVYSTAR XL (93% on FLAGLE and 81% on FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

In one supportive trial, the efficacy of ADM.03503.F.1.A at 1.00 L/ha (91% on FLAGLE and 70% on FLMI1) was similar or inferior to REVYTREX/REVYSTAR XL (93% on FLAGLE and 81% on FLMI1). No significant difference was at least noted in all assessments on FLAGLE and FLMI1.

Finally, the difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE, FLMI1 and FLMI2) (Figure 3.2-35). Overall, ADM.03503.F.1.A at 1.25 L/ha had at least the same level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-35 Efficacy of ADM.03503.F.1.A - Rye - PUCCRE - Last valid assessment - Box Plot graphic (3 trials - 8 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PUCCRE in rye crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a moderate to good control of brown rust of rye similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control brown rust according to the disease pressure.

The authorisation of a rye crop fungicide versus the disease brown rust, can be granted based on extrapolated data generated in wheat brown rust trials. In the BAD, a total of 36 trials are presented to support this use.

This includes 3 supportive trials in rye (presented above) and 33 wheat supportive trials (relevant by extrapolation). These additional trials are presented above in Section 3.2.3.2.2 Brown rust of wheat (*Puccinia recondita* - PUCCRT).

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of brown rust of rye (*Puccinia recondita* - PUCCRE).

3.2.3.4.3 Control of disease complex - Green leaf area

Attacks by pathogens reduce green leaf area and thus grain yield. Thus, the green area is a good indicator of the level of efficacy of one product. Therefore, a total of **8 valid efficacy trials** were carried out to confirm the effect of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha on the green leaf area. These trials were carried out **from 2020 to 2021** in the Maritime (4 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (1 trial in Hungary, and 2 trials in Romania) EPPO climatic zones in winter rye.

Table 3.2-83 summarises the effect on the increase of the green leaf area after an application of ADM.03503.F.1.A in rye crops.

Table 3.2-83: Effect of ADM.03503.F.1.A on the green leaf area - Rye - Increase of green leaf area (%)

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	Increase of green leaf area (%)															
					Untreated Green leaf area (%)				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha			
									Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Metconazole			
									75+150 g a.s./ha				93.75+187.5 g a.s./ha				125+90 g a.s./ha			
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.			
All diseases Green leaf area (%)	Last valid assessment	Maritime	Leaves	4	36.6	20.0	51.3	44.0	23.1	71.2	20.0	53.7	23.1	86.5	22.8	43.0	12.8	80.8	26.8	
		Northeast	Leaves	2	18.1	15.0	21.3	18.5	14.7	22.2	3.8	26.1	22.1	30.2	4.1	29.4	20.6	38.1	8.8	
		Southeast	Leaves	2	70.0	65.0	75.0	65.0	50.0	80.0	15.0	75.7	71.4	80.0	4.3	75.7	71.4	80.0	4.3	
		All EPPO climatic zones	Leaves	8	40.3	15.0	75.0	42.9	14.7	80.0	23.1	52.3	22.1	86.5	24.1	47.8	12.8	80.8	26.0	

8 trials are available to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The green leaf area in the untreated plot covered from 15% to 75%.

Maritime EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 54% of green leaf area (in 4 trials), superior to LIBRAX (43%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 44% of green leaf area (in 4 trials), similar to LIBRAX (43%).

Northeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 26% of green leaf area (in 2 trials), similar to LIBRAX (29%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 19% of green leaf area (in 2 trials), inferior to LIBRAX (29%).

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 76% of green leaf area (in 2 trials), similar to LIBRAX (76%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 65% of green leaf area (in 2 trials), inferior to LIBRAX (76%).

Central registration zone

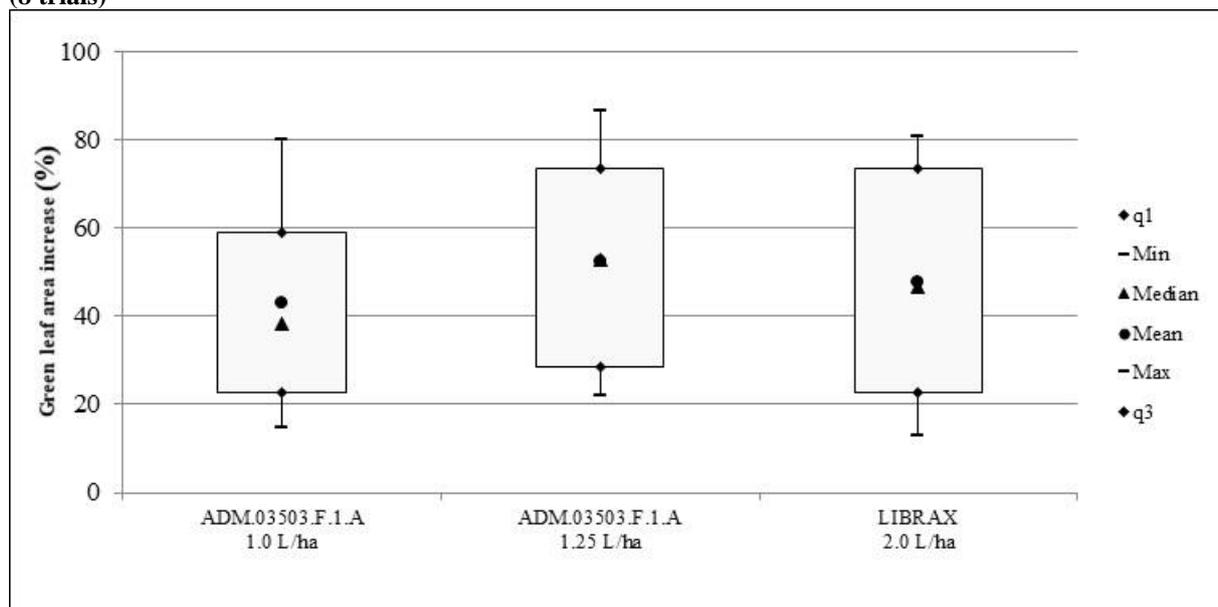
Finally, a total of 8 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in rye crops.

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 52% of green leaf area, similar or even slightly superior to LIBRAX (48%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 43% of green leaf area, slightly inferior to LIBRAX (48%).

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-36). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same (or even better) effect on the increasing green leaf area and the same dispersion and variation between means than LIBRAX.

Figure 3.2-36 Effect of ADM.03503.F.1.A on the green leaf area- Rye - Increase of the green leaf area (8 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the green leaf area in rye crops at least like the reference standard LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the green leaf area in rye crops like LIBRAX.

3.2.3.4.4 Positive effect on the yield in efficacy trials

A total of **8 valid efficacy trials** with sufficient disease pressure were harvested to confirm the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2020 to 2021** in the Maritime (4 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (1 trial in Hungary, and 2 trials in Romania) EPP0 climatic zones in winter rye.

Table 3.2-84 summarises the positive effect on the yield and yield parameters (TGW and HLW) of ADM.03503.F.1.A in rye crops with sufficient disease pressure (RHYNSE, PUCCRE).

Table 3.2-84: Positive effect on the yield of ADM.03503.F.1.A - Rye - Yield parameters

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of Untreated (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ > ; = ; < to LIBRAX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
All diseases	Yield (t/ha)	Maritime	Grains	4	8.3	6.1	12.3	112.7	111.1	115.7	1.9	113.6	111.1	117.6	2.4	110.7	109.1	113.7	1.8	0> ; 4= ; 0<	0> ; 4= ; 0<
		Northeast	Grains	2	7.0	5.8	8.1	124.6	122.4	126.7	2.2	126.3	120.8	131.8	5.5	123.8	116.2	131.4	7.6	0> ; 2= ; 0<	0> ; 2= ; 0<
		Southeast	Grains	2	6.1	5.6	6.6	103.0	101.0	105.0	2.0	103.2	101.0	105.5	2.2	103.4	101.2	105.5	2.2	0> ; 2= ; 0<	0> ; 2= ; 0<
		All EPPO climatic zones	Grains	8	7.4	5.6	12.3	113.2	101.0	126.7	7.9	114.2	101.0	131.8	8.9	112.2	101.2	131.4	8.5	0> ; 8= ; 0<	0> ; 8= ; 0<
	TGW (g)	Maritime	Grains	4	32.3	26.0	37.7	107.2	98.6	113.1	5.9	107.1	96.8	113.5	6.4	105.5	97.6	109.7	4.8	0> ; 3= ; 0<	0> ; 3= ; 0<
		Northeast	Grains	2	23.9	22.7	25.1	109.7	108.9	110.4	0.7	109.7	106.8	112.5	2.9	107.9	105.8	110.0	2.1	0> ; 2= ; 0<	0> ; 2= ; 0<
		Southeast	Grains	2	31.1	31.1	31.2	103.2	102.7	103.7	0.5	103.5	103.3	103.7	0.2	103.0	102.7	103.3	0.3	0> ; 2= ; 0<	0> ; 2= ; 0<
		All EPPO climatic zones	Grains	8	29.9	22.7	37.7	106.8	98.6	113.1	4.8	106.8	96.8	113.5	5.2	105.5	97.6	110.0	4.0	0> ; 7= ; 0<	0> ; 7= ; 0<
	HLW (kg)	Maritime	Grains	4	74.3	67.7	81.6	100.4	98.4	101.7	1.2	100.8	99.0	102.0	1.1	100.6	98.0	101.7	1.5	0> ; 3= ; 0<	0> ; 3= ; 0<
		Northeast	Grains	2	70.9	70.6	71.2	101.3	100.4	102.1	0.9	100.6	100.0	101.2	0.6	100.2	99.9	100.4	0.2	0> ; 2= ; 0<	0> ; 2= ; 0<
		Southeast	Grains	2	69.2	69.0	69.5	102.1	101.2	103.0	0.9	102.2	101.7	102.6	0.5	101.9	101.2	102.6	0.7	0> ; 2= ; 0<	0> ; 2= ; 0<
		All EPPO climatic zones	Grains	8	72.2	67.7	81.6	101.1	98.4	103.0	1.3	101.1	99.0	102.6	1.1	100.8	98.0	102.6	1.3	0> ; 7= ; 0<	0> ; 7= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

8 trials are available to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The yield in the untreated plot was from 5.6 to 12.3 t/ha.

Maritime EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 14 points compared to Untreated in 4 trials similar to LIBRAX (111%). No significant difference was noted with LIBRAX in all trials. ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 13 points compared to Untreated in 4 trials similar to LIBRAX (111%). No significant difference was noted with LIBRAX in all trials. Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 7 points or HLW with a positive effect of 1 point even if the differences on these yield parameters are less pronounced.

Northeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 26 points compared to Untreated in 2 trials similar to LIBRAX (124%). No significant difference was noted with LIBRAX in all trials. ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 25 points compared to Untreated in 2 trials similar to LIBRAX (124%). No significant difference was noted with LIBRAX in all trials. Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 10 points or HLW with a positive effect of 1 point even if the differences on these yield parameters are less pronounced.

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 3 points compared to Untreated in 2 trials similar or even slightly superior to LIBRAX (103%). No significant difference was noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 3 points compared to Untreated in 2 trials similar to LIBRAX (103%). No significant difference was noted with LIBRAX in all trials. Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 3-4 points or HLW with a positive effect of 2 points even if the differences on these yield parameters are less pronounced.

Central registration zone

Finally, a total of 8 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in rye crops.

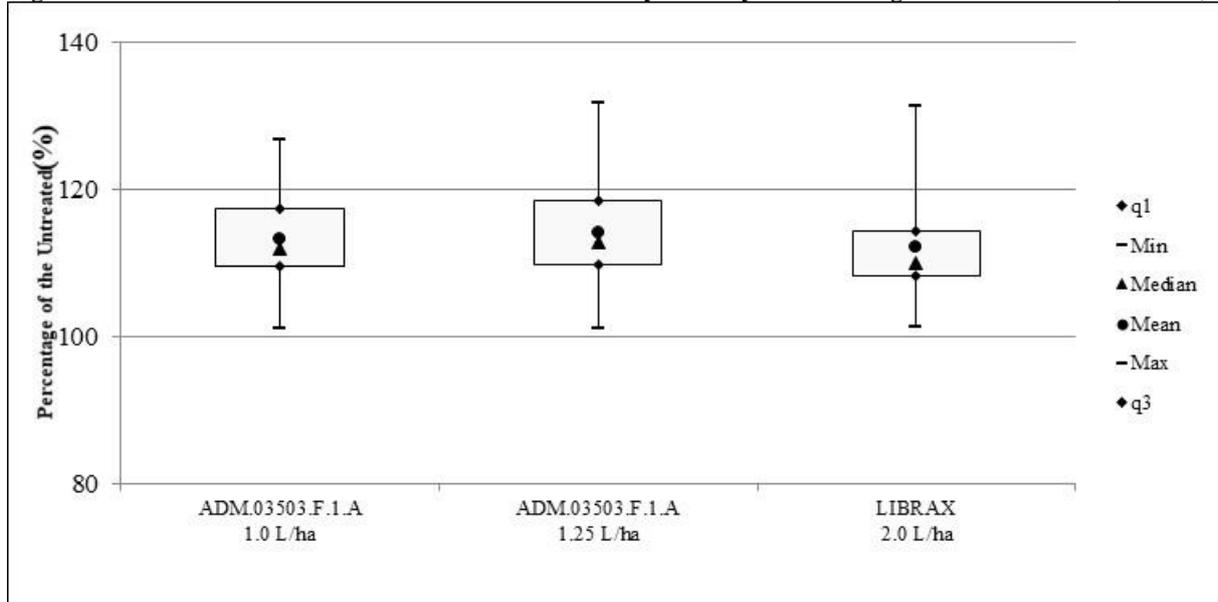
ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 14 points compared to Untreated in 8 trials similar to LIBRAX (112%). No significant difference was noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 13 points compared to Untreated in 8 trials similar to LIBRAX (112%). No significant difference was noted with LIBRAX in all trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 7 points or HLW with a positive effect of 1 points even if the differences on these yield parameters are less pronounced.

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-24). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same effect on the yield and the same dispersion and variation between means than LIBRAX.

Figure 3.2-37 Positive effect of ADM.03503.F.1.A on the yield - Rye - Percentage of the untreated (8 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the yield in rye crops like or even better than the reference standard LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the yield in rye crops like LIBRAX.

3.2.3.4.5 Zonal conclusion on efficacy of test product against rye diseases

A total of **8 valid efficacy trials** carried out from **2020 to 2021** are provided to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone in rye crops.

Table 3.2-85 summarises the efficacy of ADM.03503.F.1.A to control rye disease complex from all valid efficacy trials.

Table 3.2-85: Efficacy of ADM.03503.F.1.A - Rye - All valid efficacy trials

Target Parameters	Parts	No. of trials	Percentage of efficacy (%)											
			Untreated			ADM.03503.F.1.A 1.00 L/ha			ADM.03503.F.1.A 1.25 L/ha			LIBRAX 2.00 L/ha		
						Fluxapyroxad + Prothioconazole 75+150 g a.s./ha			Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha			Fluxapyroxad + Metconazole 125+90 g a.s./ha		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
RHYNSE	FLAGLE	6	15.1	5.1	25.8	69.7	58.7	85.4	80.2	70.4	91.4	86.5	80.9	94.6
	FLMI1	6	28.3	7.3	77.5	79.3	71.4	100.0	87.1	76.9	100.0	90.7	80.1	100.0
	FLMI2	7	35.9	13.2	99.0	69.8	57.1	75.8	79.1	69.6	86.1	84.2	74.5	91.0
PUCCRE	FLAGLE	3	6.0	4.5	8.4	70.8	52.5	100.0	75.9	42.6	100.0	82.8	48.5	100.0
	FLMI1	3	8.9	4.5	11.6	79.2	52.0	100.0	85.4	56.3	100.0	84.5	53.4	100.0
	FLMI2	2	10.4	7.5	13.3	78.0	56.0	100.0	79.9	59.7	100.0	78.6	57.2	100.0

(1) Comparison based on statistics carried out in each trial report.

Therefore, provided data are sufficient to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha to control rye disease complex.

zRMS comments on efficacy in Rye:

The efficacy levels reported and the effect on yield observed, both as stand-alone results as well as relative to the standard reference products, theoretically allow for the authorization of the ADM.03503.F.1.A in rye, in the Member States of the Central zone concerned with this submission. Unfortunately, the number and the zonal distribution of the efficacy trials submitted make granting the authorization difficult.

In the Maritime zone the ADM.03503.F.1.A could be authorized in winter rye in control of **RHYNSE**, provided that the concerned Member States would accept, in addition to 3 German trials, the **four** NE zone trials as supporting data: 2 of them from Poland, and 1 trial from each Lithuania and Latvia (Table 3.2-80), from the North administrative part of the NE EPPo zone, which are in fact (theoretically) supportive only for Poland. Taken the fact that ADM.03503.F.1.A is a new product the zRMS considers such operation as not entirely appropriate and as quite unlikely to be accepted by the cMSs of the Maritime zone. One other option is to accept the use in rye based on extrapolation from barley, as proposed by the applicant (BE, UK, IE, FR, DE), to which the zRMS agrees. The use in control of RHYNSE can be authorised for the Maritime zone, based on such extrapolation.

Altogether 3 DE trials and one LV trial include **PUCCRE** control in rye. This use can be nevertheless authorized in the Maritime zone based on extrapolation from wheat, as proposed by the applicant and to which the zRMS agrees. The number of wheat trials in the Maritime zone testing for PUCCR(T) is **15**.

The South-Eastern zone (Hungary, Slovakia and Slovenia) There have been only 3 trials carried out in the SE zone: one in Hungary and two in Romania, testing control of RHYNSE, and the HU trial is not taken into account in the summary “due to a low pest pressure”. However, 6 trials in control of RHYNSE in barley have been submitted in this zone (SK and RO), making extrapolation possible based on the two RO trials in rye. The use can be accepted.

None of the SE zone rye trials includes control of neither PUCCRE nor PUCCST (the latter pathogen listed only in GAP but not summarized as it did not occurred in any trial). The PUCCRE situation is therefore different here from that observed in the Maritime zone: To the opinion of zRMS, in the complete absence of data from **rye** the extrapolation using the 14 SE zone wheat trials testing for the control of PUCCR(T), as suggested by the applicant, should not be allowed.

The North-Eastern zone: 2 PL trials in rye with RHYNSE are not robust themselves and are thus **not comparable** to the 2 supporting trials from Lithuania and Latvia. The zRMS is reluctant to accept authorization based on such limited a data set. Extrapolation from barley has been considered but not agreed, for there are only 4 trials with RHYNSE in barley in the NE zone to extrapolate from and this is assessed as too wobbly an operation considered that the test item is the **new product**.

There are no trials with PUCCRE control in rye from Poland, the only one coming from the NE zone is from Latvia. Three German trials make no good basis for authorization of this use, of the new product, in the North-Eastern zone either, and the extrapolation option, if considered, should be based on only 4 trials in wheat in control of PUCCRT, in the NE zone, which is assessed insufficient the same as for RHYNSE and for the same reason: new product. **The use in rye is therefore not authorized in Poland.**

WHEAT

BARLEY

TRITICALE

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3.2.3.5 Efficacy trials results for the control of triticale diseases

A total of **14 efficacy trials** were carried out in the Central registration zone to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2020 to 2021** in the Maritime (1 trial in Czech Republic and 3 trials in Germany), the Northeast (4 trials in Poland) and the Southeast (5 trials in Hungary and 1 trial in Romania) EPPO climatic zones.

One out of 14 trials are not taken into account in the efficacy analysis below due to a low pest pressure conditions or an abnormal level of efficacy of the reference standards. Thus, this trial is excluded from the analysis of efficacy. However, the potential crop phytotoxicity symptoms observed in this trial is analysed in Section 3.4.1.

Therefore, a total of **13 valid efficacy trials** in the Maritime (4 trials), the Northeast (4 trials) and the Southeast (5 trials) EPPO climatic zone were available to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of triticale diseases.

3.2.3.5.1 Leaf spot of triticale (*Zymoseptoria tritici* - SEPTTR)

One valid efficacy trial was carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of SEPTTR. This trial was carried out **in 2020** in the Maritime EPPO climatic zone in Czech Republic in winter triticale.

Moreover, to complete the data package, **2 efficacy trials** performed **from 2020 to 2021** in the Maritime and the Northeast EPPO climatic zone in Denmark and Latvia are also provided as supportive data.

Table 3.2-86 and Table 3.2-87 summarises the efficacy of ADM.03503.F.1.A against leaf spot.

Table 3.2-86: Efficacy of ADM.03503.F.1.A - Triticale - SEPTTR - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)													No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX			
					Untreated			ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
								Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A	
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
SEPTTR Disease severity	Last valid assessment after application A	Maritime	FLMI2	1	5.4	-	-	88.0	-	-	-	89.2	-	-	-	88.3	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Last valid assessment after application B	Maritime	FLAGLE	1	5.6	-	-	85.9	-	-	-	88.8	-	-	-	82.8	-	-	-	0> ; 1= ; 0<	1> ; 0= ; 0<
			FLMI1	1	8.6	-	-	86.0	-	-	-	87.3	-	-	-	81.3	-	-	-	1> ; 0= ; 0<	1> ; 0= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-87: Efficacy of ADM.03503.F.1.A - Triticale - LEPTNO or SEPTTR - Disease severity on leaves (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)													No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to REVYTREX REVYSTAR XL			
					Untreated			ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				REVYTREX REVYSTAR XL 1.5 L/ha					
								Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Mefentrifluconazole 100+100 g a.s./ha 150+75 g a.s./ha				ADM.03503.F.1.A	
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
SEPTTR Disease severity	Last valid assessment after application B	Maritime	FLMI2	1	25.0	-	-	92.0	-	-	-	93.0	-	-	-	92.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		Northeast	FLMI1	1	6.6	-	-	84.6	-	-	-	100.0	-	-	-	92.5	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

One trial is available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked 5% of the flag leaves minus 2 (FLMI2) area. After the second application, the disease in the untreated plot attacked 6% of the flag leaves (FLAGLE) area and 9% of the flag leaves minus 1 (FLMI1) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPP0 climatic zone

At the last valid assessment, only one trial is available. ADM.03503.F.1.A at 1.25 L/ha showed a good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (89% on FLAGLE, 87% on FLMI1 and 89% on FLMI2) was similar or even superior to LIBRAX (83% on FLAGLE, 81% on FLMI1 and 88% on FLMI2). This difference was significant on FLAGLE and FLMI1.

In one supportive trial, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% on FLMI2) was similar to REYXTREX/REYSTAR XL (92%). No significant difference was noted in this trial.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of SEPTTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (86% on FLAGLE and FLMI1 and 88% on FLMI2) was similar or even superior to LIBRAX (83% on FLAGLE, 81% on FLMI1 and 88% on FLMI2). This difference was significant on FLMI1.

In one supportive trial, the efficacy of ADM.03503.F.1.A at 1.00 L/ha (92% on FLMI2) was similar to REYXTREX/REYSTAR XL (92%). No significant difference was noted in this trial.

Northeast EPP0 climatic zone

In one supportive trial, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% on FLMI1) was similar or even superior to REYXTREX/REYSTAR XL (93%). No significant difference was noted in this trial.

In one supportive trial, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (85% on FLMI1) was inferior to REYXTREX/REYSTAR XL (93%). However, no significant difference was noted in this trial.

To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of SEPTTR in triticale crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a good control of leaf spot of triticale similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control leaf spot according to the disease pressure.

The authorization of a triticale crop fungicide versus the disease leaf spot, can be also granted based on extrapolated data generated in wheat leaf spot trials. In the BAD, a total of 64 trials are presented to support this use.

This includes 1 supportive trial in triticale (presented above), and 63 wheat supportive trials (relevant by extrapolation). These additional trials are presented above in Section 3.2.3.2.1 Leaf spot of wheat (*Zymoseptoria tritici* - SEPTTR).

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of leaf spot of triticale (*Zymoseptoria tritici* - SEPTTR).

3.2.3.5.2 Brown rust of triticale (*Puccinia recondita* - PUCCRE)

A total of **8 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PUCCRE. These trials were carried out **from 2020 to 2021** in the Maritime (1 trial in Czech Republic and 2 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (2 trials in Hungary and 1 trial in Romania) EPPO climatic zones in winter triticale.

Table 3.2-88 summarises the efficacy of ADM.03503.F.1.A against PUCCRE.

Table 3.2-88: Efficacy of ADM.03503.F.1.A - Triticale - PUCCRE - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max
PUCCRE Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	8.8	-	-	45.7	-	-	-	60.0	-	-	-	60.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	1	42.5	-	-	52.9	-	-	-	55.9	-	-	-	55.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		Northeast	FLMI1	1	7.3	-	-	86.2	-	-	-	86.2	-	-	-	86.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	1	8.3	-	-	85.1	-	-	-	91.0	-	-	-	87.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		All EPPO climatic zones	FLMI1	2	8.0	7.3	8.8	65.9	45.7	86.2	20.2	73.1	60.0	86.2	13.1	73.1	60.0	86.2	13.1	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	2	25.4	8.3	42.5	69.0	52.9	85.1	16.1	73.4	55.9	91.0	17.5	71.9	55.9	87.9	16.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
	Last valid assessment after application B	Maritime	FLAGLE	3	14.5	5.8	28.8	77.6	47.8	100.0	21.9	82.5	60.9	100.0	16.2	79.2	56.5	100.0	17.8	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI1	2	28.6	9.7	47.5	55.4	28.9	81.9	26.5	62.1	39.5	84.7	22.6	56.5	34.2	78.8	22.3	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	1	45.0	-	-	66.7	-	-	-	75.0	-	-	-	63.9	-	-	-	0> ; 1= ; 0<	1> ; 0= ; 0<	
		Northeast	FLAGLE	2	6.6	5.8	7.5	93.3	86.6	100.0	6.7	100.0	100.0	100.0	0.0	98.2	96.4	100.0	1.8	0> ; 1= ; 1<	0> ; 2= ; 0<	
			FLMI1	2	10.3	9.5	11.0	86.8	84.1	89.4	2.7	92.1	84.1	100.0	8.0	95.1	94.7	95.5	0.4	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	1	16.0	-	-	84.3	-	-	-	98.3	-	-	-	96.7	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<	
		Southeast	FLAGLE	2	5.5	5.4	5.6	100.0	100.0	100.0	0.0	100.0	100.0	100.0	0.0	100.0	100.0	100.0	0.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	8.2	7.4	9.3	94.8	84.3	100.0	7.4	96.7	90.2	100.0	4.7	95.9	87.6	100.0	5.8	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI2	3	12.8	8.4	16.3	92.5	77.4	100.0	10.6	94.5	83.5	100.0	7.8	93.4	80.3	100.0	9.3	0> ; 3= ; 0<	0> ; 3= ; 0<	
		All EPPO climatic zones	FLAGLE	7	9.7	5.4	28.8	88.5	47.8	100.0	17.7	92.5	60.9	100.0	13.7	90.6	56.5	100.0	15.3	0> ; 6= ; 1<	0> ; 7= ; 0<	
			FLMI1	7	14.6	7.4	47.5	81.2	28.9	100.0	22.5	85.5	39.5	100.0	19.9	84.4	34.2	100.0	21.7	0> ; 7= ; 0<	0> ; 7= ; 0<	
			FLMI2	5	19.9	8.4	45.0	85.7	66.7	100.0	13.0	91.4	75.0	100.0	10.3	88.2	63.9	100.0	14.2	0> ; 4= ; 1<	1> ; 4= ; 0<	
	PUCCRE Disease severity	Last valid assessment	Maritime	FLAGLE	3	14.5	5.8	28.8	77.6	47.8	100.0	21.9	82.5	60.9	100.0	16.2	79.2	56.5	100.0	17.8	0> ; 3= ; 0<	0> ; 3= ; 0<
				FLMI1	2	28.6	9.7	47.5	55.4	28.9	81.9	26.5	62.1	39.5	84.7	22.6	56.5	34.2	78.8	22.3	0> ; 2= ; 0<	0> ; 2= ; 0<
FLMI2				1	45.0	-	-	66.7	-	-	-	75.0	-	-	-	63.9	-	-	-	0> ; 1= ; 0<	1> ; 0= ; 0<	
Northeast		FLAGLE	2	6.6	5.8	7.5	93.3	86.6	100.0	6.7	100.0	100.0	100.0	0.0	98.2	96.4	100.0	1.8	0> ; 1= ; 1<	0> ; 2= ; 0<		
		FLMI1	2	10.3	9.5	11.0	86.8	84.1	89.4	2.7	92.1	84.1	100.0	8.0	95.1	94.7	95.5	0.4	0> ; 2= ; 0<	0> ; 2= ; 0<		
		FLMI2	2	12.1	8.3	16.0	84.7	84.3	85.1	0.4	94.6	91.0	98.3	3.7	92.3	87.9	96.7	4.4	0> ; 1= ; 1<	0> ; 2= ; 0<		
Southeast	FLAGLE	2	5.5	5.4	5.6	100.0	100.0	100.0	0.0	100.0	100.0	100.0	0.0	100.0	100.0	100.0	0.0	0> ; 2= ; 0<	0> ; 2= ; 0<			

			FLMI1	3	8.2	7.4	9.3	94.8	84.3	100.0	7.4	96.7	90.2	100.0	4.7	95.9	87.6	100.0	5.8	0> ; 3= ; 0<	0> ; 3= ; 0<
			FLMI2	3	12.8	8.4	16.3	92.5	77.4	100.0	10.6	94.5	83.5	100.0	7.8	93.4	80.3	100.0	9.3	0> ; 3= ; 0<	0> ; 3= ; 0<
		All EPPO climatic zones	FLAGLE	7	9.7	5.4	28.8	88.5	47.8	100.0	17.7	92.5	60.9	100.0	13.7	90.6	56.5	100.0	15.3	0> ; 6= ; 1<	0> ; 7= ; 0<
			FLMI1	7	14.6	7.4	47.5	81.2	28.9	100.0	22.5	85.5	39.5	100.0	19.9	84.4	34.2	100.0	21.7	0> ; 7= ; 0<	0> ; 7= ; 0<
			FLMI2	6	18.0	8.3	45.0	85.6	66.7	100.0	11.8	91.3	75.0	100.0	9.4	88.1	63.9	100.0	12.9	0> ; 5= ; 1<	1> ; 5= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Eight trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked from 7% to 9% of the flag leaves minus 1 (FLMI1) area and from 8% to 73% of the flag leaves minus 2 (FLMI2) area. After the second application, the disease in the untreated plot attacked from 5% to 29% of the flag leaves (FLAGLE) area, from 7% to 48% of the flag leaves minus 1 (FLMI1) area and from 8% to 45% of the flag leaves minus 2 (FLMI2) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a moderate to good control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (83% in 3 trials on FLAGLE, 62% in 2 trials on FLMI1 and 75% in 1 trial on FLMI2) was similar or even superior to LIBRAX (79% on FLAGLE, 57% on FLMI1 and 64% on FLMI2). This difference was significant in the trial on FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (78% in 3 trials on FLAGLE, 55% in 2 trials on FLMI1 and 67% in 1 trial on FLMI2) was similar to LIBRAX (79% on FLAGLE, 57% on FLMI1 and 64% on FLMI2). No significant difference was noted in all assessments on FLAGLE, FLMI1 and FLMI2.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good to high control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% in 2 trials on FLAGLE, 92% in 2 trials on FLMI1 and 95% in 2 trials on FLMI2) was similar to LIBRAX (98% on FLAGLE, 95% on FLMI1 and 92% on FLMI2). No significant difference was noted in all assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a good to very good control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (93% in 2 trials on FLAGLE, 87% in 2 trials on FLMI1 and 85% in 2 trials on FLMI2) was slightly inferior to LIBRAX (98% on FLAGLE, 95% on FLMI1 and 92% on FLMI2). However, no significant difference was noted in 4 out of 6 assessments on FLAGLE, FLMI1 and FLMI2.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a high control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% in 2 trials on FLAGLE, 97% in 3 trials on FLMI1 and 95% in 3 trials on FLMI2) was similar to LIBRAX (100% on FLAGLE, 96% on FLMI1 and 93% on FLMI2). No significant difference was noted in all assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a very good to high control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (100% in 2 trials on FLAGLE, 95% in 3 trials on FLMI1 and 93% in 3 trials on FLMI2) was similar to LIBRAX (100% on FLAGLE, 96% on FLMI1 and 93% on FLMI2). No significant difference was noted in all assessments on FLAGLE, FLMI1 and FLMI2.

Central registration zone

Finally, a total of 8 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in triticale against PUCCRE.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good to very good control of PUCCRE.

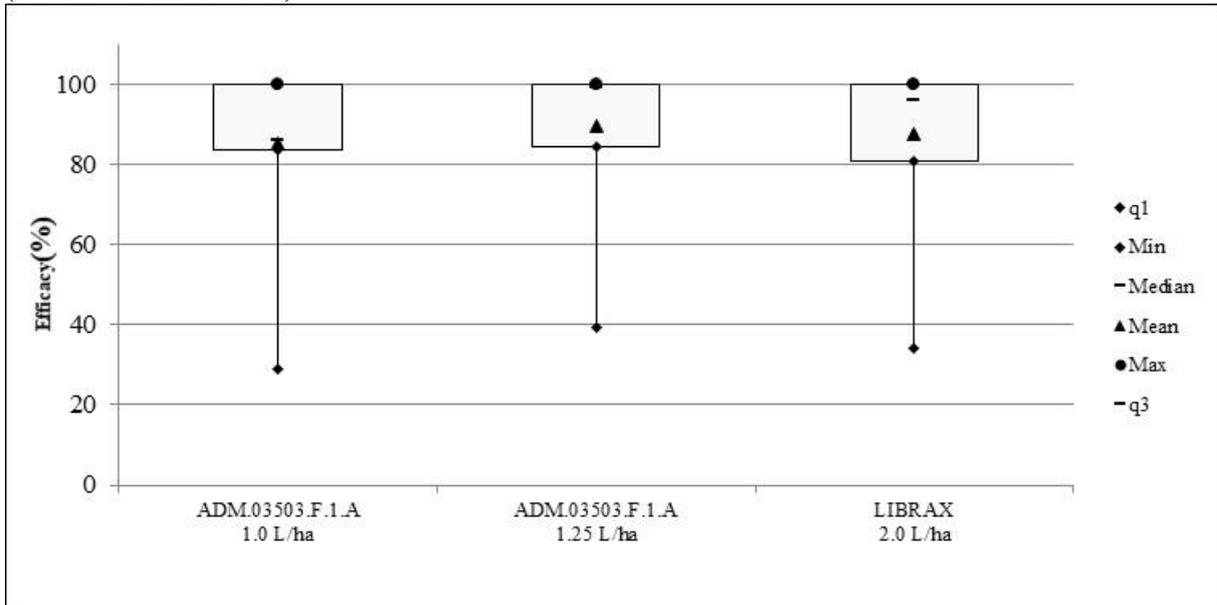
The efficacy of ADM.03503.F.1.A at 1.25 L/ha (93% in 7 trials on FLAGLE, 86% in 7 trials on FLMI1 and 91% in 6 trials on FLMI2) was similar to LIBRAX (91% on FLAGLE, 84% on FLMI1 and 88% on FLMI2). No significant difference was at least noted in all assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of PUCCRE.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (89% in 7 trials on FLAGLE, 81% in 7 trials on FLMI1 and 86% in 6 trials on FLMI2) was similar to LIBRAX (91% on FLAGLE, 84% on FLMI1 and 88% on FLMI2). No significant difference was noted in 18 out of 20 assessments on FLAGLE, FLMI1 and FLMI2.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE, FLMI1 and FLMI2) (Figure 3.2-38). Overall, ADM.03503.F.1.A at 1.25 L/ha had at least the same level of efficacy and the same dispersion and variation between means than LIBRAX.

Figure 3.2-38 Efficacy of ADM.03503.F.1.A - Triticale - PUCCRE - Last valid assessment - Box Plot graphic (8 trials - 20 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PUCCRE in triticale crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a good control of brown rust of triticale similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control brown rust according to the disease pressure.

The authorisation of a triticale crop fungicide versus the disease brown rust, can be granted based on extrapolated data generated in wheat brown rust trials. In the BAD, a total of 41 trials are presented to support this use.

This includes 8 supportive trials in triticale (presented above) and 33 wheat supportive trials (relevant by extrapolation). These additional trials are presented above in Section 3.2.3.2.2 Brown rust of wheat (*Puccinia recondita* - PUCCRT).

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L /ha for the control of brown rust of triticale (*Puccinia recondita* - PUCCRE).

3.2.3.5.3 Yellow rust of triticale (*Puccinia striiformis* - PuccST)

One valid efficacy trial was carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PuccST. This trial was carried out **in 2020** in the Maritime EPPO climatic zone in Germany in winter triticale.

Moreover, to complete the data package, **2 efficacy trials** performed **from 2020 to 2021** in the Maritime EPPO climatic zone in Denmark and Sweden are also provided as supportive data.

Table 3.2-89 and Table 3.2-90 summarise the efficacy of ADM.03503.F.1.A against PuccST.

Table 3.2-89: Efficacy of ADM.03503.F.1.A - Triticale - PUCST - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
PUCST Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	5.3	-	-	90.5	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI2	1	5.3	-	-	90.5	-	-	-	95.2	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Last valid assessment after application B	Maritime	FLAGLE	1	76.3	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI1	1	99.0	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI2	1	99.0	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-90: Efficacy of ADM.03503.F.1.A - Triticale - PUCST - Disease severity on leaves (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Untreated			Percentage of efficacy (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to REVYTREX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				REVYTREX 1.5 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Mefentrifluconazole 100+100 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
PUCST Disease severity	Last valid assessment after application A	Maritime	FLMI1	1	5.8	-	-	89.0	-	-	-	89.0	-	-	-	87.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Last valid assessment after application B	Maritime	FLAGLE	1	51.3	-	-	89.3	-	-	-	89.1	-	-	-	92.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI1	1	68.8	-	-	95.3	-	-	-	94.6	-	-	-	96.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
PUCST Disease severity	Last valid assessment	Maritime	FLAGLE	1	51.3	-	-	89.3	-	-	-	89.1	-	-	-	92.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI1	2	37.3	5.8	68.8	92.2	89.0	95.3	3.2	91.8	89.0	94.6	2.8	91.6	87.0	96.2	4.6	0> ; 2= ; 0<	0> ; 2= ; 0<

(1) Comparison based on statistics carried out in each trial report.

One trial is available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked 5% of the flag leaves minus 1 (FLMI1) or flag leaves minus 2 (FLMI2) areas. After the second application, the disease in the untreated plot attacked 76% of the flag leaves (FLAGLE) area and 99% of the flag leaves minus 1 (FLMI1) or flag leaves minus 2 (FLMI2) areas.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, only one trial is available. ADM.03503.F.1.A at 1.25 L/ha showed a high control of PUC CST.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% on FLAGLE, FLMI1 and FLMI2) was similar to LIBRAX (100% on FLAGLE, FLMI1 and FLMI2).

In two supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (89% on FLAGLE and 92% on FLMI1) was similar to REVYTREX (92% on FLAGLE and FLMI1). No significant difference was noted in this trial.

ADM.03503.F.1.A at 1.00 L/ha showed a high control of PUC CST.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (100% on FLAGLE, FLMI1 and FLMI2) was similar to LIBRAX (100% on FLAGLE, FLMI1 and FLMI2).

In two supportive trials, the efficacy of ADM.03503.F.1.A at 1.00 L/ha (89% on FLAGLE and 92% on FLMI1) was similar to REVYTREX (92% on FLAGLE and FLMI1). No significant difference was noted in this trial.

To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PUC CST in triticale crops similar to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha showed also a good control of yellow rust of triticale similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control leaf spot according to the disease pressure.

The authorization of a triticale crop fungicide versus the disease yellow rust, can be also granted based on extrapolated data generated in wheat yellow rust trials. In the BAD, a total of 29 trials are presented to support this use.

This includes 1 supportive trial in triticale (presented above), and 28 wheat supportive trials (relevant by extrapolation). These additional trials are presented above in Section 3.2.3.2.3 Yellow rust of wheat (*Puccinia striiformis* - PUC CST).

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of yellow rust of triticale (*Puccinia striiformis* - PUC CST).

3.2.3.5.4 Tan spot of triticale (*Pyrenophora tritici-repentis* - PYRNTR)

A total of **6 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of PYRNTR. These trials were carried out **in 2020** in the Maritime (1 trial in Czech Republic and 1 trial in Germany), the Northeast (2 trials in Poland) and the Southeast (2 trials in Hungary) EPPO climatic zones in winter triticale.

Moreover, to complete the data package, **3 efficacy trials** performed **from 2020 to 2021** in the Northeast EPPO climatic zone in Latvia are also provided as supportive data.

Table 3.2-91 and Table 3.2-92 summarise the efficacy of ADM.03503.F.1.A against PYRNTR.

Table 3.2-91: Efficacy of ADM.03503.F.1.A - Triticale - PYRNTR - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
PYRNTR Disease severity	Last valid assessment after application A	Northeast	FLMI1	1	15.5	-	-	83.9	-	-	-	87.0	-	-	-	95.2	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
			FLMI2	1	21.8	-	-	83.0	-	-	-	89.5	-	-	-	97.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
	Last valid assessment after application B	Maritime	FLAGLE	2	52.4	5.9	99.0	87.6	83.6	91.7	4.0	89.4	85.3	93.4	4.1	83.5	75.3	91.7	8.2	1> ; 1= ; 0<	1> ; 1= ; 0<
			FLMI1	2	53.2	7.4	99.0	89.0	83.2	94.7	5.8	90.6	84.2	97.0	6.4	85.7	76.6	94.7	9.1	1> ; 1= ; 0<	1> ; 1= ; 0<
		FLMI2	1	99.0	-	-	97.0	-	-	-	98.5	-	-	-	96.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		Northeast	FLMI1	2	14.5	7.5	21.5	82.0	80.3	83.7	1.7	89.2	86.6	91.8	2.6	89.7	81.8	97.6	7.9	0> ; 1= ; 1<	0> ; 2= ; 0<
			FLMI2	2	21.4	14.0	28.8	79.2	79.1	79.3	0.1	88.7	86.9	90.5	1.8	91.2	84.1	98.3	7.1	0> ; 0= ; 2<	0> ; 1= ; 1<
		Southeast	FLMI2	2	4.9	4.7	5.1	86.9	84.0	89.7	2.9	94.4	93.6	95.1	0.8	93.7	93.2	94.1	0.5	0> ; 1= ; 1<	0> ; 2= ; 0<
		All EPPO climatic zones	FLAGLE	2	52.4	5.9	99.0	87.6	83.6	91.7	4.0	89.4	85.3	93.4	4.1	83.5	75.3	91.7	8.2	1> ; 1= ; 0<	1> ; 1= ; 0<
			FLMI1	4	33.9	7.4	99.0	85.5	80.3	94.7	5.5	89.9	84.2	97.0	4.9	87.7	76.6	97.6	8.7	1> ; 2= ; 1<	1> ; 3= ; 0<
FLMI2	5	30.3	4.7	99.0	85.8	79.1	97.0	6.8	92.9	86.9	98.5	4.0	93.3	84.1	98.3	4.9	0> ; 2= ; 3<	0> ; 4= ; 1<			

(1) Comparison based on statistics carried out in each trial report.

Table 3.2-92: Efficacy of ADM.03503.F.1.A - Triticale - PYRNTR - Disease severity on leaves (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to REVYTREX REVYSTAR XL		
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				REVYTREX REVYSTAR XL 1.5 L/ha				
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Mefentrifluconazole 100+100 g a.s./ha 150+75 g a.s./ha				ADM.03503.F.1.A				
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha
PYRNTR Disease severity	Last valid assessment after application B	Northeast	FLMI1	3	12.2	8.8	19.1	77.6	66.1	100.0	15.8	79.8	59.9	98.6	15.8	76.4	59.1	98.6	16.5	0> ; 3= ; 0<	0> ; 3= ; 0<
			FLMI2	1	40.6	-	-	93.8	-	-	-	94.0	-	-	-	94.6	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<

(1) Comparison based on statistics carried out in each trial report.

Six trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked 16% of the flag leaves minus 1 (FLMI1) area and 22% of the flag leaves minus 2 (FLMI2) area. After the second application, the disease in the untreated plot attacked from 6% to 99% of the flag leaves (FLAGLE) area, from 7% to 99% of the flag leaves minus 1 (FLMI1) area and from 5% to 99% of the flag leaves minus 2 (FLMI2) area.

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PYRNTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (89% in 2 trials on FLAGLE, 91% in 2 trials on FLMI1 and 99% in 1 trial on FLMI2) was similar or even superior to LIBRAX (84% on FLAGLE, 86% on FLMI1 and 97% on FLMI2). This difference was significant in 1 out of 2 trials on FLAGLE and FLMI1. ADM.03503.F.1.A at 1.00 L/ha showed a good to very good control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (88% in 2 trials on FLAGLE, 89% in 2 trials on FLMI1 and 97% in 1 trial on FLMI2) was similar or even superior to LIBRAX (84% on FLAGLE, 86% on FLMI1 and 97% on FLMI2). This difference was significant in 1 out of 2 trials on FLAGLE and FLMI1.

Northeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good control of PYRNTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (89% in 2 trials on FLMI1 and 89% in 2 trials on FLMI2) was similar to LIBRAX (90% on FLMI1 and 91% on FLMI2). No significant difference was noted in 3 out of 4 assessments on FLMI1 and FLMI2.

In three supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (80% on FLMI1 and 94% on FLMI2) was similar to REVYTREX/REVYSTAR XL (76% on FLMI1 and 95% on FLMI2). No significant difference was noted in this trial.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (82% in 2 trials on FLMI1 and 79% in 2 trials on FLMI2) was inferior to LIBRAX (90% on FLMI1 and 91% on FLMI2).

In three supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (78% on FLMI1 and 94% on FLMI2) was similar to REVYTREX/REVYSTAR XL (76% on FLMI1 and 95% on FLMI2). No significant difference was noted in this trial.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good control of PYRNTR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (94% in 2 trials on FLMI2) was similar to LIBRAX (94%). No significant difference was noted in all assessments.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00L/ha (87% in 2 trials on FLMI2) was inferior to LIBRAX (94%). However, no significant difference was noted in 1 out of 2 assessments.

Central registration zone

Finally, a total of 6 efficacy trials across Eppo climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in triticale against PYRNTR.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a good to very good control of PYRNTR.

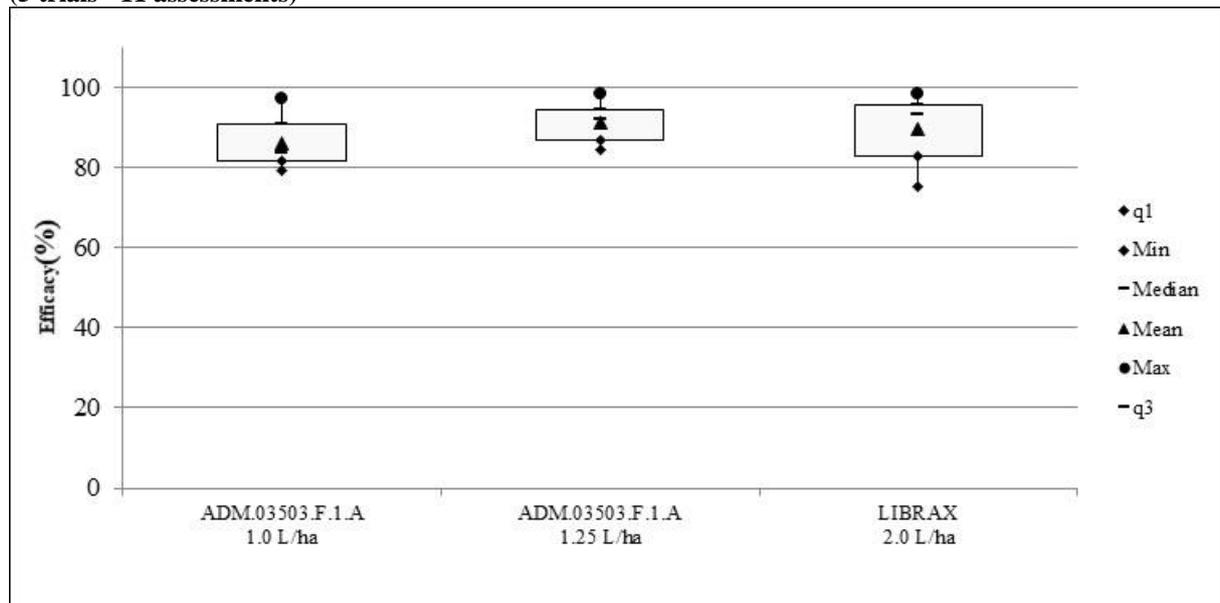
The efficacy of ADM.03503.F.1.A at 1.25 L/ha (89% in 2 trials on FLAGLE, 90% in 4 trials on FLMI1 and 93% in 5 trials on FLMI2) was similar to LIBRAX (84% on FLAGLE, 88% on FLMI1 and 93% on FLMI2). No significant difference was at least noted in 10 out of 11 assessments on FLAGLE, FLMI1 and FLMI2.

ADM.03503.F.1.A at 1.00 L/ha showed a good control of PYRNTR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (88% in 2 trials on FLAGLE, 86% in 4 trials on FLMI1 and 86% in 5 trials on FLMI2) was similar to LIBRAX (84% on FLAGLE, 88% on FLMI1 and 93% on FLMI2). No significant difference was at least noted in 7 out of 11 assessments on FLAGLE, FLMI1 and FLMI2.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLAGLE, FLMI1 and FLMI2) (Figure 3.2-39). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-39 Efficacy of ADM.03503.F.1.A - Triticale - PYRNTR - Last valid assessment - Box Plot graphic (5 trials - 11 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of PYRNTR in triticale crops superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha also showed a good control of tan spot of triticale similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control tan spot according to the disease pressure.

The authorisation of a triticale crop fungicide versus the disease tan spot, can be also granted based on extrapolated data generated in wheat tan spot trials. In the BAD, a total of 20 trials are presented to support this use.

This includes 5 supportive trials in triticale (presented above) and 15 wheat supportive trials (relevant by extrapolation). These additional trials are presented above in Section 3.2.3.2.4 Tan spot of wheat (*Pyrenophora tritici-repentis* - PYRNTR).

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of tan spot of triticale (*Pyrenophora tritici-repentis* - PYRNTR).

3.2.3.5.5 Powdery mildew of triticale (*Blumeria graminis* - ERYSGR)

A total of **5 valid efficacy trials** were carried out to confirm the efficacy of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha for the control of ERYSGR. These trials were carried out **from 2020 to 2021** in the Maritime (1 trial in Germany), the Northeast (2 trials in Poland) and the Southeast (2 trials in Hungary) EPPO climatic zones in winter triticale.

Moreover, to complete the data package, **5 efficacy trials** performed **from 2020 to 2021** in the Maritime and the Northeast EPPO climatic zone in Sweden (2 trials) and Latvia (3 trials) are also provided as supportive data.

Table 3.2-93 and Table 3.2-94 summarise the efficacy of ADM.03503.F.1.A against ERYSGR.

Table 3.2-93: Efficacy of ADM.03503.F.1.A - Triticale - ERYSGR - Disease severity on leaves

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)														No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX			
					Untreated				ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
					Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha				ADM.03503.F.1.A					
					Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	1.00 L/ha	1.25 L/ha
ERYSGR Disease severity	Last valid assessment after application A	Northeast	FLMI1	1	4.8	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	1	13.5	-	-	77.7	-	-	-	92.6	-	-	-	90.5	-	-	-	0> ; 0= ; 1<	0> ; 1= ; 0<	
			FLMI3	2	13.9	8.3	19.5	77.4	75.7	79.1	1.7	90.1	89.7	90.5	0.4	91.7	83.3	100.0	8.3	1> ; 0= ; 1<	1> ; 1= ; 0<	
		Southeast	FLMI2	2	7.7	5.3	10.2	95.5	90.9	100.0	4.6	96.1	92.1	100.0	4.0	100.0	100.0	100.0	0.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI3	2	15.4	10.9	19.9	87.1	76.9	97.2	10.2	92.4	86.5	98.2	5.9	95.8	93.8	97.7	2.0	0> ; 2= ; 0<	0> ; 2= ; 0<	
			All EPPO climatic zones	FLMI1	1	4.8	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		FLMI2	3	9.7	5.3	13.5	89.5	77.7	100.0	9.2	94.9	92.1	100.0	3.6	96.8	90.5	100.0	4.5	0> ; 2= ; 1<	0> ; 3= ; 0<		
		FLMI3	4	14.6	8.3	19.9	82.2	75.7	97.2	8.7	91.2	86.5	98.2	4.3	93.7	83.3	100.0	6.4	1> ; 2= ; 1<	1> ; 3= ; 0<		
	Last valid assessment after application B	Maritime	FLMI3	1	6.8	-	-	77.8	-	-	-	77.8	-	-	-	88.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			Northeast	FLMI1	1	5.8	-	-	91.7	-	-	-	100.0	-	-	-	91.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				FLMI2	1	16.5	-	-	92.4	-	-	-	93.9	-	-	-	92.4	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		FLMI3		2	26.8	23.5	30.0	82.0	80.0	84.0	2.0	94.5	94.2	94.7	0.3	94.0	90.4	97.6	3.6	0> ; 0= ; 2<	1> ; 1= ; 0<	
		Southeast	FLMI1	1	5.4	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	11.7	7.4	16.0	92.6	91.2	93.9	1.4	96.7	93.4	100.0	3.3	95.8	94.6	97.0	1.2	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI3	1	31.4	-	-	83.1	-	-	-	89.6	-	-	-	98.4	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
		All EPPO climatic zones	FLMI1	2	5.6	5.4	5.8	95.8	91.7	100.0	4.2	100.0	100.0	100.0	0.0	95.8	91.7	100.0	4.2	0> ; 2= ; 0<	0> ; 2= ; 0<	
FLMI2	3	13.3	7.4	16.5	92.5	91.2	93.9	1.1	95.8	93.4	100.0	3.0	94.7	92.4	97.0	1.9	0> ; 3= ; 0<	0> ; 3= ; 0<				
FLMI3	4	22.9	6.8	31.4	81.2	77.8	84.0	2.5	89.1	77.8	94.7	6.8	93.8	88.9	98.4	4.2	0> ; 2= ; 2<	1> ; 3= ; 0<				
ERYSGR Disease severity	Last valid assessment	Maritime	FLMI3	1	6.8	-	-	77.8	-	-	-	77.8	-	-	-	88.9	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			Northeast	FLMI1	1	5.8	-	-	91.7	-	-	-	100.0	-	-	-	91.7	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
				FLMI2	1	16.5	-	-	92.4	-	-	-	93.9	-	-	-	92.4	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<
		FLMI3		2	26.8	23.5	30.0	82.0	80.0	84.0	2.0	94.5	94.2	94.7	0.3	94.0	90.4	97.6	3.6	0> ; 0= ; 2<	1> ; 1= ; 0<	
		Southeast	FLMI1	1	5.4	-	-	100.0	-	-	-	100.0	-	-	-	100.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	11.7	7.4	16.0	92.6	91.2	93.9	1.4	96.7	93.4	100.0	3.3	95.8	94.6	97.0	1.2	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI3	2	21.1	10.9	31.4	90.2	83.1	97.2	7.1	93.9	89.6	98.2	4.3	96.1	93.8	98.4	2.3	0> ; 2= ; 0<	0> ; 2= ; 0<	
		All EPPO climatic zones	FLMI1	2	5.6	5.4	5.8	95.8	91.7	100.0	4.2	100.0	100.0	100.0	0.0	95.8	91.7	100.0	4.2	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI2	3	13.3	7.4	16.5	92.5	91.2	93.9	1.1	95.8	93.4	100.0	3.0	94.7	92.4	97.0	1.9	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI3	5	20.5	6.8	31.4	84.4	77.8	97.2	6.8	90.9	77.8	98.2	7.1	93.8	88.9	98.4	3.8	0> ; 3= ; 2<	1> ; 4= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Table 3.2-94: Efficacy of ADM.03503.F.1.A - Triticale - ERYSGR - Disease severity on leaves (Supportive data)

Target Parameters	Assessment timing	EPPO climatic zone	Parts	No. of trials	Percentage of efficacy (%)																No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >;=< to REVYTREX REVYSTAR XL	
					Untreated			ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				REVYTREX REVYSTAR XL 1.5 L/ha						
								Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Mefentrifluconazole						
								75+150 g a.s./ha				93.75+187.5 g a.s./ha				100+100 g a.s./ha 150+75 g a.s./ha						
					Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	ADM.03503.F.1.A 1.00 L/ha	ADM.03503.F.1.A 1.25 L/ha	
ERYSGR Disease severity	Last valid assessment after application A	Maritime	FLAGLE	1	5.5	-	-	64.0	-	-	-	75.0	-	-	-	66.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	1	22.5	-	-	69.0	-	-	-	81.0	-	-	-	74.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	13.3	6.6	20.0	86.3	87.5	85.0	1.3	91.6	89.1	94.0	2.5	87.2	85.3	89.0	1.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
	Last valid assessment after application B	Northeast	FLAGLE	2	11.8	7.6	15.9	79.7	61.4	98.0	18.3	78.4	61.3	95.4	17.1	78.7	65.1	92.3	13.6	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	23.6	17.5	31.3	74.7	54.9	100.0	18.8	79.6	[56.6	99.3	17.6	67.9	46.3	95.7	20.6	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI2	3	42.7	24.1	63.4	93.2	88.4	100.0	4.9	92.3	86.6	100.0	5.7	84.6	72.8	95.7	9.4	0> ; 3= ; 0<	0> ; 3= ; 0<	
ERYSGR Disease severity	Last valid assessment	Maritime	FLAGLE	1	5.5	-	-	64.0	-	-	-	75.0	-	-	-	66.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI1	1	22.5	-	-	69.0	-	-	-	81.0	-	-	-	74.0	-	-	-	0> ; 1= ; 0<	0> ; 1= ; 0<	
			FLMI2	2	13.3	6.6	20.0	86.3	87.5	85.0	1.3	91.6	89.1	94.0	2.5	87.2	85.3	89.0	1.9	0> ; 2= ; 0<	0> ; 2= ; 0<	
		Northeast	FLAGLE	2	11.8	7.6	15.9	79.7	61.4	98.0	18.3	78.4	61.3	95.4	17.1	78.7	65.1	92.3	13.6	0> ; 2= ; 0<	0> ; 2= ; 0<	
			FLMI1	3	23.6	17.5	31.3	74.7	54.9	100.0	18.8	79.6	[56.6	99.3	17.6	67.9	46.3	95.7	20.6	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI2	3	42.7	24.1	63.4	93.2	88.4	100.0	4.9	92.3	86.6	100.0	5.7	84.6	72.8	95.7	9.4	0> ; 3= ; 0<	0> ; 3= ; 0<	
		All EPPO climatic zones	FLAGLE	3	9.7	5.5	15.9	74.5	61.4	98.0	16.7	77.2	61.3	95.4	14.0	74.5	65.1	92.3	12.6	0> ; 3= ; 0<	0> ; 3= ; 0<	
			FLMI1	4	23.3	17.5	31.3	73.3	54.9	100.0	16.5	79.9	[56.6	99.3	15.2	69.5	46.3	95.7	18.1	0> ; 4= ; 0<	0> ; 4= ; 0<	
			FLMI2	5	30.9	6.6	63.4	90.4	85.0	100.0	5.2	92.0	86.6	100.0	4.7	85.6	72.8	95.7	7.5	0> ; 5= ; 0<	0> ; 5= ; 0<	

⁽¹⁾ Comparison based on statistics carried out in each trial report.

Five trials are available to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. After the first application, the disease in the untreated plot attacked 5% of the flag leaves minus 1 (FLMI1) area, from 5% to 14% of the flag leaves minus 2 (FLMI2) and from 11% to 20% of the flag leaves minus 3 (FLMI3). After the second application, the disease in the untreated plot attacked from 5% to 6% of the flag leaves minus 1 (FLMI1) area, from 7% to 17% of the flag leaves minus 2 (FLMI2) and from 7% to 31% of the flag leaves minus 3 (FLMI3)..

In the synthesis table, an evaluation was performed after the first application, after the second application and finally for the last valid assessment including data from trials with one or two applications. To simplify the approach and as few data are available after one application (earlier in the season, thus with few infestation), only last valid assessment is commented hereafter.

Maritime Eppo climatic zone

At the last valid assessment, only one trial is available. ADM.03503.F.1.A at 1.25 L/ha showed a moderate control of ERYSGR.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (78% on FLMI3) was inferior to LIBRAX (89%). However, no significant difference was noted.

In two supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (75% on FLAGLE, 81% on FLMI1 and 92% on FLMI2) was similar or even superior to REVYTREX/REVYSTAR XL (66% on FLAGLE, 74% on FLMI1 and 87% on FLMI2). No significant difference was noted in this trial.

ADM.03503.F.1.A at 1.00 L/ha showed a moderate to good control of ERYSGR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (78% on FLMI3) was inferior to LIBRAX (89%). However, no significant difference was noted.

In two supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (80% on FLAGLE, 75% on FLMI1 and 93% on FLMI2) was similar or even superior to REVYTREX/REVYSTAR XL (66% on FLAGLE, 74% on FLMI1 and 87% on FLMI2). No significant difference was noted in this trial.

Northeast Eppo climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a high control of ERYSGR.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% in 1 trial on FLMI1, 97% in 1 trial on FLMI2, and 95% in 2 trials on FLMI3) was similar or even superior to LIBRAX (92% on FLMI1 and FLMI2 and 94% on FLMI3). This difference was significant in 1 out of 2 trials on FLMI3.

In three supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (78% on FLAGLE, 80% on FLMI1 and 92% on FLMI2) was similar to REVYTREX/REVYSTAR XL (79% on FLAGLE, 68% on FLMI1 and 85% on FLMI2). No significant difference was noted in this trial.

ADM.03503.F.1.A at 1.00 L/ha showed a good to very good control of ERYSGR.

The efficacy of ADM.03503.F.1.A at 1.00 L/ha (92% in 1 trial on FLMI1, 92% in 1 trial on FLMI2, and 82% in 2 trials on FLMI3) was inferior to LIBRAX (92% on FLMI1 and FLMI2 and 94% on FLMI3). However, no significant difference was at least noted in 2 out of 4 assessments.

In three supportive trials, the efficacy of ADM.03503.F.1.A at 1.00 L/ha (80% on FLAGLE, 75% on FLMI1 and 93% on FLMI2) was similar to REVYTREX/REVYSTAR XL (79% on FLAGLE, 68% on FLMI1 and 85% on FLMI2). No significant difference was noted in this trial.

Southeast EPPO climatic zone

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a high control of ERYSGR. The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% in 1 trial on FLMI1, 97% in 2 trials on FLMI2, and 94% in 2 trials on FLMI3) was similar to LIBRAX (100% on FLMI1 and 96% on FLMI2 and 96% on FLMI3). No significant difference was noted in all assessments.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of ERYSGR. The efficacy of ADM.03503.F.1.A at 1.00 L/ha (100% in 1 trial on FLMI1, 93% in 2 trials on FLMI2, and 90% in 2 trials on FLMI3) was similar to LIBRAX (100% on FLMI1 and 96% on FLMI2 and 96% on FLMI3). No significant difference was noted in all assessments.

Central registration zone

Finally, a total of 5 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in triticale against ERYSGR.

At the last valid assessment, ADM.03503.F.1.A at 1.25 L/ha showed a very good to high control of ERYSGR.

The efficacy of ADM.03503.F.1.A at 1.25 L/ha (100% in 2 trials on FLMI1, 96% in 3 trials on FLMI2, and 91% in 5 trials on FLMI3) was similar to LIBRAX (96% on FLMI1 and 95% on FLMI2 and 94% on FLMI3). No significant difference was at least noted in all assessments on FLMI1, FLMI2 and FLMI3.

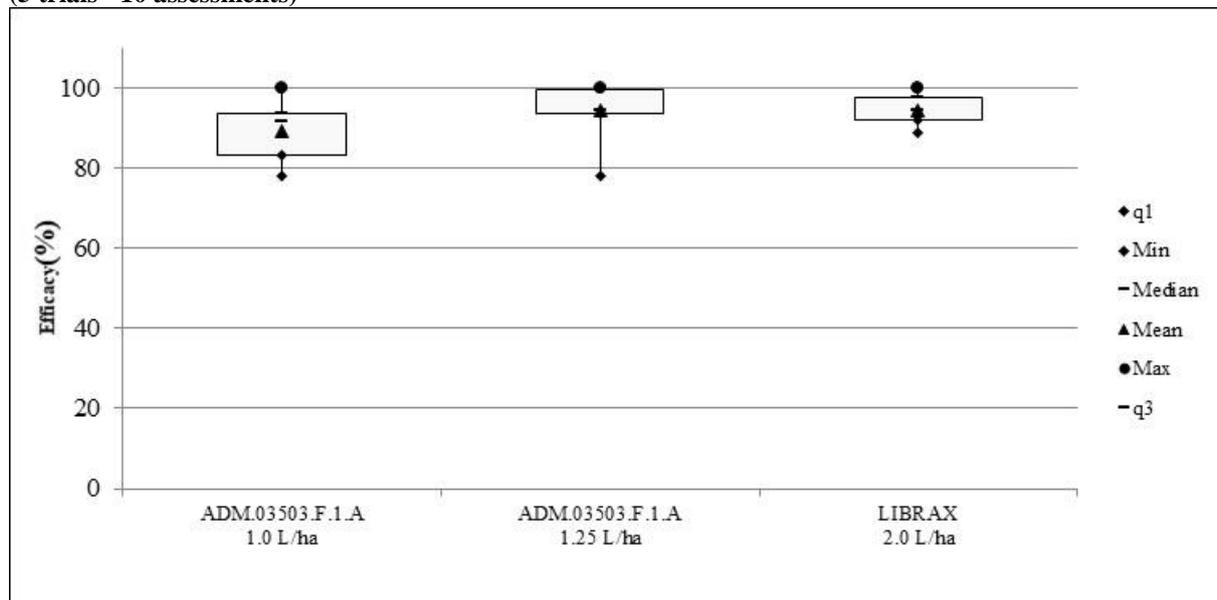
In five supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (77% on FLAGLE, 80% on FLMI1 and 92% on FLMI2) was similar or even superior to REVYTREX/REVYSTAR XL (75% on FLAGLE, 70% on FLMI1 and 90% on FLMI2). No significant difference was noted in this trial.

ADM.03503.F.1.A at 1.00 L/ha showed a very good control of ERYSGR. The efficacy of ADM.03503.F.1.A at 1.00 L/ha (96% in 2 trials on FLMI1, 93% in 3 trials on FLMI2, and 84% in 5 trials on FLMI3) was similar to LIBRAX (96% on FLMI1 and 95% on FLMI2 and 94% on FLMI3). No significant difference was at least noted in 8 out of 10 assessments on FLMI1, FLMI2 and FLMI3.

In five supportive trials, the efficacy of ADM.03503.F.1.A at 1.25 L/ha (75% on FLAGLE, 73% on FLMI1 and 93% on FLMI2) was similar or even superior to REVYTREX/REVYSTAR XL (75% on FLAGLE, 70% on FLMI1 and 90% on FLMI2). No significant difference was noted in this trial.

The difference between the reference standards can be illustrated by box plot graphic on leaves (FLMI1, FLMI2 and FLMI3) (Figure 3.2-40). Overall, ADM.03503.F.1.A at 1.25 L/ha had a better level of efficacy and a lower dispersion and variation between means than LIBRAX.

Figure 3.2-40 Efficacy of ADM.03503.F.1.A - Triticale - ERYSGR - Last valid assessment - Box Plot graphic (5 trials - 10 assessments)



To conclude, ADM.03503.F.1.A at 1.25 L/ha provided efficient and reliable control of ERYSGR in triticale crops superior to LIBRAX.

ADM.03503.F.1.A at 1.00 L/ha also showed a very good control of powdery mildew of triticale similar to LIBRAX. Therefore, the efficacy of ADM.03503.F.1.A at 1.00 L/ha is also acceptable to control powdery mildew according to the disease pressure.

The authorisation of a triticale crop fungicide versus the disease powdery mildew, can be also granted based on extrapolated data generated in wheat and barley powdery mildew trials. In the BAD, a total of 50 trials are presented to support this use.

This includes 5 supportive trials in triticale (presented above) 19 wheat supportive trials and 26 barley supportive trials (relevant by extrapolation). These additional trials are presented above in Section 3.2.3.2.5 Powdery mildew of wheat (*Blumeria graminis* - ERYSGT) and Section 3.2.3.3.5 Powdery mildew of barley (*Blumeria graminis* - ERYSGH).

Based on this, the authorization of ADM.03503.F.1.A is requested from 1.00 L/ha to 1.25 L/ha for the control of powdery mildew of triticale (*Blumeria graminis* - ERYSGR).

3.2.3.5.6 Control of disease complex - Green leaf area

Attacks by pathogens reduce green leaf area and thus grain yield. Thus, the green area is a good indicator of the level of efficacy of one product. Therefore, a total of **10 valid efficacy trials** were carried out to confirm the effect of ADM.03503.F.1.A applied from 1.00 L/ha to 1.25 L/ha on the green leaf area. These trials were carried out **from 2020 to 2021** in the Maritime (1 trial in Czech Republic and 3 trials in Germany), the Northeast (2 trials in Poland) and the Southeast (3 trials in Hungary and 1 trial in Romania) EPPO climatic zones in winter triticale.

Table 3.2-95 summarises the effect on the increase of the green leaf area after an application of ADM.03503.F.1.A in triticale crops.

Table 3.2-95: Effect of ADM.03503.F.1.A on the green leaf area - Triticale - Increase of green leaf area (%)

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	Increase of green leaf area (%)														
					Untreated Green leaf area (%)			ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha			
								Fluxapyroxad + Prothioconazole				Fluxapyroxad + Prothioconazole				Fluxapyroxad + Metconazole			
								75+150 g a.s./ha				93.75+187.5 g a.s./ha				125+90 g a.s./ha			
			Mean	Min	Max	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.		
All diseases Green leaf area (%)	Last valid assessment	Maritime	Leaves	4	24.4	0.0	63.8	31.8	20.5	45.5	10.3	47.0	23.3	64.5	14.9	43.7	20.5	58.3	14.6
		Northeast	Leaves	2	35.0	20.0	50.0	36.3	12.5	60.0	23.8	38.6	17.2	60.0	21.4	40.2	20.3	60.0	19.9
		Southeast	Leaves	4	49.1	27.5	67.5	46.1	29.2	74.2	18.2	55.8	31.0	84.6	23.9	51.0	31.0	74.2	19.1
		All EPPO climatic zones	Leaves	10	36.4	0.0	67.5	38.4	12.5	74.2	18.1	48.8	17.2	84.6	21.3	45.9	20.3	74.2	18.1

10 trials are available to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The green leaf area in the untreated plot covered from 0% to 68%.

Maritime EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 47% of green leaf area (in 4 trials), similar to LIBRAX (44%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 32% of green leaf area (in 4 trials), similar to LIBRAX (44%).

Northeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 39% of green leaf area (in 2 trials), similar to LIBRAX (40%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 36% of green leaf area (in 2 trials), similar to LIBRAX (40%).

Southeast EPPO climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 56% of green leaf area (in 2 trials), similar or slightly superior to LIBRAX (51%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 46% of green leaf area (in 2 trials), similar or slightly inferior to LIBRAX (51%).

Central registration zone

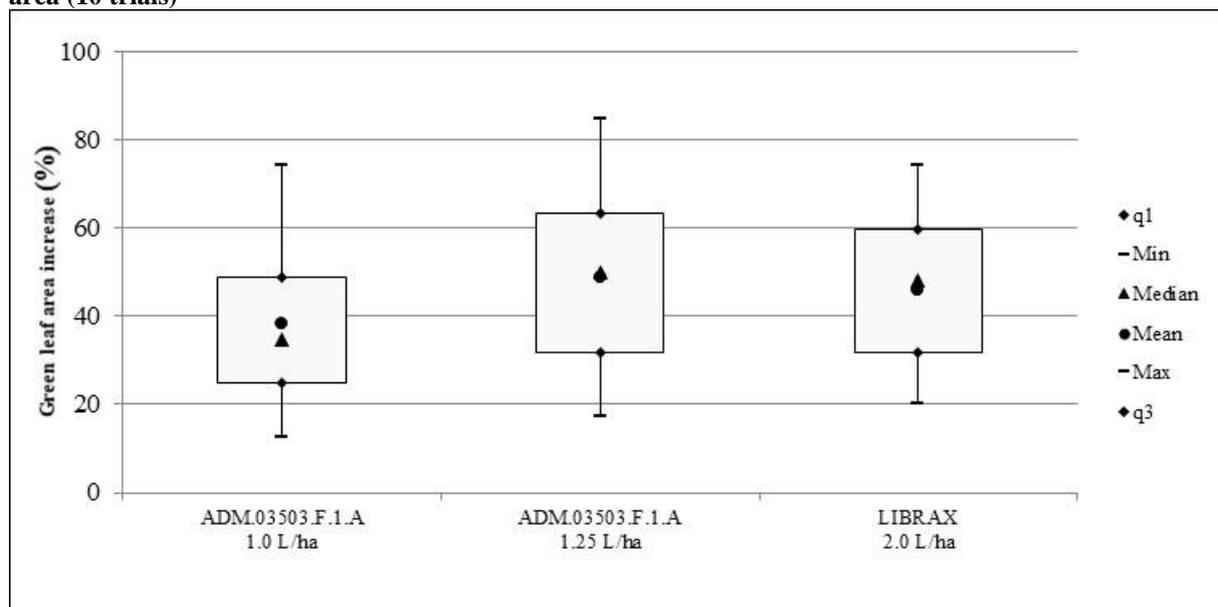
Finally, a total of 10 efficacy trials across EPPO climatic zones concerned in the Central registration zone are summarised to show the effect on the green leaf area of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in triticale crops.

ADM.03503.F.1.A at 1.25 L/ha showed an increase of 49% of green leaf area, similar to LIBRAX (46%).

ADM.03503.F.1.A at 1.00 L/ha showed an increase of 38% of green leaf area, inferior to LIBRAX (46%).

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-41). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same (or even better) effect on the increasing green leaf area and the same dispersion and variation between means than LIBRAX.

Figure 3.2-41 Effect of ADM.03503.F.1.A on the green leaf area- Triticale - Increase of the green leaf area (10 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the green leaf area in triticale crops at least like the reference standard LIBRAX. ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the green leaf area in triticale crops like LIBRAX.

3.2.3.5.7 Positive effect on the yield in efficacy trials

A total of **13 valid efficacy trials** with sufficient disease pressure were harvested to confirm the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha. These trials were carried out **from 2020 to 2021** in the Maritime (1 trial in Czech Republic and 3 trials in Germany), the Northeast (4 trials in Poland) and the Southeast (4 trials in Hungary and 1 trial in Romania) EPPO climatic zones in winter triticale.

Table 3.2-96 summarises the positive effect on the yield and yield parameters (TGW and HLW) of ADM.03503.F.1.A in triticale crops with sufficient disease pressure (SEPTTR, PUCCRE, PUCST, PYRNTR, and/or ERYSGR).

Table 3.2-96: Positive effect on the yield of ADM.03503.F.1.A - Triticale - Yield parameters

Targets	Parameters	EPPO climatic zone	Parts	No. of trials	<i>Untreated</i>			Percentage of Untreated (%)												No. of assessments where ADM.03503.F.1.A is significantly ⁽¹⁾ >=; < to LIBRAX	
								ADM.03503.F.1.A 1.00 L/ha				ADM.03503.F.1.A 1.25 L/ha				LIBRAX 2.00 L/ha					
								Fluxapyroxad + Prothioconazole 75+150 g a.s./ha				Fluxapyroxad + Prothioconazole 93.75+187.5 g a.s./ha				Fluxapyroxad + Metconazole 125+90 g a.s./ha					
								Mean	Min	Max	S.D.	Mean	Min	Max	S.D.	Mean	Min	Max	S.D.		
All diseases	Yield (t/ha)	Maritime	Grains	4	5.7	4.1	7.6	118.4	101.1	159.4	23.8	123.0	106.8	163.3	23.4	116.3	97.7	156.8	23.6	0> ; 4= ; 0<	0> ; 4= ; 0<
		Northeast	Grains	4	6.9	5.5	8.7	110.6	104.7	114.6	3.6	112.9	102.5	118.1	6.1	111.3	103.4	117.9	5.3	0> ; 4= ; 0<	0> ; 4= ; 0<
		Southeast	Grains	5	6.4	5.4	7.6	106.9	104.9	113.3	3.3	106.6	102.5	112.6	3.3	105.9	101.6	113.3	4.0	0> ; 5= ; 0<	0> ; 5= ; 0<
		All EPPO climatic zones	Grains	13	6.3	4.1	8.7	111.6	101.1	159.4	14.3	113.6	102.5	163.3	15.2	110.7	97.7	156.8	14.3	0> ; 13= ; 0<	0> ; 13= ; 0<
	TGW (g)	Maritime	Grains	4	36.8	32.4	43.7	107.5	98.0	129.1	12.6	110.9	101.2	134.1	13.4	107.0	98.2	128.7	12.7	0> ; 4= ; 0<	0> ; 4= ; 0<
		Northeast	Grains	4	39.0	36.6	41.7	100.7	97.7	102.9	1.9	101.5	99.5	103.8	1.5	101.3	99.6	103.3	1.3	0> ; 4= ; 0<	0> ; 4= ; 0<
		Southeast	Grains	5	39.8	36.6	42.6	102.9	100.8	106.9	2.2	103.3	100.4	106.3	1.9	102.9	101.3	105.3	1.4	0> ; 5= ; 0<	0> ; 5= ; 0<
		All EPPO climatic zones	Grains	13	38.6	32.4	43.7	103.6	97.7	129.1	7.7	105.1	99.5	134.1	8.6	103.6	98.2	128.7	7.5	0> ; 13= ; 0<	0> ; 13= ; 0<
	HLW (kg)	Maritime	Grains	4	70.8	60.0	74.6	101.6	99.8	105.9	2.5	101.9	99.1	106.0	2.5	99.6	93.9	104.6	3.8	0> ; 4= ; 0<	0> ; 4= ; 0<
		Northeast	Grains	4	67.7	53.8	73.0	102.9	100.7	109.4	3.8	105.2	100.5	117.2	7.0	104.7	100.6	116.4	6.8	2> ; 2= ; 0<	1> ; 3= ; 0<
		Southeast	Grains	5	73.1	70.1	74.6	101.3	100.5	102.3	0.7	102.2	100.7	105.3	1.6	101.6	100.3	103.9	1.3	0> ; 5= ; 0<	0> ; 5= ; 0<
		All EPPO climatic zones	Grains	13	70.8	53.8	74.6	101.9	99.8	109.4	2.6	103.0	99.1	117.2	4.5	101.9	93.9	116.4	4.8	2> ; 11= ; 0<	1> ; 12= ; 0<

⁽¹⁾ Comparison based on statistics carried out in each trial report.

13 trials are available to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone. The yield in the untreated plot was from 4.1 to 8.7 t/ha.

Maritime Eppo climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 23 points compared to Untreated in 4 trials similar or even slightly superior to LIBRAX (116%). No significant difference was noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 18 points compared to Untreated in 4 trials similar or even slightly superior to LIBRAX (116%). No significant difference was noted with LIBRAX in all trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 8-11 points or HLW with a positive effect of 2 points even if the differences on these yield parameters are less pronounced.

Northeast Eppo climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 13 points compared to Untreated in 2 trials similar to LIBRAX (111%). No significant difference was noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 11 points compared to Untreated in 2 trials similar to LIBRAX (111%). No significant difference was noted with LIBRAX in all trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 1-2 points or HLW with a positive effect of 3-5 points even if the differences on these yield parameters are less pronounced.

Southeast Eppo climatic zone

ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 7 points compared to Untreated in 2 trials similar or even slightly superior to LIBRAX (106%). No significant difference was noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 7 points compared to Untreated in 2 trials similar to LIBRAX (106%). No significant difference was noted with LIBRAX in all trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 3 points or HLW with a positive effect of 1-2 points even if the differences on these yield parameters are less pronounced.

Central registration zone

Finally, a total of 13 efficacy trials across Eppo climatic zones concerned in the Central registration zone are summarised to show the positive effect on the yield of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in triticale crops.

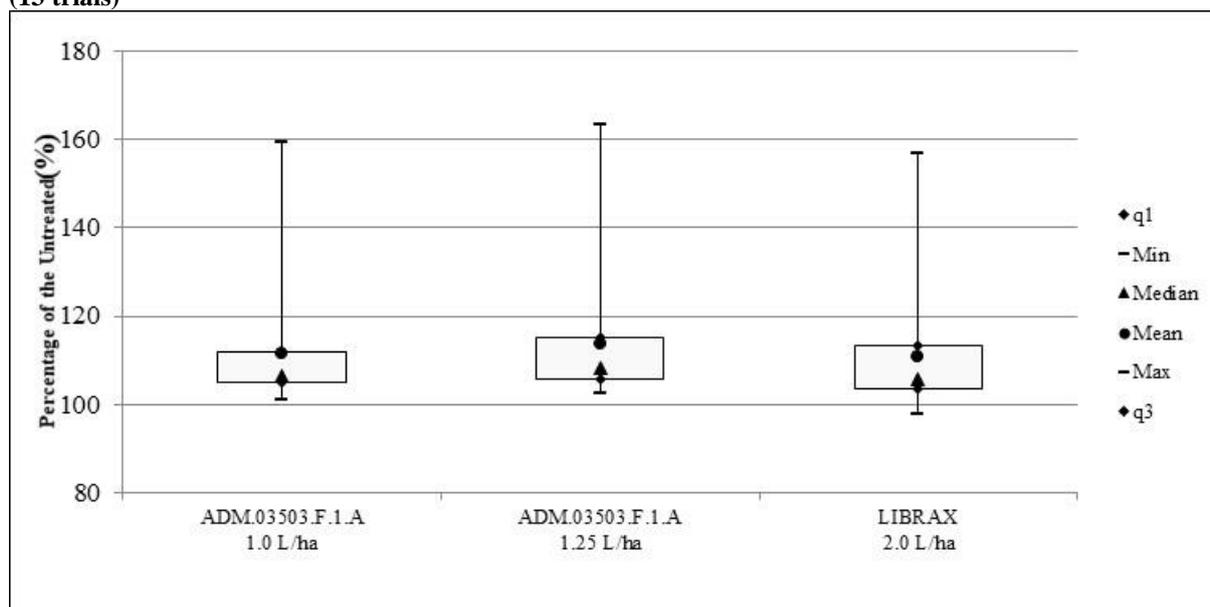
ADM.03503.F.1.A at 1.25 L/ha showed a positive effect on the yield of 14 points compared to Untreated in 13 trials similar or even slightly superior to LIBRAX (111%). No significant difference was noted with LIBRAX in all trials.

ADM.03503.F.1.A at 1.00 L/ha showed a positive effect on the yield of 12 points compared to Untreated in 13 trials similar to LIBRAX (114%). No significant difference was noted with LIBRAX in all trials.

Overall, the same conclusion can be noted with the other yield parameters TGW with a positive effect of 4-5 points or HLW with a positive effect of 2-3 points even if the differences on these yield parameters are less pronounced.

The difference between the reference standards can be illustrated by box plot graphic (Figure 3.2-42). Overall, ADM.03503.F.1.A applied at 1.25 L/ha had the same effect on the yield and the same dispersion and variation between means than LIBRAX.

Figure 3.2-42 Positive effect of ADM.03503.F.1.A on the yield - Triticale - Percentage of the untreated (13 trials)



To conclude, ADM.03503.F.1.A at 1.25 L/ha allowed to increase the yield in triticale crops like or even better than the reference standard LIBRAX. ADM.03503.F.1.A at 1.00 L/ha allowed also to increase the yield in triticale crops like LIBRAX.

3.2.3.5.8 Zonal conclusion on efficacy of test product against triticale diseases

A total of **13 valid efficacy trials** carried out **from 2019 to 2021** are provided to confirm the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha in the Central registration zone in triticale crops. Table 3.2-97 summarises the efficacy of ADM.03503.F.1.A to control triticale disease complex from all valid efficacy trials.

Table 3.2-97: Efficacy of ADM.03503.F.1.A - Triticale - All valid efficacy trials

Target Parameters	Parts	No. of trials	Untreated			Percentage of efficacy (%)								
						ADM.03503.F.1.A 1.00 L/ha			ADM.03503.F.1.A 1.25 L/ha			LIBRAX 2.00 L/ha		
						Fluxapyroxad + Prothioconazole			Fluxapyroxad + Prothioconazole			Fluxapyroxad + Metconazole		
						75+150 g a.s./ha			93.75+187.5 g a.s./ha			125+90 g a.s./ha		
			Mean	Min	Max	Mean	Min	Max	Mean	Min	Max	Mean	Min	Max
SEPTTR	FLAGLE	1	5.6	-	-	88.8	-	-	66.4	-	-	82.8	-	-
	FLMI1	1	8.6	-	-	87.3	-	-	69.5	-	-	81.3	-	-
	FLMI2	1	5.4	-	-	89.2	-	-	81.8	-	-	88.3	-	-
PUCCRE	FLAGLE	7	9.7	5.4	28.8	88.5	47.8	100.0	92.5	60.9	100.0	90.6	56.5	100.0
	FLMI1	7	14.6	7.4	47.5	81.2	28.9	100.0	85.5	39.5	100.0	84.4	34.2	100.0
	FLMI2	6	18.0	8.3	45.0	85.6	66.7	100.0	91.3	75.0	100.0	88.1	63.9	100.0
PUC CST	FLAGLE	1	76.3	-	-	100.0	-	-	100.0	-	-	100.0	-	-
	FLMI1	1	99.0	-	-	100.0	-	-	100.0	-	-	100.0	-	-
	FLMI2	1	99.0	-	-	100.0	-	-	100.0	-	-	100.0	-	-
PYRNTR	FLAGLE	2	52.4	5.9	99.0	87.6	83.6	91.7	89.4	85.3	93.4	83.5	75.3	91.7
	FLMI1	4	33.9	7.4	99.0	85.5	80.3	94.7	89.9	84.2	97.0	87.7	76.6	97.6
	FLMI2	5	30.3	4.7	99.0	85.8	79.1	97.0	92.9	86.9	98.5	93.3	84.1	98.3
ERYSGR	FLMI1	2	5.6	5.4	5.8	86.7	73.3	100.0	100.0	100.0	100.0	95.8	91.7	100.0
	FLMI2	3	13.3	7.4	16.5	69.7	41.3	85.9	95.8	93.4	100.0	94.7	92.4	97.0
	FLMI3	5	20.5	6.8	31.4	62.4	37.6	77.8	90.9	77.8	98.2	93.8	88.9	98.4

(1) Comparison based on statistics carried out in each trial report.

Therefore, provided data are sufficient to justify the efficacy of ADM.03503.F.1.A from 1.00 L/ha to 1.25 L/ha to control triticale disease complex.

zRMS comments on efficacy in Triticale:

The efficacy levels reported and the effect on yield observed, both as stand-alone results as well as relative to the standard reference products, do allow for the authorization of the ADM.03503.F.1.A in rye, **triticale**, in the Member States of the Central zone concerned with this submission. However, the number and the zonal distribution of the efficacy trials submitted make majority of these authorizations based on extrapolation.

Only three trials support directly the use against **SEPTTR** in triticale: carried out in CZ, DK and LV. The use in control of **SEPTTR** in triticale could be nevertheless accepted by zRMS based on the extrapolation from trials in wheat submitted in the Central zone: 38 in the Maritime zone, 5 in the NE zone (Poland) and 19 in the SE zone, with German and Czech trials supporting the deficient wheat trial count (5) for the NE zone. Unfortunately, no triticale trials are available from the SE zone, making extrapolation impossible. The concerned Member States in this zone are kindly encouraged to consider the CZ trial as basis for extrapolation.

Similarly, the extrapolation makes authorization possible for the use against **PUCCRE** in triticale, based on 15 trials in wheat in control of **PUCCR(T)** in the Maritime zone, 4 in the NE zone (Poland) and 14 in the SE zone, with German and Czech trials supporting the deficient wheat trial count (4) for the NE zone. The data in control of **PUCCRE** in triticale, making basis for the extrapolation, have been submitted from the 3 EPPO zones concerned.

Since the only 3 trials supporting directly the use in control of **PUC CST** in triticale come from DE, DK and SE, this use can be also accepted only through extrapolation and it can be authorized only in the Maritime zone. Although the supportive wheat + **PUC CST** data exist from the NE and the SE EPPO zones, no triticale + **PUC CST** data have been submitted from these zones, which might make basis for this extrapolation.

Six trials supporting directly the use in control of **PYRNTR** in triticale come from all 3 EPPO zones (CZ(1), DE(1), PL(2), LV(3), HU(2)). This use can be also accepted in each zone only through extrapolation, but it can be authorized in the Maritime, NE and SE EPPO zones, for there are respectively 8, 3 and 4 extrapolation-supporting wheat + **PYRNTR** trials from these zones, with German and Czech trials supporting the deficient wheat trial count for the NE zone (3) and (possibly) the single Czech trial supporting the deficient count of the SE zone wheat trials (4), the latter depending on the decision of the cMSs in that zone.

For the control of **ERYSGR** in triticale 5 main trials and 5 supporting trials have been submitted: DE(1), HU(2), PL(2) and LV(3) plus SE(2), respectively. The applicant refers to wheat and barley trials as supporting the extrapolation, but only wheat data can be used (the pathogen infecting barley is another taxonomic entity, not infecting cereals having no *Hordeum* genes; the view is even expressed in the EPPO code: **ERYSGH**).

There are 8, 6 and 5 wheat + **ERYSGT** trials available as extrapolation support in the Maritime, NE and SE

zones respectively and all zones have data making basis for the extrapolation. The use can be authorized.

In conclusion:

In the Maritime zone ADM.03503.F.1.A can be authorized for a single application per growth season within the BBCH 30-69, at the dose rate of 1.25 L/ha, in control of SEPTTR, PUCCRE, PUCST, PYRNTR and ERYSGT in triticale.

In the South-Eastern zone (Hungary, Slovakia and Slovenia), the **dose range** of 1.00-1.25 L/ha can be authorized in control of SEPTTR (in case the single CZ trial in TTLWI is accepted as extrapolation basis for this target), PUCCRE, PYRNTR and ERYSGT in triticale, by a single application per growth season within the BBCH 30-69.

In Poland, **the North-Eastern zone**, the **dose range** of 1.00-1.25 L/ha can be authorized in control of SEPTTR, PUCCRE, PYRNTR and ERYSGT in triticale, by a single application per growth season within the BBCH 30-69.

WHEAT
BARLEY
RYE

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3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

3.3.1 Introduction

ADM.03503.F.1.A is a fungicide for control several diseases of cereals at the maximum dose of 1.25 L/ha. The formulation contains 75 g/L fluxapyroxad and 150 g/L prothioconazole as active substances. A resistance risk analysis has been conducted in accordance with EPPO guideline PP1/213(3) ‘Resistance risk analysis’.

3.3.2 Mode of Action

Fluxapyroxad is a fungicide which inhibits succinate ubiquinone oxidoreductase, also known as SQR, complex II or succinate dehydrogenase⁵. Fluxapyroxad has the same biochemical target site as fungicides like benzovindiflupyr, bixafen, boscalid, fluopyram, isofetamid, isopyrazam, penthiopyrad, penflufen, and sedaxane. The molecule is classified by FRAC in group7 (C2, Complex II, succinate-dehydrogenase, SDHI fungicides)⁶.

The biological mode of action of prothioconazole has been shown to be based on inhibition of the sterol biosynthesis pathway in fungi. 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 plant⁷. At the target site level prothioconazole inhibits C-14 demethylase of ergosterol precursors, which then accumulate at the expense of ergosterol, and it belongs to the group of compounds collectively termed as De-Methylation Inhibitors (DMIs). The molecule is classified by FRAC in group3 (G1, C-14 demethylase in sterol biosynthesis (erg11/cyp51)⁶.

3.3.3 Mechanism and evidence of Resistance

3.3.3.1 Mechanism and evidence of resistance to SDHI fungicides

The primary resistance mechanisms are target site mutations resulting in modification of the target protein SQR with subsequent reduced binding and fungicidal activity. Mutation sites have been reported on 3 of the 4 genes controlling SQR, with some subunit genes (e. g. sdhB) having more than one mutation site. Multiple amino acid alterations at each mutation site have been associated with reduced SDHI sensitivity. Resistance to SDHI fungicides either induced by chemical or UV mutagenesis or naturally occurring has been reported in many Ascomycete and Basidiomycete fungi as well as 2 bacteria. The list of these pathogenic fungi and bacteria with the mutations conferring resistance to SDHI fungicides, detected until now (2020) is given in Table 3.3-1.

⁵ Yanase, Y., Y. Yoshikawa, J. Kishi, H. Katsuta. 2007. The history of complex II inhibitors and the discovery of penthiopyrad. Chap 31, pp 295-303 in Pesticide Chemistry. Crop Protection, Public Health, Environmental Safety. H. Ohkawa, H. Miyagawa, P. W. Lee (eds). Wiley-VCH Verlag GmBH & Co. Weinheim.

⁶ https://www.frac.info/docs/default-source/publications/frac-code-list/frac-code-list-2021--final.pdf?sfvrsn=f7ec499a_2

⁷ <http://www.frac.info/>

Table 3.3-1: List of fungal species with resistance reports towards SDHI fungicides and mutations in the succinate dehydrogenase gene^{8,9}

Species name	Reported from host	Origin	Resistance mechanism (Subunit-mutation)
<i>Alternaria alternata</i>	Pistachio	Field	B-H277Y/R, C-H134R, D-D123E, D-H133R
<i>Alternaria solani</i>	Potato	Field	B-H277Y/R, D-H133R
<i>Aspergillus oryzae</i>	(Laboratory)	Laboratory mutants	B-H249Y/L/N, C-T90I, D-D124E
<i>Blumeriella jaapii</i> ¹⁰	Cherry	Field	H272R
<i>Botrytis cinerea</i>	Different hosts	Field	B-P225L/T/F, B-H272Y/R/L/V, B-N230I, D-H132R, C-A85V
<i>Botrytis elliptica</i>	Lilies	Field	B-H272Y/R
<i>Coprinus cinereus</i>	(Laboratory)	Laboratory mutants	C-N80K
<i>Corynespora cassiicola</i>	Cucurbits	Field	B-H278Y/R, C-S73P, D-S89P, D-G109V
<i>Didymella bryoniae</i>	Cucurbits	Field	B-H277R/Y
<i>Monilinia fructicola</i>	Peach	Field	-
<i>Phakopsara pachyrhize</i>	Soybean	Field	-
<i>Podosphaera xanthii</i>	Cucurbits	Field	B-H->Y (homologous to H272 in <i>B. cinerea</i>)
<i>Pyrenophora teres</i>	Barley	Field	B-H277Y, C-N75S, C-G79R, C-H134R, C-S135R, D-D124N/E, DH134R, D-D145G
<i>Ramularia collo-cygni</i>	Barley	Field	C-H142R, C-H149R, C-N83S
<i>Sclerotinia sclerotiorum</i>	Oilseed rape	Field	B-H273Y, C-H146R, D-H132R
<i>Stemphylium botryosum</i>	Asparagus	Field	B-P225L, H272Y/R
<i>Ustilago maydis</i>	(Laboratory)	Laboratory mutants	B-H257L
<i>Ustilago nuda</i>	Barley	Field	-
<i>Venturia inaequalis</i>	Pomme fruit	Field	C-H151R
<i>Zymoseptoria tritici</i>	(Laboratory)	Laboratory mutants	B-N225I, B-H267Y/R/L, B-I269V, C-A84V, C-H152R, C-T79I, CN86K, C-G90R, D-H129E, and several others
	Wheat	Field	B-N225T, C-T79N, C-W80S, C-N86S

3.3.3.2 Mechanism and evidence of resistance to DMI fungicides

DMI fungicides are considered to have a medium risk of resistance development. Resistant isolates to DMI fungicides have been detected in several pathogens including amongst others *Fusarium graminearum*, *Microdochium nivale*, *Puccinia striiformis* (laboratory studies), *Blumeria graminis*, *Zymoseptoria tritici* and *Pyrenophora tritici-repentis* (field studies) in wheat and *Blumeria graminis*, *Pyrenophora teres* and *Rhynchosporium secalis* (field studies) in barley⁷.

The primary mechanism of resistance is the accumulation of several independent mutations in the target site. Each individual mutation typically causes only a small reduction in sensitivity, and it is not observed to impact efficacy under field conditions until multiple mutations accumulate in an isolate that are large enough to cause a reduction in sensitivity. Hence, resistance to DMI's is mostly characterised by a slow, step-wise erosion of efficacy over several years of intensive use rather than by a rapid loss of control. More detailed information in this area is especially available for *Zymoseptoria tritici*, the causal agent of leaf blotch, the most important disease of wheat in Europe. A shift in sensitivity of *Zymoseptoria tritici* populations to DMI fungicides has been observed since their introduction in the 1980s. The decrease in sensitivity is supposed to be based on different mechanisms, such as mutations in the target gene coding for the cytochrome P450-dependent C14 α - demethylase (CYP51), overexpression of the CYP51 gene and increased DMI efflux due to overexpression of transporter genes.

⁸ https://www.frac.info/docs/default-source/publications/list-of-resistant-plant-pathogens/list-of-first-confirmed-cases-of-plant-pathogenic-organisms-resistant-to-disease-control-agents_05_2020.pdf?sfvrsn=7073499a_2

⁹ https://www.frac.info/docs/default-source/working-groups/sdhi-references/list-of-species-resistant-to-sdhis-april-2015.pdf?sfvrsn=2d144a9a_2

¹⁰ Outwater, C. A., Sundin, G. W., Proffer, T. J. 2013. Detection of boscalid resistance and the H272R mutation in the SdhB gene of *Blumeriella jaapii*. Phytopathology 103(6): 191-191.

3.3.4 Cross-resistance

Cross resistance has been shown between all members of the **SDHI** fungicides. All **DMI** fungicides inhibit pathogens by interacting with the same target site (C14 - demethylase) and are therefore considered to be cross - resistant with each other. Generally, compounds within each subgroup of SBI's (DMI's, amines, KRI's) are cross - resistant with other members within the same group, but there is no cross - resistance between members of different groups. Furthermore, DMI's show no cross - resistance to any of the other major cereal fungicide classes like SDHI's.

3.3.5 Sensitivity data

3.3.5.1 Sensitivity data to SDHI fungicides

Regarding pathogens mentioned below, the statement published on the FRAC website in 2021¹¹ confirms that, when used according to FRAC guidelines, the performance of SDHI containing products within spray programmes was good and that SDHIs continue to contribute to overall disease management.

In 2020, the geographic distribution and the frequency of SDHI resistance in Europe was as follows:

Leaf spot (*Zymoseptoria tritici*) - Wheat

Extensive monitoring programs were carried out since 2003. Most isolates tested in routine monitoring programs were sensitive, within the baseline. **Since 2012, few isolates with reduced sensitivity**, bearing C-T79N, C-W80S, C-N86S, B-N225T and B-T268I mutations, were detected in France and in some other countries of Western Europe. However, their resistance factors were low and field performance was not affected.

In 2015 and 2016, single isolates with moderate resistance factors and bearing the mutation H152R (SDH subunit C) were detected in Ireland and the United Kingdom. The mutation was detected for the first time in Italy and the Netherlands in 2016. The overall frequency of this mutation remains at a low level and has not increased at the European level.

The following new mutations with low resistance factors were reported for the first time: B-T268A, B-N225I, C-T79I, C-R151S, C-N86A. The following mutations were also reported for the first time but are not associated with any sensitivity change: C-N33T, C-N34T.

In 2017, sensitivity data for roughly 2.500 isolates were presented from a broad range of countries. The majority of isolates was sensitive; a few showed slightly reduced sensitivity. These isolates, showing low resistance factors, were detected at higher frequency in Ireland and at low frequency in North-Germany, United Kingdom, Netherlands, New Zealand and even lower in France. Such strains were not detected in Ukraine, Poland, Slovakia, Czech Republic, Italy, Spain, Denmark, Sweden, Latvia, Lithuania, Switzerland, Croatia, Greece, Romania, Russia and Tunisia. These isolates are mainly associated to the following mutations: B-T268I/A, B-N225I, B-R265P, CT168R, C-T79N/I, C-R151S/T/M, C-N86S/A, C-W80S, C-V166M, D-I50F, D-M114V.

Single isolates with moderate resistance factors and bearing the mutation H152R (SDH subunit C) were detected in 2017 again in Ireland and the United Kingdom and for the first time in Germany. The overall frequency of this mutation remains at a low level at the European level.

Disease pressure in 2018 was overall low. Field performance of SDHI fungicides against Septoria was good.

In 2018, sensitivity data for more than 2.000 isolates were presented from a broad range of countries. The majority of isolates was sensitive. Compared to 2017, the frequency of isolates showing low resistance factors increased in Northern-Germany, Ireland, the Netherlands and the United Kingdom. These isolates were detected again at low frequency in Denmark, France, Southern-Germany, Poland and for the first time in Ukraine. These isolates are mainly associated to the following mutations: B-T268I/A, BN225I, B-R265P, C-A84F, C-P127A, C-T168R, C-T79N/I, C-R151S/T/M, C-N86S/A, CW80S, C-V166M, D-I50F, D-M114V, D-D129G. Among the mentioned mutations, the CT79N and C-N86S were the most frequent mutations in the last years.

All isolates from Austria, Bulgaria, Czech Republic, Hungary, Italy, Latvia, Lithuania, Slovakia, Spain, Sweden, Switzerland, Romania and Russia were sensitive.

¹¹ https://www.frac.info/docs/default-source/working-groups/sdhi-fungicides/sdhi-meeting-minutes/minutes-of-the-2021-sdhi-meeting-with-recommendations-for-2021-last-update-october-2021.pdf?sfvrsn=122c4e9a_2

Single isolates with moderate resistance factors and bearing the mutation H152R (SDH subunit C) were also detected in 2018 in Germany, Ireland, the Netherlands and the United Kingdom. For the first time, this mutation was detected in low frequency in a single population originating from France (Normandie). The overall frequency of this mutation in Europe remains at a low level.

The following mutations were also reported but are not associated with any sensitivity change: B-C266G, C-N33T, C-N34T, C-L184W.

Disease pressure in 2019 was overall moderate. Field performance of SDHI-fungicides against *Septoria* was good.

In 2019, the majority of isolates was sensitive, and the overall situation stable compared to 2018, as was the frequency for the isolates showing low resistance factors. C-T79N and C-N86S were the most frequent mutations in this group in the last years. All isolates from Austria, Bulgaria, Croatia, Czech Republic, Greece, Hungary, Italy, Latvia, Lithuania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Romania, Russia and Ukraine were sensitive.

A mostly sensitive situation was monitored in France with a low frequency of isolates with low resistance factors at few sites.

As in previous years, isolates bearing the mutation C-H152R continued to be detected at overall low frequencies in 2019 in Germany, Ireland, the Netherlands and the United Kingdom.

Single strains carrying double mutations associated with C-N86S and C-T79N were reported for the first time. The impact on sensitivity ranges from low to high depending on the combination. The fitness of these isolates and impact on product performance is still under investigation.

Disease pressure in 2020 was low to moderate with very dry conditions in some countries. Field performance of SDHI-fungicides when applied according to manufacturers' recommendations against *Septoria* was good.

All isolates from Bulgaria, Croatia, Czech Republic, Denmark, Hungary, Norway, Slovakia, Spain, Turkey, Romania, Russia and Ukraine were sensitive.

As in 2019, the **majority of isolates in 2020** was sensitive in Europe with the exception of Ireland and the United Kingdom. C-T79N and C-N86S were the most frequent mutations with low resistance factor in the last years.

Brown Rust (*Puccinia recondita*) - Wheat

Extensive monitoring programs were carried out since 2005.

Samples from the following countries were tested in 2018: Belgium, Denmark, France, Germany, Hungary, Sweden and the United Kingdom. All tested isolates were sensitive, within the baseline.

One single isolate, showing a low resistance factor (~5) has been identified in Pas de Calais, France and was genetically characterized without any detection of a mutation in *sdh* subunits B, C and D.

In 2019, samples were analysed from Belgium, Czech Republic, France, Germany, Italy, Poland, Slovakia and the United Kingdom and showed full sensitivity.

In 2020, samples originating from France, Poland, Denmark, Germany, Hungary and the United Kingdom showed full sensitivity.

Yellow Rust (*Puccinia striiformis*) - Wheat

In 2019, samples from Belgium, Denmark, Germany, Latvia, Sweden and the United Kingdom were tested and showed full sensitivity, within the baseline.

In 2020, samples originating from Belgium, Denmark, Germany, France, Italy, Poland, Portugal, Spain and the United Kingdom showed full sensitivity.

Powdery mildew (*Blumeria graminis*) - Barley

Monitoring programs carried out in 2017 confirmed the results from previous years and showed full sensitivity of isolates originating from the United Kingdom, France, Belgium, Germany and Denmark, Czech Republic.

In 2018, full sensitivity was found in Belgium, Denmark, France, Germany and the United Kingdom.

In 2019, full sensitivity was found in Czech Republic, Poland and the United Kingdom.

In 2020, samples from Denmark, France, Germany and the United Kingdom showed full sensitivity.

Tan spot (*Pyrenophora tritici-repentis*) - Wheat

In 2019, samples from Finland, Latvia and the United Kingdom showed full sensitivity.

In 2020, samples from Czech Republic, Germany, Hungary, Poland, Romania, Sweden showed always full sensitivity.

Snow mould (*Microdochium nivale*) - Wheat

Monitoring programs carried out in 2015 showed full sensitivity of isolates from Germany, France, Italy, Slovakia and the United Kingdom, confirming the results from 2014.

Data from 2016 and 2017 from Belgium, Germany, Denmark, Finland, France, Italy, Lithuania, Latvia, Poland, Russia, Sweden, Ukraine and the United Kingdom showed a fully sensitive situation.

Disease pressure in 2018 was very low. Isolates from France, Hungary, Italy, Poland and Spain were fully sensitive.

In 2019, Isolates from Belgium, Germany, Hungary, the Netherlands, Ukraine and the United Kingdom were fully sensitive. Single resistant isolates bearing the mutation BH253Q were detected in Italy and characterized as *Microdochium nivale* var. *majus*. However, SDHI containing products were still effective.

In 2020 Samples from the United Kingdom showed full sensitivity.

Net blotch (*Pyrenophora teres*) - Barley

Extensive monitoring programs were carried out since 2003. Until 2011, all tested isolates were sensitive, within the baseline. In 2012, for the first time, the sensitivity of 2 isolates from North-Germany was outside of the baseline range. A target site mutation was identified in the SDH-B subunit at position 277 (B-H277Y).

In 2013 and 2014, more isolates were detected with reduced sensitivity, carrying different mutations in Germany, France, Italy and the United Kingdom. The predominant mutation was C-G79R. The resistance factors were low for B-H277Y, D-D124E, D-D145G and moderate for C-G79R, C-H134R, C-S135R, C-N75S, C-R64K, D-H134R, C-K49E. The mutation D-G138V was detected for the first time in 2015 and found to be associated to very low resistance factors.

The sensitivity situation in 2016 was similar to 2015: The frequency of mutations was low in the United Kingdom, Czech Republic, Poland, Italy, Southern France, Southern Germany and Denmark. Moderate frequencies were observed in Northern France and Northern Germany. Among the mutations with moderately decreased sensitivity, CG79R and C-H134R are the most frequently detected mutations. While in France, C-G79R is the predominating mutation, in Germany, C-H134R is observed to be the more frequent mutation.

No mutations were detected in Estonia, Ireland, Hungary, Latvia, Lithuania, Slovakia, Spain, Bulgaria, Romania, Ukraine, Finland, Sweden and Russia (in 2016).

In 2017, control of net blotch, esp. in areas in France, was difficult and potentially related to e.g. the high disease pressure, low varietal diversity, coupled with the breakdown of variety-resistance at significant cultivation areas and higher frequencies of mutated strains.

In 2017, the frequency of mutations or insensitive isolates was low in the Czech Republic, Denmark, Greece (trial site), Italy, Lithuania, Poland, Sweden and the Ukraine. Moderate frequencies were observed in Germany and the United Kingdom but moderate to high in France. Among the mutations with moderately decreased sensitivity, C-G79R and CH134R are the most frequently detected mutations. In France, C-G79R is the predominating mutation. In the United Kingdom, C-H134R is the more frequent mutation. Whereas in Germany, both mutations are found at similar levels.

No mutations or reduced sensitivity were detected in Bulgaria, Estonia, Finland, Hungary, Ireland, Latvia, Romania, Russia, Slovakia and Spain.

Disease pressure was generally low in 2018. Thus, the field performance of SDHI containing fungicides against net blotch is hard to evaluate.

In 2018, the frequency of mutations was comparable to the previous season. The frequency of insensitive isolates was low in the Czech Republic, Denmark, Hungary, Italy, Poland, Sweden and Ukraine. Moderate to high frequencies were observed in Belgium, France, Germany, Ireland, the Netherlands and the United Kingdom. Among the mutations with moderately decreased sensitivity, C-G79R, C-H134R and C-S135R are the most frequently detected mutations.

No mutations or reduced sensitivity were detected in Bulgaria, Finland, Latvia, Romania, Russia, Slovakia and Spain.

In 2019, the frequency of mutations was similar to the previous season. The frequency of insensitive isolates was low in Bulgaria, Czech Republic, Denmark, Greece, Hungary, Italy, Poland, Spain, Sweden, Switzerland and Ukraine. Moderate to high frequencies were observed in Austria, Belgium, France,

Germany, Ireland, the Netherlands and the United Kingdom. Among the mutations with moderately decreased sensitivity, C-G79R, C-H134R and C-S135R are the most frequently detected mutations. No mutations or reduced sensitivity were detected in Hungary, Latvia, Lithuania, Romania, Russia and Slovakia.

Disease pressure in 2020 was low to moderate. The frequency of mutations was similar to the previous season.

No mutations or reduced sensitivity were detected in Bulgaria, Romania, Russia and Slovakia. The frequency of mutations or reduced sensitivity was low in Czech Republic, Denmark, Hungary, Italy, Latvia, Lithuania, Spain, Sweden, Switzerland and Ukraine. Moderate to high frequencies were observed in Austria, Belgium, France, Germany, Ireland, Poland, the Netherlands and the United Kingdom. Among the mutations with moderately decreased sensitivity, C-G79R, C-H134R and C-S135R are the most frequently detected mutations.

Leaf blotch (*Rhynchosporium secalis*) - Barley

Extensive monitoring programs were carried out since 2003.

In 2017, isolates were tested from France, the United Kingdom, Germany, Denmark, Spain, Latvia, Italy, Czech Republic and Poland and were sensitive, within the baseline.

In 2018, isolates coming from Denmark, France, Germany, Ireland, Poland and the United Kingdom showed full sensitivity.

In 2019, isolates coming from Belgium, France, Germany, Ireland, Poland and the United Kingdom showed full sensitivity.

In 2020, samples originating from France, Germany, Hungary, Ireland, Italy, Latvia, the Netherlands, Poland, Slovakia, Spain, Ukraine, the United Kingdom showed full sensitivity.

Brown rust (*Puccinia hordei*) - Barley

Monitoring programs were carried out since 2006. All isolates tested were sensitive, within the baseline. No monitoring was carried out in 2015, 2016 and 2017.

In 2018, few isolates with a low resistance factor have been identified for the first time in France and the United Kingdom. All isolates originating from Denmark, Germany and Sweden were fully sensitive.

In 2019, samples from France and the United Kingdom showed a similar sensitivity pattern as observed in 2018 with some isolates showing low resistance factors (no impact on field efficacy reported).

In 2020, samples from Denmark, France, Germany, Italy, Poland, Romania, Spain, United Kingdom showed full sensitivity. Monitoring is ongoing.

Ramularia leaf spot (*Ramularia collo-cygni*) - Barley

In 2014, single isolates with slightly decreased sensitivity were detected from France and Germany. Retesting of 2014 isolates showed full sensitivity. Isolates sampled in 2014 from the Czech Republic were sensitive, within the baseline.

In 2015, extensive monitoring in Germany showed particularly in trial-sites for the first-time occurrence of strains with strongly decreased dose-response in bioassays, carrying the mutation C-H146R or C-H153R. Another mutation, C-N87S, which was found to be associated with low resistance factors, was found in Germany, Ireland and Slovenia in single isolates. No mutations were detected in Austria and Croatia.

In 2016, no mutations were detected in Sweden, Denmark, Estonia, Slovakia, France and Greece. Samples carrying the mutations C-H146R or C-H153R, associated with significantly decreased sensitivity, were detected in Germany, Ireland, the Netherlands and the United Kingdom. Observations in trial sites confirmed the results from 2015. A decreased dose response was observed in field trial sites in Germany and the United Kingdom with high proportions of SDHIs in spray programs. Samples taken from the untreated plots at the same sites showed baseline level sensitivity.

In 2017 (disease pressure moderate), reported data show no mutations in Finland, Norway, Spain and Greece. Low frequency had been found in Estonia, Latvia, Italy, Austria, Switzerland, Czech Republic, Denmark and Sweden. A heterogeneous situation, ranging from low to high (frequency of mutations and sensitivity), was observed in Germany, France, United Kingdom, Ireland and Netherlands.

Disease pressure was low in 2018. No mutations were found in Czech Republic, Finland, Italy, Latvia, Norway, Romania, Russia, Spain, Sweden and Switzerland. Low frequency has been found in Austria,

France, Hungary, Poland and the Ukraine. A heterogeneous situation, ranging from low to high (frequency of mutations and sensitivity), was observed in Belgium, Germany, Denmark, the United Kingdom, Ireland and the Netherlands. Significantly decreased sensitivity is mainly associated with the mutations C-G91R, CH146R/L, C-G171D or C-H153R. Additionally, a mutation linked to lower resistance factors (C-N87S) was detected.

Data from 2019 showed no mutations in Austria, Italy, Latvia, Norway, Spain, Slovenia, Slovakia and Switzerland. Low frequency has been found in Austria, Hungary, Poland, Sweden and Ukraine. A heterogeneous situation, ranging from low to high (frequency of mutations and sensitivity), was observed in Belgium, Germany and the Netherlands. Moderate to high frequencies of mutations were detected in Denmark, France, Ireland and the United Kingdom.

Data from 2020 showed no mutations in Czech Republic and Slovakia. Low frequency has been found in Hungary, Italy, Spain and Switzerland. A heterogeneous situation, ranging from low to high (frequency of mutations and sensitivity), was observed in Germany, Denmark, France, Lithuania, Sweden and the United Kingdom. Moderate to high frequencies of mutations were detected in Ireland. Significantly decreased sensitivity is mainly associated with the mutations C-G91R, CH146R/L, C-G171D or C-H153R. Additionally, mutations linked to lower resistance factors (C-N87S, B-T267I, B-N224T) were detected. Historical background:

3.3.5.2 Sensitivity data to DMI fungicides

The following information on the resistance status of various pathogens (for which control is claimed on the ADM.03503.F.1.A label) is available, from the Sterol Biosynthesis Inhibitor (SBI) Working Group (2021 meeting), FRAC (Fungicide Resistance Action Committee)¹²:

Leaf spot (*Zymoseptoria tritici*) - Wheat

Monitoring 2020 was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom.

After the slight increase in the frequency of less sensitive isolates from 2002 to 2004, the situation had stabilised between 2005 and 2008. In 2009 a trend to slightly higher EC50 values was observed in important cereal growing areas (France, Germany, Ireland, United Kingdom), this trend has slowed down in 2010 to 2012 and was stable in 2013. 2014 sensitivity was in the same range as 2011.

In 2015 depending on the individual active substance and regions slight shifts of sensitivity of populations have been observed. Highest EC50 values were observed in areas of elevated disease pressure 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 2016 and also in 2017 the sensitivity of the populations was overall stable on a European level with regional differences also based on different disease epidemics. In regions with lower sensitivity in 2015 the sensitivity of the populations was stable and, in some areas, even partially increased.

In 2018 the sensitivity of the populations was overall stable on the European level. In 2019, the sensitivity of the populations was overall stable on European level with EC50 sensitivity values slightly higher compared to 2018 in some geographies but overall in the range of previous years.

In 2020, disease pressure was low to moderate with very dry conditions in some countries. DMIs field performance was good when used according to the manufacturers and FRAC recommendations. No general field resistance has been reported. The sensitivity of populations was also overall stable on European level with EC50 sensitivity values in the range of previous years.

Overall, as already reported in 2019, DMI EC50 sensitivity values were somewhat higher in the United Kingdom and Ireland than observed on the European continent where a gradient can be observed from North-West to South-East. In regions with limited options in fungicides classes and/or a common practice of significantly reduced rates DMIs are at higher risk and performance might be impacted.

In *Zymoseptoria tritici*, different DMI haplotypes can lead to varying levels of sensitivity depending on the chemical structure. As DMIs are generally cross-resistant, resistance management approaches should be the same for all DMIs.

¹² https://www.frac.info/docs/default-source/working-groups/sbi-fungicides/group/minutes-of-the-2021-sbi-telco-meeting-recommendations-for-2021-from-15th-sept-2021-sbi.pdf?sfvrsn=92c4e9a_2

In addition, a routine monitoring for *Zymoseptoria tritici* was carried out by ADAMA from 2016 to 2020. Since then, every year samples of infected wheat leaves are collected in different European countries of Europe and analysed in order to follow changes in sensitivity of this pathogen. Wheat leaves bearing typical symptoms of *Zymoseptoria tritici* (teleomorph: *Mycosphaerella graminicola*) are collected mainly from untreated plots of field trials, but also from commercial fields. From 2 to 5 single pycnidium isolates per sample are tested.

From 2016 to 2020, 167 samples in 139 sites across 14 countries and 57 regions were examined toward prothioconazole. The following concentrations of prothioconazole in the nutrient broth were prepared: 0 (control), 0.03, 0.10, 0.30, 1.00, 3.00, 10.00, 30.00 mg/l.

The analysis of the data, presented in Table 3.3-2 (2016), Table 3.3-3 (2017), Table 3.3-4 (2018) and Table 3.3-5 (2020), suggests a possible shift in sensitivity compared to the sensitivity of reference isolates. However, between 2016 and 2020 this sensitivity shift was overall stable and not drastic.

Table 3.3-2: *Zymoseptoria tritici*: Distribution of sensitivities to prothioconazole of single pycnidium isolates collected in different European countries in 2016

Year	Country	Region	Location	# samples	EC50			EC98		
					Mean	min	max	Mean	min	max
2016	United Kingdom	Yorkshire-Humberside	Gowdall	4	8.11	5.51	9.76	25.43	24.41	26.99
		West Midlands	Penkridge	4	5.99	4.66	7.90	24.83	21.29	29.39
		East Midlands	Caythorpe	4	6.52	2.10	9.74	20.96	10.61	26.93
			Weston	2	9.46	9.24	9.67	26.12	25.51	26.75
		East Anglia	Swaffham Bullbeck	4	6.22	5.02	10.61	24.63	22.44	29.44
			Aythorpe Roding	4	6.60	5.40	9.50	27.25	26.20	30.01
		Southwest	Foxhill	4	8.37	6.03	9.46	26.41	25.28	28.36
			Crockernwell	4	7.16	5.04	9.12	26.07	24.45	29.83
	Southeast	Fritwell	4	7.48	5.88	9.14	27.64	24.58	32.08	
	Netherlands	Overijssel	Deventer	4	6.08	5.13	8.86	24.88	23.14	27.52
		Gelderland	Valburg	4	6.59	5.62	9.16	26.66	25.13	29.15
	Belgium	Wallonie	Wasmes-Audeméz-Briffoeil	3	6.32	5.27	9.02	24.24	23.78	24.88
			Dommartin	4	6.29	6.23	6.38	30.26	28.73	31.55
	France	Nord-Pas de Calais	St Amand le Pas	4	7.51	5.91	9.56	26.91	24.76	29.29
			Martinpuich	4	5.82	4.93	8.43	23.88	23.09	24.92
			Ayette	4	7.35	5.33	9.34	26.48	24.37	30.55
		Picardie	Menessis	4	8.32	5.91	9.67	26.25	23.92	27.87
		Bretagne	Bédée	4	5.62	2.86	8.71	26.74	21.41	31.84
		Bourgogne	Saint Maurice en Riviere	3	6.21	4.61	9.98	23.59	20.00	27.64
		Midi-Pyrenees	Corbarieu	4	2.15	1.49	2.46	15.40	7.24	20.76
			Villematier	4	3.01	0.57	9.72	14.56	2.84	26.87
	Blan		4	7.70	5.31	9.00	24.28	23.53	25.10	
	Denmark	Midtjylland	Ørum Djurs	4	4.53	2.07	8.69	18.27	10.31	23.92
	Germany	Schleswig-Holstein	Bad Oldesloe	4	5.78	3.43	10.36	20.73	9.44	28.82
		Hessen	Runkel	4	4.65	3.09	5.82	18.79	8.56	26.19
		Thüringen	Thiemendorf	3	6.12	4.48	9.38	23.36	19.59	25.90
		Sachsen	Matterwitz	3	9.50	9.18	9.78	26.25	25.34	27.04
		Baden-Württemberg	Poppenhausen	4	5.98	4.86	9.34	23.10	20.65	25.79
		Bayern	Niedersemsing	4	7.29	5.85	9.74	26.84	22.98	29.31
	Latvija	Zemgale	Platone	4	6.11	4.94	8.28	25.28	22.76	31.40
	Czech Republic	Středočeský kraj	Čáslav	4	5.68	4.57	8.84	22.57	20.76	24.35
				3	3.03	2.79	3.24	28.74	27.31	30.50
Královéhradecký kraj		Nechanice	4	5.38	4.82	5.85	25.03	22.13	27.19	
Austria	Oberösterreich	Katsdorf	1	5.92	-	-	29.89	-	-	

Year	Country	Region	Location	# sam ples	EC50			EC98		
					Mea n	min	max	Mea n	min	max
	Spain	Andalucia	Los Morales	4	6.35	2.96	9.96	26.8 5	25.7 7	28.1 2
			La Penalosa	4	7.77	5.23	9.88	28.6 2	24.9 3	36.8 6
	Italy	Piemonte	Montiglio Monferrato	4	0.35	0.25	0.57	1.47	0.71	3.14
			Guarene	4	1.04	0.51	5.51	5.90	2.33	27.4 1
		Friuli-Venezia Giulia	Villa Vicentina- Fiumicellio	4	5.02	4.89	5.32	23.5 1	23.2 0	24.0 0
		Emilia Romagna	Palata Pepoli	4	1.14	0.26	5.48	5.44	0.73	25.7 7
2016	GeomMean (MEC50/98)			-	0.33	-	-	1.58	-	-

Table 3.3-3: *Zymoseptoria tritici*: Distribution of sensitivities to prothioconazole of single pycnidium isolates collected in different European countries in 2017

Year	Country	Region	Location	# samples	EC50			EC98		
					Mean	min	max	Mean	min	max
2017	United Kingdom	Yorkshire-Humberside	Hatfield Woodhouse	5	5.04	3.52	6.14	21.83	9.32	32.94
		West Midlands	Penalt	5	4.37	3.18	9.14	13.37	8.78	25.22
			Hoalwithy	5	4.20	3.36	8.64	12.91	9.25	23.79
			Armscote	2	4.14	3.38	5.08	14.07	9.31	21.24
		East Midlands	Fulbeck	5	4.34	3.33	8.60	13.17	9.19	23.66
			Haltham	5	3.44	1.67	5.67	15.87	8.41	25.04
		East Anglia	Aythorpe Roding	5	5.52	4.90	7.67	18.05	9.32	21.40
		Southwest	Aldbourn	5	4.96	3.31	6.08	20.49	9.13	29.58
			Crockernwell	5	6.39	5.20	8.60	23.71	22.39	25.78
			Howley	5	6.29	2.97	9.18	21.77	8.22	34.19
		Southeast	King's Sutton	5	5.25	4.87	5.93	23.98	21.84	27.83
	Red Rice		5	6.60	5.49	9.12	24.66	22.29	26.18	
	Netherlands	Drenthe	Valthermond	5	3.25	1.47	6.82	11.26	7.07	33.72
		Flevoland	Lelystad	4	4.17	3.46	5.23	14.54	9.53	23.91
	France	Picardie	Sancourt	5	5.80	4.76	9.26	24.69	22.45	27.28
				2	7.13	5.42	9.38	25.65	25.39	25.90
			Bazentin	5	5.43	3.17	9.02	16.66	8.75	25.88
			Sailly le sec	2	7.38	6.28	8.66	26.45	23.85	29.34
		Bretagne	Janz	4	6.78	4.99	9.52	24.55	23.79	26.30
	Sweden	Skåne	Lomma	5	3.02	1.45	4.74	10.19	7.06	20.28
		Östergötland	Fornåsa	5	2.74	1.84	5.48	10.60	8.83	19.05
	Denmark	Syddanmark	Bramstrup	2	7.22	5.83	8.94	25.74	24.64	26.88
		Sjælland	Lellinge	5	4.10	2.62	5.25	18.29	9.46	22.51
	Germany	Niedersachsen	Semmenstedt	5	4.69	3.34	8.55	16.10	9.21	24.24
		Thüringen	Eisenberg	5	3.21	1.44	5.00	12.10	7.15	22.99
				4	4.74	3.45	5.55	18.69	9.49	24.72
		Sachsen	Motterwitz	2	5.79	5.58	6.02	26.30	25.38	27.24
		Baden-Württemberg	Poppenhausen	5	5.66	1.67	10.46	19.12	7.96	29.01
	Bayern	Salching	5	3.89	1.77	5.95	20.74	8.54	27.25	
	Latvija	Zemgale	Peterlauki	5	0.80	0.46	1.79	3.71	2.00	8.43
			Sesava	5	1.12	0.47	4.73	4.78	2.19	20.25
	Poland	Wielkopolskie	Kolniczki	5	2.72	0.68	5.86	12.96	3.30	29.77
Opolskie		Skoroszyce	2	1.11	0.93	1.34	4.08	2.56	6.51	
Warminsko-Mazurskie		Gietrzwałd	5	6.06	2.35	8.94	23.14	19.98	25.40	
		Kajkowo	5	3.57	0.97	9.66	13.64	2.69	27.41	

Year	Country	Region	Location	# samples	EC50			EC98		
					Mean	min	max	Mean	min	max
2017	Czech Republic	Středočesk kraj	Čáslav	3	5.28	4.86	5.77	27.31	26.06	28.62
	Austria	Oberösterreich	Katsdorf	2	3.38	2.17	5.26	20.63	17.83	23.88
	Spain	Navarra	Tafalla	5	0.45	0.23	2.75	1.74	0.81	22.61
		Andalucia	Salteras	5	3.92	2.85	4.86	23.77	20.44	29.77
	Italy	Piemonte	Neive	5	0.30	0.15	0.96	1.23	0.66	7.73
		Veneto	Caorle	5	0.32	0.21	0.61	1.12	0.72	2.98
		Emilia Romagna	San Martino	5	1.23	0.31	5.16	5.26	0.86	23.30
2017	GeomMean (MEC50/98)			-	0.15	-	-	0.47	-	-

Table 3.3-4: *Zymoseptoria tritici*: Distribution of sensitivities to prothioconazole of single pycnidium isolates collected in different European countries in 2018

Year	Country	Region	Location	# samples	EC50			EC98		
					Mean	min	max	Mean	min	max
2018	United Kingdom	Yorkshire-Humberside	Sawdon	8	7.24	5.39	10.98	28.27	24.58	32.85
		East Anglia	Wyboston	8	7.11	5.46	10.56	29.87	25.06	35.45
		Southwest	Foxhill	8	5.99	4.87	8.73	24.04	22.04	28.79
			Crockernwell	8	7.24	5.33	9.38	24.57	21.85	27.58
			Corse	8	7.58	4.58	10.27	25.19	20.06	28.46
		Southeast	Red Rice	7	6.05	4.68	9.18	25.87	20.53	29.57
			North Stoke	8	5.99	5.24	8.86	26.13	23.65	30.71
			Lenham	7	6.80	4.01	10.56	26.96	9.32	38.53
				7	6.85	3.26	9.44	25.59	21.28	30.92
		Netherlands	Flevoland (Oost-NI)	Emmeloord	7	6.14	5.74	7.08	30.40	26.78
	Gelderland (Oost-NI)		Elst	8	6.38	3.44	10.38	24.92	9.46	33.05
	Zuid-Holland (West-NI)		Westmaas	8	5.93	4.95	6.84	28.78	21.34	35.14
	Belgium	Vlaams	Walshoutem	8	6.56	2.84	11.01	29.06	19.32	35.30
		Wallonie	Anthée	4	8.22	6.14	10.61	30.71	28.60	33.48
	France	Nord-Pas de Calais	Martinpuich	8	5.35	2.07	9.16	20.83	9.32	31.36
		Picardie	Mennessis	8	6.80	5.11	9.08	24.22	22.98	26.52
			Daours	8	6.53	4.77	9.56	24.63	20.96	27.68
			Villers aux Erables	8	5.23	3.22	9.26	23.23	9.33	30.99
			Sancourt	8	6.23	3.59	9.56	26.36	22.94	34.72
			Pozières	8	6.09	3.61	9.78	27.13	22.45	31.72
		Bretagne	Janz	8	6.91	3.47	9.94	22.96	9.56	27.70
	Denmark	Midtjylland	Ørum Djurs	8	6.29	5.09	10.07	27.62	25.22	33.72
		Sjælland	Holeby	8	6.92	4.64	9.50	26.65	20.45	32.37
	Germany	Niedersachsen	Semmenstedt	8	5.36	3.48	9.28	21.79	9.58	25.62
		Thüringen	Thiemendorf	8	6.46	4.08	10.41	29.89	21.91	38.99
		Baden-Württemberg	Wittigheusen-Poppenhausen	8	5.49	4.81	5.97	25.87	21.48	28.57
		Bayern	Salching	5	7.20	4.84	9.72	24.63	20.50	29.32
	Lithuania	Lietuva	Prastavoniai	7	3.68	1.32	9.02	15.23	6.63	29.45
			Prastavoniai	8	4.47	1.71	9.74	20.38	7.76	32.14
	Czech Republic	Středočeský kraj	Čáslav	2	8.17	6.51	10.25	29.67	28.40	30.99
		Královéhradecký kraj	Libčany	2	6.62	6.56	6.68	32.74	32.53	32.95
			Nechanice	2	5.25	5.22	5.28	25.89	25.58	26.20
Jihomoravský kraj		Kroměříž	2	1.99	1.64	2.42	11.93	7.17	19.86	
Olomoucký kraj		Velký Týnec	8	3.44	0.98	10.98	13.43	2.71	30.50	

Year	Country	Region	Location	# samples	EC50			EC98		
					Mean	min	max	Mean	min	max
	Austria	Oberösterreich	Au/Engerwitzdorf	6	5.12	3.87	6.22	26.72	20.93	38.39
	Spain	Castilla y Leon	Suzana	7	1.00	0.19	4.64	4.09	0.87	21.34
		Navarra	Villava	8	2.69	0.37	5.98	11.00	1.00	28.51
		Andalucia	Montellano	7	7.19	3.42	10.48	27.14	22.43	31.06
	Italy	Piemonte	Govone	3	0.40	0.11	1.07	1.37	0.29	9.44
		Veneto	Caorle	3	0.36	0.17	1.00	1.18	0.75	2.76
		Emilia Romagna	Bologna	8	6.40	3.61	10.48	21.29	9.92	29.08
		Lazio	Ronciglione	2	3.26	1.59	6.70	15.82	7.27	34.42
			San Felice Circeo	3	0.26	0.17	0.35	0.61	0.28	0.95
2018	GeomMean (MEC50/98)			-	0.24	-	-	0.95	-	-

Table 3.3-5: *Zymoseptoria tritici*: Distribution of sensitivities to prothioconazole of single pycnidium isolates collected in different European countries in 2020

Year	Country	Region	Location	# samples	EC50			EC98		
					Mean	min	max	Mean	min	max
2020	United Kingdom	Yorkshire-Humberside	Holme on Spalding Moor	5	6.17	3.30	9.26	21.27	9.09	28.52
		West Midlands	Leinthal Earls	5	4.74	2.78	9.68	20.12	9.63	26.76
		East Anglia	Henham	5	5.15	4.22	9.58	21.05	19.21	26.47
		Southwest	Ottery St Mary	5	6.20	5.21	9.20	26.14	24.46	27.64
			Crockernwell	5	6.23	4.89	9.56	25.80	21.56	31.78
			Drewsteignton, Exeter	5	3.75	2.00	6.03	23.48	9.94	30.40
		Southeast	Lenham	5	4.86	3.16	5.55	25.36	24.51	26.44
			Ipsden	5	4.40	3.40	6.58	21.03	9.38	32.22
			Red Rice	3	8.14	5.67	9.84	27.18	26.76	27.57
	Netherlands	Gelderland (Oost-NL)	Elst	5	5.25	4.91	5.66	23.89	22.51	26.05
			Oldebroek	5	5.38	3.44	8.33	20.25	9.46	28.19
		Flevoland (Oost-NL)	Lelystad	5	5.90	3.42	9.68	19.76	9.42	26.76
	France	Nord-Pas de Calais	Gaudiempré	5	4.88	3.56	5.92	20.10	9.78	28.22
		Picardie	Harbonnieres	5	5.36	5.11	5.56	24.19	22.95	25.33
		Champagne- Ardenne	Bercenay le Hayer	5	5.32	3.22	9.74	20.38	8.89	26.93
		Bretagne	Breal sous Montfort	5	5.14	3.30	6.56	26.96	22.67	31.65
		Pays de Loire	Les Rosiens sur Loire	5	5.76	3.24	9.02	24.26	22.20	28.62
		Aquitaine	Casseneuil	5	6.95	5.38	9.52	25.66	23.27	27.26
		Midi-Pyrenees	Lelin-Lapujolle	5	6.52	3.72	9.74	28.61	26.50	35.59
	Sweden	Östergötland	Fornåsa	5	5.57	4.52	6.36	26.51	19.67	31.14
	Denmark	Midtjylland	Kjellerup	5	6.47	3.24	10.00	27.81	24.93	31.66
	Germany	Schleswig-Holstein	Haby	5	6.61	5.40	9.04	24.74	23.53	25.42
		Niedersachsen	Garbsen- Horst	5	5.01	3.07	6.10	27.24	23.01	30.59
		Thüringen	Thiemendorf	5	4.38	1.94	6.08	24.53	10.08	39.73
		Sachsen	Grimma	5	4.20	3.14	5.52	28.88	21.70	41.71
		Baden-Württemberg	Ilsfeld	5	6.06	5.15	7.90	25.30	21.66	29.76
			Wittighaus en-Poppenhausen	5	4.12	2.06	6.17	22.31	10.74	40.23
		Bayern	Kag/Straubing	5	6.26	5.35	9.54	27.22	25.67	29.80
	Poland	Zachodniopomorskie	Dobino	1	6.84			35.03		
		Dolnoslaskie	Jaksin	5	5.04	2.02	8.66	21.69	10.44	33.05
Opolskie		Wierzbnik	5	5.31	4.54	6.80	24.43	19.84	33.48	
Lubelskie		Józefów	5	5.54	4.60	6.23	26.22	20.11	30.48	
			5	4.37	2.78	6.29	26.07	23.41	30.23	
Baltic States	Lietuva	Mantviliskis	4	7.01	5.35	9.16	25.69	25.02	27.49	

Year	Country	Region	Location	# samples	EC50			EC98		
					Mean	min	max	Mean	min	max
2020	Latvija		Dotnuva	5	5.86	5.07	8.20	24.94	22.53	27.21
			Pūstapédziai	5	4.98	2.50	8.86	23.50	20.54	29.87
			Glušninkai	2	5.16	4.69	5.69	23.05	20.16	26.36
		Latvija	Poki. Platone	5	7.03	5.21	9.80	26.72	24.22	28.68
			Svēte	5	4.43	2.25	9.12	21.68	11.53	32.52
	Czech Republic	Královéhradecký kraj	Nechanice	5	3.46	2.88	5.45	20.91	9.15	27.51
				5	4.26	2.15	8.00	20.67	11.03	29.38
		Kraj Vysočina	Janovice	5	4.81	3.11	9.00	20.92	8.61	26.73
		Moravskoslezský kraj	Kujavy	2	7.07	5.65	8.84	24.97	24.35	25.61
	Austria	Oberösterreich	Ried i.d. Riedmark	5	5.89	5.09	6.50	27.55	22.88	31.03
	Spain	Andalucia	Lebrija	4	5.72	5.37	6.15	27.22	25.13	29.09
	Italy	Friuli-Venezia Giulia	Udine	3	2.42	1.17	4.02	17.67	10.53	25.73
		Emilia Romagna	Poggio Renatico	5	4.94	3.02	9.86	26.84	24.16	31.45
		Puglia	Spinazzola	5	2.75	0.35	5.51	13.45	0.97	33.61
	2020	GeomMean (MEC50/98)			-	0.64	-	-	3.21	-

Brown Rust (*Puccinia recondita*) - Wheat

Brown rust disease pressure was low to moderate in most of the countries in Europe. Good field performance of DMIs against rust has been maintained. Monitoring in 2020 has been carried out in Belgium, Czech Republic, Denmark, France, Germany, Hungary, Italy, Poland, Romania, Slovakia, Spain and United Kingdom. Sensitivity data from 2020 for wheat brown rust showed that sensitivities were in the range of those of the last 20 years as observed in monitoring from other FRAC member companies.

Yellow Rust (*Puccinia striiformis*) - Wheat

Disease pressure was low to moderate in 2020. Monitoring was carried out in Denmark, France, Germany, Italy, Poland, Portugal, Spain and the United Kingdom. The first monitoring in 2015 showed high sensitivity and low diversity and from 2016 to 2020 a stable situation was reported.

Tan spot (*Pyrenophora tritici-repentis*) - Wheat

In 2020, a limited monitoring was carried out in Czech Republic, Romania, and Sweden. A stable and sensitive situation was observed.

Monitoring data from 2019 in Finland, Lithuania and the United Kingdom showed a narrow range of sensitivity in line with results from previous years.

Fusarium Head Blight (*Fusarium graminearum*) - Wheat

Monitoring was carried out in France in 2019. For the past 10 years, a stable sensitivity situation was observed.

Snow mould (*Microdochium nivale*) - Wheat

In 2020, monitoring was carried in France and the United Kingdom. In 2019, monitoring was carried out in Belgium, France, Germany, Hungary Italy, Sweden Ukraine and the United Kingdom. In general, a stable sensitivity situation has been reported for the past six years.

Powdery mildew (*Blumeria graminis*) - Barley

Monitoring was carried out in Czech Republic, Denmark (2016), France, Germany, Latvia, Sweden (2016), Ukraine, and the United Kingdom.

In 2020, disease pressure was low in Europe. In 2020, DMI products performed well. The sensitivity of the populations stayed in the range observed for more than 15 years.

Net blotch (*Pyrenophora teres*) - Barley

Monitoring was carried out in Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, The Netherlands, Poland, Slovakia, Spain and the 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.

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.

Overall, the sensitivity of populations monitored in 2020 stayed in the range observed in previous years, without any major geographical differences across Europe.

Leaf blotch (*Rhynchosporium secalis*) - Barley

Field performance of DMIs was good. Monitoring was carried out in Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, The Netherlands, Poland, Slovakia, Spain and the United Kingdom. Stable situation. The sensitivity of the populations stayed in the range observed in the previous 15 years.

Brown rust (*Puccinia hordei*) - Barley

Monitoring was carried out in 2014, 2018 and 2019 in Denmark, France, Germany, Sweden and the United Kingdom in 2014, 2018 and 2019. In this five-year interval, a very stable situation with a narrow range of sensitivity was observed.

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 the United Kingdom.

Isolates were detected showing significant loss of sensitivity. Relevant CYP51- mutations explaining the effects have been identified (I325T, I328L, Y403C/Y405H).

Field performance can be regionally significantly affected, due to the low disease pressure hard to evaluate in 2018.

2016: 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 the United Kingdom. No detection of resistance in Estonia.

First data from 2016 showed high frequency of resistant strains in Denmark, Ireland and the 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.

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 the United Kingdom.

3.3.6 Use pattern

In the most intensive cereal growing regions of Europe and especially in seasons with high disease pressure up to four foliar sprays per crop are done. Treatment frequency in wheat is higher compared to barley, rye and triticale. Selection pressure resulting from unrestricted use pattern would increase the risk of quick resistance development compared to a usage according to a management strategy.

3.3.7 Resistance risk assessment of unrestricted use pattern

This analysis is conducted according to the EPPO guidance document PP/213 “Resistance risk analysis”. The actual risk for the evolution of resistance towards each of the components in the mixture

fluxapyroxad/prothioconazole depends on three different parameters: mechanism of resistance against the compound (intrinsic fungicide risk), biology of the pathogen (pathogen risk) and on agronomical factors (agronomic risk). Additionally, to the risk of resistance development towards the individual fungicide, also the combined risk towards the mixture needs to be considered.

3.3.7.1 Inherent active substance associated risk

According to FRAC, the SDHI fungicides like are classified as substances exerting a medium-high risk of resistance development.

The DMI fungicides like prothioconazole are classified as substances exerting a medium risk of resistance development.

3.3.7.2 Inherent pathogen associated risk

Large differences in pathogen risk can be found among certain genera and species of plant pathogens. Factors relating directly to disease epidemiology combined with genetic factors can influence the pathogen risk. The most important factors determining pathogen risk appear to be:

- Life cycle of pathogen; the shorter the generation time, the more frequent the need for exposure to the fungicide and the faster the build - up of resistance.
- Abundance of sporulation; the more spores that are released in the crop the greater the availability of individual genomes for mutation and selection, and the faster the spread of resistant mutants.
- Ability of spores to spread between plants, crops and regions.
- Ability to infect at all crop stages, requiring repeated fungicide treatment.
- Occurrence of a sexual stage in the life cycle; this could either favour or hinder resistance development.
- Ability to mutate or express mutant genes; certain pathogens seem to produce fit mutants more readily than others (FRAC, 2007)

As no scientific criteria are available to accurately determine the risk of pathogen to develop resistance, the FRAC classification is based on the reported resistance claims over the last 40 years.

Therefore, FRAC considers the pathogen risk as medium to high only if resistance was reported in commercial situations for more than one fungicide class (FRAC, 2013). In conclusion, the resistance risk of the diseases for which registration is requested can be summarised as follow

Table 3.3-6: Pathogen risk summary

Pathogen	Crop	Risk	Risk class
<i>Zymoseptoria tritici</i>	Wheat	Medium	2
<i>Parastagonospora nodorum</i>	Wheat	Medium Low	2
<i>Blumeria graminis</i>	Wheat and Barley	High	3
<i>Fusarium sp.</i>	Wheat	Low	1
<i>Microdochium nivale</i>	Wheat	Medium	2
<i>Puccinia recondita</i>	Wheat	Low	1
<i>Puccinia striiformis</i>	Wheat and Barley	Low	1
<i>Puccinia hordei</i>	Barley	Low	1
<i>Puccinia coronata</i>	Oat	Low	1
<i>Pyrenophora teres</i>	Barley	Medium	2
<i>Pyrenophora tritici - repentis</i>	Wheat	Medium	2
<i>Ramularia collo - cygni</i>	Barley	High	3
<i>Rhynchosporium secalis</i>	Barley	Low	1

3.3.7.3 Inherent combined risk

When the pathogen risk is reported in a table with the inherent resistance risk of the SDHI's group and DMIs group, the combined resistance risk for each pathogen/fungicide combination can be estimated as follow (FRAC, 2019)¹³.

¹³ <https://www.frac.info/docs/default-source/publications/pathogen-risk/frac-pathogen-list-2019.pdf>

Table 3.3-7: Combined Inherent risk for each active substance contained in ADM.03503.F.1.A

Molecule Risk ↓	Combined Risk		
Medium-high = 3 fluxapyroxad	3	6	9
Medium = 2 prothioconazole	2	4	6
Low=1	1	2	3
Pathogen risk →	Low = 1	Medium = 2	High = 3
Pathogen →	Parastagonospora nodorum (LEPTNO) Puccinia spp. (PUC CST, PUC CRT, PUC CHD, PUC CO) Fusarium sp. (FUS ASS FUS ASP) Rhynchosporium secalis (RHYNSE)	Zymoseptoria tritici (SEPTTR) Parastagonospora nodorum (LEPTNO) Microdochium nivale (MONGNI) Pyrenophora tritici-repentis (PYRNTR) Pyrenophora teres (PYRNTE)	Blumeria graminis (ERYSGR) Ramularia collo - cygni (RAMUCC)

Combined Risk: 1 = low, 2 to 6 medium, 9 high (FRAC, 2019)

According to the Table 3.3-7, the combined inherent risk for fluxapyroxad is medium-high and for prothioconazole is medium for the diseases that a registration demand is asked. However this table does not consider the agronomy agronomic risk.

The actual risk of resistance depends not only on the inherent risk of a particular fungicide - pathogen combination, as indicated in the previous table, but also on the conditions of fungicide use. In fact, there are important parameters of resistance risk in practice that must be included in an integral part of resistance risk assessment.

The most important conditions of use that can affect resistance risk are:

- Number of repeated applications of the fungicide; the more frequent the product is applied to the pathogen, the more rapid the selection of mutants
- Exclusivity of the product, the more exclusive the products with the same mode of action, the more sustained the selection pressure; alternation or combined application with other types of fungicides with different mechanisms of action can reduce resistance risk
- Amounts of pathogen exposed to the fungicide; if disease incidence is relatively low or irregular from season to season, then occurrence and selection of possible resistant mutants is reduced.

Table 3.3-8 reports the combined risk for ADM.03503.F.1.A considering the agronomic risk.

Table 3.3-8: Possible combined risk for ADM.03503.F.1.A in relation with to the agronomic risk level

Molecule Risk ↓	Combined risk			Agronomic Risk
Medium-high =6 (fluxapyroxad)	6 3 1,5	12 6 3	18 9 4,5	High =1 Medium = 0.5 Low = 0.25
Medium=4 (prothioconazole)	4 2 1	8 4 2	12 6 3	High =1 Medium = 0.5 Low = 0.25
Low=1	1 0,5 0,25	2 1 0,5	3 1,5 0,75	High =1 Medium = 0.5 Low = 0.25
Pathogen risk →	Low = 1	Medium = 2	High = 3	
Pathogen	Parastagonospora nodorum (LEPTNO) Puccinia spp. (PUC CST, PUC CRT, PUC CHD, PUC CO) Fusarium sp. (FUS ASS FUS ASP) Rhynchosporium secalis (RHYNSE)	Zymoseptoria tritici (SEPTTR) Parastagonospora nodorum (LEPTNO) Microdochium nivale (MONGNI) Pyrenophora tritici-repentis (PYRNTR)	Blumeria graminis (ERYSGR) Ramularia collo - cygni (RAMUCC)	

		<i>Pyrenophora teres</i> (PYRNTE)		
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Highest possible value = 18 (high molecule risk high pathogen risk and high agronomy risk).

For all those diseases, fungicides are not systematically applied. Application is performed according to the ~~disease contamination~~ pathogen infection level and is based on the assessment carried out by the plant protection technical department of various partners. Those assessments are completed by modelling systems which refine the date of application. All the results are communicated to farmers through various supports. This process avoids excessive number of applications on pathogens. According to the Good Agricultural Practices, ADM.03503.F.1.A is applied only once and in consequence the agronomic risk on those diseases is low and equal to 0.25. Considering the agronomic risk, the combined risk adapted to the use of ADM.03503.F.1.A is the following one:

Table 3.3-9: Summary of the combined risk for ADM.03503.F.1.A

Pathogen	Crop	Fluxapyroxad Combined Risk	Prothioconazole Combined Risk
<i>Blumeria graminis</i> (ERYSGR)	Wheat and barley	4.5	<u>3</u>
<i>Ramularia collo - cygni</i> (RAMUCC)	Barley	4.5	<u>3</u>
<i>Zymoseptoria tritici</i> (SEPTTR)	Wheat	3	2
<i>Parastagonospora nodorum</i> (LEPTNO)	Wheat	3 1.5	2 1
<i>Microdochium nivale</i> (MONGNI)	Wheat	3	2
<i>Pyrenophora tritici - repentis</i> (PYRNTR)	Wheat	3	2
<i>Pyrenophora teres</i> (PYRNTE)	Barley	3	2
<i>Puccinia spp.</i> (PUC CST, PUC CRT, PUC CHD, PUC CCO)	Wheat, barley and oat	1.5	1
<i>Fusarium sp.</i> (FUS ASS FUSASP)	Wheat	1.5	1
<i>Rhynchosporium secalis</i> (RHYNSE)	Barley	1.5	1

In conclusion the combined risk is low to medium since the highest value reaches 4.5. In addition, ADM.03503.F.1.A is an association of 2 active substances of different fungicide group (SDHI and DMI) without cross resistance. The resistance risk is therefore acceptable.

zRMS comments:

Since the pathogen risk assumed by the applicant for LEPTNO has been corrected in tables 3.3-6 - 3.3-8, based on the FRAC's Pathogen Risk List (2019), the respective value in the summary Table 3.3-9 was amended either.

3.3.8 Management Strategy

Although the risk evaluation is acceptable, additional recommendations can be proposed.

First, agronomical means as the use of tolerant cultivars, crop rotation to break the disease cycle or cultivation in order to reduce the inoculum in the soil must be applied. Then as described above, application of ADM.03503.F.1.A must be carried out according to the ~~contamination~~ infection level or modelling that forecast the disease pressure and the date of application based on the weather conditions and also according to preliminary assessments in field and other parameters.

Even if only one application is requested, ADM.03503.F.1.A will be applied within fungicide programme in alternation with other mode of action (QoI's, multisite moA ...). Alternation programmes can also include mixtures.

ADAMA will continue to be active members of the FRAC and FRAG networks.

zRMS comments on the risk of resistance development:

The theoretical estimation of resistance risk, according to the PP 1/213(3) EPP0 guideline and following the method of risk quantification assumed by FRAC, points at two (three) targets of the highest combined risk of resistance to both actives of the ADM.03503.F.1.A: *B. graminis* (in both wheat and barley) and *R. collo-cygni* in barley.

Field monitoring of SDHIs efficacy is reported by means of the FRAC statement alone, accessed by the applicant in 2021 and quoted *verbatim* in the dRR text. The same text updated in April 2023, reveals that *B. graminis*

sampled in 2022 had nevertheless shown “full sensitivity” to SDHIs in both wheat and barley (it is not even listed in the Table 3.3-1), while the sensitivity is quite unstable in *R. collo-cygni*, and the situation is rather complex with *Zymoseptoria tritici*, the latter being so for the high number of mutations, their fluctuating frequency in sampled material and variable degree to which they affect performance of the SDHI fungicides.

Sensitivity to DMIs is presented first based on FRAC reports. Additionally, the applicant’s own data on *Z. tritici* sensitivity to DMIs are presented, from the research by the external unit EpiLogic (prochloraz, tebuconazole, difenoconazole and prothioconazole in 2016-2018, difenoconazole and prothioconazole in 2020). These data seem less user-friendly when tabulated site by site in dRR, but their synthetic, graphical representation in the respective reports (KCP 6.3-001 – 6.3-004) neatly fits in the multi-annual pattern reported by the FRAC members, that is: sensitivity fluctuating steadily in particular pathogens but threatening no dramatic change to the group’s performance in the field. One exception is *Ramularia collo-cygni*, of which the strains highly resistant to DMIs have been already recorded with high frequency.

While the current (2023) FRAC recommendations for use of SDHIs in cereals do not name any particular pathogens of “special attention”, they nonetheless include a condition that “*The mixture partner should provide satisfactory disease control when used alone on the target disease and must have a different mode of action.*” Then the “cereal” recommendations for DMIs read as follows: “*Given that there already exist populations of Ramularia collo-cygni in Europe resistant to all main site-specific modes of actions it is recommended to add precautionary a multi-site to ensure robust disease control and an effective resistance management in barley.*” (**bolding** by zRMS). Consequently, since prothioconazole may not always show the effective stand-alone partner for fluxapyroxad against some of **Ramularia strains**, and fluxapyroxad itself is certainly not multi-site a fungicide, then ADM.03503.F.1.A may not always show reliable a product in control of this particular pathogen.

The reasoning and calculation presented by the applicant, following the EPP0 PP 1/213(4) guidance and the assumptions of the FRAC Pathogen Risk List respectively, are correct. Factors potentially reducing the agronomic risk are, in this case, single application and the fact that the product is a mixture of two “non cross-resistant” actives. However, as has been reasoned above, the sheer fact of “non-cross resistance” may be unimportant if one of the partners happens to be ineffective against a particular strain. That is why the applicant’s conclusion of low to medium modified risk, based on the assumed 0.25 value for the agronomic risk is, to the opinion of zRMS, not correct with respect to *Ramularia*, the pathogen of high intrinsic risk of resistance and at the same time the one infesting one of the two major cereal crops. ADM.03503.F.1.A no doubt deserves a chance to prove its merits in action, but the combined, agronomic risk for *Ramularia* should be assumed higher than proposed by the applicant; to the opinion of zRMS 0.5 would be adequate, thus enhancing the risk for this pathogen to high, for both actives.

The risk-mitigating measures listed in the product label should include as follows:

- 1) Single application per growth season and predominant preventive use. Curative application should be avoided (in line with FRAC recommendations for **both** SDHIs and DMIs).
- 2) The assumed spraying program should contain fungicides of other MoA groups, including multi-site MoA fungicides, where possible (a number of multi-site fungicides have been phased out recently, including uses in cereals).
- 3) The dose rates recommended by the manufacturer must be observed and followed at all time, and the decision to apply the lower doses of the authorised dose range should be taken based on infection monitoring, and only in case when low intensity of infection is concluded.
- 4) Commonly acknowledged agronomic means capable of reducing the infection levels, such as appropriate crop rotation, use of resistant cultivars and **non-reduced** soil tillage, must all be used along with the chemical protection.

The cMSs are kindly advised to incorporate content to the similar meaning in their own, national labels.

[To the zRMS Abstract](#)

3.4 Adverse effects on treated crops (KCP 6.4)

Information on trials submitted (3.4 Adverse effects on treated crops)

The crop sensitivity of ADM.03503.F.1.A was studied from a set of **300 efficacy trials** carried out **from 2019 to 2021** in wheat (159 trials), barley (118 trials), rye (9 trials), and triticale (14 trials).

Fluxapyroxad and prothioconazole based products have been registered for a long time for disease control of cereals and no adverse effect on transformation processes (bread and beer making processes) have been reported. Therefore, no label restrictions regarding use on cereals for baking or brewing are mentioned. Therefore, the risk of the undesirable effect on crops used for baking or brewing can be considered as very low.

However, the possible effect of ADM.03503.F.1.A on the transformation processes was studied from a set of 9 confirmatory processing trials implemented in 2020 and 2021 in France in the Maritime EPPO climatic zone. The purpose of these studies is to discover the potential unintentional effects of ADM.03503.F.1.A applied in winter (3 trials) and spring (3 trials) barley crops on the production and the quality of malt and beer and applied in winter wheat (3 trials) on the production and the quality of bread.

Trial sites were carried out in commercially grown crops. All trials were subject to normal agricultural inputs, according to the principles of good agricultural practice (GAP). All plants in all trials were well established with good uniformity and vigour prior to the application of the fungicide treatment. Table 3.4-1 presents a summary of all processing trials provided in the BAD.

Table 3.4-1: Processing trials - Repartition distribution of trials

Process	Crop	EPPO Climatic zone	Country	Year		Total
				2020	2021	
Breadmaking process	Winter wheat	Maritime	France	-	3	3
Beer making process	Winter barley	Maritime	France	3	-	3
	Spring barley	Maritime	France	3	-	3
Total				6	3	9

An overview of available trials is provided in Table 3.4-2.

Table 3.4-2: Processing trials - Barley - Presentation of trials

Crop(s) ⁽¹⁾	Process	EPPO climatic zone ⁽²⁾	Country	Year	Type of trial ⁽³⁾	No. of	GEP, non-GEP, official ⁽⁴⁾
Winter wheat	Breadmaking	Maritime	France	2021	Process	3 trials	GEP
Spring barley	Beermaking	Maritime	France	2020	Process	3 trials	GEP
Winter barley	Beermaking	Maritime	France	2020	Process	3 trials	GEP

⁽¹⁾ According to the GAP table.

⁽²⁾ According to EPPO guideline PP 1/241(1) "Guidance on comparable climates".

⁽³⁾ Process: Processing trials

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

Table 3.4-3 presents the plant protection products used as reference standard and the dose rates applied in the efficacy trials.

About the wheat processing trials, the efficacy of ADM.03503.F.1.A was compared to the efficacy of reference standards containing fluxapyroxad at 125 g a.s./ha and metconazole at 90 g a.s./ha. This reference standard used to justify the absence of adverse effects of ADM.03503.F.1.A, are grouped under a single name: LIBRAX.

About the barley processing trials, the efficacy of ADM.03503.F.1.A was compared to the efficacy of reference standards containing prothioconazole at 200 g a.s./ha. This reference standard used to justify the absence of adverse effects of ADM.03503.F.1.A, are grouped under a single name: PROLINE.

Further details are presented in the section 3.4.4 Effects on transformation processes (KCP 6.4.4)

Figure 3.4-1 Processing trials - Location of the trial sites

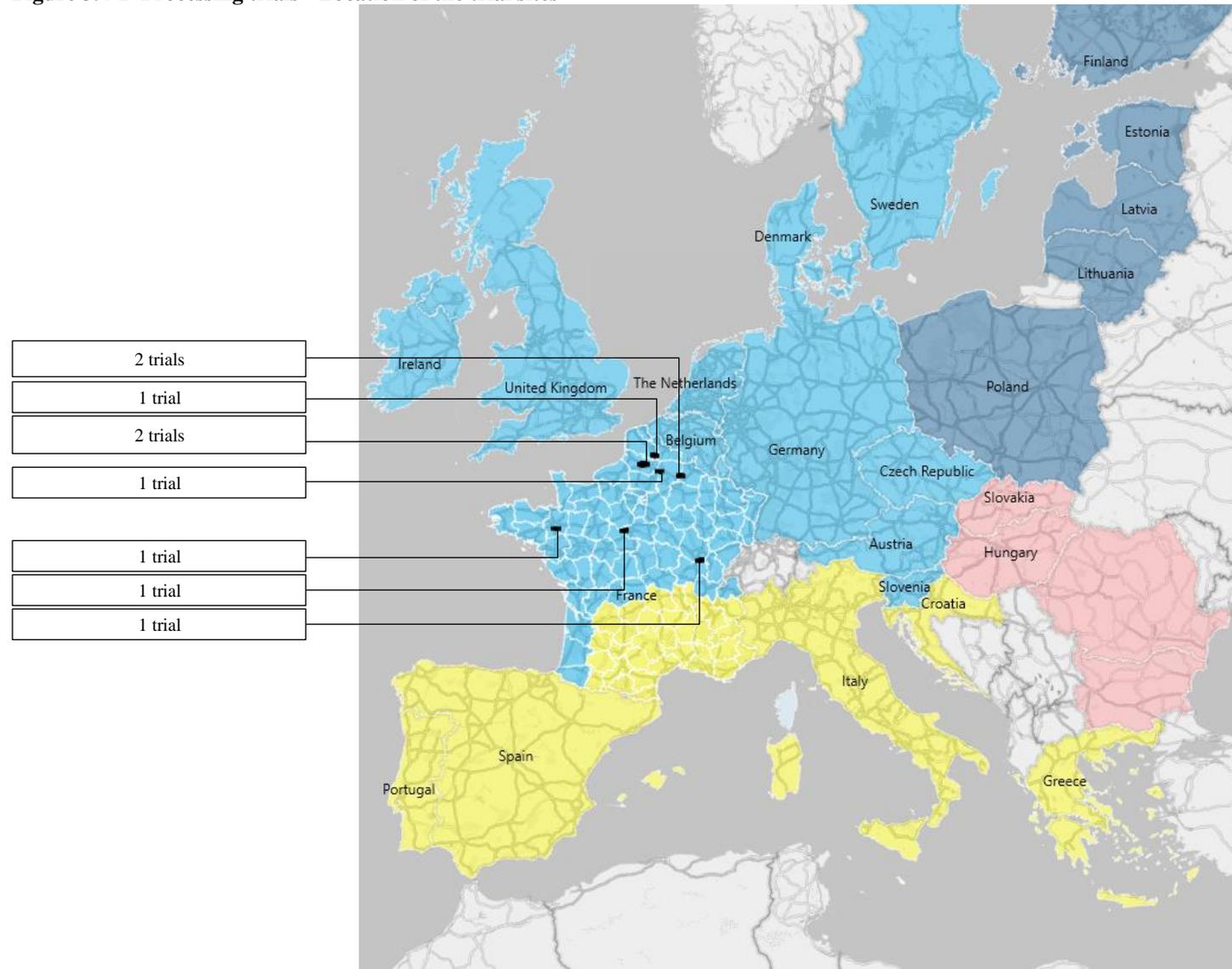


Table 3.4-3: Processing trials - Presentation of reference standards

Crop(s) ⁽¹⁾	Process	Reference standard	Country(ies) where the product is used ⁽¹⁾	Authorization number	Active substance(s)	Formulation		Registered application rate ⁽³⁾	Dose rate in trials (per treatment)	Rate of active substance per ha	Remark ⁽⁴⁾
						Type ⁽²⁾	Concentration of a.s.				
Wheat	Breadmaking process	LIBRAX	France	2140173	Fluxapyroxad + Metconazole	EC	62.5 g/L + 45 g/L	2.0 L/ha	2.0 L/ha	125 g a.s./ha + 90 g a.s./ha	Named LIBRAX in this dRR
Barley	Beermaking process	JOAO	France	2060116	Prothioconazole	EC	250 g/L	0.8 L/ha	0.6 L/ha 0.8 L/ha	150 g a.s./ha 200 g a.s./ha	Named PROLINE in this dRR

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

⁽²⁾ EC: Emulsifiable concentrate

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

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

3.4.1.1 Material and Methods

Material and Methods used in efficacy trials are given within Section 3.2.3.1 and not repeated here.

3.4.1.2 Crop safety results on winter wheat

The crop sensitivity was assessed in **159 efficacy trials** performed from 2019 to 2021 (presented in Section 3.2) in winter wheat. All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP).

Phytotoxicity assessments are summarised in Table 3.4-4.

Table 3.4-4: Selectivity of ADM.03503.F.1.A (1.25 L/ha) – Winter wheat - Efficacy trials

Number of trials with...	ADM.03503.F.1.A - 1.25 L/ha		LIBRAX - 2.00 L/ha
	Fluxapyroxad +Prothioconazole		Fluxapyroxad +Metconazole
	93.75+187.5 g a.s./ha		125+90 g a.s./ha
Winter wheat			
Maximum of phytotoxicity recorded during the trials	0%	159	159
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	159	159
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

No phytotoxicity symptoms caused by ADM.03503.F.1.A at the proposed dose of 1.25 L/ha were recorded in all efficacy trials and can be considered safe to apply to wheat when applied according to the proposed GAP and label recommendations. The potential impact of variety on the occurrence of phytotoxicity was observed in 100 different varieties of winter wheat (Table 3.4-5).

Table 3.4-5: Phytotoxicity assessments of ADM.03503.F.1.A - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Winter wheat (TRZAW)	159	100	Akteur (3), Alixan (1), Amandus (2), Amboise (1), Amicus (1), Anapurna (1), Antonius (1), Apache (3), Apostel (1), Ariesan (4), Arkadia (4), Arkeos (1), Asano (1), Attraktion (1), Aurelius (1), Avenue (1), Belissa (1), Benchmark (2), Bemington (1), Bermude (2), Bernstein (1), Bilans (3), Bussard (2), Capo (1), Cellule (1), Chevron (2), Claire (1), Costello (2), Creek (3), Crusoe (2), Cubus (2), Dekan (2), Delavar (2), Depot (1), Dickens (1), Dinosor (1), Discus (1), Elation (2), Etana (1), Evina (1), Exotic (1), Fairplay (1), Federer (1), Fidelius (1), Genius (4), GK Bago (1), GK Bekes (5), GK Körös (1), GK Petur (1), Glosa (2), Hardy (2), Hyfi (1), Illustrious (2), IS Carnea (1), JB Diego (1), Judita (1), Julie (1), Julius (1), Kashmir (1), Kometus (1), Kws Extase (1), KWS Kerrin (1), KWS Santiago (1), Leeds (1), LG Mocca (1), Linus (1), Lukullus (3), Madejka (1), Matrix (1), Medalistka (1), Miranda (1), Montana (1), Monte Cristo (1), Mutic (2), MV Kolompos (2), MV Menrot (1), MV Nador (3), Nemo (3), Oregrain (2), Ostroga (1), Pamir (1), Pannonikus (1), Porthus (1), Princeps (3), Providence (1), PS Kvalitas (1), RGT Reform (1), Rubisko (2), Sheriff (1), Siskin (1), Skagen (3), Skyscraper (1), Smaragd (1), Sorial (5), Svitava (1), Talent (1), Terroir (1), Tobak (7), Tonacja (1), Tyanica (1).

Therefore, no effect is expected in wheat crops if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

zRMS comments: Crop safety results in winter wheat confirmed.

3.4.1.3 Crop safety results on barley

The crop sensitivity was assessed in **118 efficacy trials** performed from 2019 to 2021 (presented in Section 3.2) in winter barley (108 trials) and spring barley (10 trials). All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP).

Phytotoxicity assessments are summarised in Table 3.4-6.

Table 3.4-6: Selectivity of ADM.03503.F.1.A (1.25 L/ha) - Barley - Efficacy trials

Number of trials with...		ADM.03503.F.1.A - 1.25 L/ha		LIBRAX - 2.00 L/ha	
		Fluxapyroxad +Prothioconazole		Fluxapyroxad +Metconazole	
		93.75+187.5 g a.s./ha		125+90 g a.s./ha	
Winter barley					
Maximum of phytotoxicity recorded during the trials	0%	108		108	
	>0 - 4.9%	0		0	
	5 - 9.9%	0		0	
	10 - 14.9%	0		0	
	15% and more	0		0	
Level of symptoms at the last assessments	0%	108		108	
	>0 - 4.9%	0		0	
	5 - 9.9%	0		0	
	10 - 14.9%	0		0	
	15% and more	0		0	
Spring barley					
Maximum of phytotoxicity recorded during the trials	0%	10		10	
	>0 - 4.9%	0		0	
	5 - 9.9%	0		0	
	10 - 14.9%	0		0	
	15% and more	0		0	
Level of symptoms at the last assessments	0%	10		10	
	>0 - 4.9%	0		0	
	5 - 9.9%	0		0	
	10 - 14.9%	0		0	
	15% and more	0		0	

No phytotoxicity symptoms caused by ADM.03503.F.1.A at the proposed dose of 1.25 L/ha were recorded in all efficacy trials and can be considered safe to apply to wheat when applied according to the proposed GAP and label recommendations. The potential impact of variety on the occurrence of phytotoxicity was observed in 58 different varieties of winter barley and 8 different varieties of spring barley (Table 3.4-7).

Table 3.4-7: Phytotoxicity assessments of ADM.03503.F.1.A - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Winter barley (HORVW)	108	58	<i>Amistar</i> (1), <i>Antonella</i> (2), <i>Astaire</i> (1), <i>Atlantic</i> (3), <i>Azrah</i> (1), <i>Bazooka</i> (1), <i>California</i> (1), <i>Calypto</i> (3), <i>Cardinal</i> (1), <i>Carmina</i> (1), <i>Casanova</i> (1), <i>Cassia</i> (5), <i>Etincel</i> (7), <i>Funky</i> (1), <i>Gerlach</i> (4), <i>GK Judy</i> (1), <i>Gloria</i> (2), <i>Hawking</i> (1), <i>Higgins</i> (1), <i>Hirondella</i> (1), <i>Jaguar</i> (2), <i>Jakubus</i> (1), <i>Jalon</i> (1), <i>Jule</i> (1), <i>Jup</i> (4), <i>Kosmos</i> (3), <i>KWS Faro</i> (2), <i>KWS Higgins</i> (1), <i>KWS Jaguar</i> (1), <i>KWS Joy</i> (1), <i>KWS Keeper</i> (2), <i>KWS Orwell</i> (5), <i>KWS Scala</i> (1), <i>Laverda</i> (1), <i>LG Castings</i> (1), <i>LG Triumph</i> (2), <i>Lomerit</i> (2), <i>Margaux</i> (1), <i>Memento</i> (2), <i>Metaksa</i> (2), <i>Pixel</i> (5), <i>Rosita</i> (1), <i>Sandra</i> (5), <i>Scala</i> (2), <i>Seduction</i> (2), <i>SU Ellen</i> (2), <i>SU Jule</i> (1), <i>SU Vireni</i> (1), <i>Titus</i> (2), <i>Tower</i> (2), <i>Valerie</i> (1), <i>Vanessa</i> (1), <i>Wintmalt</i> (3), <i>Wotan</i> (1), <i>Zebra</i> (1), <i>Zenek</i> (1), <i>Zita</i> (1), <i>Zophia</i> (1),
Spring barley (HORVS)	10	8	<i>Concerto</i> (1), <i>Explorer</i> (1), <i>Francin</i> (1), <i>Grace</i> (1), <i>Kangoo</i> (1), <i>Laudis 550</i> (1), <i>Malz</i> (3), <i>Tungsten</i> (1).

Therefore, no effect is expected in barley crops if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

zRMS comments: Crop safety results in winter and spring barley confirmed.

3.4.1.4 Crop safety results on rye

The crop sensitivity was assessed in **9 efficacy trials** performed from 2020 to 2021 (presented in Section 3.2). All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP). Phytotoxicity assessments are summarised in Table 3.4-8.

Table 3.4-8: Selectivity of ADM.03503.F.1.A (1.25 L/ha) - Rye - Efficacy trials

Number of trials with...		ADM.03503.F.1.A - 1.25 L/ha	LIBRAX - 2.00 L/ha
		Fluxapyroxad +Prothioconazole 93.75+187.5 g a.s./ha	Fluxapyroxad +Metconazole 125+90 g a.s./ha
Winter rye			
Maximum of phytotoxicity recorded during the trials	0%	9	9
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	9	9
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

No phytotoxicity symptoms caused by ADM.03503.F.1.A at the proposed dose of 1.25 L/ha were recorded in all efficacy trials and can be considered safe to apply to wheat when applied according to the proposed GAP and label recommendations. The potential impact of variety on the occurrence of phytotoxicity was observed in 7 different varieties of rye (Table 3.4-9).

Table 3.4-9: Phytotoxicity assessments of ADM.03503.F.1.A - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Rye (SECSS)	9	7	<i>Dankowskie Diament</i> (1), <i>Dukato</i> (1), <i>Helltop</i> (1), <i>Jethro</i> (1), <i>KWS Binntto</i> (1), <i>Poznańskie</i> (2), <i>Suceveana</i> (2).

Therefore, no effect is expected in rye crops if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

zRMS comments: Crop safety results in winter rye confirmed.

3.4.1.5 Crop safety results on triticale

The crop sensitivity was assessed in **14 efficacy trials** performed from 2020 to 2021 (presented in Section 3.2). All trials were carried out by testing facilities officially recognised according to Good Experimental Practice (GEP). Phytotoxicity assessments are summarised in Table 3.4-10.

Table 3.4-10: Selectivity of ADM.03503.F.1.A (1.25 L/ha) - Triticale - Efficacy trials

Number of trials with...		ADM.03503.F.1.A - 1.25 L/ha	LIBRAX - 2.00 L/ha
		Fluxapyroxad +Prothioconazole 93.75+187.5 g a.s./ha	Fluxapyroxad +Metconazole 125+90 g a.s./ha
Winter triticale			
Maximum of phytotoxicity recorded during the trials	0%	14	14
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0
Level of symptoms at the last assessments	0%	14	14
	>0 - 4.9%	0	0
	5 - 9.9%	0	0
	10 - 14.9%	0	0
	15% and more	0	0

No phytotoxicity symptoms caused by ADM.03503.F.1.A at the proposed dose of 1.25 L/ha were recorded in all efficacy trials and can be considered safe to apply to wheat when applied according to the proposed GAP and label recommendations. The potential impact of variety on the occurrence of phytotoxicity was observed in 12 different varieties of triticale (Table 3.4-11).

Table 3.4-11: Phytotoxicity assessments of ADM.03503.F.1.A - Varieties tested in efficacy trials

Crop	No of trials	No of varieties	Variety names (No of trials)
Triticale (TTLSS)	14	12	<i>Cedrico</i> (1), <i>GK Maros</i> (1), <i>GK Szemes</i> (1), <i>Grenado</i> (1), <i>Lanetto</i> (1), <i>Leontino</i> (3), <i>Lombardo</i> (1), <i>Orinoko</i> (1), <i>Rotondo</i> (1), <i>Tarzan</i> (1), <i>Temuco</i> (1), <i>Trapero</i> (1).

Therefore, no effect is expected in triticale crops if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

zRMS comments: Crop safety results in winter triticale confirmed.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

3.4.2.1 Material and Methods

Material and Methods used in efficacy trials are given within Section 3.4.1.1 and not repeated here.

3.4.2.2 Effect on the yield of wheat

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on the yield and no difference with the reference standard LIBRAX was noted in the 139 valid efficacy trials harvested (see Section 3.2.3.2.8).

Therefore, no adverse effect on the yield of wheat is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.2.3 Effect on the yield of barley

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on the yield and no difference with the reference standard LIBRAX was noted in the 94 valid efficacy trials harvested (see Section 3.2.3.3.7).

Therefore, no adverse effect on the yield of wheat is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.2.4 Effect on the yield of rye

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on the yield and no difference with the reference standard LIBRAX was noted in the 8 valid efficacy trials harvested (see Section 3.2.3.4.4).

Therefore, no adverse effect on the yield of rye is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.2.5 Effect on the yield of triticale

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on the yield and no difference with the reference standard LIBRAX was noted in the 13 valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the yield of triticale is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

3.4.3.1.1 Material and Methods

Material and Methods used in efficacy trials are given within Section 3.2.3.1 and not repeated here.

3.4.3.2 Effect on the quality of wheat

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on different quality parameter (thousand grain weight and specific weight) and no difference with the reference standard LIBRAX was noted in the 116 (thousand grain weight) and 138 (specific weight) valid efficacy trials harvested (see Section 3.2.3.2.8).

Therefore, no adverse effect on the quality of wheat is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.3.3 Effect on the quality of barley

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on different quality parameter (thousand grain weight and specific weight) and no difference with the reference standard LIBRAX was noted in the 74 (thousand grain weight) and 90 (specific weight) valid efficacy trials harvested (see Section 3.2.3.3.7).

Therefore, no adverse effect on the quality of wheat is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.3.4 Effect on the quality of rye

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on different quality parameter (thousand grain weight and specific weight) and no difference with the reference standard LIBRAX was noted in the 8 valid efficacy trials harvested (see Section 3.2.3.4.4).

Therefore, no adverse effect on the quality of rye is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

3.4.3.5 Effect on the quality of triticale

Fluxapyroxad and prothioconazole are existing active substances and no effect on the yield is known. In addition, no adverse effect on different quality parameter (thousand grain weight and specific weight) and no difference with the reference standard LIBRAX was noted in the 13 valid efficacy trials harvested (see Section 0).

Therefore, no adverse effect on the quality of triticale is expected if ADM.03503.F.1.A is applied at the maximum requested rate of 1.25 L/ha according to the Good Agricultural Practices and label recommendations.

zRMS comments on 3.4.2 and 3.4.3:

The yield and yield quality data are included in the submitted trials and, although not presented in the dRR, are summarized in the BAD, Tables 3.2-145 to 3.2-220.

The non-submission of the yield data for fungicide products has been accepted by zRMS based on the EPPO guideline PP 1/135 (4) *Phytotoxicity assessment*.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Concerning cereals, as ADM.03503.F.1.A by its nature is a fungicidal compound, it is important to investigate the potential impact of any residues remaining on the crop at harvest on fermentation processes. However, fluxapyroxad and prothioconazole based products have been registered since a long time for disease control of cereals and no adverse effect on transformation processes (bread and beer making processes) have been reported. Therefore, no label restrictions regarding use on cereals for baking or brewing are mentioned. Therefore, the risk of the undesirable effect on crops used for baking or brewing can be considered as very low.

However, the possible effect of ADM.03503.F.1.A on the transformation processes was studied from a set of 9 confirmatory processing trials implemented in 2020 and 2021 in France in the Maritime EPPO climatic zone.

The purpose of these studies is to discover the potential unintentional effects of ADM.03503.F.1.A applied in winter (3 trials) and spring (3 trials) barley crops on the production and the quality of malt and beer and applied in winter wheat (3 trials) on the production and the quality of bread.

Therefore, no effect is expected on transformation processes if ADM.03503.F.1.A is used according to the GAP and label recommendations.

3.4.4.1 Effect on the breadmaking process

3.4.4.1.1 Material and methods

Experimental details

Three wheat processing trials were carried out by officially recognized organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed in accordance with EPPO guidelines or recommendations published by the CEB (“*Commission des Essais Biologiques*”). The “CEB” methods are in accordance with EPPO directives.

Main characteristics are summarised in following Table 3.4-12.

Table 3.4-12: Details on trial methodology - Processing trials - Wheat - Breadmaking process

Guidelines	General Guidelines	PP1/135(3): “ <i>Phytotoxicity assessment</i> ”. PP1/181(4): “ <i>Conduct and reporting of efficacy evaluation trials, including good experimental practice</i> ”.
	Specific Guidelines	CEB No.218: “ <i>Method for studying the unintentional effects of plant protection products on quality of soft wheat and on baking</i> ”.
Experimental design	Plot design	Randomized Complete Block (RCB).
	Plot size	25-30 m ² .
	Number of replications	3 replications.
Crop	Number of trials	3 trials
	Varieties	<i>Oregrain (1)</i> , <i>Tenor (1)</i> , <i>RGT Volupto (1)</i>
Application	Application timing	BBCH 39
	Number of applications	1 application.
	Spray volumes	200 L/ha.
Assessment	Assessment dates	Phytotoxicity in %, yield, moisture, specific weight, protein content, impurity rate, Hagberg falling number, Zeleny index, Chopin alveogram and breadmaking test, (triangle) taint test.
	Assessment types	Harvest and post-harvest.
Results and analysis	Statistical analysis	-

Treatments and reference standards

ADM.03503.F.1.A was tested at 1.25 L/ha (N dose) and compared with reference standard LIBRAX at 2.0 L/ha described in Table 3.4-3. Each product is applied in accordance with good agricultural practices and label recommendations.

Assessment methods

The assessment of unintended effects of plant protection products on quality of wheat, flour and bread was performed in three steps:

1. Verifying the quality of wheat grains,
2. Verifying the quality of flours,
3. Evaluation of breadmaking process and sensory properties of bread.

3.4.4.1.2 Summary and evaluation of individual results on the breadmaking process

Analysis of wheat

At harvest, except in 1 out of 3 trials with the moist content and the yield of treated plots with ADM.03503.F.1.A at 1.25 L/ha were statistically higher than treated plots with reference LIBRAX at 2.0 L/ha, no significant difference was observed between ADM.03503.F.1.A and LIBRAX about moist content, the yield and the specific weight (Table 3.4-13). No difference was also observed concerning the impurity rate.

Table 3.4-13: Detailed results: Effect of ADM.03503.F.1.A (1.25 L/ha) on transformation processes - Breadmaking trials - Results of wheat analysis

Parameter	Crop	Trial code	ADM.03503.F.1. A 1.25 L/ha		LIBRAX 2.0 L/ha		Difference	Tolerance
Yield								
Yield (t/ha)	Winter wheat	FR21FPTRZAW563A	9.57	a	9.13	b	0.44	**
	Winter wheat	FR21FPTRZAW563B	12.95	a	12.86	a	0.09	
	Winter wheat	FR21FPTRZAW563C	7.79	a	7.80	a	-0.01	
Quality of grains								
HLW (kg/hL)	Winter wheat	FR21FPTRZAW563A	71.5	a	71.3	a	0.2	**
	Winter wheat	FR21FPTRZAW563B	68.0	a	67.8	a	0.2	
	Winter wheat	FR21FPTRZAW563C	72.7	a	73.0	a	-0.3	
Moist content (%)	Winter wheat	FR21FPTRZAW563A	12.3	a	12.2	b	0.1	**
	Winter wheat	FR21FPTRZAW563B	11.0	a	11.0	a	0.0	
	Winter wheat	FR21FPTRZAW563C	12.9	a	13.3	a	-0.4	
Impurity rate* (%)	Winter wheat	FR21FPTRZAW563A	0.18		0.17		0.01	-
	Winter wheat	FR21FPTRZAW563B	1.10		1.55		-0.45	
	Winter wheat	FR21FPTRZAW563C	0.10		0.11		-0.01	

*Broken grain, shrunken grain, sprouted grain, rooten grain...

** Acceptability according to the analysis of variance (ANOVA) results.

Baking value

Results concerning the baking value of flours are presented in Table 3.4-14.

In the first trial, the baking value of wheat was quite good. Zeleny index was good due to a high protein rate. The W of the Chopin alveograph was high with a good balance at P/L. In the second trial, the baking value of wheat was low. Zeleny index was low due to a low protein rate. The characteristics of the Chopin alveograph are low. In the last trial, the baking value of wheat is low. Zeleny index was good due to a high protein rate.

In conclusion, despite these differences, overall, no difference was noted between the baking value of flours issued of grains treated with ADM.03503.F.1.A at 1.25 L/ha or LIBRAX at 2.0 L/ha.

Table 3.4-14: Detailed results: Effect of ADM.03503.F.1.A (1.25 L/ha) on transformation processes - Breadmaking trials - Baking value

Parameter	Crop	Trial code	ADM.03503.F.1. A 1.25 L/ha		LIBRAX 2.0 L/ha		Difference	Tolerance
Protein content (%)	Winter wheat	FR21FPTRZAW563A	12.90		12.94		0.04%	0.25%
	Winter wheat	FR21FPTRZAW563B	9.96		9.87		0.09%	
	Winter wheat	FR21FPTRZAW563C	12.34		12.66		0.32%	
Hagberg (s)	Winter wheat	FR21FPTRZAW563A	386		403		4.22%	10%
	Winter wheat	FR21FPTRZAW563B	126		139		9.35%	
	Winter wheat	FR21FPTRZAW563C	361		361		0.00%	
Zeleny index (mL)	Winter wheat	FR21FPTRZAW563A	46		46		0.00%	10%
	Winter wheat	FR21FPTRZAW563B	30		30		0.00%	
	Winter wheat	FR21FPTRZAW563C	45		48		6.30%	
Chopin alveograph								
W	Winter wheat	FR21FPTRZAW563A	237		236		0.42%	15%
	Winter wheat	FR21FPTRZAW563B	78		89		12.36%	
	Winter wheat	FR21FPTRZAW563C	140		157		10.80%	
P	Winter wheat	FR21FPTRZAW563A	70		68		2.94%	12%
	Winter wheat	FR21FPTRZAW563B	54		55		1.85%	

Parameter	Crop	Trial code	ADM.03503.F.1. A 1.25 L/ha	LIBRAX 2.0 L/ha	Difference	Tolerance
	Winter wheat	FR21FPTRZAW563C	42	41	2.40%	
G	Winter wheat	FR21FPTRZAW563A	23.2	53.3	1.7	10%
	Winter wheat	FR21FPTRZAW563B	13.4	13.9	3.6	
	Winter wheat	FR21FPTRZAW563C	25.9	28.9	10.4%	
L	Winter wheat	FR21FPTRZAW563A	109.4	111.5	-2.1	-
	Winter wheat	FR21FPTRZAW563B	36.0	39.0	-3.0	
	Winter wheat	FR21FPTRZAW563C	135.0	168.0	-33.0	
P/L	Winter wheat	FR21FPTRZAW563A	0.64	0.61	0.03	-
	Winter wheat	FR21FPTRZAW563B	1.50	1.41	0.09	
	Winter wheat	FR21FPTRZAW563C	0.31	0.24	0.07	
Ic	Winter wheat	FR21FPTRZAW563A	53.3	53.7	-0.4	-
	Winter wheat	FR21FPTRZAW563B	0.0	0.0	0.0	
	Winter wheat	FR21FPTRZAW563C	44.4	45.2	-0.8	

Breadmaking tests

Results concerning the breadmaking process are presented in Table 3.4 15. In the first trial, an excess of elasticity limits development in the oven. The notes on the bread are therefore low. In the second trial, the characteristics of breadmaking doughs are low with very little extensibility. However, in conclusion, despite these differences, overall, no difference was noted between the breadmaking parameters of flours issued of grains treated with ADM.03503.F.1.A at 1.25 L/ha or LIBRAX at 2.0 L/ha.

Table 3.4-15: Detailed results: Effect of ADM.03503.F.1.A (1.25 L/ha) on transformation processes - Breadmaking trials - Breadmaking parameters

Parameter	Crop	Trial code	ADM.03503.F.1. A 1.25 L/ha	LIBRAX 2.0 L/ha	Difference	Tolerance
Hydratation (%)	Winter wheat	FR21FPTRZAW563A	60.5	60.5	0.0	-
	Winter wheat	FR21FPTRZAW563B	59.6	59.5	0.1	
	Winter wheat	FR21FPTRZAW563C	58.7	58.6	0.1	
Volume (cm ³)	Winter wheat	FR21FPTRZAW563A	1298	1370	-72	-
	Winter wheat	FR21FPTRZAW563B	966	929	37	
	Winter wheat	FR21FPTRZAW563C	1480	1632	-152	
Dough (0-100)	Winter wheat	FR21FPTRZAW563A	75	87	12	5
	Winter wheat	FR21FPTRZAW563B	52	52	0	
	Winter wheat	FR21FPTRZAW563C	87	87	0	
Bread (0-100)	Winter wheat	FR21FPTRZAW563A	29	31	2	10
	Winter wheat	FR21FPTRZAW563B	20	20	0	
	Winter wheat	FR21FPTRZAW563C	54	61	7	
Bread crumb (0-100)	Winter wheat	FR21FPTRZAW563A	94	94	0	-
	Winter wheat	FR21FPTRZAW563B	82	82	0	
	Winter wheat	FR21FPTRZAW563C	100	100	0	
Breadmaking Global (0-300)	Winter wheat	FR21FPTRZAW563A	198	212	14	15
	Winter wheat	FR21FPTRZAW563B	154	154	0	
	Winter wheat	FR21FPTRZAW563C	241	248	7	

Sensory analysis

Triangular test with comments was carried out for each wheat processing trial to evaluate the nature of the difference between samples. No statistically significant differences were observed concerning the sensory properties, assessed by a panel using a triangular test. The experimental product ADM.03503.F.1.A does not have a negative effect on gustatory and olfactory qualities of bread.

zRMS summary of the breadmaking trials:

Trial FR21FPTRZAW563A (KCP 6.4-301):

Hagberg falling number 386 vs 403 (ADM.03503.F.1.A vs Librax), Zeleny index 46 vs 46, Alveogram nearly identical (W=237 vs W=236), suggesting relatively high baking strength, but with low P/L ratio (0.64 vs 0.61) pointing at extensible yet weak dough properties. The “Dough” score in breadmaking assessment is lower in test item by 12%, exceeding the 10% tolerance limit. The “Bread” and “Global” scores nevertheless allow for equal quality conclusion (Table in the page 5, EUROFINS GALYS data), perhaps for the relatively high bread volume – 1298 vs 1370 ccm (Table in Appendix 6, page 26). The result of the taint test was insignificant (5 correct

answers in 16 tasters; Table 3 page 32).

Trial FR21FPTRZAW563B (**KCP 6.4-302**) demonstrates **generally low quality of the material** from both test item and standard treatments: Hagberg falling number 126 vs 139 (lower for test item-treated material, with the difference approaching the 10% tolerance limit); Zeleny index equal (=30) but pointing to moderate quality protein complex compared to KCP 6.4-301 trial. Alveograph parameters suggest low baking strength (W=78 vs W=89) while P/L (1.50 vs 1.41) values suggest inextensible dough. The bread volumes are lower by ca 30% compared to the KCP 6.4-301 trial – 966 vs 929 ccm (Table in Appendix 6, page 23). The scores for bread quality are equal for the test and standard product, yet they are both lower compared to the first trial (Table in the page 4, EUROFINS GALYS data). The result of the taint test was insignificant (4 correct answers in 16 tasters; Table 3 page 29).

Trial FR21FPTRZAW563C (**KCP 6.4-303**):

Hagberg falling number 361 vs 361, Zeleny index almost equal (45 vs 48); both indices the level of the first trial, the KCP 6.4-301. Alveograph parameters suggest moderate baking strength, some way between the two other trials but closer to the worse result of the KCP 6.4-302 (W=140 vs W=157) and P/L values (0.31 vs 0.24) point at extensible, weak dough. The bread volumes are the highest compared to both other trials – 1480 vs 1632 ccm (Table in Appendix 6, page 22). The scores for dough and bread quality are equal for the test and the standard product, while they are the highest compared to both other trials (Table in the page 4, EUROFINS GALYS data). The result of the taint test was insignificant (5 correct answers in 16 tasters; Table 3 page 28).

Conclusion:

Low Hagberg and Zeleny indices in the data set presented by the applicant testify to compromised grain quality in only one of the 3 trials submitted (KCP 6.4-302). Consequently, baking properties of the material obtained from that trial are inferior compared to the two remaining trials, but not to the extent that would make baking process non-feasible. By default, the breadmaking tests include no statistics. Instead, tolerance limits are set for the variability between the tested batches. Except for the “Dough” score in the first trial these limits were not exceeded.

On the contrary, the results of the taint test are interpreted using statistics, and none of the 3 taint tests carried out revealed significant differences in taste or flavour of the baked product.

The guidance PP 1/243 (2) *Effects of plant protection products on transformation processes* does not determine the minimum number of trials. Therefore it is the opinion of zRMS that the applicant`s conclusions are justified: the data set submitted demonstrates that the test item ADM.03503.F.1.A has no detrimental effect on breadmaking process overall. It does not affect the sensory perception and gustatory quality of the final product either.

[To the zRMS Abstract](#)

3.4.4.2 Effects on beer making processes

3.4.4.2.1 Material and methods

Experimental details

Six processing trials were carried out by officially recognized organisations in accordance with the Principles of Good Experimental Practice (GEP). These trials were performed in accordance with EPPO guidelines or recommendations published by the CEB (“*Commission des Essais Biologiques*”). The “CEB” methods are in accordance with EPPO directives.

Main characteristics are summarised in following Table 3.4-16 16.

Table 3.4-16 16: Details on trial methodology - Processing trials - Barley - Beer making process

Guidelines	General Guidelines	PP1/135(3): “ <i>Phytotoxicity assessment</i> ”. PP1/181(4): “ <i>Conduct and reporting of efficacy evaluation trials, including good experimental practice</i> ”.
	Specific Guidelines	PP1/243(2): “ <i>Effects of plant protection products on transformation processes</i> ”. CEB No.185: “ <i>Method for studying the unintentional effects of plant protection products on malting and brewing</i> ”.
Experimental design	Plot design	Randomized Complete Block (RCB).
	Plot size	75-157.5 m ² .
	Number of replications	3 replications.
Crop	Number of trials	6 typical field selectivity trials carried out to obtain material, 1 (one) separate report of laboratory tests on the material obtained, for all the quality, malting and brewing parameters.
	Varieties	Winter barley: <i>Etince</i> (3). Spring barley: <i>RGT Planet</i> (3).
Application	Application timing	BBCH-59 BBCH: 59-69-77, 59-61-75, 59-41-59 (marked as A, B and C respectively, trial FR20FPHORVS502C (KCP 6.4-306), 59-69-77, 59-69-83, 59-65-75
	Number of applications	1 application According to “Application description” table in each one of the 6 reports, 3 applications were carried out in each trial.
	Spray volumes	From 150 L/ha to 250 L/ha (150, 220, 200, 200, 225, 250)
Assessment	Assessment dates	Analysis of barley, analysis of malt, Brewing and fermentation analysis, sensory analysis.
	Assessment types	Harvest and post-harvest.
Results and analysis	Statistical analysis	-

Treatments and reference standards

ADM.03503.F.1.A was tested at 1.25 L/ha (N dose) and compared with reference standard PROLINE at 0.8 L/ha described in Table 3.4-3. Each product is applied in accordance with good agricultural practices and label recommendations.

Assessment methods

The assessment of unintended effects of plant protection products on quality of malt and beer was performed in three steps:

zRMS comments / warning:

Any attempt to correct the following numbered list ↓↓↓ triggers MS Word crash and has been therefore abandoned by zRMS.

4. Verifying the malting quality of barley,
5. Monitoring the processing and evaluation of malt quality,
6. Evaluation of brewing process, physico-chemical quality and sensory properties of beer.

3.4.4.2.2 Summary and evaluation of individual results on the beer making process

Analysis of barley

The barley specimens are considered conforms to the following brewing criteria if:

The barley specimen is considered suitable for brewing if:

- Protein content: between 9 and 12%
- Germination after 3 days superior to 95%
- Kernel size of barley (>2.5 mm) superior to 60%
- Barley infested by mould <2%
- Moist content up to 15%

In winter barley, in one trial, the protein content was abnormal (<9%). Therefore, the specimens from this trial were destroyed and not used for malting process.

In spring barley, in two trials, the protein content was abnormal (<9% or >12%). As given the particularity of the 2020 harvest for barleys in France (the protein levels are low or high due to climatic and agronomic conditions), an amendment was emitted* to transform the specimens from one trial in spite of a protein content <9%. The specimens from the other trial were destroyed and not used for malting process.

zRMS comments: “emitted” – should probably be meant that the testing unit assumed the use of these samples, in the transformation study, as acceptable. For details see the zRMS [summary](#) of this chapter.

On parameters such as moist and protein contents, the Kernel size of barley and germination rate, they were all considered normal as their values were within indicated normal ranges. There were no significant differences observed between the test and the reference standard. No negative effects on the malting quality on barley were observed.

Table 3.4-17: Detailed results: Assessments of ADM.03503.F.1.A (1.25 L/ha) in processing trials - Results of barley analysis

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Moist content (%)	Winter barley	FR20FPHORVW501A	12.6	12.6	0.0	1
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	10.9	11.0	0.0	
		FR20FPHORVS502B				
Protein content (%)	Winter barley	FR20FPHORVW501A	10.1	10.2	-0.1	1
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	10.3	10.2	0.1	
		FR20FPHORVS502B				
Kernel size (>2.5 mm) (%)	Winter barley	FR20FPHORVW501A	89.4	86.6	2.8	15
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	90.0	90.2	-0.2	
		FR20FPHORVS502B				
Germination index	Winter barley	FR20FPHORVW501A	9.6	9.7	-0.1	1
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	9.8	9.7	0.1	
		FR20FPHORVS502B				
Ergosterol (mg/kg)	Winter barley	FR20FPHORVW501A	4.3	3.8	0.5	2.0
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	4.5	4.3	0.2	

7 Fusarium species, *Microdochium nivale*, *Microdochium majus* and *Fusarium* sp. were quantified by PCR. No unacceptable level was measured for samples treated with ADM.03503.F.1.A and PROLINE which means that they were practically Fusarium-free (within normal range).

According to these results (protein, moisture content, percentage of graded grains, germination and Fusarium level as stated in CEB 185) and the agreement of the study director, 4 out of 6 trials were valid for malting process.

Analysis of malt

ADM.03503.F.1.A and PROLINE were compared in terms of technological and physico-chemical malt quality. Overall, on every tested parameter (moisture content, malt extracts, α -amylase, soluble nitrogen, viscosity, β -glucans, disaggregation and homogeneity rates (Calcofluor test), friability and filtration Tepral tests, reference malts PROLINE were comparable to those from grains treated with ADM.03503.F.1.A applied at 1.25 L/ha. Therefore, no significant differences in terms of technological and physico-chemical malt quality were observed between spring barley treated with ADM.03503.F.1.A applied at 1.25 L/ha and PROLINE at 0.8 L/ha.

Table 3.4-18: Detailed results: Assessments of ADM.03503.F.1.A (1.25 L/ha) in processing trials - Physico-chemical analysis of malt

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Moist content (%)	Winter barley	FR20FPHORVW501A	4.8	4.3	0.5	1
		FR20FPHORVW501C	4.2	4.6	-0.4	
	Spring barley	FR20FPHORVS502A	4.7	4.7	0.0	
		FR20FPHORVS502B	5.0	5.0	0.0	
Fine grind extract (% dry matter)	Winter barley	FR20FPHORVW501A	79.4	79.3	0.1	1.0
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	84.4	84.6	-0.2	0.5
		FR20FPHORVS502B				
Soluble proteins (% dry matter)	Winter barley	FR20FPHORVW501A	3.6	3.6	0.0	0.2
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	4.8	4.9	-0.1	
		FR20FPHORVS502B				
α -amylase (D.U. 20°C)	Winter barley	FR20FPHORVW501A	50.0	49.0	1.0	7.0
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	68.0	71.0	-3.0	
		FR20FPHORVS502B				
Viscosity (mPa.s)	Winter barley	FR20FPHORVW501A	1.7	1.7	0.0	0.10
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	1.5	1.5	0.0	0.05
		FR20FPHORVS502B				
β -glucans (mg/L)	Winter barley	FR20FPHORVW501A	286.0	322.0	-36.0	50
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	64.0	63.0	1.0	30
		FR20FPHORVS502B				
Friability (% flour)	Winter barley	FR20FPHORVW501A	80.0	78.0	2.0	10
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	88.0	89.0	-1.0	
		FR20FPHORVS502B				
Calcofluor % Modification	Winter barley	FR20FPHORVW501A	94.0	91.0	3.0	10
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	97.0	98.0	-1.0	
		FR20FPHORVS502B				
Calcofluor % Homogeneity	Winter barley	FR20FPHORVW501A	80.0	79.0	1.0	10
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	92.0	92.0	0.0	
		FR20FPHORVS502B				

Table 3.4-19: Detailed results: Assessments of ADM.03503.F.1.A (1.25 L/ha) in processing trials - Functional tests of malt

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Filtration rate (g/min)	Winter barley	FR20FPHORVW501A	26.0	22.0	4.0	15
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	38.0	39.0	-1.0	10
		FR20FPHORVS502B				
Washing rate (g/min)	Winter barley	FR20FPHORVW501A	31.0	29.0	2.0	15
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	50.0	53.0	-3.0	10
		FR20FPHORVS502B				
Quantity of filtered wort (g)	Winter barley	FR20FPHORVW501A	386.0	382.0	4.0	10
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	400.0	404.0	-4.0	
		FR20FPHORVS502B				

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Attenuation limit (%)	Winter barley	FR20FPHORVS502B	79.4	79.1	0.3	1.5
		FR20FPHORVW501A				
	FR20FPHORVW501C					
	Spring barley	FR20FPHORVS502A	81.4	81.3	0.1	
FR20FPHORVS502B						
Apparent gravity, day 8 (°plato)	Winter barley	FR20FPHORVW501A	4.9	5.0	-0.1	1.0
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	5.5	5.4	0.1	
		FR20FPHORVS502B				

Brewing and fermentation

Firstly, wort analysis was performed. In both trials, the difference between ADM.03503.F.1.A and PROLINE was laid within the normal range.

Overall, saccharification and filtration durations of both modalities were considerably identical. Beer was filtered using a plate filter and analysed.

Overall, there was no difference between ADM.03503.F.1.A and PROLINE on several brewing and fermentation parameters. These results indicate that the transformation process and the physico-chemical quality of beer of barley treated with ADM.03503.F.1.A is not affected compared to treatments with PROLINE.

Table 3.4-20: Detailed results: Assessments of ADM.03503.F.1.A (1.25 L/ha) in processing trials - Mashing monitoring

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Saccharificatio n rate at 74°C (min)	Winter barley	FR20FPHORVW501A	15	15	0.0	-
		FR20FPHORVW501C	15	15	0.0	
	Spring barley	FR20FPHORVS502A	15	15	0.0	
		FR20FPHORVS502B	15	15	0.0	
Mash filtration (min)	Winter barley	FR20FPHORVW501A	77	82	-5.0	-
		FR20FPHORVW501C	83	81	2.0	
	Spring barley	FR20FPHORVS502A	83	92	-9.0	
		FR20FPHORVS502B	85	80	5.0	
Brewing yield (%)	Winter barley	FR20FPHORVW501A	72.3	71.0	1.3	-
		FR20FPHORVW501C	67.5	67.6	-0.1	
	Spring barley	FR20FPHORVS502A	79.1	80.1	-1.0	
		FR20FPHORVS502B	70.2	72.8	-2.6	

Table 3.4-21: Detailed results: Assessments of ADM.03503.F.1.A (1.25 L/ha) in processing trials - Filtration and wort analysis

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Specific gravity (°Plato)	Winter barley	FR20FPHORVW501A	12.6	12.3	12.6	-
		FR20FPHORVW501C	12.6	12.5	12.6	
	Spring barley	FR20FPHORVS502A	12.4	12.4	12.4	
		FR20FPHORVS502B	12.4	12.5	12.4	
pH	Winter barley	FR20FPHORVW501A	5.87	5.98	5.87	-
		FR20FPHORVW501C	5.86	5.87	5.86	
	Spring barley	FR20FPHORVS502A	5.70	5.82	5.70	
		FR20FPHORVS502B	5.81	5.83	5.81	
Colour (°EBC)	Winter barley	FR20FPHORVW501A	7.7	9.7	7.7	-
		FR20FPHORVW501C	6.9	7.1	6.9	
	Spring barley	FR20FPHORVS502A	9.4	8.6	9.4	
		FR20FPHORVS502B	9.5	10.5	9.5	
Duration of wort filtration (min)	Winter barley	FR20FPHORVW501A	80.0	82.0	-2.0	10
		FR20FPHORVW501C	80.0	82.0	-2.0	
	Spring barley	FR20FPHORVS502A	84.0	86.0	-2.0	
		FR20FPHORVS502B	84.0	86.0	-2.0	
Free amino agent (mg/L)	Winter barley	FR20FPHORVW501A	171.0	168.0	3.0	20
		FR20FPHORVW501C	171.0	168.0	3.0	
	Spring barley	FR20FPHORVS502A	224.0	233.0	-9.0	
		FR20FPHORVS502B	224.0	233.0	-9.0	
Attenuation limit (%)	Winter barley	FR20FPHORVW501A	82.0	81.9	0.1	1.5
		FR20FPHORVW501C	82.0	81.9	0.1	
	Spring barley	FR20FPHORVS502A	86.1	86.2	-0.1	

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
		FR20FPHORVS502B				

Table 3.4-22: Detailed results: Assessments of ADM.03503.F.1.A (1.25 L/ha) in processing trials - Fermentation monitoring

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Time to ferment 5°Plato (hour)	Winter barley	FR20FPHORVW501A	72.0	74.0	-4.0	12
		FR20FPHORVW501C	70.0	76.0		
	Spring barley	FR20FPHORVS502A	76.0	76.0	1.5	
		FR20FPHORVS502B	72.0	69.0		
Time to reach 95% fermentation extract (hours)	Winter barley	FR20FPHORVW501A	133.0	134.0	-1.0	12
		FR20FPHORVW501C	141.0	142.0		
	Spring barley	FR20FPHORVS502A	137.0	137.0	-0.5	
		FR20FPHORVS502B	141.0	142.0		
Percentage attenuation at 7 th day (%)	Winter barley	FR20FPHORVW501A	97.8	97.8	0.0	2
		FR20FPHORVW501C	97.8	97.8		
	Spring barley	FR20FPHORVS502A	97.9	99.0	-1.1	
		FR20FPHORVS502B	97.8	98.9		
Harvested yeast viability (10 ⁸ cells/g)	Winter barley	FR20FPHORVW501A	16.0	16.0	-1.0	5
		FR20FPHORVW501C	18.0	20.0		
	Spring barley	FR20FPHORVS502A	15.0	18.0	-2.0	
		FR20FPHORVS502B	20.0	21.0		
Apparent gravity at the end of maturation (°Plato)	Winter barley	FR20FPHORVW501A	2.5	2.5	-0.1	1
		FR20FPHORVW501C	2.3	2.5		
	Spring barley	FR20FPHORVS502A	2.1	2.2	0.1	
		FR20FPHORVS502B	2.2	2.0		
Apparent attenuation at the end of maturation (%)	Winter barley	FR20FPHORVW501A	78.8	78.6	1.0	1.5
		FR20FPHORVW501C	80.0	78.3		
	Spring barley	FR20FPHORVS502A	81.7	81.4	-0.6	
		FR20FPHORVS502B	80.9	82.5		

Table 3.4-23: Detailed results: Assessments of ADM.03503.F.1.A (1.25 L/ha) in processing trials - Beer analysis

Parameter	Crop	Trial code	ADM.03503.F.1.A 1.25 L/ha	PROLINE 0.8 L/ha	Difference	Tolerance
Alcohol (% V/V)	Winter barley	FR20FPHORVW501A	4.9	4.9	0.1	0.2
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	5.0	5.2	-0.2	
		FR20FPHORVS502B				
Apparent extract (°Plato)	Winter barley	FR20FPHORVW501A	2.3	2.4	-0.1	0.25
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	2.1	2.0	0.1	
		FR20FPHORVS502B				
Colour (EBC)	Winter barley	FR20FPHORVW501A	4.1	4.0	0.1	2.0
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	5.8	6.0	-0.2	
		FR20FPHORVS502B				
Head retention (sec)	Winter barley	FR20FPHORVW501A	259.0	245.0	14.0	15
		FR20FPHORVW501C				
	Spring barley	FR20FPHORVS502A	269.0	263.0	6.0	
		FR20FPHORVS502B				

Sensory analysis

Triangular test with comments was carried out to evaluate the nature of the difference between samples. No statistically significant differences were observed concerning the sensory properties, assessed by a panel using a triangular test. Therefore, it is concluded that treatment with ADM.03503.F.1.A applied at 1.25 L/ha did not affect the organoleptic beer quality.

zRMS comments on the effect on beer making process:

Material

The following trials: FR20FPHORVS502A (KCP 6.4-304), FR20FPHORVS502B (KCP 6.4-305), FR20FPHORVS502C (KCP 6.4-306), FR20FPHORVW501A (KCP 6.4-307), FR20FPHORVW501B (KCP 6.4-308) and FR20FPHORVW501C (KCP 6.4-309) are field selectivity trials (with phytotoxicity, yield, specific weight and moisture content recorded), the material from which was taken to IFBM* for analyses of malting and brewing properties, demonstrated in another trial report: **R-A-F-1144** (KCP 6.4-310).

Grain samples from trials KCP 6.4-306 (spring barley) and KCP 6.4-308 (winter barley) have been considered as unsuitable for transformation study, for their “abnormal” protein content (>12% and <9%, respectively, in all treatments and replicates). Notwithstanding the protein content <9% found in spring barley samples from another trial: KCP 6.4-304, the testing unit admitted use of these samples in the transformation study. Hence overall, the transformation study related to beer-making is based on samples from 4 trials, including samples from one trial with sub-critical protein content.

Material analysis

According to the tolerance limits assumed by CEB 185, the grain and malt properties, malt functional quality, wort properties alone and the parameters of brewing and fermentation were uniform, across the material treated with the test item and with the standard reference product.

Product analysis

According to the R-A-F-1144 report, the sensory analysis was launched for the product samples brewed from the material of each of the 4 trials independently.

In the course of the evaluation zRMS requested the applicant to deliver the full text of the EBC 13.7 method, for it is EBC 13.7 that has been referred to, in the laboratory test report R-A-F-1144 (KCP 6.4-310).

Since the ECB 13.7 has been neither submitted, nor any place where it can be found as coherent text was indicated by the applicant, the zRMS concluded on the validity of the sensory analysis based on the ISO 4120 norm.

When judged by criteria laid out in the ISO 4120: 2021 [E], Annex A, Table A.1, the results presented in R-A-F-1144 report demonstrate no perceptible gustatory differences between the samples brewed from the test item-treated or the reference-treated barley.

To the zRMS abstract

3.4.4.3 Conclusion on the transformation processes

The potential unintentional effects of ADM.03503.F.1.A at 1.25 L/ha in spring and winter barley on beer and malt quality and malting and brewing processes ~~has~~ have been assessed in 6 4 processing trials and ADM.03503.F.1.A applied at 1.25 L/ha did not lead to negative significant changes to barley, fermentation, taste and smell criteria, in comparison with the PROLINE at 0.8 L/ha.

The potential unintentional effects of ADM.03503.F.1.A at 1.25 L/ha in winter wheat on flour and bread quality and breadmaking process ~~has~~ have been assessed in 3 processing trials and ADM.03503.F.1.A applied at 1.25 L/ha did not lead to any significant modifications in comparison with the LIBRAX at 2.0 L/ha.

Therefore, no adverse influence on the transformation processes is expected if ADM.03503.F.1.A is used in accordance with good agricultural practices, including label instructions.

zRMS comments:

The applicant`s conclusions are considered valid and have been accepted.

3.4.5 Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

Any potential impact of ADM.03503.F.1.A on seeds would principally be related to the active substances. Fluxapyroxad and prothioconazole are used in Europe for many years and no effect on treated plants or plant products to be used for propagation is known in Europe. Moreover, no problem with respect to propagation has been encountered during the experimental testing of ADM.03503.F.1.A which has been used to treat plants with no negative impact. Based on this, further investigation of the effects of treatments with ADM.03503.F.1.A was considered unnecessary.

However, a summary of the range of varieties tested and the extent of crop damage observed is provided in Section 3.4.1 to support the use of ADM.03503.F.1.A on plants used for propagation purposes. Finally, it is concluded that no negative impact on plant propagation will occur to these crops. **Therefore, no effect on parts of plant used for propagating purposes is expected if ADM.03503.F.1.A is applied in accordance with the Good Agricultural Practices and label recommendations.**

zRMS comments:

Considered the fact that ADM.03503.F.1.A is a mixture of two actives and the absence of germination data other than those produced for barley within the brewing study, in the course of the evaluation the zRMS had requested the applicant to cover the section 3.4.5 more extensively. However, the update submitted does not include any new information pertaining to this part.

3.5 Observations on other undesirable or unintended side - effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, barley, rye and triticale) in any of the 300 efficacy trials where ADM.03503.F.1.A was applied as a straight product up to 1.25 L/ha. For more details on phytotoxicity results, please refer to Section 3.4.1. In addition, any potential impact of ADM.03503.F.1.A on succeeding crops would principally be related to the active substances. Fluxapyroxad and prothioconazole are used in Europe for many years and no effect on succeeding crops is known in Europe.

Moreover, further information on the fate and behaviour of the active substances in the soil can be found in the relevant section in Part B Section 9 (“Ecotoxicology”) of the Registration Report. A summary of this data is provided below. No significant adverse effects were observed from ADM.03503.F.1.A on any of the crops tested in the Seedling emergence and Vegetative vigour studies. Therefore it can be concluded there are no risks to Succeeding crops from ADM.03503.F.1.A applied according to the GAP. **Therefore, no impact is expected on succeeding crops if ADM.03503.F.1.A is used according to the Good Agricultural Practices and label recommendations.**

zRMS comments:

In the course of the evaluation the zRMS had requested the applicant to cover the section 3.5.1 more extensively. The update submitted includes the reference to Part B Section 9 as can be seen above, and an excerpt from that section, that is pasted below, in the 3.5.2.

3.5.2 Impact on other plants including adjacent crops (KCP 6.5.2)

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable on cereals (wheat, barley, rye and triticale) in any of the 300 efficacy trials where ADM.03503.F.1.A was applied as a straight product up to 1.25 L/ha. For more details on phytotoxicity results, please refer to Section 3.4.1. In addition, any potential impact of ADM.03503.F.1.A on adjacent crops would principally be related to the active substances. Fluxapyroxad and prothioconazole are used in Europe for many years and no effect on adjacent crops is known in Europe.

Moreover, further information on the non - target plant studies can be found in Part B Section 9 (“Ecotoxicological studies”) of the Registration Report. No significant adverse effects were observed from ADM.03503.F.1.A on any of the crops tested in the Seeding emergence and Vegetative vigour studies. Therefore it can be concluded there are no risks to Adjacent crops from ADM.03503.F.1.A applied according to the GAP.

Therefore, no impact is expected on adjacent crops if ADM.03503.F.1.A is used according to the Good Agricultural Practices and label recommendations.

Effects on non-target terrestrial plants

The available information from the vegetative vigour and seedling emergence studies conducted on a range of representative crops as submitted in dRR section B9 (Ecotoxicology), is provided below:

Toxicity data

Studies on the toxicity to non-target terrestrial plants was carried out with representative products of the active substances fluxapyroxad and prothioconazole during EU review. In addition, data are available for the technical active substance prothioconazole. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of ADM.03503.F.1.A were not evaluated as part of the EU assessments of the active substances fluxapyroxad and prothioconazole. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2 of dRR section B9 Ecotoxicology.

The selection of studies and endpoints for the risk assessment deviates from the results of the EU review process. Justifications are provided below.

Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
ADM.03503.F.1.A				
<i>Allium cepa</i> (m) <i>Triticum aestivum</i> (m) <i>Lactuca sativa</i> (d) <i>Helianthus annuus</i> (d) <i>Solanum lycopersicum</i> (d) <i>Glycine max</i> (d)	ADM.03503.F.1.A	21 d Seedling emergence	ER₅₀ > 1.193 L product/ha (No phytotoxic symptoms or effects on seedling emergence, plant survival, height and shoot dry weight)	KCP 10.6.2/01 Friedemann, 2021a
<i>Allium cepa</i> (m) <i>Triticum aestivum</i> (m) <i>Lactuca sativa</i> (d) <i>Helianthus annuus</i> (d) <i>Solanum lycopersicum</i> (d) <i>Glycine max</i> (d)	ADM.03503.F.1.A	21 d Vegetative vigour	ER₅₀ > 1.193 L product/ha (No effects on plant survival, height and shoot dry weight; phytotoxic effects in sunflower, tomato and soybean ≤ 10%)	KCP 10.6.2/02 Friedemann, 2021b
Representative product for fluxapyroxad				
<i>Allium cepa</i> (m) <i>Avena sativa</i> (m) <i>Lolium multiflorum</i> (m) <i>Zea mays</i> (m) <i>Daucus carota</i> (d) <i>Helianthus annuus</i> (d) <i>Brassica napus</i> (d) <i>Beta vulgaris</i> (d) <i>Pisum sativum</i> (d) <i>Vicia faba</i> (d)	BAS 700 00 F (62.5 g fluxapyroxad/L EC) ^{a)}	21 d Seedling emergence	ER ₅₀ > 2.0 L product/ha	EFSA Journal 2012; 10(1): 2522

Species	Substance	Exposure System	Results	Reference
<i>Allium cepa</i> (m) <i>Avena sativa</i> (m) <i>Lolium multiflorum</i> (m) <i>Zea mays</i> (m) <i>Daucus carota</i> (d) <i>Helianthus annuus</i> (d) <i>Brassica napus</i> (d) <i>Beta vulgaris</i> (d) <i>Pisum sativum</i> (d) <i>Vicia faba</i> (d)	BAS 700 00 F (62.5 g fluxapyroxad/L EC) ^{a)}	21 d Vegetative vigour	ER ₅₀ > 2.0 L product/ha	EFSA Journal 2012; 10(1): 2522
Prothioconazole and representative formulated product				
5 mono- and 6 dicotyledoneous species	Prothioconazole	Pre- and postemergence application	Pre-emergence: max. 5% phytotoxicity at 200 g a.s./ha Post-emergence: max. 10% phytotoxicity at 250 g a.s./ha (i.e. ER ₅₀ > 200 g a.s./ha)	EFSA Scientific Report (2007) 106, 1-98
5 mono- and 6 dicotyledoneous species	Prothioconazole 250 g/L EC ^{a)}	Pre- and postemergence application	Pre-emergence: max. 5% phytotoxicity at 200 g a.s./ha Post-emergence: max. 0% phytotoxicity at 250 g a.s./ha (i.e. ER ₅₀ > 200 g a.s./ha)	EFSA Scientific Report (2007) 106, 1-98

m: monocotyledonous; d: dicotyledonous; Endpoints in **bold** are relevant for risk assessments.

Grey shading: Data for representative products during EU review of the active substances. Data not considered for the assessments for ADM.03503.F.1.A.

^{a)} Nominal content.

Justification for new endpoints

The intended use of ADM.03503.F.1.A is as a fungicide in cereals. There is no indication of herbicidal activity of either of the active substances. Accordingly, no Tier 2 testing is required. However, the Applicant provides rate-response data for seedling emergence and growth as well as vegetative vigour for six plant species each.

Risk assessments are most adequately based on the data for the actual formulated product ADM.03503.F.1.A which also cover potential effects from combined exposure towards the active substances fluxapyroxad and prothioconazole. Data for technical active substance (referred to in the EU review for prothioconazole) or representative products for both active substances, all indicating low toxicity towards terrestrial non-target plants, are not further considered for risk assessment.

Risk assessment

Tier-1 risk assessment (based on screening data)

No screening data are required. Reference is made to available Tier 2 rate-response (seedling emergence and growth as well as vegetative vigour) data on six plant species.

Tier-2 risk assessment (based on dose response data)

The risk assessment is based on the “Guidance Document on Terrestrial Ecotoxicology”, (SANCO/10329/2002 rev.2 final, 2002)¹⁴. It is restricted to off-field situations, as non-target plants are non-crop plants located outside the treated area.

To achieve a concise risk assessment, the risk envelope approach is applied, i.e. for a maximum single use rate of 1.25 L product/ha corresponding to 93.75 g fluxapyroxad/ha and 187.5 prothioconazole/ha, respectively for a maximum BBCH range of 30 to 69.

The off-field risk is assessed based on predicted exposure for field crops at the default distance of 1 m relating to 90th percentile drift values (2.77% at 1 m) as provided by BBA (2000¹⁵).

Assessment of the risk for non-target plants due to the use of ADM.03503.F.1.A in cereals

Intended use Product Application rate [L/ha]		Cereals (BBCH 30-69) ^{a)} ADM.03503.F.1.A 1 × 1.25		
Test species	ER ₅₀ [L/ha]	90 th percentile drift value [%]	PER _{off-field} [L/ha]	TER criterion: TER ≥ 5
Seedling emergence and growth				
6 species	> 1.193	2.77 (1 m)	0.035	> 34.1
Vegetative vigour				
6 species	> 1.193	2.77 (1 m)	0.035	> 34.1

MAF: Multiple application factor; PER: Predicted environmental rate; TER: Toxicity to Exposure Ratio. TER values shown in **bold** fall below the relevant trigger.

The TERs indicate an acceptable off-field risk for terrestrial non-target plants from exposure to ADM.03503.F.1.A for the intended worst-case use, without the necessity to consider risk mitigations. The less than 50% effect levels observed at the application rate of 1.193 L product/ha in the studies which is close to the maximum in-field rate of 1.25 L product/ha also demonstrate an acceptable risk for terrestrial non-target plants.

¹⁴ European Commission Health & Consumer Protection Directorate-General. Directorate E – Food Safety: plant health, animal health and welfare, international questions (2002): DRAFT Working Document. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC. SANCO/10329/2002 rev final. 17 October 2002.

¹⁵ 90th percentile drift according to BBA (2000): Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000). Bekanntmachung über die Abdrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

Higher tier risk assessment

No higher tier considerations are required for terrestrial non-target plants. An acceptable risk is indicated based on Tier 2 data.

Risk mitigation measures

No risk mitigation is needed. An acceptable risk is indicated based on Tier 2 data without the necessity to account for risk mitigations.

Overall conclusions

An acceptable risk is indicated for exposure of terrestrial non-target plants towards the formulated product for the intended worst-case use of ADM.03503.F.1.A without the necessity to account for risk mitigations.

No significant adverse effects were observed from ADM.03503.F.1.A on any of the crops tested in the Seedling emergence and Vegetative vigour studies. Therefore it can be concluded there are no risks to Succeeding or Adjacent crops from ADM.03503.F.1.A applied according to the GAP.

zRMS comments:

The zRMS appreciates the applicant's update. The conclusions for the adjacent crops have been accepted, based on the dose-response data presented and the assumed drift pattern. Since succeeding crops represent lower exposure scenario compared to adjacent crops, the conclusions are valid for them either.

3.5.3 Effects on beneficial and other non - target organisms (KCP 6.5.3)

No side-effect on beneficial and other non - target organisms were observed in the 300 efficacy trials carried out in ~~on~~ cereals (wheat, barley, rye and triticale) where ADM.03503.F.1.A was applied as a straight product up to 1.25 L/ha. Moreover, information on beneficial organisms' studies can be found in Part B Section 9 ("Ecotoxicological studies") of the Registration Report.

Therefore, no effect is expected on beneficial or other non - target organisms if ADM.03503.F.1.A is used according to the Good Agricultural Practices and label recommendations.

From these results it can be concluded that the proposed use pattern of ADM.03503.F.1.A will not pose any significant risk to beneficial organisms.

3.6 Other/special studies

3.6.1 Tank Cleaning

Procedures for cleaning application equipment

The following standard procedures for cleaning the application equipment according to Good Agricultural Practice are recommended following the use of ADM.03503.F.1.A.

All equipment and contaminated clothing should be thoroughly washed/cleaned with water-diluted detergent solution and rinsed with clean water three times. After each step of washing the drain sprayer, spray out completely. Ensure all liquid is removed from the sprayer tank, pump and hoses. Remove nozzles, open tank and drain pump to allow free access of air to all parts of the system.

Care should be taken not to rinse the contaminated washings from application equipment into wastewater channels. Contaminated cleaning liquids should be disposed of safely according to local regulations. Operators should read the sprayer manufacturer’s instructions before beginning to wash out sprayers.

Effectiveness of the cleaning procedure

Fungicides usually do not exhibit herbicidal activity. Phytotoxicity was considered as acceptable in cereals (wheat, barley, rye and triticale oat) in any of the 300 efficacy trials where ADM.03503.F.1.A was applied as a straight product up to 1.25 L/ha. Therefore, no specific study was necessary for the product ADM.03503.F.1.A to investigate the effectiveness of the cleaning procedure detailed above. Nevertheless, the efficacy of cleaning application equipment with regard to impact on crops can be estimated on the basis of the CRD Efficacy Guideline 302.

The maximum permitted rate of use for ADM.03503.F.1.A is 1.25 L/ha for spraying in a water volume of 100-400 L/ha. 100 L/ha will give the highest concentration of product, so we have regarded this as the worst-case scenario for ADM.03503.F.1.A in the initial spray operation. Therefore, at worst case, the following prerequisites were considered:

- Maximum rate per application: 1.25 L/ha corresponding to 93.75 g/ha fluxapyroxad and 187.5 g/ha prothioconazole.
- Spray volume: 100-400 L/ha
- Spray volume used for assessment of effectiveness: 100 L/ha.
- Tank volume: 2000 L.
- Volume remaining in spray lines and pump: 20 L.

Based on these prerequisites and in consideration of 3 rinses each with 200-400 L of water based on good agricultural cleaning procedures detailed above, residues remaining in the tank after spraying will be diluted to the following levels:

Cleaning step	Water volumes (L)	Residues	
		Fluxapyroxad	Prothioconazole
Tank filling (1.25 L/ha ADM.03503.F.1.A)	2000	0.94 g/L	1.88 g/L
Residue after spraying	20	0.94 g/L (total 19 g)	1.88 g/L (total 38 g)
1 st step 1/10 dilution	200	0.094 g/L	0.188 g/L
Residue	20	0.094 g/L (total 1.9 g)	0.188 g/L (total 3.8 g)
2 nd step 20% of tank volume added	400	0.0047 g/L	0.0094 g/L
Residue	20	0.0047 g/L (total 0.094 g)	0.0094 g/L (total 0.188 g)
3 rd step 20% tank volume added	400	0.000235 g/L	0.00047 g/L
Residue	20	0.000235 g/L (total 0.0047 g)	0.00047 g/L (total 0.0094 g)
Addition of fresh spray solution	2000	2.4 x10 ⁻⁶ g/L	4.7 x10 ⁻⁶ g/L

Based on the calculation above, residue remaining in the spraying equipment after the last of three cleaning steps was estimated to be a total of 4.7 mg of fluxapyroxad and 9.4 mg of prothioconazole in the 20L remaining. This results in a residual concentration of 2.4 µg/L fluxapyroxad and 4.7 µg/L prothioconazole after refilling the tank for the next spraying operation. Assuming a spray volume of 400L/ha (worst case) to be applied to crops **0.96 mg /ha of fluxapyroxad and 1.88 mg of prothioconazole would be applied to the crop by re-use of the application equipment.**

zRMS comments:

Neither the CRD (PSD) Efficacy Guideline 302 “*Cleaning Application Equipment – Efficacy Aspects*” (September 2005) nor the EPP0 guidance PP 1/292 (1) “*Cleaning pesticide application equipment (PAE) – efficacy aspects*”(September 2016) do require the cleaning procedure testing for products which do not show phytotoxicity symptoms or other effects in the target or subsequently treated crops. The test item has demonstrated safety for the treated target crop plants in the efficacy trials, and its safety for the subsequently treated plant species is inferred from the fact of it`s being a fungicide.

The applicant`s calculation presented in the non-numbered table above has been verified, although it is unclear why had the applicant assumed rinsing with 20% instead of typical 10% tank capacity, in the steps 2 and 3. Even using 10% capacity in rinsing steps 2 and 3, along with the “worst case” scenario of the 400L/ha at the re-use application, would apply 3.75 and 7.50 mg/ha fluxapyroxad and prothioconazole, respectively. The amount is 25000-fold lower compared to 93.75 g/ha and 187.50 g/ha of the actives used per 1 ha on typical application, thus presenting still decent safety margin. Therefore it has been concluded that a standard sprayer cleaning procedure is sufficient to provide safety to the subsequently treated crops, and no further data is required.

3.7 List of test facilities including the corresponding certificates

The majority of corresponding certificates, confirming that all the test facilities mentioned have been officially recognized as organizations for efficacy testing of plant protection products according to the Directive 93/71/EC, are available in the GEP certibase (www.gepcertibase.eu). Corresponding certificates are available in each trial report.

Table 3.7-1: List of test facilities

Testing facilities	Address	Year	Link GEP Certibase
University of Aarhus - Pesticide Efficacy Testing Flakkebjerg	Forsogsvej DK-4200 Slagelse Denmark	2021	1d6ca7e6ce1
Acceres Field Research Germany GmbH	Loofter Strasse 9 25593 Christenthal Germany	2021	1d6ca7e6dd2
Adas UK Ltd	Spring Lodge, 172 Chester Road WA6 0AR Helsby United Kingdom	2019-2021	1d691e7bb1f
Agrartest GmbH	Palmbachstraße 37 D-65328 Aarbergen Germany	2020-2021	1d5db8867fd
Agreco Sp. z o.o.	Al. Lipowa 21 Iok. 1 53-124 Wroclaw Poland	2020	1d691e7bb5
Agricola	Tannenstr. 2 94339 Leiblfing Germany	2019-2021	1d691e7bb77
Zemledsky vyzkumny ustav Kromeriz, s.r.o.	Havlíčková 2787/121 767 01 Kromeriz Czech Republic	2019	1d617202511
Agro Research Consulting	Nadbzurzańska 32, 99-400 Łowicz, Poland	2021	1d6ca7e6bdc
Agro-Check Dr. Teresiak & Erdmann GbR	Dorfstraße 15 D-16833 Lentzke Germany	2020-2021	1d6529c6bc4
Agrolab Sverige AB	Backgården SE-241 93 Eslov Sweden	2021	1d61b33d9ea
AgroProspect S.R.L.	Fantana Village, no.1, Brasov county 507099 Hoghiz Romania	2020	1d68dc1b722

Testing facilities	Address	Year	Link GEP Certibase
Agrotest	ZI de la Pomme - 17, avenue Marie Curie 31250 Revel France	2019-2021	1d6196274bc
Anadiag France	14 Rue de la Bourbre 38301 Ruy France	2020	1d653de6156
Antedis	48 Rue de la Madeleine 60000 Beauvais France	2019-2020	1d68dc1b6eb
Armstrong Fisher Ltd	Hill Crest, Main street PE9 3BH Ufford Stamford - Lincolnshire United Kingdom	2020	1d6ca7e6d5e
Berberis s.r.o.	Boliarov 54 044 47 Boliarov Slovakia	2020-2021	1d691e7ba53
BioChem Agrar GmbH	Bunnert 72 D-47589 Uedem Germany	2019-2021	1d5daeb3dac
Biotek Agriculture	Route de Viélaines 10120 Saint Pouange France	2019	1d6925d398f
Blumeria Consulting s.r.o.	L'Okanika 590/4 949 01 Nitra Slovakia	2019-2021	1d691e7b959
CPR Europe Kft.	Torok ignac u.30 9700 Szombathely Hungary	2020-2021	1d691e7bb6c
Walloon Agricultural Research Center	Rue du Bordia 11 5030 Gembloux Belgium	2021	1d6ca7e67df
Ditana spol. s.r.o.	ČSA 780 783 53 Velka Bystrice Czech Republic	2020-2021	1d691e7b922
SARL Ephydia	8 Bis Gr Grande Rue 62450 Martinpuich France	2020-2021	1d5dae82eee
Essais Plus	1 rue du 8 mai 62128 Boyelles France	2019-2021	1d5daecc31a
Eurofins Ireland	Unit 2 Southcourt Wexford Road, Business Park, Carlow, R93 HR65 Ireland	2020-2021	1d6ca7e6d9c
Eurofins ELST BREDELAAR	Reethsestraat 17b, 6662 PK Elst The Netherlands	2020	No link
Eurofins Agrosience Services Srl (Romania)	Strada Academician Petre P. Negulescu, nr. 1 30263 Timisoara Romania	2019-2021	1d5dae82faa
Eurofins Agrosience Services Ltd (UK)	Slade Lane, Wilson, Melbourne DE73 8AG Derby United Kingdom	2020-2021	1d61bd8a4fc
Fertico Sp. Z O.O.	Grójecka 26 05-620 Błędów Poland	2020	1d5daecc0fb
Field Research Support (DE)	Leinechausee 75 D-31515 Wunstorf Germany	2021	1d5db886882
FYSE s.r.o. Odd. AgroLab Kolare	Skolska 90 993 09 Kolare Slovakia	2019-2020	1d5dae8301d
Hetterich Fieldwork GbR	Bamberger Straße 50 D-97359 Schwarzach am Main Germany	2019-2021	1d61bd8a568
HUSEC AB	Borgeby Slottsväg 11 23791 Bjärred	2021	1d5db88685b

Testing facilities	Address	Year	Link GEP Certibase
	Sweden		
InTec Agro Trials s.r.o.	Blatnická 179 687 24 Uherský Ostroh Czech Republic	2020	1d6925d3848
Latvian Plant Protection Research Centre Riga - VSIA Latvijas Augu aizsardzības pētniecības centrs	Strukturu iela 14 a LV-1039 Riga Latvia	2020-2021	1d5dae9b746
Institute of Agriculture, Lithuanian Research Centre for Agriculture and Forestry	Akademija, Kedainiai district Lithuania	2020	1d6168da7ae
Martin Feldversuchswesen	Im Grund 20 D-78359 Orsingen-Nenzingen Germany	2019-2021	1d5dd416339
NPPC, VURV, VSS	Viglas-Pstrusa 962 12 Detva Slovakia	2020-2021	1d691e7bac4
Oxford Agricultural Trials Ltd	West Farm Barn, Launton Rd, Stratton Audley OX27 9AS Bicester United Kingdom	2019-2021	1d656391a6b
Gemerprodukt Valice ovocinársko-vinohradnícke družstvo	Okresná 3771 979 01 Rimavská Sobota Slovakia	2020-2021	1d5dd41626d
Plantus-GbR	Husumer Str.6 26197 Huntlosen Germany	2021	No Link
Poznan University of Life Sciences	ul. Mazowiecka 45/46 60623 Poznan Poland	2020-2021	1d691e7b488
Promo-Vert	Rue d'Aste Béon BP 27 64121 Serres Castet France	2020	1d5db8868cc
Qualiphyt SAS	80 chemin de Riboulin 26270 Loriol - sur - Drôme France	2020-2021	1d691e7bb76
Quintus GmbH	Hallaliter Weg 29 D-17195 Vollrathsrühe Germany	2021	1d61962750d
SGS Hungaria Kft	Syraly u. 4 H-1124 Budapest Hungary	2020	1d6c948abe0
Staphyt Austria GmbH.	Am Futterpl. 2471 Rohrau Austria	2020	1d6ca7e6d71
Staphyt (France)	23 Route de Moeuvres 62860 Inchy en Artois France	2019-2021	1d61bd8a477
Staphyt GmbH	Langenburger Str. 35 74572 Blauffelden Germany	2021	1d6ca7e6deb
Staphyt Sp. z o.o.	Ziębicka 2, 60-164 Poznan Poland	2020-2021	1d691e7bb80
Trial-Tec	Kampenredder 5 24363 Haby Germany	2019-2021	1d6529c6ba8
U. A. S. Umwelt - und Agrarstudien GmbH	Ilmstrass 6, 07743 Jena Germany	2019-2021	1d691e7baff
Ustredný kontrolný a skusobný ústav poľnohospodársky v Bratislave - Bratislava	Matuskova 21 833 16 Bratislava Slovakia	2020	1d61cff224e
Zkusební stanice Nechanice s.r.o.	Husovo nám. 34 503 15 Nechanice Czech Republic	2020-2021	1d6172024c9

Testing facilities	Address	Year	Link GEP Certibase
Zemedelska zkusebni stanice Kujavy, s.r.o.	Kujavy 48 CZ-742 44 Kujavy Czech Republic	2020	1d5dbf7cc35

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.0-1	Adama	2022	DRAFT REGISTRATION REPORT - Part B - Section 3 - Efficacy Data and Information - Detailed summary - Product code: ADM.03503.F.1.A- CORE ASSESSMENT (authorization) ADAMA Makhteshim Ltd Not GEP Unpublished	N	Y	New study	ADM
KCP 6.1-001	Voisin, J.F.	2019	An evaluation of different ratios of fluxapyroxad +prothioconazole for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in France, 2019 Agrotest, France, Report No. E-1939 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX112A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-002	Voisin, J.F.	2019	An evaluation of different ratios of fluxapyroxad +prothioconazole for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in France, 2019 Agrotest, France, Report No. E-1940 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX112B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-003	Pierucci, S.	2019	Evaluation of different ratios of fluxapyroxad + prothioconazole for the control of rust (PUCCSP) on Winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03110-AC ADAMA Makhteshim Ltd, Report No. FR19FETRZAX113A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-004	Hetterich, A.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW911A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-005	Martin, T.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control rusts (PUCCSP) on winter wheat in (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW912A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-006	Kay, C.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1037A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW350A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-007	Makó, I.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control rusts (PUCCSP) on winter wheat in Hungary, 2019 SynTech Research, Hungary, Report No. SRHU19-026-135FE ADAMA Makhteshim Ltd, Report No. HU19FETRZAW299A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-008	Tvaruzek, L.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of <i>Pyrenophora teres</i> (PYRNTE) on barley in the Czech Republic, 2019 Agricultural Research , Czech Republic ADAMA Makhteshim Ltd, Report No. CZ19FEHORVW353A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-009	Rivet, J.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of <i>Rhynchosporium</i> (RHYNSE) on barley, in France 2019 Essais +, France, Report No. 19 38 F 02 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX109B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-010	Kay, C.	2019	An evaluation of different ratios of fluxapyroxad + prothioconazole for the control of <i>Rhynchosporium</i> (RHYNSE) on barley in the UK, 2019 OAT, United Kingdom, Report No. 19-1038A-ADA ADAMA Makhteshim Ltd, Report No. UK19FEHORVX352A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-011	Hrabovsky, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. 20H25 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-012	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-013	Gouille, L.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Puccinia striiformis</i> (PUCCST) on winter wheat in France, 2019 Biotek Agriculture, France, Report No. BPE19/286/FGC01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAW110A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-014	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019. Staphyt, France, Report No. FVT-19-40058-FR01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-015	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019 Staphyt, France, Report No. FVT-19-40058-FR02 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-016	Boeuf, V..	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03107-AR ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-017	Deberny, E.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03108-CA ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-018	Ternois, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Ephydia, France, Report No. FRM-20-F13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-019	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Staphyt, France, Report No. JFT-20-45675-FR01 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-020	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in France in 2021 Ephydia, France, Report No. FRM-21-F20 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-021	Flahaut, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in France in 2021 Staphyt, France, Report No. JFT-21-50445-FR01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551C GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-022	Labusch, U.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 BioChem Agrar, Germany, Report No. 19 1069 5062 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-023	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-071 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-024	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PUCCRT) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW906A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-025	Wolf, P.	2019	Efficacy of ADM.3503.F.1.A in comparison to the equivalent tank mix vs. Yellow Rust (PUCCSI) in Winter Wheat Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW907A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-026	Perner, J.	2019	Efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora (Drechslera) tritici-repentis</i> (PYRNTR) on winter wheat in Germany, 2019 U.A.S., Germany, Report No. 170_19_Z ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-027	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora (Drechslera) tritici-repentis</i> (PYRNTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-072 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-028	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-222 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW500A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-029	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Ireland, 2020 Eurofins, Ireland, Report No. S20-02701-01 ADAMA Makhteshim Ltd, Report No. IE20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-030	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-02 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-031	Van Tilburg, F.W.G.	2020	Control of <i>Zymoseptoria tritici</i> in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02814-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW010A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-032	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-033	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034B-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-034	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1022-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-035	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1074-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-036	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44718-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-037	Rusek, K.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland 2020 Fertico, Poland, Report No. 57_01_F20_77 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-038	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 71_01_F21_178 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-039	Tuna, V.	2019	Determination of Efficacy of ADM.3503.f.1.A compared to the equivalent tank mix, applied post-emergence against <i>Zymoseptoria tritici</i> (SEPTTR) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03922-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW169A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-040	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Yellow rust (Puccst) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03923-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW170A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-041	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-042	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-043	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-044	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-045	Hudec, K.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (Puccrt) on winter wheat in Slovakia, 2019 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK19FETRZAW345A GEP Unpublished	N	Y	New study	ADM

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KCP 6.1-046	Ondisová, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Slovakia, 2020 UKSUP, Slovakia, Report No. KE-F-04-2020 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-047	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Slovakia, 2020 Blumeria Consulting, Slovakia, Report No. ADA-301B-O ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-048	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-049	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against net blotch on winter barley CRA-W, Belgium, Report No. MAL-HORVW-21-E-19 ADAMA Makhteshim Ltd, Report No. BE21FEHORVW035A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-050	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in the Czech Republic, 2020 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS315A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-051	Negrini, P	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of RAMUCC and PYRNTE on Barley in France in 2019 Antedis, France, Report No. ADA-FE19OH-03109-CA ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-052	Flahaut, J.	2019	An efficacy comparison of ADM.03503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) and <i>Rhynchosporium secalis</i> (RHYNSE) on barley in France, 2019 Staphyt, France, Report No. JFT-19-40084-FR01 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX108A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-053	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2018 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW512C GEP Unpublished	N	Y	New study	ADM
KCP 6.1-054	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Leaf Blotch) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F19 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX514A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-055	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20100F25 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW514C GEP Unpublished	N	Y	New study	ADM
KCP 6.1-056	Rouane, W.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in France, 2020 Anadiag, France, Report No. FR203031PS303 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW517B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-057	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F18 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX512A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-058	Negrini, P	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC on Barley in France in 2020 Antedis, France, Report No. ADA-FE20OH-05273-PR ADAMA Makhteshim Ltd, Report No. FR20FEHORVX517A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-059	Wallart, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in France in 2021 Ephydia, France, Report No. FRM-21-F19 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW558B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-060	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107D07 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-061	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107F15 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-062	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-063	Thomas Martin	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-064	Peter Wolf	2019	Efficacy of ADM.3503.F.1.A compared to the equivalent active ingredients in tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) in Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW910B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-065	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03247 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW228A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-066	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WG-147 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW229A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-067	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWG 20 ADA 231A ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-068	Peter Wolf	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-069	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. FWG 21 ADA 507A ADAMA Makhteshim Ltd, Report No. DE21FEHORVX507A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-070	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in Germany in 2021 U.A.S., Germany, Report No. 148_21_Z ADAMA Makhteshim Ltd, Report No. DE21FEHORVX508A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-071	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia</i>) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-017 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX510A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-072	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-073	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-074	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-02 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-075	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03303-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX325A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-076	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley in the UK, 2019 ADAS, Ireland, Report No. WA19-WB-Adama 9T (348) ADAMA Makhteshim Ltd, Report No. UK19FEHORVX348A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-077	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1028A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX314A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-078	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1030-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX317A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-079	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1079B-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-080	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 Eurofins, Derby, United Kingdom, Report No. S21-03034-01 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308C GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-081	Sawinska, Z.	2020	The evaluation of efficacy ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter barley cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/JO/19/Pr/067A ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-082	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0677-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-083	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Fertico, Poland, Report No. 61_01_F20_81 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-084	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44722-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-085	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Rhynchosporium secalis</i> (RHYNSE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 75_01_F21_182 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-086	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/ZI/030B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-087	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Pyrenophora teres</i> (PYRNTE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 76_01_F21_183 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-088	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against <i>Pyrenophora teres</i> (PYRNTE) in barley, outdoor 2019 Eurofins, Romania, Report No. S19-03924-01 ADAMA Makhteshim Ltd, Report No. RO19FEHORVW171A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-088	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-090	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-091	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-092	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211A GEP Unpublished	N	Y	New study	ADM

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KCP 6.1-093	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-094	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02899-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW212A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-095	Holcikova, D.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley Slovakia, 2019 FYSE,Slovakia, Report No. FYSE-103201915 ADAMA Makhteshim Ltd, Report No. SK19FEHORVW348A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-096	Kovacova Holcikova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202015 ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-097	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-098	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315A GEP Unpublished	N	Y	New study	ADM

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KCP 6.1-099	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW307A - ZV04 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW307A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-100	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW308A- ZV03 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW308A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-101	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on rye in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WR-148 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-102	Magyaróvári, V.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on rye in Germany, 2020 Agrartest, Germany, Report No. S20-03246-01 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232B GEP Unpublished	N	Y	New study	ADM
KCP 6.1-103	Wied, H.M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (<i>Puccinia recondita</i>) on rye in Germany in 2021 Staphyt, Germany, Report No. HWD-21-50086-DE01 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-104	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in Germany in 2021 Field Research Support, Germany, Report No. FRS105/21 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.1-105	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter rye , Poland, 2020 Poznań University, Germany, Report No. AF/20/ŻO/19/BR/070A ADAMA Makhteshim Ltd, Report No. PL20FESECSS070A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-106	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter rye cultivation, Poland, 2021 Poznań University, Germany, Report No. AF/21/ŻO/9/Br/033A ADAMA Makhteshim Ltd, Report No. PL21FESECSS033A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-107	Macsim, C.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02902-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS214A GEP Unpublished	N	Y	New study	ADM
KCP 6.1-108	Macsim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-04520 - 01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS250A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-001	Herzmaier, C.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of <i>Puccinia triticina</i> (brown rust) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45585-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW221A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-002	Kempernek, H.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (DTR) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45586-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW224A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-003	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against brown rust on winter wheat CRA-W, Belgium, Report No. MAL2021-04 ADAMA Makhteshim Ltd, Report No. BE21FETRZAW034A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-004 Submitted under KCP 6.1-011	Hrabovsky, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. 20H25 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-005	Bezdičková, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-006	Bauer, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in the Czech Republic, 2020 InTec Agro Trials, Czech Republic, Report No. F-20-G-574-01 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW308A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-007	Bezdičková, A.	2020	An efficacy evaluation of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-008 Submitted under KCP 6.1-012	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW300A GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-009	Bezdičková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-010 Submitted under KCP 6.1-013	Gouille, L.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Puccinia striiformis</i> (PUCST) on winter wheat in France, 2019 Biotek Agriculture, France, Report No. BPE19/286/FGC01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAW110A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-011 Submitted under KCP 6.1-014	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019. Staphyt, France, Report No. FVT-19-40058-FR01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-012 Submitted under KCP 6.1-015	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019 Staphyt, France, Report No. FVT-19-40058-FR02 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-013 Submitted under KCP 6.1-016	Boeuf, V..	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03107-AR ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-014 Submitted under KCP 6.1-017	Deberny, E..	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (PUCCRE) on winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03108-CA ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109B GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-015 Submitted under KCP 6.1-018	Ternois, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Ephydia, France, Report No. FRM-20-F13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-016 Submitted under KCP 6.1-019	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Staphyt, France, Report No. JFT-20-45675-FR01 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-017	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20098A21 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-018	Crepin, D.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A against brown rust on winter wheat, in France in 2020 Essais +, France, Report No. 20 38 F 13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-019	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F14 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-020	Maitte, B.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in FRANCE, 2020 Promo Vert, France, Report No. 20F FCEADA FR15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504C GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-021	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-022	Jondot, A.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT on Winter Wheat in France in 2020 Antedis, France, Report No. ADA-FE20BT-05271-SV ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-023	Ballan, J.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT, SEPTTR and PUCCSI on Winter Wheat in France in 2020 Antedis, France, Report No. ADA-FE20BT-05272-JA ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-024	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F16 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-025	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20099H07 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-026 Submitted under KCP 6.1-020	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in France in 2021 Ephydia, France, Report No. FRM-21-F20 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551A GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-027 Submitted under KCP 6.1-021	Flahaut, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in France in 2021 Staphyt, France, Report No. JFT-21-50445-FR01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-028	Crepin, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in FRANCE in 2021 Essais +, France, Report No. 21 38 F 27 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-029	Voisin, J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in FRANCE in 2021 Agrotest, France, Report No. E-2154 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-030	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (<i>Puccinia striiformis tritici</i>) on winter wheat in France in 2021. Biotek Agriculture, France, Report No. BPE21/205/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW553B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-031	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) and SEPTTR (Septoria) on winter wheat in France in 2021 Ephydia, France, Report No. FRM-21-F21 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW554A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-032	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> (FUSACU in artificial contamination) in winter wheat at T3 in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21106E23 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW556B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-033 Submitted under KCP 6.1-022	Labusch, U.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 BioChem Agrar, Germany, Report No. 19 1069 5062 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-034 Submitted under KCP 6.1-023	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-071 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-035 Submitted under KCP 6.1-024	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PUCCRT) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW906A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-036 Submitted under KCP 6.1-025	Wolf, P.	2019	Efficacy of ADM.3503.F.1.A in comparison to the equivalent tank mix vs. Yellow Rust (PUCCSI) in Winter Wheat Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW907A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-037 Submitted under KCP 6.1-026	Perner, J.	2019	Efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora (Drechslera) tritici-repentis</i> (PYRNTR) on winter wheat in Germany, 2019 U.A.S., Germany, Report No. 170_19_Z ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-038 Submitted under KCP 6.1-027	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora (Drechslera) tritici-repentis</i> (PYRNTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-072 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-039	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 221A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-040	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-141 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-041	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in Germany, 2020 Agrartest, Germany, Report No. S20-03244-01 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-042	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5128 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-043	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 223A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-044	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-142 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-045	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-143 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-046	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-144 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-047	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 224C ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-048	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5129 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-049	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-145 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-050 Submitted under KCP 6.1-028	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-222 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW500A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-051	Hapke, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Acceres, Germany, Report No. F21NMW35 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-052	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-053	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-235 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW502A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-054	Wolf, P.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in Germany in 2021 Agricola, Germany, ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-055	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Germany in 2021 U.A.S., Germany, Report No. 147_21_Z ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-056	Rohr, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-223 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-057	Maleck, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 Agro-check, Germany, Report No. AC/21/050 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-058	Zickart, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 BioChem Agrar, Germany, Report No. 21 1064 1192 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-059	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-HE-WW-224 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-060	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-061 Submitted under KCP 6.1-029	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Ireland, 2020 Eurofins, Ireland, Report No. S20-02701-01 ADAMA Makhteshim Ltd, Report No. IE20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-062 Submitted under KCP 6.1-030	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-02 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-063 Submitted under KCP 6.1-031	Van Tilburg, F.W.G.	2020	Control of <i>Zymoseptoria tritici</i> in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02814-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW010A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-064	Van Tilburg, F.W.G.	2020	Control of <i>Puccinia recondita</i> in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02815-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW011A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-065 Submitted under KCP 6.1-032	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-066 Submitted under KCP 6.1-033	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034B-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-067 Submitted under KCP 6.1-034	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1022-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-068	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1023-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW302A GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-069	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-070	Armstrong, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in the UK, 2020 Armstrong Fisher, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-071	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1025-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW306A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-072	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in the UK, 2020 ADAS, United Kingdom, Report No. GT20/031 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-073	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in the UK, 2020 Eurofins, Derby, United Kingdom, Report No. S20-02732-01 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-074 Submitted under KCP 6.1-035	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1074-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW300A GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-075	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 1075-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-076	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1076-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW302A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-077	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in the UK in 2021 ADAS, United Kingdom, Report No. GT21-035 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-078	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in the UK in 2021 ADAS, United Kingdom, Report No. GT21-036 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-079 Submitted under KCP 6.1-036	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44718-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-080 Submitted under KCP 6.1-037	Rusek, K.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland 2020 Fertico, Poland, Report No. 57_01_F20_77 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-081	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter wheat, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/BR/061A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-082	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in Poland 2020 Fertico, Poland, Report No. 58_01_F20_78 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-083	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44719-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-084	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0692-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-085	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/063A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-086	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Poland, 2020 Fertico, Poland, Report No. 59_01_F20_79 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063B GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-087	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A , ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0693-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-088	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44720-PL01 PHA ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-089	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/065A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-090	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Poland, 2020 Agreco, Poland, Report No. 20ADA0694-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-091 Submitted under KCP 6.1-038	Rusek, K	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 71_01_F21_178 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-092	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/024A ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-093	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50274-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-094	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_09 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-095	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Puccinia striiformis tritici</i> (PUCCSI) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 72_01_F21_179 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-096	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50275-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW026A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-097	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Pyrenophora tritici repentis</i> (PYRNTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 73_01_F21_180 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW027A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-098	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50278-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-099	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/028B ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-100	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-116-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-101	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-117-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-102	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-112-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW512A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-103	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-115-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-104	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 04 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514C GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-105	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-090-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-106	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust of wheat) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-091-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW302A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-107	Makó, I.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-093-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-108	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-096-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-109 Submitted under KCP 6.1-039	Tuna, V.	2019	Determination of Efficacy of ADM.3503.f.1.A compared to the equivalent tank mix, applied post-emergence against <i>Zymoseptoria tritici</i> (SEPTTR) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03922-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW169A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-110 Submitted under KCP 6.1-040	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Yellow rust (PUC CST) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03923-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW170A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-111 Submitted under KCP 6.1-041	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-112 Submitted under KCP 6.1-042	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-113	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-114	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-115	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-116	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-117	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-118	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-119	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-120	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-121	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-122	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-123 Submitted under KCP 6.1-043	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-124 Submitted under KCP 6.1-044	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-125	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-126	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-127	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCST (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-128	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-03 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW219A GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-129	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02896-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW219A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-130 Submitted under KCP 6.1-045	Hudec, K.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (Puccrt) on winter wheat in Slovakia, 2019 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK19FETRZAW345A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-131 Submitted under KCP 6.1-046	Ondisová, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Slovakia, 2020 UKSUP, Slovakia, Report No. KE-F-04-2020 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-132 Submitted under KCP 6.1-047	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Slovakia, 2020 Blumeria Consulting, Slovakia, Report No. ADA-301B-O ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-133	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccrt (brown rust) on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE-103202016 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-134	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccrt (brown rust) on winter wheat in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-135	Kovacova Holcikova, D	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202017 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-136	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-137	Malovcová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Slovakia, 2020 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW306A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-138	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE-103202018 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-139 Submitted under KCP 6.1-048	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-140	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW301A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-141	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW302A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-142	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-143	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-144 Submitted under KCP 6.1-049	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against net blotch on winter barley CRA-W, Belgium, Report No. MAL-HORVW-21-E-19 ADAMA Makhteshim Ltd, Report No. BE21FEHORVW035A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-145	Roslupil, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. R20/04 ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS311A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-146 Submitted under KCP 6.1-050	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in the Czech Republic, 2020 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS315A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-147	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS306A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-148	Bezdičková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS307A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-149 Submitted under KCP 6.1-051	Negrini, P	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of RAMUCC and PYRNTE on Barley in France in 2019 Antedis, France, Report No. ADA-FE19OH-03109-CA ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-150 Submitted under KCP 6.1-052	Flahaut, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) and <i>Rhynchosporium secalis</i> (RHYNSE) on barley in France, 2019 Staphyt, France, Report No. JFT-19-40084-FR01 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX108A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-151	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F17 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX510A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-152	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (leaf blotch) and PYRNTE (net blotch) on barley in FRANCE, 2020 Staphyt, France, Report No. JFT-20-45676-FR01 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW510B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-153 Submitted under KCP 6.1-053	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2018 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW512C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-154 Submitted under KCP 6.1-054	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Leaf Blotch) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F19 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX514A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-155 Submitted under KCP 6.1-055	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20100F25 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW514C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-156	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2020 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW516D GEP Unpublished	N	Y	New study	ADM
KCP 6.2-157 Submitted under KCP 6.1-056	Rouane, W.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in France, 2020 Anadiag, France, Report No. FR203031PS303 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW517B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-158 Submitted under KCP 6.1-057	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F18 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX512A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-159 Submitted under KCP 6.1-058	Negrini, P	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC on Barley in France in 2020 Antedis, France, Report No. ADA-FE200H-05273-PR ADAMA Makhteshim Ltd, Report No. FR20FEHORVX517A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-160	Rouane, W.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Anadiag, France, Report No. FR213045DP303 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-161	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Ephydia, France, Report No. FRM-21-F23 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-162 Submitted under KCP 6.1-059	Wallart, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in France in 2021 Ephydia, France, Report No. FRM-21-F19 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW558B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-163 Submitted under KCP 6.1-060	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107D07 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-164 Submitted under KCP 6.1-061	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107F15 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559B GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-165	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (<i>Blumeria graminis hordei</i>) on winter barley in France in 2021. Biotek Agriculture, France, Report No. BPE21/206/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-166	Voisin J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in France in 2021 Agrotest, France, Report No. E-2156 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-167 Submitted under KCP 6.1-062	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-168 Submitted under KCP 6.1-063	Thomas Martin	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-169 Submitted under KCP 6.1-064	Peter Wolf	2019	Efficacy of ADM.3503.F.1.A compared to the equivalent active ingredients in tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) in Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW910B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-170	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SN-WG-146 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-171	Holger Teresiak	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Agro-check, Germany, Report No. AC/20/090 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-172 Submitted under KCP 6.1-065	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03247 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW228A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-173 Submitted under KCP 6.1-066	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WG-147 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW229A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-174	Lamers, K	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5130 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-175	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03245 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-176 Submitted under KCP 6.1-067	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWG 20 ADA 231A ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-177 Submitted under KCP 6.1-068	Wolf, P.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-178	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. HWG 21 ADA 506A ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-179	Wönckhaus, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in Germany in 2021 Agrartest, Germany, Report No. S21-02913-01 ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-180 Submitted under KCP 6.1-069	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. FWG 21 ADA 507A ADAMA Makhteshim Ltd, Report No. DE21FEHORVX507A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-181 Submitted under KCP 6.1-070	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in Germany in 2021 U.A.S., Germany, Report No. 148_21_Z ADAMA Makhteshim Ltd, Report No. DE21FEHORVX508A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-182	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-236 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509A GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-183	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-016 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-184 Submitted under KCP 6.1-071	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia</i>) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-017 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX510A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-185 Submitted under KCP 6.1-072	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-186 Submitted under KCP 6.1-073	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-187 Submitted under KCP 6.1-074	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-02 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-188 Submitted under KCP 6.1-075	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03303-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX325A GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-189 Submitted under KCP 6.1-076	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley in the UK, 2019 ADAS, Ireland, Report No. WA19-WB-Adama 9T (348) ADAMA Makhteshim Ltd, Report No. UK19FEHORVX348A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-190	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1026A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-191	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 20-1026B-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-192 Submitted under KCP 6.1-077	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1028A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX314A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-193	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1029-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-194	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 ADAS, United Kingdom, Report No. GT20/024 ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316B GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-195 Submitted under KCP 6.1-078	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1030-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX317A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-196	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the UK in 2021 OAT, United Kingdom, Report No. 1077-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX306A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-197 Submitted under KCP 6.1-079	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1079B-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-198 Submitted under KCP 6.1-080	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 Eurofins, Derby, United Kingdom, Report No. S21-03034-01 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-199	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1080-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-200	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 ADAS, United Kingdom, Report No. HM21-063 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309B GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-201	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Fertico, Poland, Report No. 60_01_F20_80 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-202	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44721-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-203 Submitted under KCP 6.1-081	Sawinska, Z.	2020	The evaluation of efficacy ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter barley cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/JO/19/Pr/067A ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-204 Submitted under KCP 6.1-082	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0677-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-205 Submitted under KCP 6.1-083	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Fertico, Poland, Report No. 61_01_F20_81 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-206 Submitted under KCP 6.1-084	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44722-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-207	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Fertico, Poland, Report No. 62_01_F20_82 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-208	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0678-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-209	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Puccinia hordei</i> (PUCCHD) on winter barley in Poland, 2021 Fertico, Poland, Report No. 74_01_F21_181 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-210	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/Br/029B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-211 Submitted under KCP 6.1-085	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Rhynchosporium secalis</i> (RHYNSE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 75_01_F21_182 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-212 Submitted under KCP 6.1-086	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/ZI/030B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030B GEP Unpublished	N	Y	New study	ADM

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KCP 6.2-213 Submitted under KCP 6.1-087	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Pyrenophora teres</i> (PYRNTE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 76_01_F21_183 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-214	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Blumeria graminis hordei</i> (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_01_F21_184 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-215	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Blumeria graminis hordei</i> (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_02_F21_185 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-216	Benczés, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-124-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520C GEP Unpublished	N	Y	New study	ADM
KCP 6.2-217	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (<i>Pyrenophora teres</i>) on barley in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-098-002FE ADAMA Makhteshim Ltd, Report No. HU21FEHORVW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-218 Submitted under KCP 6.1-088	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against <i>Pyrenophora teres</i> (PYRNTE) in barley, outdoor 2019 Eurofins, Romania, Report No. S19-03924-01 ADAMA Makhteshim Ltd, Report No. RO19FEHORVW171A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-219	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-220	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-221 Submitted under KCP 6.1-089	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-222 Submitted under KCP 6.1-090	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-223 Submitted under KCP 6.1-091	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-224	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-225	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-226 Submitted under KCP 6.1-092	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-227 Submitted under KCP 6.1-093	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-228 Submitted under KCP 6.1-094	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02899-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW212A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-229	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503. F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-230	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-231 Submitted under KCP 6.1-095	Holcikova, D.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley Slovakia, 2019 FYSE,Slovakia, Report No. FYSE-103201915 ADAMA Makhteshim Ltd, Report No. SK19FEHORVW348A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-232	Malovcova, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Slovakia, 2020 NPPC - VURV Piestany,Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVVS316A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-233	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW311A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-234 Submitted under KCP 6.1-096	Kovacova Holcikova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202015 ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-235 Submitted under KCP 6.1-097	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-236 Submitted under KCP 6.1-098	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-237	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVS309A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-238	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-239	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-240 Submitted under KCP 6.1-099	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW307A - ZV04 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW307A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-241 Submitted under KCP 6.1-100	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW308A- ZV03 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW308A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-242 Submitted under KCP 6.1-101	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on rye in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WR-148 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-243 Submitted under KCP 6.1-102	Magyaróvári, V.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on rye in Germany, 2020 Agrartest, Germany, Report No. S20-03246-01 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-244 Submitted under KCP 6.1-103	Wied, H.M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (<i>Puccinia recondita</i>) on rye in Germany in 2021 Staphyt, Germany, Report No. HWD-21-50086-DE01 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-245 Submitted under KCP 6.1-104	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in Germany in 2021 Field Research Support, Germany, Report No. FRS105/21 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-246 Submitted under KCP 6.1-105	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter rye , Poland, 2020 Poznań University, Germany, Report No. AF/20/ŻO/19/BR/070A ADAMA Makhteshim Ltd, Report No. PL20FESECSS070A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-247 Submitted under KCP 6.1-106	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter rye cultivation, Poland, 2021 Poznań University, Germany, Report No. AF/21/ŻO/9/Br/033A ADAMA Makhteshim Ltd, Report No. PL21FESECSS033A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-248 Submitted under KCP 6.1-107	Macsim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02902-01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS214A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-249 Submitted under KCP 6.1-108	Macsim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-04520 - 01 ADAMA Makhteshim Ltd, Report No. RO21FESECSS250A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-250	Ramanauskiene, J.	2020	Efficacy of ADM.03503.F.1.A for <i>Rhynchosporium secalis</i> control in winter rye in Lithuania in 2020 LRCAF, Lithuania ADAMA Makhteshim Ltd, Report No. LT20FESECSS517A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-251	Brauna-Mozevska, E.	2021	Efficacy of ADM.03503.F.1.A for <i>Rhynchosporium secalis</i> control in winter rye in Latvia in 2021 LAAPC, Latvia, Report No. F-21-02-OT-3817 ADAMA Makhteshim Ltd, Report No. LV21FESECSS460A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-252	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale the Czech republic, 2020 ZS Nechanice, Czech Republic, Report No. CZOR-ATA20-TTLSS-036NEC ADAMA Makhteshim Ltd, Report No. CZ20FETTLWI324A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-253	Teresiak, H.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRE (brown rust) on triticale in Germany, 2020 Agro-check, Czech Republic, Report No. AC/20/091 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS233A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-254	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-TR-149 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS234A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-255	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium secalis</i>) on triticale in Germany in 2021 Field Research Support, Germany, Report No. FRS106/21 ADAMA Makhteshim Ltd, Report No. DE21FETTLSS512A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-256	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRE (brown rust) on triticale in Poland, 2020 Fertico, Poland, Report No. 63_01_F20_83 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS071A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-257	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Poland, 2020 Fertico, Poland, Report No. 64_01_F20_84 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-258	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Poland, 2020 Staphyt, Poland, Report No. APK-20-44723-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-259	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (Brown rust) on triticale in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50285-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETTLSS034A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-260	Ritecz, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRE (brown rust) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-126-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLWI540A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-261	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-127-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1541A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-262	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-128-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLW1541B GEP Unpublished	N	Y	New study	ADM
KCP 6.2-263	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (Brown rust) on triticale in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-100-002FE ADAMA Makhteshim Ltd, Report No. HU21FETTLW312A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-264	Macsim, C.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (Brown rust) on triticale in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02903-01 ADAMA Makhteshim Ltd, Report No. RO21FETTLSS220A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-265	Jørgensen, L.N.	2021	Efficacy evaluation of ADM.03503.F.1.A for brownrust (PUCCTR) control in triticale in Denmark in 2021 Aarhus University, Denmark, Report No. 32723421 ADAMA Makhteshim Ltd, Report No. DK21FETTLSS206A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-266	Treikale, O.	2020	Efficacy evaluation of fungicide ADM.03503.F.1.A for <i>Pyrenophora tritici-repens</i> control in winter triticale in Latvia in 2020 LAAPC, Latvia, Report No. F-20-03-OT-3604 ADAMA Makhteshim Ltd, Report No. LV20FETTLSS506A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.2-267	Brauna-Mozevska, E.	2021	Efficacy of ADM.03503.F.1.A for <i>Pyrenophora tritici-repens</i> control in winter triticale in Latvia in 2021 LAAPC, Latvia, Report No. F-21-03-OT-3818 ADAMA Makhteshim Ltd, Report No. LV21FETTLSS462A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-268	Broms, C.	2021	Efficacy of ADM.03503.F.1.A against ERYSGR in triticale in Sweden 2020 Husec, Sweden, Report No. HUM065 ADAMA Makhteshim Ltd, Report No. SE20FETTLSS252A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-269	Vilka, L.	2021	Efficacy of ADM.03503.F.1.A for <i>Pyrenophora tritici-repentis</i> control in winter triticale in Sweden in 2020 Agrolab, Sweden, Report No. 2674 ADAMA Makhteshim Ltd, Report No. SE20FETTLSS253A GEP Unpublished	N	Y	New study	ADM
KCP 6.2-270	Brauna-Morzevska, E	2021	Efficacy of ADM.03503.F.1.A for <i>Blumeria graminis</i> (ERYSGR) control in winter triticale in Latvia in 2021 Latvian Plant Protection Research Centre, LV21FETTLSS461A ADAMA Makhteshim Ltd, Report No. LV21FETTLSS461A GEP Unpublished	N	Y	New study	ADM
KCP 6.3-001	Felsenstein F.G. Jaser B.	2016	Sensitivity of <i>Septoria tritici</i> in different regions of Europe towards prochloraz, tebuconazole, difenoconazole, propiconazole and prothioconazole, 2016 EpiLogic, Germany GEP Unpublished	N	Y	New study	ADM
KCP 6.3-002	Felsenstein F.G. Jaser B.	2017	Sensitivity of <i>Septoria tritici</i> in different regions of Europe towards prochloraz, tebuconazole, difenoconazole, and prothioconazole, 2017 EpiLogic, Germany GEP Unpublished	N	Y	New study	ADM
KCP 6.3-003	Felsenstein F.G. Jaser B.	2018	Sensitivity of <i>Septoria tritici</i> in different regions of Europe towards prochloraz, tebuconazole, difenoconazole and prothioconazole, 2018 EpiLogic, Germany GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.3-004	Felsenstein F.G. Jaser B.	2020	Sensitivity of (<i>Zymo</i>) <i>Septoria tritici</i> in different regions of Europe towards difenoconazole and prothioconazole 2020 EpiLogic, Germany GEP Unpublished	N	Y	New study	ADM
KCP 6.4-001 Submitted under KCP 6.2-001	Herzmaier, C.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of <i>Puccinia triticina</i> (brown rust) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45585-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW221A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-002 Submitted under KCP 6.2-002	Kempernek, H.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of <i>Pyrenophora tritici-repentis</i> (DTR) on winter wheat, GEP Trial, AUSTRIA, 2020 Staphyt, Austria, Report No. HWD-20-45586-AT01 ADAMA Makhteshim Ltd, Report No. AT20FETRZAW224A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-003 Submitted under KCP 6.2-003	Bataille, C..	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against brown rust on winter wheat CRA-W, Belgium, Report No. MAL2021-04 ADAMA Makhteshim Ltd, Report No. BE21FETRZAW034A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-004 Submitted under KCP 6.1-011	Hrabovsky, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. 20H25 ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-005 Submitted under KCP 6.2-005	Bezdičková, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-006	Bauer, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in the Czech Republic, 2020 InTec Agro Trials, Czech Republic, Report No. F-20-G-574-01	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
Submitted under KCP 6.2-006			ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW308A GEP Unpublished				
KCP 6.4-007 Submitted under KCP 6.2-007	Bezdičková, A.	2020	An efficacy evaluation of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in the Czech Republic, 2020 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FETRZAW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-008 Submitted under KCP 6.1-012	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-009 Submitted under KCP 6.2-009	Bezdičková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-010 Submitted under KCP 6.1-013	Gouille, L.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Puccinia striiformis</i> (PUCST) on winter wheat in France, 2019 Biotek Agriculture, France, Report No. BPE19/286/FGC01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAW110A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-011 Submitted under KCP 6.1-014	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019. Staphyt, France, Report No. FVT-19-40058-FR01 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-012 Submitted under KCP 6.1-015	Varret, F.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat, in France 2019 Staphyt, France, Report No. FVT-19-40058-FR02 ADAMA Makhteshim Ltd, Report No. FR19FETRZAX108B	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
			GEP Unpublished				
KCP 6.4-013 Submitted under KCP 6.1-016	Boeuf, V.	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (Puccre) on winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03107-AR ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-014 Submitted under KCP 6.1-017	Deberny, E..	2019	Efficacy comparison of ADM.3503.F.1.A with its equivalent tank mix for the control of Brown rust (Puccre) on winter wheat in France in 2019 Antedis, France, Report No. ADA-FE19BT-03108-CA ADAMA Makhteshim Ltd, Report No. FR19FETRZAX109B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-015 Submitted under KCP 6.1-018	Ternois, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Ephydia, France, Report No. FRM-20-F13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-016 Submitted under KCP 6.1-019	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Staphyt, France, Report No. JFT-20-45675-FR01 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW500B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-017 Submitted under KCP 6.2-017	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20098A21 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-018 Submitted under KCP 6.2-018	Crepin, D.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A against brown rust on winter wheat, in France in 2020 Essais +, France, Report No. 20 38 F 13 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW502B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-019 Submitted under KCP 6.2-019	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F14 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-020 Submitted under KCP 6.2-020	Maitte, B.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in FRANCE, 2020 Promo Vert, France, Report No. 20F FCEADA FR15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW504C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-021 Submitted under KCP 6.2-021	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F15 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-022 Submitted under KCP 6.2-022	Jondot, A.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT on Winter Wheat in France in 2020 Antedis, France, Report No. ADA-FE20BT-05271-SV ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-023 Submitted under KCP 6.2-023	Ballan, J.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT, SEPTTR and PUCCSI on Winter Wheat in France in 2020 Antedis, France, Report No. ADA-FE20BT-05272-JA ADAMA Makhteshim Ltd, Report No. FR20FETRZAW506C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-024 Submitted under KCP 6.2-024	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in France, 2020 Ephydia, France, Report No. FRM-20-F16 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-025 Submitted under KCP 6.2-025	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20099H07 ADAMA Makhteshim Ltd, Report No. FR20FETRZAW509C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-026 Submitted under KCP 6.1-020	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in France in 2021 Ephydia, France, Report No. FRM-21-F20 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-027 Submitted under KCP 6.1-021	Flahaut, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in France in 2021 Staphyt, France, Report No. JFT-21-50445-FR01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW551C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-028 Submitted under KCP 6.2-028	Crepin, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in FRANCE in 2021 Essais +, France, Report No. 21 38 F 27 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-029 Submitted under KCP 6.2-029	Voisin, J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in FRANCE in 2021 Agrotest, France, Report No. E-2154 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW552C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-030 Submitted under KCP 6.2-030	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (<i>Puccinia striiformis tritici</i>) on winter wheat in France in 2021. Biotek Agriculture, France, Report No. BPE21/205/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW553B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-031 Submitted under KCP 6.2-031	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) and SEPTTR (Septoria) on winter wheat in France in 2021 Ephydia, France, Report No. FRM-21-F21 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW554A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-032 Submitted under KCP 6.2-032	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> (FUSACU in artificial contamination) in winter wheat at T3 in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21106E23 ADAMA Makhteshim Ltd, Report No. FR21FETRZAW556B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-033 Submitted under KCP 6.1-022	Labusch, U.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 BioChem Agrar, Germany, Report No. 19 1069 5062 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-034 Submitted under KCP 6.1-023	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-071 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW905B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-035 Submitted under KCP 6.1-024	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PUCCRT) on winter wheat in (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW906A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-036 Submitted under KCP 6.1-025	Wolf, P.	2019	Efficacy of ADM.3503.F.1.A in comparison to the equivalent tank mix vs. Yellow Rust (PUCCSI) in Winter Wheat Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FETRZAW907A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-037 Submitted under KCP 6.1-026	Perner, J.	2019	Efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in Germany, 2019 U.A.S., Germany, Report No. 170_19_Z ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-038 Submitted under KCP 6.1-027	Rohr, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Pyrenophora (Drechslera) tritici-repentis (PYRNTR) on winter wheat in (Germany), 2019 Trial-Tec, Germany, Report No. 19-ADA-HE-WW-072 ADAMA Makhteshim Ltd, Report No. DE19FETRZAW908B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-039 Submitted under KCP 6.2-039	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 221A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-040 Submitted under KCP 6.2-040	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-141 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW221B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-041 Submitted under KCP 6.2-041	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in Germany, 2020 Agrartest, Germany, Report No. S20-03244-01 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-042 Submitted under KCP 6.2-042	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5128 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW222B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-043 Submitted under KCP 6.2-043	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 223A ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-044 Submitted under KCP 6.2-044	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-142 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW223B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-045 Submitted under KCP 6.2-045	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WW-143 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-046 Submitted under KCP 6.2-046	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-144 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-047 Submitted under KCP 6.2-047	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWW 20 ADA 224C ADAMA Makhteshim Ltd, Report No. DE20FETRZAW224C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-048 Submitted under KCP 6.2-048	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5129 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-049 Submitted under KCP 6.2-049	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WW-145 ADAMA Makhteshim Ltd, Report No. DE20FETRZAW225B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-050 Submitted under KCP 6.1-028	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-222 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW500A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-051 Submitted under KCP 6.2-051	Hapke, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Acceres, Germany, Report No. F21NMW35 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-052 Submitted under KCP 6.2-052	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW501B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-053 Submitted under KCP 6.2-053	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-235 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW502A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-054 Submitted under KCP 6.2-054	Wolf, P.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in Germany in 2021 Agricola, Germany, ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-055 Submitted under KCP 6.2-055	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Germany in 2021 U.A.S., Germany, Report No. 147_21_Z ADAMA Makhteshim Ltd, Report No. DE21FETRZAW503B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-056 Submitted under KCP 6.2-056	Rohr, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-SH-WW-223 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-057 Submitted under KCP 6.2-057	Maleck, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 Agro-check, Germany, Report No. AC/21/050 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-058 Submitted under KCP 6.2-058	Zickart, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Germany in 2021 BioChem Agrar, Germany, Report No. 21 1064 1192 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW504C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-059 Submitted under KCP 6.2-059	Rohr, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Germany in 2021 Trial-Tec, Germany, Report No. 21-ADA-HE-WW-224 ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-060 Submitted under KCP 6.2-060	Endres, U.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Germany in 2021 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE21FETRZAW505B GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-061 Submitted under KCP 6.1-029	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Ireland, 2020 Eurofins, Ireland, Report No. S20-02701-01 ADAMA Makhteshim Ltd, Report No. IE20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-062	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-01 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-063 Submitted under KCP 6.1-030	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Ireland in 2021 Eurofins, Ireland, Report No. S21-03031-02 ADAMA Makhteshim Ltd, Report No. IE21FETRZAW322B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-064 Submitted under KCP 6.1-031	Van Tilburg, F.W.G.	2020	Control of <i>Zymoseptoria tritici</i> in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02814-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW010A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-065 Submitted under KCP 6.2-064	Van Tilburg, F.W.G.	2020	Control of <i>Puccinia recondita</i> in winter wheat in the Netherlands, 2020 Eurofins, Netherlands, Report No. S20-02815-01 ADAMA Makhteshim Ltd, Report No. NL20FETRZAW011A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-066 Submitted under KCP 6.1-032	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034A-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-067 Submitted under KCP 6.1-033	Kay, C.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in the UK, 2019 OAT, United Kingdom, Report No. 19-1034B-ADA ADAMA Makhteshim Ltd, Report No. UK19FETRZAW344B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-068 Submitted under KCP 6.1-034	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1022-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-069 Submitted under KCP 6.2-068	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1023-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW302A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-070 Submitted under KCP 6.2-069	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-071 Submitted under KCP 6.2-070	Armstrong, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in the UK, 2020 Armstrong Fisher, United Kingdom, Report No. 1024-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW304B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-072 Submitted under KCP 6.2-071	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in the UK, 2020 OAT, United Kingdom, Report No. 1025-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FETRZAW306A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-073 Submitted under KCP 6.2-072	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in the UK, 2020 ADAS, United Kingdom, Report No. GT20/031 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-074 Submitted under KCP 6.2-073	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in the UK, 2020 Eurofins, Derby, United Kingdom, Report No. S20-02732-01 ADAMA Makhteshim Ltd, Report No. UK20FETRZAW309B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-075 Submitted under KCP 6.1-035	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1074-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-076 Submitted under KCP 6.2-075	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 1075-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-077 Submitted under KCP 6.2-076	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in the UK in 2021 OAT, United Kingdom, Report No. 21-1076-ADA ADAMA Makhteshim Ltd, Report No. UK21FETRZAW302A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-078 Submitted under KCP 6.2-077	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in the UK in 2021 ADAS, United Kingdom, Report No. GT21-035 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW303A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-079 Submitted under KCP 6.2-078	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in the UK in 2021 ADAS, United Kingdom, Report No. GT21-036 ADAMA Makhteshim Ltd, Report No. UK21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-080 Submitted under KCP 6.1-036	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44718-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-081 Submitted under KCP 6.1-037	Rusek, K.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland 2020 Fertico, Poland, Report No. 57_01_F20_77 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW060B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-082 Submitted under KCP 6.2-081	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter wheat, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/BR/061A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-083 Submitted under KCP 6.2-082	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRT (brown rust) on winter wheat in Poland 2020 Fertico, Poland, Report No. 58_01_F20_78 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW061B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-084 Submitted under KCP 6.2-083	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCSI (yellow rust) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44719-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-085 Submitted under KCP 6.2-084	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0692-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW062B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-086 Submitted under KCP 6.2-085	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/063A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-087 Submitted under KCP 6.2-086	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Poland, 2020 Fertico, Poland, Report No. 59_01_F20_79 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW063B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-088 Submitted under KCP 6.2-087	Kukuła, A.	2020	The evaluation of efficacy of ADM.03503.F.1.A , ADM.01352.F.3.A for the control of fungal diseases on winter wheat Agreco, Poland, Report No. 20ADA0693-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-089 Submitted under KCP 6.2-088	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Poland, 2020 Staphyt, Poland, Report No. APK-20-44720-PL01 PHA ADAMA Makhteshim Ltd, Report No. PL20FETRZAW064B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-090 Submitted under KCP 6.2-089	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/PO/19/Pr/065A ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-091 Submitted under KCP 6.2-090	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Poland, 2020 Agreco, Poland, Report No. 20ADA0694-1 ADAMA Makhteshim Ltd, Report No. PL20FETRZAW065B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-092	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_23 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-093 Submitted under KCP 6.1-038	Rusek, K	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Zymoseptoria tritici</i> (SEPTTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 71_01_F21_178 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW023B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-094 Submitted under KCP 6.2-092	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/024A ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-095 Submitted under KCP 6.2-093	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50274-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW024B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-096 Submitted under KCP 6.2-094	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_09 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-097 Submitted under KCP 6.2-095	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Puccinia striiformis tritici</i> (PUCCSI) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 72_01_F21_179 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW025B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-098 Submitted under KCP 6.2-096	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50275-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW026A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-099	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_24 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW026B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-100 Submitted under KCP 6.2-097	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Pyrenophora tritici repentis</i> (PYRNTR) on winter wheat in Poland, 2021 Fertico, Poland, Report No. 73_01_F21_180 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW027A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-101	Gajek, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Poland in 2021 Agro Research Consulting, Poland, Report No. ARC21_TRZAW_ADAM_25 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW027B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-102 Submitted under KCP 6.2-098	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50278-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-103 Submitted under KCP 6.2-099	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter wheat cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/PO/9/Pr/028B ADAMA Makhteshim Ltd, Report No. PL21FETRZAW028B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-104	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-113-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW510A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-105	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 03 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW510B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-106 Submitted under KCP 6.2-100	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-116-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-107 Submitted under KCP 6.2-101	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-117-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW511B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-108 Submitted under KCP 6.2-102	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-112-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW512A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-109	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 02 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW512B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-110	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-111-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW513A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-111	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 01 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW513B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-112	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-114-135FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-113 Submitted under KCP 6.2-103	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-115-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-114 Submitted under KCP 6.2-104	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on winter wheat in Hungary, 2020 SGS, Hungary, Report No. 20 FE 04 SG1 ADAMA Makhteshim Ltd, Report No. HU20FETRZAW514C GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-115	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-109-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW515A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-116	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-110-002FE ADAMA Makhteshim Ltd, Report No. HU20FETRZAW515B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-117 Submitted under KCP 6.2-105	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-090-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-118 Submitted under KCP 6.2-106	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust of wheat) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-091-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW302A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-119	Varga, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-092-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-120 Submitted under KCP 6.2-107	Makó, I.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-093-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-121	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-094-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-122	Németh, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTR (DTR) on winter wheat in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-095-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW304C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-123 Submitted under KCP 6.2-108	Nagy, Z.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-096-002FE ADAMA Makhteshim Ltd, Report No. HU21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-124 Submitted under KCP 6.1-039	Tuna, V.	2019	Determination of Efficacy of ADM.3503.f.1.A compared to the equivalent tank mix, applied post-emergence against <i>Zymoseptoria tritici</i> (SEPTTR) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03922-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW169A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-125 Submitted under KCP 6.1-040	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against Yellow rust (Puccst) in Winter Wheat, outdoor 2019 Eurofins, Romania, Report No. S19-03923-01 ADAMA Makhteshim Ltd, Report No. RO19FETRZAW170A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-126 Submitted under KCP 6.1-041	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-127 Submitted under KCP 6.1-042	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW248B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-128 Submitted under KCP 6.2-113	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-129 Submitted under KCP 6.2-114	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCRT (brown rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW249B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-130 Submitted under KCP 6.2-115	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-131 Submitted under KCP 6.2-116	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW250B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-132 Submitted under KCP 6.2-117	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-133 Submitted under KCP 6.2-118	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW251B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-134 Submitted under KCP 6.2-119	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-135 Submitted under KCP 6.2-120	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FETRZAW252B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-136 Submitted under KCP 6.2-121	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-137 Submitted under KCP 6.2-122	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02895-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW213B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-138 Submitted under KCP 6.1-043	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-139 Submitted under KCP 6.1-044	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02892-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW215B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-140 Submitted under KCP 6.2-125	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-141 Submitted under KCP 6.2-126	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02893-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW216B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-142	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-143 Submitted under KCP 6.2-127	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUC CST (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-02 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-144 Submitted under KCP 6.2-128	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02894-03 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW217C GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-145 Submitted under KCP 6.2-129	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02896-01 ADAMA Makhteshim Ltd, Report No. RO21FETRZAW219A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-146 Submitted under KCP 6.1-045	Hudec, K.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of Brown rust (PuccrT) on winter wheat in Slovakia, 2019 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK19FETRZAW345A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-147 Submitted under KCP 6.1-046	Ondisová, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Slovakia, 2020 UKSUP, Slovakia, Report No. KE-F-04-2020 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-148 Submitted under KCP 6.1-047	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in Slovakia, 2020 Blumeria Consulting, Slovakia, Report No. ADA-301B-O ADAMA Makhteshim Ltd, Report No. SK20FETRZAW301B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-149 Submitted under KCP 6.2-133	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PuccrT (brown rust) on winter wheat in Slovakia, 2020 FYSE, Slovakia, Report No. FYSE-103202016 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-150 Submitted under KCP 6.2-134	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PuccrT (brown rust) on winter wheat in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW303B GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-151 Submitted under KCP 6.2-135	Kovacova Holcikova, D	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202017 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-152 Submitted under KCP 6.2-136	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCSI (yellow rust) on winter wheat in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW305B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-153 Submitted under KCP 6.2-137	Malovcová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGT (powdery mildew) on winter wheat in Slovakia, 2020 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FETRZAW306A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-154 Submitted under KCP 6.2-138	Kovacova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of <i>Fusarium</i> and <i>Microdochium</i> at T3 on winter wheat in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE-103202018 ADAMA Makhteshim Ltd, Report No. SK20FETRZAW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-155 Submitted under KCP 6.1-048	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against SEPTTR (<i>Zymoseptoria tritici</i>) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW300A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-156 Submitted under KCP 6.2-140	Forgáčová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRT (Brown rust) on winter wheat in (Slovakia) in 2021 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW301A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-157 Submitted under KCP 6.2-141	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCSI (Yellow rust) on winter wheat in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW302A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-158 Submitted under KCP 6.2-142	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGT (Powdery mildew) on winter wheat in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW303A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-159 Submitted under KCP 6.2-143	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against <i>Fusarium</i> and <i>Microdochium</i> in winter wheat at T3 in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FETRZAW305A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-160 Submitted under KCP 6.1-049	Bataille, C.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against net blotch on winter barley CRA-W, Belgium, Report No. MAL-HORVW-21-E-19 ADAMA Makhteshim Ltd, Report No. BE21FEHORVW035A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-161 Submitted under KCP 6.2-145	Roslupil, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in the Czech Republic, 2020 ZZS Kujavy, Czech Republic, Report No. R20/04 ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS311A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-162 Submitted under KCP 6.1-050	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in the Czech Republic, 2020 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ20FEHORVS315A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-163 Submitted under KCP 6.2-147	Čáp, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the Czech Republic in 2021 ZS Nechanice, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS306A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-164 Submitted under KCP 6.2-148	Bezdičková, A.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in the Czech Republic in 2021 Ditana, Czech Republic ADAMA Makhteshim Ltd, Report No. CZ21FEHORVS307A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-165 Submitted under KCP 6.1-051	Negrini, P	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of RAMUCC and PYRNTE on Barley in France in 2019 Antedis, France, Report No. ADA-FE19OH-03109-CA ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-166	Aingueneau, L	2019	Efficacy comparison of ADM.3503.F.1.A to the equivalent tank mix for the control of <i>Rhynchosporium secalis</i> (RHYNSE) on Barley in France in 2019 Antedis, France, Report No. ADA-FE19OH-03334-BR ADAMA Makhteshim Ltd, Report No. FR19FEHORVX107B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-167 Submitted under KCP 6.1-052	Flahaut, J.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) and <i>Rhynchosporium secalis</i> (RHYNSE) on barley in France, 2019 Staphyt, France, Report No. JFT-19-40084-FR01 ADAMA Makhteshim Ltd, Report No. FR19FEHORVX108A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-168 Submitted under KCP 6.2-151	Lombart, L.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F17 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX510A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-169 Submitted under KCP 6.2-152	Flahaut, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (leaf blotch) and PYRNTE (net blotch) on barley in FRANCE, 2020 Staphyt, France, Report No. JFT-20-45676-FR01 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW510B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-170 Submitted under KCP 6.1-053	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2018 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW512C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-171 Submitted under KCP 6.1-054	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (Leaf Blotch) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F19 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX514A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-172 Submitted under KCP 6.1-055	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20100F25 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW514C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-173	Biaunier, M.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in FRANCE, 2020 Qualiphyt, France, Report No. QUALI20101H08 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW516B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-174 Submitted under KCP 6.2-156	Voisin, J.F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in FRANCE, 2020 Agrotest, France, Report No. E-2020 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW516D GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-175 Submitted under KCP 6.1-056	Rouane, W.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in France, 2020 Anadiag, France, Report No. FR203031PS303 ADAMA Makhteshim Ltd, Report No. FR20FEHORVW517B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-176 Submitted under KCP 6.1-057	Wallart, F.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in France, 2020 Ephydia, France, Report No. FRM-20-F18 ADAMA Makhteshim Ltd, Report No. FR20FEHORVX512A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-177 Submitted under KCP 6.1-058	Negrini, P.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC on Barley in France in 2020 Antedis, France, Report No. ADA-FE200H-05273-PR ADAMA Makhteshim Ltd, Report No. FR20FEHORVX517A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-178 Submitted under KCP 6.2-160	Rouane, W.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Anadiag, France, Report No. FR213045DP303 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-179 Submitted under KCP 6.2-161	Lombart, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in France in 2021 Ephydia, France, Report No. FRM-21-F23 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW557C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-180 Submitted under KCP 6.1-059	Wallart, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in France in 2021 Ephydia, France, Report No. FRM-21-F19 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW558B GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-181 Submitted under KCP 6.1-060	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107D07 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-182 Submitted under KCP 6.1-061	Biaunier, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in FRANCE in 2021 Qualiphyt, France, Report No. QUALI21107F15 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW559B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-183 Submitted under KCP 6.2-165	Gouaille, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (<i>Blumeria graminis hordei</i>) on winter barley in France in 2021. Biotek Agriculture, France, Report No. BPE21/206/FGC01 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-184 Submitted under KCP 6.2-166	Voisin J.F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in France in 2021 Agrotest, France, Report No. E-2156 ADAMA Makhteshim Ltd, Report No. FR21FEHORVW560C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-185 Submitted under KCP 6.1-062	Hetterich, A.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Hetterich Fieldwork, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-186 Submitted under KCP 6.1-063	Thomas Martin	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley (Germany), 2019 Martin Feldversuchswesen, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW909B GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-187 Submitted under KCP 6.1-064	Peter Wolf	2019	Efficacy of ADM.3503.F.1.A compared to the equivalent active ingredients in tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) in Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE19FEHORVW910B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-188 Submitted under KCP 6.2-170	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SN-WG-146 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-189 Submitted under KCP 6.2-171	Holger Teresiak	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on winter barley in Germany, 2020 Agro-check, Germany, Report No. AC/20/090 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW227B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-190 Submitted under KCP 6.1-065	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03247 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW228A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-191 Submitted under KCP 6.1-066	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-HE-WG-147 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW229A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-192 Submitted under KCP 6.2-172	Lamers, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 BioChem Agrar, Germany, Report No. 20 1069 5130 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-193 Submitted under KCP 6.2-175	Magyaróvári, V.	2020	Efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Germany, 2020 Agrartest, Germany, Report No. S20-03245 ADAMA Makhteshim Ltd, Report No. DE20FEHORVW230B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-194 Submitted under KCP 6.1-067	Martin, T.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany, 2020 Martin Feldversuchswesen, Germany, Report No. FWG 20 ADA 231A ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-195 Submitted under KCP 6.1-068	Wolf, P.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on Barley Agricola, Germany ADAMA Makhteshim Ltd, Report No. DE20FEHORVW231B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-196 Submitted under KCP 6.2-178	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. HWG 21 ADA 506A ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-197 Submitted under KCP 6.2-179	Wönckhaus, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in Germany in 2021 Agrartest, Germany, Report No. S21-02913-01 ADAMA Makhteshim Ltd, Report No. DE21FEHORVW506B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-198 Submitted under KCP 6.1-069	Martin, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Germany in 2021 Martin Feldversuchswesen, Germany, Report No. FWG 21 ADA 507A ADAMA Makhteshim Ltd, Report No. DE21FEHORVX507A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-199 Submitted under KCP 6.1-070	Perner, J.	2021	Evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in Germany in 2021 U.A.S., Germany, Report No. 148_21_Z ADAMA Makhteshim Ltd, Report No. DE21FEHORVX508A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-200 Submitted under KCP 6.2-182	Torkler, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in Germany in 2021 Quintus, Germany, Report No. K-136-QUI-21-236 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-201 Submitted under KCP 6.2-183	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-016 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX509B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-202 Submitted under KCP 6.1-071	Ommen, T.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia</i>) on barley in Germany in 2021 Plantus, Germany, Report No. 21F-2-PLA-017 ADAMA Makhteshim Ltd, Report No. DE21FEHORVX510A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-203	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02703-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX313A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-204	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02704-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX315A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-205 Submitted under KCP 6.1-072	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-01 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-206	Packwood, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in Ireland, 2020 Eurofins, Ireland, Report No. S20-02702-02 ADAMA Makhteshim Ltd, Report No. IE20FEHORVX318B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-207 Submitted under KCP 6.1-073	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-208 Submitted under KCP 6.1-074	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03032-02 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX323B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-209 Submitted under KCP 6.1-075	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia</i>) on barley in Ireland in 2021 Eurofins, Ireland, Report No. S21-03303-01 ADAMA Makhteshim Ltd, Report No. IE21FEHORVX325A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-210 Submitted under KCP 6.1-076	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley in the UK, 2019 ADAS, Ireland, Report No. WA19-WB-Adama 9T (348) ADAMA Makhteshim Ltd, Report No. UK19FEHORVX348A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-211	Joynt, R.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Pyrenophora teres</i> (PYRNTE) on barley in the UK, 2019 ADAS, Ireland, Report No. HM19/WB13 ADAMA Makhteshim Ltd, Report No. UK19FEHORVX349A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-212 Submitted under KCP 6.2-190	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1026A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-213 Submitted under KCP 6.2-191	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in the UK, 2020 OAT, United Kingdom, Report No. 20-1026B-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX310B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-214	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1027-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX312A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-215 Submitted under KCP 6.1-077	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1028A-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX314A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-216 Submitted under KCP 6.2-193	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1029-20-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-217 Submitted under KCP 6.2-194	Joynt, R.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in the UK, 2020 ADAS, United Kingdom, Report No. GT20/024 ADAMA Makhteshim Ltd, Report No. UK20FEHORVX316B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-218 Submitted under KCP 6.1-081	Kay, C.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RAMUCC (<i>Ramularia collo-cygni</i>) on barley in the UK, 2020 OAT, United Kingdom, Report No. 1030-ADA ADAMA Makhteshim Ltd, Report No. UK20FEHORVX317A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-29 Submitted under KCP 6.2-196	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in the UK in 2021 OAT, United Kingdom, Report No. 1077-21-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX306A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-220	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1078-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX307A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-221 Submitted under KCP 6.1-079	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1079B-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-222 Submitted under KCP 6.1-080	Hill, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in the UK in 2021 Eurofins, Derby, United Kingdom, Report No. S21-03034-01 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX308C GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-223 Submitted under KCP 6.2-199	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1080-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-224 Submitted under KCP 6.2-200	Joynt, R.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in the UK in 2021 ADAS, United Kingdom, Report No. HM21-063 ADAMA Makhteshim Ltd, Report No. UK21FEHORVX309B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-225	Kay, C.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RAMUCC (<i>Ramularia</i>) on barley in the UK in 2021 OAT, United Kingdom, Report No. 21-1081-ADA ADAMA Makhteshim Ltd, Report No. UK21FEHORVX310A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-226 Submitted under KCP 6.2-201	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Fertico, Poland, Report No. 60_01_F20_80 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-227 Submitted under KCP 6.2-202	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCHD (brown rust) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44721-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW066B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-228 Submitted under KCP 6.1-079	Sawinska, Z.	2020	The evaluation of efficacy ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter barley cultivation, Poland 2020 Poznań University, Poland, Report No. AF/20/JO/19/Pr/067A ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-229 Submitted under KCP 6.1-082	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0677-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW067B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-230 Submitted under KCP 6.1-083	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Fertico, Poland, Report No. 61_01_F20_81 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-231 Submitted under KCP 6.1-084	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PYRNTE (Net Blotch) on barley in Poland, 2020 Staphyt, Poland, Report No. APK-20-44722-PL01 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW068B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-232 Submitted under KCP 6.2-207	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Fertico, Poland, Report No. 62_01_F20_82 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-233 Submitted under KCP 6.2-208	Kukuła, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Poland, 2020 Agreco, Poland, Report No. 20ADA0678-1 ADAMA Makhteshim Ltd, Report No. PL20FEHORVW069B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-234 Submitted under KCP 6.2-209	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Puccinia hordei</i> (PUCCHD) on winter barley in Poland, 2021 Fertico, Poland, Report No. 74_01_F21_181 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-235 Submitted under KCP 6.2-210	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/Br/029B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW029B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-236 Submitted under KCP 6.1-085	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Rhynchosporium secalis</i> (RHYNSE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 75_01_F21_182 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-237 Submitted under KCP 6.1-086	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter barley cultivation, Poland 2021 Poznań University, Poland, Report No. AF/21/JO/9/Z1/030B ADAMA Makhteshim Ltd, Report No. PL21FEHORVW030B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-238 Submitted under KCP 6.1-087	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Pyrenophora teres</i> (PYRNTE) on winter barley in Poland, 2021 Fertico, Poland, Report No. 76_01_F21_183 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-239	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in POLAND in 2021 Staphyt, Poland, Report No. MP2-21-50283-PL01 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW031B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-240 Submitted under KCP 6.2-214	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Blumeria graminis hordei</i> (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_01_F21_184 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-241 Submitted under KCP 6.2-215	Rusek, K.	2021	Efficacy evaluation of ADM.03503.F.1.A against <i>Blumeria graminis hordei</i> (ERYSGH) on winter barley in Poland, 2021 Fertico, Poland, Report No. 77_02_F21_185 ADAMA Makhteshim Ltd, Report No. PL21FEHORVW032B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-242	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of powdery mildew on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-123-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-243	Juhász, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Hungary, 2020 SGS, Hungary, Report No. 20 FE 05 SG1 ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-244 Submitted under KCP 6.2-216	Benczés, B.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-124-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX520C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-245	Olasz, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-118-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX521A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-246	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-121-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX522A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-247	Nagy, Z.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-122-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX522B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-248	Varga, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-119-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX523A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-249	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-120-002FE ADAMA Makhteshim Ltd, Report No. HU20FEHORVX523B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-250	Németh, S.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (Leaf blotch of cereals) on barley in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-097-002FE ADAMA Makhteshim Ltd, Report No. HU21FEHORVW306A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-251 Submitted under KCP 6.2-217	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (<i>Pyrenophora teres</i>) on barley in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-098-002FE ADAMA Makhteshim Ltd, Report No. HU21FEHORVW309A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-252 Submitted under KCP 6.1-088	Tuna, V.	2019	Determination of Efficacy of ADM.3503.F.1.A compared to the equivalent tank mix, applied post-emergence against <i>Pyrenophora teres</i> (PYRNTE) in barley, outdoor 2019 Eurofins, Romania, Report No. S19-03924-01 ADAMA Makhteshim Ltd, Report No. RO19FEHORVW171A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-253 Submitted under KCP 6.2-219	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-254 Submitted under KCP 6.2-220	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW245B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-255	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-256 Submitted under KCP 6.1-089	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW246B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-257 Submitted under KCP 6.1-090	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-258 Submitted under KCP 6.1-091	Botoman, G.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley GEP Trial, ROMANIA, 2020 AgroProspect, Romania ADAMA Makhteshim Ltd, Report No. RO20FEHORVW247B GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-259 Submitted under KCP 6.2-224	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-260 Submitted under KCP 6.2-225	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02897-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW210B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-261 Submitted under KCP 6.1-092	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-262 Submitted under KCP 6.1-093	Tuna, V.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02898-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW211B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-263 Submitted under KCP 6.1-094	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02899-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW212A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-264 Submitted under KCP 6.2-229	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503. F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-01 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-265 Submitted under KCP 6.2-230	Tuna, V.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02901-02 ADAMA Makhteshim Ltd, Report No. RO21FEHORVW218B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-266 Submitted under KCP 6.1-095	Holcikova, D.	2019	An efficacy comparison of ADM.3503.F.1.A compared to the equivalent tank mix for the control of <i>Rhynchosporium</i> (RHYNSE) on barley Slovakia, 2019 FYSE,Slovakia, Report No. FYSE-103201915 ADAMA Makhteshim Ltd, Report No. SK19FEHORVW348A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-267 Submitted under KCP 6.2-232	Malovcova, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of ERYSGH (powdery mildew) on barley in Slovakia, 2020 NPPC - VURV Piestany,Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVS316A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-268 Submitted under KCP 6.2-233	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PUCCHD (brown rust) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW311A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-269 Submitted under KCP 6.1-096	Kovacova Holcikova, D.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Slovakia, 2020 FYSE,Slovakia, Report No. FYSE103202015 ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-270 Submitted under KCP 6.1-097	Tóth, F.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on barley in Slovakia, 2020 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW313B GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-271 Submitted under KCP 6.1-098	Forgáčová, L.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Berberis, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-272	Hudec, K.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of PYRNTE (Net Blotch) on barley in Slovakia, 2020 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK20FEHORVW315B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-273 Submitted under KCP 6.2-237	Malovcová, L.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against ERYSGH (Powdery mildew) on barley in (Slovakia) in 2021 NPPC - VURV Piestany, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVS309A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-274 Submitted under KCP 6.2-238	Hudec, K.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 Blumeria Consulting, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-275 Submitted under KCP 6.2-239	Tóth, F.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCHD (Brown rust) on barley in (Slovakia) in 2021 OVD, Slovakia ADAMA Makhteshim Ltd, Report No. SK21FEHORVW306B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-276 Submitted under KCP 6.1-099	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW307A - ZV04 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW307A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-277 Submitted under KCP 6.1-100	Kováčová Holčíková, D.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PYRNTE (Net Blotch) on barley in (Slovakia) in 2021 Berberis, Slovakia, Report No. SK21FEHORVW308A- ZV03 ADAMA Makhteshim Ltd, Report No. SK21FEHORVW308A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-278 Submitted under KCP 6.1-101	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on rye in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-WR-148 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-279 Submitted under KCP 6.1-102	Magyaróvári, V.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on rye in Germany, 2020 Agrartest, Germany, Report No. S20-03246-01 ADAMA Makhteshim Ltd, Report No. DE20FESECSS232B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-280 Submitted under KCP 6.1-103	Wied, H.M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (<i>Puccinia recondita</i>) on rye in Germany in 2021 Staphyt, Germany, Report No. HWD-21-50086-DE01 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-281 Submitted under KCP 6.1-104	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in Germany in 2021 Field Research Support, Germany, Report No. FRS105/21 ADAMA Makhteshim Ltd, Report No. DE21FESECSS511B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-282 Submitted under KCP 6.1-105	Sawinska, Z.	2020	The evaluation of efficacy of ADM.03503.F.1.A and ADM.01352.F.3.A in fungal diseases control in winter rye , Poland, 2020 Poznań University, Germany, Report No. AF/20/ŽO/19/BR/070A ADAMA Makhteshim Ltd, Report No. PL20FESECSS070A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-283 Submitted under KCP 6.1-106	Sawinska, Z.	2021	The evaluation of efficacy and phytotoxicity of ADM.03503.F.1.A in fungal diseases control in winter rye cultivation, Poland, 2021 Poznań University, Germany, Report No. AF/21/ŽO/9/Br/033A ADAMA Makhteshim Ltd, Report No. PL21FESECCS033A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-284	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of RHYNSE (<i>Rhynchosporium secalis</i>) on rye in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-125-002FE ADAMA Makhteshim Ltd, Report No. HU20FESECCW530A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-285 Submitted under KCP 6.1-107	Macsim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02902-01 ADAMA Makhteshim Ltd, Report No. RO21FESECCS214A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-286 Submitted under KCP 6.1-108	Macsim, C.	2021	Determination of An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium</i>) on rye in ROMANIA in 2021 Eurofins, Romania, Report No. S21-04520 - 01 ADAMA Makhteshim Ltd, Report No. RO21FESECCS250A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-287 Submitted under KCP 6.2-252	Čáp, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale the Czech republic, 2020 ZS Nechanice, Czech Republic, Report No. CZOR-ATA20-TTLSS-036NEC ADAMA Makhteshim Ltd, Report No. CZ20FETTLWI324A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-288 Submitted under KCP 6.2-253	Teresiak, H.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRE (brown rust) on triticale in Germany, 2020 Agro-check, Czech Republic, Report No. AC/20/091 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS233A GEP Unpublished	N	Y	New study	ADM

Annex point	Author	Year	Title Source (where different from company) Company, Report No. GLP or GEP status Published or Unpublished	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCP 6.4-289 Submitted under KCP 6.2-254	Rohr, J.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Germany, 2020 Trial-Tec, Germany, Report No. 20-ADA-SH-TR-149 ADAMA Makhteshim Ltd, Report No. DE20FETTLSS234A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-290 Submitted under KCP 6.2-255	Zöllner, H.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against RHYNSE (<i>Rhynchosporium secalis</i>) on triticale in Germany in 2021 Field Research Support, Germany, Report No. FRS106/21 ADAMA Makhteshim Ltd, Report No. DE21FETTLSS512A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-291 Submitted under KCP 6.2-256	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of PUCCRE (brown rust) on triticale in Poland, 2020 Fertico, Poland, Report No. 63_01_F20_83 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS071A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-292 Submitted under KCP 6.2-257	Rusek, K.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Poland, 2020 Fertico, Poland, Report No. 64_01_F20_84 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-293 Submitted under KCP 6.2-258	Pawlak, A.	2020	An efficacy evaluation of ADM.03503.F.1.A and ADM.01352.F.3.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Poland, 2020 Staphyt, Poland, Report No. APK-20-44723-PL01 ADAMA Makhteshim Ltd, Report No. PL20FETTLSS072B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-294 Submitted under KCP 6.2-259	Pszczółkowski, M.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against PUCCRE (Brown rust) on triticale in Poland in 2021 Staphyt, Poland, Report No. MP2-21-50285-PL01 ADAMA Makhteshim Ltd, Report No. PL21FETTLSS034A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-295 Submitted under KCP 6.2-260	Ritecz, J.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of Puccre (brown rust) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-126-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLWI540A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-296 Submitted under KCP 6.2-261	Makó, I.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-127-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLWI541A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-297 Submitted under KCP 6.2-262	Németh, S.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-128-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLWI541B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-298	Rábai, A.	2020	An efficacy evaluation of ADM.03503.F.1.A for the control of DTR (<i>Pyrenophora tritici-repentis</i>) on triticale in Hungary, 2020 CPR Europe, Hungary, Report No. CPRHU20-129-002FE ADAMA Makhteshim Ltd, Report No. HU20FETTLWI541C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-299 Submitted under KCP 6.2-263	Ritecz, J.	2021	An evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccre (Brown rust) on triticale in Hungary in 2021 CPR Europe, Hungary, Report No. CPRHU21-100-002FE ADAMA Makhteshim Ltd, Report No. HU21FETTLWS312A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-300 Submitted under KCP 6.2-264	Macsim, C.	2021	Determination of an evaluation of the efficacy and crop safety of ADM.03503.F.1.A against Puccre (Brown rust) on triticale in ROMANIA in 2021 Eurofins, Romania, Report No. S21-02903-01 ADAMA Makhteshim Ltd, Report No. RO21FETTLSS220A GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-301	Flahaut, J.	2021	Evaluation of the influence of a fungicide product ADM.03503.F.1.A on the quality of bread making on winter wheat, in France 2021 Staphyt, France, Report No. JFT-21-50809-FR01 ADAMA Makhteshim Ltd, Report No. FR21FPTRZAW563A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-302	Flahaut, J.	2021	Evaluation of the influence of a fungicide product ADM.03503.F.1.A on the quality of bread making on winter wheat, in France 2021 Staphyt, France, Report No. JFT-21-50809-FR02 ADAMA Makhteshim Ltd, Report No. FR21FPTRZAW563B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-303	Flahaut, J.	2021	Evaluation of the influence of a fungicide product ADM.03503.F.1.A on the quality of bread making on winter wheat, in France 2021 Staphyt, France, Report No. JFT-21-50809-FR03 ADAMA Makhteshim Ltd, Report No. FR21FPTRZAW563C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-304	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on spring barley, in France 2020 Staphyt, France, Report No. JFT-20-46079-FR01 ADAMA Makhteshim Ltd, Report No. FR20FPHORVS502A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-305	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on spring barley, in France 2020 Staphyt, France, Report No. JFT-20-46079-FR02 ADAMA Makhteshim Ltd, Report No. FR20FPHORVS502B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-306	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on spring barley, in France 2020 Staphyt, France, Report No. JFT-20-46079-FR03 ADAMA Makhteshim Ltd, Report No. FR20FPHORVS502C GEP Unpublished	N	Y	New study	ADM

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KCP 6.4-307	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on winter barley, in France 2020 Staphyt, France, Report No. JFT-20-46078-FR01 ADAMA Makhteshim Ltd, Report No. FR20FPHORVW501A GEP Unpublished	N	Y	New study	ADM
KCP 6.4-308	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on winter barley, in France 2020 Staphyt, France, Report No. JFT-20-46078-FR02 ADAMA Makhteshim Ltd, Report No. FR20FPHORVW501B GEP Unpublished	N	Y	New study	ADM
KCP 6.4-309	Flahaut, J.	2020	Evaluate of the influence of ADM.03503.F.1.A and ADM.02154.F.2.C on the quality of beer making on winter barley, in France 2020 Staphyt, France, Report No. JFT-20-46078-FR03 ADAMA Makhteshim Ltd, Report No. FR20FPHORVW501C GEP Unpublished	N	Y	New study	ADM
KCP 6.4-310	Gless, A.E.	2019	Study of unintentional effects of ADM.02154.F.2.C and ADM.03503.F.1.A products applied on winter and spring barley, harvest 2020, on malt and beer quality and process IFBM, France, Report No. R-A-F-1144 ADAMA Makhteshim Ltd, Report No. R-A-F-1144 GEP Unpublished	N	Y	New study	ADM
KCP 6.4-311 Submitted under KCP 6.2-270	Brauna-Morzevska, E	2021	Efficacy of ADM.03503.F.1.A for <i>Blumeria graminis</i> (ERYSGR) control in winter triticale in Latvia in 2021 Latvian Plant Protection Research Centre, LV21FETTLSS461A ADAMA Makhteshim Ltd, Report No. LV21FETTLSS461A GEP Unpublished	N	Y	New study	ADM