FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: BAS 765 00 F

Product name(s): Daxur

Chemical active substance(s):

Mefentrifluconazole 100 g/L

Kresoxim-methyl 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: December 2020

MS Finalisation date: 23/02/2022

Version history

When	What
12/2020	Initial dRR – BASF DocID 2020/2032157
02/2021	Dossier sent for evaluation to Merit Mark (PL)
08/2021	zRMS finalised evaluation
11/2021	Evaluation after commenting period - RR
02/2022	Additional comments and the final evaluation

Table of Contents

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

Transformation of the dRR (applicant version) into the RR (zRMS version)

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

Comments of zRMS:	Conclusions from the assessment were prepared using grey commenting boxes placed at the end of each chapter. The parts of the text amended or added by the zRMS evaluator are highlighted in grey and the parts struck off are ~~visibly marked with the grey front~~. .

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

Abstract

zRMS

The submitted efficacy data (reports from field trials) fulfil requirements and conditions determined in the EPPO guidelines, the Commission Regulation (EU) No 545/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for plant protection products. The reports and data were submitted to support the evaluation for the authorization of BAS 765 00 F in NE EPPO climatic zone, SE EPPO climatic zone and Maritime EPPO climatic zone.

BAS 765 00 F contains 100 g/L of the new active substance - mefentrifluconazole, 150 g/L of the active substance kresoxim-methyl and is formulated as a suspension concentrate (SC). The plant protection product is used in cereals as fungicide for the control of a wide range of diseases at a dose rate of 0,6 L/ha and 1,0 L/ha with maximum 2 application in season when required.

The applicant submitted 113 reports showing the results in research into product efficacy carried out in 2018, 2019 and 2020 in NE, SE and Maritime EPPO climatic zones, on cultivars of:
- winter wheat (69 trials) against: (SEPTTR) *Zymoseptoria tritici*, (PUCCRT) *Puccinia triticina*, (ERYSGR) *Blumeria graminis*, (PYRNTR) *Pyrenophora tritici-repentis*, (FUSASP) - *Fusarium spp*., (PSDCHE) *Oculimacula spp*.;
- winter and spring barley (30 trials) against: (PYRNTE) *Pyrenophora teres*, (PUCCHD) *Puccinia hordei*, (ERYSGR) *Blumeria graminis*;
- winter triticale (7 trials) against (SEPTSP) *Septoria spp*., (PUCCRE) *Puccinia recondita*;
- rye (7 trials) against (PUCCRE) *Puccinia recondita*

to supports the registration of BAS 765 00 F in countries within the Central registration zone: PL, CZ, HU, RO, SI and SK.

The effectiveness of the product was describe according to the following scale:
≥ 80% – Effectively controlled **(E)**
60 – 80% – Medium effectively controlled **(ME)**
0 – 60% – Limiting the number of pest **(R)**

At the stage of the product commenting, the Applicant asked about evaluation 1 additional trial to prove possibility of using the water volume range 100-300 l/ha. That 1 additional report was evaluated and dRR

was changed accordingly (GAP table).

NE EPPO climatic zone (Poland)

winter wheat at a dose rate 1,0 L/ha	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **ERYSGR** *Blumeria graminis* **(E)** • **PSDCHE** *Oculimacula yallundae* **(E)**
spring wheat at a dose rate 1,0 L/ha	• **SEPTTR** ***Zymoseptoria tritici*** **(ME)** • **ERYSGR** ***Blumeria graminis*** **(E)**
winter barley at a dose rate 1,0 L/ha	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)**
spring barley at a dose rate 1,0 L/ha	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)**
winter triticale at a dose rate 1,0 L/ha	• **SEPTSP** *Septoria spp.* **(E)** • **PUCCRE** *Puccinia recondita* **(E)**
rye at a dose rate 1,0 L/ha	• **PUCCRE** *Puccinia recondita* **(E)**

Results from efficacy trials demonstrate that BAS 765 00 F at the dose rate 1,0 L/ha is a good alternative to standard fungicides for the control of several diseases in cereals. The product showed a rapid and long-lasting effect. Maximum number of applications in one season is 2, with a minimum of 14 days between applications and between growth stages 30-69. For wheat, triticale and rye, if first application is done after BBCH 49 a minimal spray interval has to be 21 days. For PSDCHE application time is BBCH 30-32 of wheat.

The evaluation of minor uses (*Triticum durum* and *Triticum spelta L.*) was not performed. In case of art. 33 of PPPR authorization the Applicant needs to present efficacy data. For the purpose of BAS 765 00 F authorization any efficacy data for minor uses were not presented by the Applicant.
In the GAP table, the Applicant asked for registration of the product also for protection of TRZAS, TTLSO. In accordance with the extrapolation rules set by Polish Ministry of Agriculture and Rural Development results from winter wheat can be extrapolated to spring wheat, winter and spring triticale. Nevertheless, according to the principles of extrapolation, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. Therefore, to support efficacy of spring wheat and spring triticale, the number 1-2 trials for the above-mentioned diseases must be submitted.

At the stage of the product commenting, the Applicant asked about evaluation 2 additional trials for spring wheat carried out in North-East EPPO zone. Those two additional reports were evaluated and dRR was changed accordingly.

SE EPPO climatic zone (Hungary, Slovakia Slovenia, Romania)

crop	dose rate 0,6 L/ha	dose rate 1,0 L/ha
winter wheat	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **ERYSGR** *Blumeria graminis* **(ME)** • **PYRNTR** *Pyrenophora tritici-repentis* **(ME)** • **PSDCHE** *Oculimacula yallundae* **(ME)**	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **ERYSGR** *Blumeria graminis* **(E)** • **PYRNTR** *Pyrenophora tritici-repenti* **(E)** • **PSDCHE** *Oculimacula yallundae* **(E)** • **FUSASP** *Fusarium spp* **(ME)**
winter barley	• **PYRNTE** *Pyrenophora teres* **(E)** • **ERYSGR** *Blumeria graminis* **(ME)**	• **PYRNTE** *Pyrenophora teres* **(E)** • **ERYSGR** *Blumeria graminis* **(E)**
spring barley	• **PYRNTE** *Pyrenophora teres* **(ME)** • **ERYSGR** *Blumeria graminis* **(ME)**	• **PYRNTE** *Pyrenophora teres* **(E)** • **ERYSGR** *Blumeria graminis* **(E)**
winter triticale	• **SEPTSP** *Septoria spp.* **(E)** • **PUCCRE** *Puccinia recondita* **(E)**	• **SEPTSP** *Septoria spp.* **(E)** • **PUCCRE** *Puccinia recondita* **(E)**
rye	• **PUCCRE** *Puccinia recondita* **(E)**	• **PUCCRE** *Puccinia recondita* **(E)**

Results from efficacy trials demonstrate that BAS 765 00 F at the dose rate 0,6 L/ha and 1,0 L/ha is a good alternative to standard fungicides for the control of several diseases in cereals. The product showed a rapid and long-lasting effect. Maximum number of applications in one sea-son is 2, with a minimum of 14 days between applications and between growth stages 30-69. For wheat, triticale and rye, if first application is done after BBCH 49 a minimal spray interval has to be 21 days. For PSDCHE application time is BBCH 30-32 of wheat.

In the GAP table, the Applicant asked for registration of the product also for protection of TRZAS, TRZDU, TRZSP, SECCS, TTLSO. Results from winter wheat might be extrapolated to TRZAS, TRZDU, TRZSP, SECCS TTLSO. Nevertheless, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. The zRMS will leave it to the decision of SE EPPO climatic zones Member States (cMS).

Maritime EPPO climatic zone (Czech Republic)

crop	dose rate 0,6 L/ha	dose rate 1,0 L/ha
winter wheat	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **ERYSGR** *Blumeria graminis* **(ME)** • **PSDCHE** *Oculimacula yallundae* **(ME)**	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **ERYSGR** *Blumeria graminis* **(E)** • **PSDCHE** *Oculimacula yallundae* **(E)**
winter barley	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)**	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)**
spring barley	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)**	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)**
winter triti-cale	• **SEPTSP** *Septoria spp.* **(E)** • **PUCCRE** *Puccinia recondita* **(E)**	• **SEPTSP** *Septoria spp.* **(E)** • **PUCCRE** *Puccinia recondita* **(E)**
rye	• **PUCCRE** *Puccinia recondita* **(E)**	• **PUCCRE** *Puccinia recondita* **(E)**

Results from efficacy trials demonstrate that BAS 765 00 F at the dose rate 0,6 L/ha and 1,0 L/ha is a good alternative to standard fungicides for the control of several diseases in cereals. The product showed a rapid and long-lasting effect. Maximum number of applications in one sea-son is 2, with a minimum of 14 days between applications and between growth stages 30-69. For wheat, triticale and rye, if first application is done after BBCH 49 a minimal spray interval has to be 21 days. For PSDCHE application time is BBCH 30-32 of wheat.

In the GAP table, the Applicant asked for registration of the product also for protection of TRZAS, TRZDU, TRZSP, TTLSO. Results from winter wheat might be extrapolated to TRZAS, TRZDU, TRZSP, TTLSO. Nevertheless, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. The zRMS will leave it to the decision of SE EPPO climatic zones Member States (cMS).

The applicant provided full information on the prevalence of resistance to both active substances in UE and in third countries. A robust risk analysis was performed to define a strategy for managing the risk of resistance to both active substances contained in the product BAS 765 00 F. The presented strategy complies with the resistance management strategy recommended by FRAC. Nevertheless in case any new information which would change the resistance risk analysis regulatory authorities should be informed about it.

BAS 765 00 F was safe to the crops on which it was applied as no phytotoxicity symptoms were observed in the efficacy tests. The product did not cause a negative impact on the yield of winter wheat, winter and spring barley, winter triticale, rye in the presence and of disease and in the absence of disease (2 trials for wheat).
The product BAS 765 00 F had no negative effect on wheat quality and the processing procedure for bread-making as well as on barley quality and processing procedure for malting and brewing barley and was safe

for the germination of the grains of treated crops.
No problems is going to be linked to BAS 765 00 F use in succeeding and adjusted crops, if product uses in accordance with the recommendations.
The two-stage cleaning of the field sprayer with water immediately after using the BAS 765 00 F is a sufficient tank cleaning procedure. Protective clothing will be cleaned effectively when washed with usual laundry detergents.
BAS 765 00 F is chemically compatible with the tested tank mix partners.

According to the above, the plant protection product BAS 765 00 F is recommended to be approved to use according to the table of intended uses for BAS 765 00 F. The evaluation was carried out in accordance with the Uniform Principles.

MRiRW asked for additional explanation supporting two applications in one season and safety of the crops when product applied 2 times in one season.

The product Daxur is proved to be efficacious when applying one dose rate in a season. Nevertheless product may be applied second time during the season when it is required, because for example of pressure another disease. Minimal interval between applications of 14 days or 21 days if first application is done after BBCH 49 have to be maintained. The phytotoxicity and yield was check for a double application of the product on winter barley (2 trials: DEV-F-2018-HU-C35-A-03.0-HU-HU0-SY2 oraz DEV-F-2018-SK-C35-A-03.0-SK-SK0-L09) and on winter wheat (one trial - DEV-F-2020-EX-CW1-V-04.0-DE-VTF-440). There were no symptoms of phytotoxicity nor the product cause a negative impact on the yield of tested crops. What is more in the test concerning germination of the grains of treated crops, it was found that treating cereals (winter wheat and winter barley) twice with the product had no effect on the germination of the harvested seeds.
Taking into account the above, it can be concluded that the product used in the second application in one season will not pose a risk to the crops - specified in the GAP table.

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. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap-plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or 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	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP	F	*Blumeria graminis* - ERYSGR *Zymoseptoria tritici* - SEPTTR *Puccinia triticina* - PUCCRT *Oculimacula* spp - PSDCHE	SP	30-69	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 - 300	35	*if first appl. after BBCH 49; min. 21 days spray interval. PSDCHE (= Eyespot): application BBCH 30-32	C
2	CZ	barley HORVW HORVS	F	*Puccinia hordei* - PUCCHD *Pyrenophora teres* - PYRNTE	SP	30-49	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 -300	35		C
3	CZ	rye SECCW SECCS SECCE	F	*Puccinia recondita* - *PUCCRE*	SP	30-69	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval.	C
4	CZ	triticale TTLWI TTLSO	F	*Septoria spp.* - *SEPTSP* *Puccinia recondita* - *PUCCRE*	SP	30-69	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval.	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap-plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
5	PL	wheat TRZAW, ~~TRZAS TRZDU, TRZSP~~	F	*Blumeria graminis* - ERYSGR *Zymoseptoria tritici* – SEPTTR *Puccinia triticina* - PUCCRT *Oculimacula* spp - PSDCHE	SP	30-69	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 -100 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval. PSDCHE (= Eyespot): application BBCH 30-32	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap-plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
6	PL	wheat, TRZAS	F	*Blumeria graminis* - *ERYSGR* *Zymoseptoria tritici* – *SEPTTR*	SP	30-69	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	100 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval.	A
7	PL	barley HORVW HORVS	F	*Puccinia hordei* - PUCCHD *Pyrenophora teres* - PYRNTE	SP	30-49	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 -300	35		A
8	PL	rye SECCW SECCS SECCE	F	*Puccinia recondita* - *PUCCRE*	SP	30-69	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval.	A
9	PL	triticale TTLWI ~~TTLSO~~	F	*Septoria spp.* - *SEPTSP* *Puccinia recondita* - *PUCCRE*	SP	30-69	a) 2 b) 2	14	a) 1.0 b) 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval.	A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap-plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
10	HU, SK, SI, RO	wheat TRZAW, TRZAS TRZDU, TRZSP	F	*Blumeria graminis* - ERYSGR *Zymoseptoria tritici* - SEPTTR *Puccinia triticina* - PUCCRT *Oculimacula* spp - PSDCHE *P. tritici-repentis* - *PYRNTR* *Fusarium spp.* *FUSASP*	SP	30-69	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval. Fusarium Head Blight control, only one appl. at BBCH 61-69 FUSASP - dose rate only 1.0 L/ha PSDCHE (= Eyespot): application BBCH 30-32	C
11	HU, SK, SI, RO	barley HORVW HORVS	F	*Blumeria graminis* - ERYSGR *Pyrenophora teres* - PYRNTE	SP	30-49	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 -300	35		C
12	HU, SK, SI, RO	rye SECCW SECCS	F	*Puccinia recondita* - *PUCCRE*	SP	30-69	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval.	C
13	HU, SK, SI, RO	triticale TTLSS	F	*Septoria spp.* - *SEPTSP* *Puccinia recondita* - *PUCCRE*	SP	30-69	a) 2 b) 2	14	a) 0.6 - 1.0 b) 0.6 - 2.0	a) 0.100/ 0.150 b) 0.200/ 0.300	~~100~~200 - 100 -300	35	*if first appl. after BBCH 49; min. 21 days spray interval.	C

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ****	**Pests or Group of pests controlled** (additionally: develop-mental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between ap-plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max			
Minor uses according to Article 51 (field uses)														
13														
14														

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

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

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

This dossier supports the registration of BAS 765 00 F in countries within the Central registration zone (CZ, HU, PL, RO, SI and SK). Poland was selected as zRMS in charge of the evaluation of the dossier.
BAS 765 00 F is a foliar fungicide containing two active substances: mefentrifluconazole (100 g/L) and kresoxim-methyl (150 g/L) as a suspension concentrate (SC).
BAS 765 00 F is a fungicide to be used in cereals (wheat, barley, triticale and rye). The targets for the use of BAS 765 00 F are the diseases: *Zymoseptoria tritici*, *Septoria* spp., *Puccinia* spp., *Pyrenophora tritici-repentis*, *Pyrenophora teres*, *Oculimacula* spp., *Blumeria graminis* and *Fusarium* spp.

Description of active substances

Mode of action

Mefentrifluconazole (BAS 750 F) is a fungicide belonging to the group of the sterol biosynthesis inhibitors (SBI, mode of action class G). Within the SBIs, it belongs to the sub group of demethylation inhibitors (DMI, G1, FRAC 2017) and the chemical group of triazoles.
The primary mode of action of DMIs is the blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol 14α-demethylase (CYP51). The depletion of ergosterol and accumulation of non-functional 14α-methyl sterols results in inhibition of growth and cell membrane disruption.
Mefentrifluconazole is the first isopropanol azole: the triazole 'head' sits on the 'neck' of a slim isopropanol linker. This chemical constellation ensures a high degree of structural flexibility that is unique among the DMI linkers. This slim isopropanol linker requires less energy to adjust its conformation compared to conventional DMIs. When mefentrifluconazole approaches the active site of its target enzyme, the flexible linker allows it to form a hook, which fits into the enzyme's binding pocket, resulting in strong inhibition of enzyme activity. This might explain the high intrinsic activity of mefentrifluconazole on the target enzyme, which has been shown in studies with the CYP51 of *Zymoseptoria tritici* in comparison with other DMIs.
In the formulation BAS 765 00 F, mefentrifluconazole is active against different fungal stages both on the plant surface and in the plant tissue. After application to the plant, the active ingredient is taken up via the leaf and slowly but consistently translocated apically via the transpiration flow. The limited translocation leads to a formation of inner-leaf reservoirs which allow a well-balanced, long lasting systemic activity. As a result, mefentrifluconazole can control fungal stages which have already become established in deeper tissue layers of the plant (curative activity). Furthermore, mefentrifluconazole shows an impressive residual activity, as the majority of leaf deposits are well-protected in the inner leaf. Since the vapour pressure of mefentrifluconazole is very low, a gas phase activity was not observed.

Kresoxim-methyl (BAS 490 F), belongs to the strobilurin group of fungicides (QoIs – quinone outside inhibitors), FRAC Code C3, and the mode of action is the inhibition of mitochondrial respiration resulting from a blockage of the electron transport from ubihydroquinone to cytochrome c by means of a binding to the ubihydroquinone oxidation center (Qo) of the cytochrome bc1 complex (Complex III). This leads to a reduction of energy-rich ATP that is available to support a range of essential processes in the fungal cell. Kresoxim-methyl is a fungicide having protective, curative and eradicative action. The active substance inhibits the spore germination and controls mycelium growth and sporulation. The current use recommendation is strictly preventively linked to the FRAC use guidelines for QoI fungicides.

Table 3.2-1: Details of the active substances

Active ingredient	**Mefentrifluconazole**	**Kresoxim-methyl**
CAS number:	1417782-03-6	143390-89-0
IUPAC name:	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	methyl (E)-methoxyimino[α-(o-tolyloxy)-o-tolyl]acetate
Molecular weight:	397.8 g/mol	313.8 g/mol
Chemical formula:	$C_{18}H_{15}ClF_3N_3O_2$	$C_{18}H_{19}NO_4$
Chemical group:	Triazoles / Isopropanol-azoles	Strobilurin
Mode of action:	blocking of ergosterol biosynthesis demethylation inhibiton (DMI)	inhibition of mitochondrial respiration
Plant translocation:	Systemic	Local systemic
Biological action:	Fungicide with preventative and curative properties	Fungicide with preventative and curative properties
Resistance group:	G1/DMI-fungicides	C3/QoI-fungicides

Description of the plant protection product

BAS 765 00 F is a novel fungicide containing 100 g/l mefentrifluconazole and 150 g/l kresoxim-methyl as a suspension concentrate (SC). BAS 765 00 F is intended for use as a foliar spray in wheat, barley, triticale and rye against the diseases *Zymoseptoria tritici, Septoria* spp., *Puccinia* spp., *Pyrenophora tritici-repentis, Pyrenophora teres, Oculimacula* spp., *Blumeria graminis* and *Fusarium* spp.
The applications should be made between growth stages 30-49 BBCH of barley and 30-69 BBCH of the other cereal crops. Maximum two applications could be made in the crop with a maximum dose rate per treatment of 1.0 L/ha.

Table 3.2-2: Simplified table of requested uses for BAS 765 00 F

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	**Target(s)**			
Wheat	*Zymoseptoria tritici*	CZ, PL, HU, RO, SK, SI	0.6-1.0 L/ha	*For N-E EPPO zone dose rate 1.0 L/ha only **For FUSASP dose rate 1.0 L/ha only
	Puccinia triticina	CZ, PL, HU, RO, SK, SI		
	Blumeria graminis	CZ, PL, HU, RO, SK, SI		
	Pyrenophora tritici-repentis	HU, RO, SK, SI		
	Oculimacula spp.	CZ, PL, HU, RO, SK, SI		
	Fusarium spp.	HU, RO, SK, SI		
Barley	*Pyrenophora teres*	CZ, PL, HU, RO, SK, SI		
	Puccinia hordei	CZ, PL		
	Blumeria graminis	HU, RO, SK, SI		
Triticale	*Septoria* spp.	CZ, PL, HU, RO, SK, SI		
	Puccinia recondita	CZ, PL, HU, RO, SK, SI		
Rye	*Puccinia recondita*	CZ, PL, HU, RO, SK, SI		

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

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

EPPO code	Scientific name	Common name
ERYSGR	*Blumeria graminis*	Powdery mildew of wheat
FUSASP	*Fusarium* spp.	Ear blight of wheat
PSDCHE	*Oculimacula* spp.	Eyespot of wheat
PUCCRT	*Puccinia triticina*	Brown rust of wheat
PYRNTR	*Pyrenophora tritici-repentis*	Tan spot of wheat
SEPTTR	*Zymoseptoria tritici*	Septoria leaf blotch of wheat
ERYSGR	*Blumeria graminis*	Powdery mildew of barley
PYRNTE	*Pyrenophora teres*	Net blotch of barley
PUCCHD	*Puccinia hordei*	Brown rust of barley
PUCCRE	*Puccinia recondita*	Brown rust of rye
PUCCRE	*Puccinia recondita*	Brown rust of triticale
SEPTSP	*Septoria* spp.	Septoria leaf blotch of triticale

Table 3.2-4: Major / minor status of intended uses (for all cMS and zRMS)

Crop and/or situation	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		Major	minor
Wheat	CZ, PL, HU, RO, SK, SI	-	*Zymoseptoria tritici*	CZ, PL, HU, RO, SK, SI	-
			Puccinia triticina	CZ, PL, HU, RO, SK, SI	-
			Blumeria graminis	CZ, PL, HU, RO, SK, SI	-
			Pyrenophora tritici-repentis	HU, RO, SK, SI	-
			Oculimacula spp.	CZ, PL, HU, RO, SK, SI	-
			Fusarium spp.	HU, RO, SK, SI	-
Barley	CZ, PL, HU, RO, SK, SI	-	*Pyrenophora teres*	CZ, PL, HU, RO, SK, SI	-
			Puccinia hordei	CZ, PL	-
			Blumeria graminis	HU, RO, SK, SI	-
Triticale	CZ, PL, HU, SK, SI	RO	*Septoria* spp.	CZ, PL, HU, SK, SI	RO
			Puccinia recondita	CZ, PL, HU, SK, SI	RO
Rye	CZ, PL, HU, SK, SI	RO	*Puccinia recondita*	CZ, PL, HU, SK, SI	RO

Compliance with the Uniform Principles

All of the efficacy trials used in this dossier are performed according to GEP and EPPO Guidelines.
In section 3.7 of this dossier the list of test facilities is included.
The same set of efficacy trials were used for sections: Minimum effective dose tests (3.2.2), Efficacy tests (3.2.3), Yield and quality in presence of disease (3.2.3), Phytotoxicity to host crop (3.4.1).
Details on the trial methodologies and performance of the efficacy trials are given in section 3.2.3 Efficacy tests (KCP 6.2) in text and tabular form.

Information on trials submitted (3.1 Efficacy data)

The same set of 113 efficacy trials are used for sections: Minimum effective dose tests (3.2.2), Efficacy tests (3.2.3), Yield and quality in presence of disease (3.2.3), Phytotoxicity to host crop (3.4.1).

Table 3.2-5: Presentation of trials

Crop(s) *	Country	Years	Number of trials			GEP, non-GEP ***
			Maritime	North-East	South-East	
Winter wheat	Austria	2019	1			GEP
	Czech Rep.	2019	2			GEP
		2020	2			
	Germany	2019	2			GEP
	France	2019	1			GEP
	UK	2019	3			GEP
	Poland	2018		6		GEP
		2019		15		GEP
	Bulgaria	2018			4	GEP
		2019			9	GEP
	Hungary	2018			3	GEP
		2019			2	GEP
		2020			2	GEP
	Romania	2018			3	GEP
		2019			6	GEP
	Slovakia	2018			3	GEP
		2019			5	GEP
	TOTAL	2018-2020	**11**	**21**	**37**	**69**
Winter barley	Poland	2018		1		GEP
		2019		10		GEP
	Bulgaria	2018			2	GEP
		2019			4	GEP
	Hungary	2018			1	GEP
	Romania	2019			2	GEP
	Slovakia	2018			1	GEP
		2019			2	GEP
	TOTAL	2018-2019		**11**	**12**	**23**
Spring barley	Poland	2018		3		GEP
		2019		3		GEP
	Slovakia	2019			1	GEP
	TOTAL	2018-2019		**6**	**1**	**7**
Triticale	Germany	2020	3			GEP
	Poland	2020		4		GEP
	TOTAL	2020	**3**	**4**		**7**
Rye	Germany	2020	4			GEP
	Poland	2020		3		GEP
	TOTAL	2020	**4**	**3**		**7**
GRAND TOTAL		2018-2020	**18**	**45**	**50**	**113**

Table 3.2-6: Presentation of reference standards used in trials

Crop(s)	Reference standard	Country(ies) where the product is registered	Authorization number	Active substance(s)	Formulation		Registered application rate	Application rate in trials (per treatment)
					Type	Conc. of a.s.		
TRZAW HORVX TTLWI SECCE	Proline BAS 93141 F	Austria Belgium Czech Republic Germany Ireland Latvia Lithuania Romania Slovakia UK	3771/0 9805P/B 4523-1 025287-00 03786 0637 AS2-6F(2018) 457PC 06-02-0768 12084	prothioconazole	EC	250 g/L	0.8 L/ha 0.8 L/ha 0.8 L/ha 0.8 L/ha 0.8 L/ha 0.6-0.8 L/ha 0.8 L/ha 0.8 L/ha 0.6-0.8 L/ha 0.8 L/ha	0.8 L/ha
	Proline 275 BAS 93144 F	UK	14790	prothioconazole	EC	275 g/L	0.72 L/ha	0.72 L/ha

Comments of zRMS:	This report summarizes the information concerning the efficacy of the plant protection product BAS 765 00 F. The product contains 100 g/L of the new active substance mefentrifluconazole, 150 g/L of the active substance kresoxim-methyl and is formulated as a suspension concentrate (SC). It is used as fungicide in cereals. The reports and data were submitted to support of the evaluation of the authorization BAS 765 00 F in Central Zone: Czech Republic, Poland, Hungary, Slovakia, Slovenia, Romania. The active substance mefentrifluconazole is included in the Annex to Commission Implementing Regulation (EU) No 540/2011 containing the active substances approved for use in plant protection products under Regulation (EC) No 1107/2009 with the expiration of approval on 20/03/2029. According to general provisions applying to all substances listed in the Annex to commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No1107/2009 of the European Parliament and of the Council as regards the list of approved active substances specific provisions of Regulation (EU) No 540/2011 were as follows: For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on mefentrifluconazole, and in particular Appendices I and II thereof, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment; — the protection of aquatic organisms. Conditions of use shall include risk mitigation measures, such as buffer zones and/or vegetative strips, where appropriate. The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards: 1. the technical specification of the active substance as manufactured (based on commercial scale production) and the compliance of the toxicity batches with the confirmed technical specification; 2. the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or ground water is abstracted for drinking water. The applicant shall submit the information referred to in point 1 by 20 March 2020 and the information referred to in point 2 within two years from the date of publication, by the Commission, of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

	The active substance kresoxim-methyl is included in the Annex to Commission Implementing Regulation (EU) No 540/2011 containing the active substances approved for use in plant protection products under Regulation (EC) No 1107/2009 with the expiration of approval on 31/12/2024. According to general provisions applying to all substances listed in the Annex to commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No1107/2009 of the European Parliament and of the Council as regards the list of approved active substances specific provisions of Regulation (EU) No 540/2011 were as follows: Only uses as fungicide may be authorised. In their decision making according to the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, Member States shall pay particular attention to the protection of groundwater under vulnerable conditions. Date of Standing Committee on Plant Health at which the review report was finalised: 16 October 1998. Appendix 1 of this document contains the list of data considered in support of the evaluation. Table 3.1-1 of this document contains the table of intended uses for BAS 765 00 F.

3.2.1 Preliminary tests (KCP 6.1)

Ratio and Co-formulation justification

BAS 765 00 F consists of mefentrifluconazole and kresoxim-methyl.

Mefentrifluconazole is a novel demethylase-inhibitor fungicide (“DMI”, FRAC code G1) with excellent activity against Septoria leaf blotch and brown rust in wheat and good activity against several other diseases.

Kresoxim-methyl is a strobilurin fungicide (“QoI”, FRAC code C3) with known efficacy against several cereal diseases such as Septoria leaf blotch, powdery mildew, eyespot and net blotch. The active ingredient is part of several co-formulations and as of today registered in a broad range of countries (Table 3.2-7).

However, all those products contain epoxiconazole as an alternative partner mode of action. Epoxiconazole is classified since 2015 as reprotoxic cat. 1B and therefore fulfils a cut-off criterion according to regulation EC 1107/2009. Recently, BASF has withdrawn the registration of epoxiconazole, therefore, epoxiconazole containing products will no longer be available for disease control in cereals.

To continuously utilize kresoxim-methyl as valuable active ingredient for cereals, the co-formulation BAS 765 00 F was developed for cereals: Mefentrifluconazole replaces as novel and highly effective triazole the epoxiconazole as complementary partner active ingredient to kresoxim-methyl.

Table 3.2-7: Product registrations with kresoxim-methyl in cereal crops in Europe

Country	Tradename	Active ingredients	Formulation		Authorisation	crops
			Type	Conc.	No.	
BULGARIA	ALEGRO	Epoxiconazole + Kresoxim-methyl	SC	125+125 G/L		cereals
CROATIA	CONTROLAN	Epoxiconazole + Kresoxim-methyl	SC	125+125 G/L	UP/I32020980126	cereals
HUNGARY	JUWEL	Epoxiconazole + Kresoxim-methyl	SC	125+125 G/L	432	cereals
NETHERLANDS	ALLEGRO	Epoxiconazole + Kresoxim-methyl	SC	125+125 G/L	W2-11826	cereals
POLAND	ALLEGRO 250 SC	Epoxiconazole + Kresoxim-methyl	SC	125+125 G/L	R-98/2014	cereals
SLOVAKIA	JUWEL	Epoxiconazole + Kresoxim-methyl	SC	125+125 G/L	98-02-0405	cereals
SWITZERLAND	JUWEL	Epoxiconazole + Kresoxim-methyl	SC	125+125 G/L	D-3832	cereals
CZECH REP.	ALLEGRO PLUS	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	125+150+125 G/L	4281-1	cereals
GERMANY	JUWEL TOP	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	125+150+125 G/L	024437-00	cereals
IRELAND	ALLEGRO PLUS	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	125+150+125 G/L	2371	cereals
SLOVAKIA	ALLEGRO PLUS	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	125+150+125 G/L	14-02-1485	cereals
ESTONIA	ALLEGRO SUPER	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	83+317+83 G/L	317	cereals
LATVIA	ALLEGRO SUPER	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	83+317+83 G/L	270	cereals
LITHUANIA	ALLEGRO SUPER	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	83+317+83 G/L	AS2-38F(2019)	cereals
POLAND	JUWEL TT 483 SE	Epoxiconazole + Fenpropimorph + Kresoxim-methyl	SE	83+317+83 G/L	R-53/2012	cereals

Justification of BAS 765 00 F

In 2017, trials were conducted to find the best kresoxim-methyl dose rate for the control of major target diseases. The results show overall moderate activity of kresoxim-methyl, which could be enhanced by using the higher dose rate of 150 gai/ha; but the standard could not be matched in average across all results (Table 3.2-8).

Table 3.2-8: Efficacy of kresoxim-methyl at different dose rates against major target diseases

Target	Number of trials	Infestation of the untreated control [% severity of attack]			[% efficacy] kresoxim-methyl 100 g ai/ha			kresoxim-methyl 150 g ai/ha			prothioconazole 0.8 l/ha Proline 200 g ai/ha		
		Mean	Min	Max	**Mean**	Min	Max	**Mean**	Min	Max	**Mean**	Min	Max
Eyespot of wheat *Oculimacula* spp.	9	**32**	17	51	**40**	15	93	**42**	15	100	**46**	0	99
Septoria leaf blotch of wheat *Zymoseptoria tritici*	9	**18**	5	48	**56**	52	86	**64**	55	92	**76**	42	89
Net blotch of barley *Pyrenophora teres*	13	**43**	7	100	**54**	23	90	**62**	25	91	**82**	58	97

The combined effect of the target dose rate of 150 gai/ha kresoxim-methyl in mix with mefentrifluconazole was investigated in 2019 against several target diseases. Besides comparison with both solo compounds, the ready-mixed co-formulation BAS 765 00 F was evaluated in comparison to the standard Proline. Details to the tested compounds are shown in Table 3.2-9.

Table 3.2-9: Products used to evaluate the activity of mefentrifluconazole and kresoxim-methyl against major target diseases

Product	Active ingredients	Formulation		Tested rate	
BAS 750 02 F	Mefentrifluconazole	400 g/l	SC	0.25 l/ha	100 g/ha
BAS 490 14 F	Kresoxim-methyl	500 g/l	SC	0.3 l/ha	150 g/ha
BAS 765 00 F	Mefentrifluconazole + Kresoxim-methyl	100 g/l +150 g/l	SC	0.6 l/ha	60 g/ha +90 g/ha
				vs. 1.0 l/ha	**100 g/ha +150 g/ha**
Revystar (BAS 750 01 F)	Mefentrifluconazole	100 g/l	EC	1.5 l/ha	150 gai/ha
Proline (BAS 9314 1F)	Prothioconazole	250 g/l	EC	0.8 l/ha	200 g/ha

The results show a moderate activity for both kresoxim-methyl at 150 gai/ha and mefentrifluconazole at 100 gai/ha against the target diseases (Table 3.2-10). Nevertheless, by combining both mefentrifluconazole and kresoxim-methyl at same rates as in the target dose rate of 1.0 l/ha BAS 765 00 F, the product shows enhanced performance of close to or above 80% efficacy (Table 3.2-10).
Thus, the efficacy of the final product is better than the standard Proline at 0.8 l/ha.
Furthermore, in the combination of mefentrifluconazole and kresoxim-methyl at 1.0 l/ha BAS 765 00 F, a better efficacy was achieved when compared to the full registered rate of 150g/ha mefentrifluconazole in Revystar (1.5 l/ha).

Table 3.2-10: Solo and combined efficacy of mefentrifluconazole and kresoxim-methyl against major target disease in cereals.

Target	Number of trials	Infestation of the untreated control [% severity of attack]			[% efficacy] mefentrifluconazole SC 100 g ai/ha			kresoxim-methyl SC 150 g ai/ha			mefentrifluconazole + kresoxim-methyl SC **0.6 l/ha BAS 765 00 F** 60 + 90 g ai/ha			mefentrifluconazole + kresoxim-methyl SC **1.0 l/ha BAS 765 00 F** 100 + 150 g ai/ha			mefentrifluconazole EC 1.5 l/ha Revystar 150 gai/ha			prothioconazole EC 0.8 l/ha Proline 200 g ai/ha		
		Mean	Min	Max	**Mean**	Min	Max	**Mean**	Min	Max	**Mean**	Min	Max	**Mean**	Min	Max	**Mean**	Min	Max	**Mean**	Min	Max
Septoria leaf blotch of wheat *Zymoseptoria tritici*	9	**21**	6	68	**66**	35	100	**55**	18	88	**65**	43	80	**81**	66	100	**77**	52	98	**72**	55	91
Net blotch of barley *Pyrenophora teres*	13	**23**	5	73	**69**	41	99	**71**	47	100	**74**	49	100	**81**	63	100	**78**	50	99	**79**	59	98
Powdery mildew *Erysiphe graminis*	10	**17**	6	37	**62**	26	75	**63**	36	81	**65**	17	79	**79**	54	92	**73**	38	93	**79**	35	93
Eye spot of wheat *Oculimacula spp.*	5	**25**	15	50	**69**	48	88	**64**	35	89	**74**	60	95	**87**	68	100	**74**	51	96	**81**	63	100

Conclusions

- Although both active ingredients show only moderate activity against the target diseases if used as solo compounds, the combination of both active ingredients in BAS 765 00 F resulted into superior activity, especially with the higher dose rate of 1.0 l/ha. The lower rate of 0.6 l/ha resulted in a lower performance compared to the full rate, but still shows satisfactory control, in most cases better than the single active ingredients.
- As both active ingredients contribute to efficacy against the target diseases, lower amounts than the registered dose rates of each individual active ingredient could be utilized.
- The combination of 100 g/ha mefentrifluconazole and 150 g/ha kresoxim-methyl (in 1.0 l/ha BAS 765 00 F) showed superior efficacy compared to a full target dose rate of 150 g/ha mefentrifluconazole (in 1.5 l/ha Revystar).
- With the target dose rate of 1.0 l/ha BAS 765 00 F, a very consistent high level of performance could be achieved.

Bridging trials (KCP 6.1)

Efficacy data with the final formulation, BAS 765 00 F, are available for trials conducted in 2019. In 2018, the very similar formulation BAS 765 AB F was used. The detailed comparison of both formulations is given in confidential document of this submission. In order to demonstrate the equivalence in terms of fungicidal performance between these formulations and to relate the 2019 data with those from 2018 in many trials carried out in 2019 BAS 765 00 F was compared to BAS 765 AB F. The efficacy results generated from these trials are reported in the following tables of this section. Registration of dose rates 0.6 L/ha and 1.0 L/ha is proposed in Maritime and South-East EPPO zones. Therefore results for efficacy of both doses are presented for Maritime and South-East zones. Since in North-East zone registration of dose rate 1.0 L/ha is proposed, results of efficacy of this dose rate are presented. For more information please see **Błąd! Nie można odnaleźć źródła odwołania.**GAP table.

***Zymoseptoria tritici* (SEPTTR) septoria leaf blotch of wheat**

Data on wheat useful for bridging were generated in 9 trials in which efficacy against *Zymoseptoria tritici* was tested. Bridging data are available from North-East (7 trials) and South-East (2 trials) EPPO climatic zones.

Table 3.2-11: *Zymoseptoria tritici* (SEPTTR) in wheat – bridging data, summary

EPPO Zone		Untreated	BAS 765 00 F		BAS 765 AB F		Proline
			0.6 L/ha	1.0 L/ha	0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East	average	19.2	-	87.8	-	84.2	73.8
	min- max	5.9-42.2	-	75.0-100.0	-	72.6-94.7	54.0-99.4
	n	7	-	7	-	7	7
South-East	average	8.2	86.2	89.5	82.5	91.6	85.3
	min- max	8.0-8.5	80.0-92.5	85.8-93.1	71.0-94.1	88.1-95.0	80.3-90.3
	n	2	2	2	2	2	2
All zones	average	16.8	-	88.2	-	85.9	76.4
	min- max	5.9-42.2	-	75.0-100.0	-	72.6-95.0	54.0-99.4
	n	9	-	9	-	9	9

Average levels of *Zymoseptoria tritici* control in wheat were similar for BAS 765 00 F and BAS 765 AB F applied at full dose rate 1.0 L/ha (88% and 86% respectively). The same was recorded for both formulations applied in South-East zone at dose rate 0.6 L/ha (86% and 83% respectively). It is therefore evident that there is full equivalence of BAS 765 00 F and BAS 765 AB F in control of *Zymoseptoria tritici* in wheat.

***Puccinia triticina* (PUCCRT), brown rust of wheat**

Data on wheat useful for bridging were generated in 13 trials in which efficacy against *Puccinia triticina* was tested. Bridging data are available from North-East (7 trials) and South-East (6 trials) EPPO climatic zones.

Table 3.2-12: *Puccinia triticina* (PUCCRT) in wheat – bridging data, summary

EPPO Zone		Untreated	BAS 765 00 F		BAS 765 AB F		Proline
			0.6 L/ha	1.0 L/ha	0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East	average	15.0	-	90.6	-	91.9	78.2
	min-max	5.6-34.8	-	78.8-100.0	-	87.3-97.3	38.5-93.6
	n	7	-	7	-	7	7
South-East	average	17.3	89.7	93.4	88.7	93.4	90.9
	min-max	6.5-28.1	86.0-95.0	90.0-100.0	79.6-96.0	85.2-100.0	87.0-96.0
	n	6	6	6	6	6	6
All zones	average	16.0	-	91.9	-	92.6	84.1
	min-max	5.6-34.8	-	78.8-100.0	-	85.2-100.0	38.5-96.0
	n	13	-	13	-	13	13

Average levels of *Puccinia triticina* control in wheat were very similar for BAS 765 00 F and BAS 765 AB F applied at dose rate 1.0 L/ha (92% and 93% respectively). The same was recorded for both formulations applied in South-East zone at dose rate 0.6 L/ha (90% and 89% respectively). It is therefore evident that there is full equivalence of BAS 765 00 F and BAS 765 AB F in control of *Puccinia triticina* in wheat.

***Oculimacula* spp. (PSDCHE), Cereal eyespot**

Data on wheat useful for bridging were generated in 7 trials in which efficacy against *Oculimacula* spp was tested. Bridging data are available from Maritime (1 trial), North-East (2 trials) and South-East (4 trials) EPPO climatic zones.

Table 3.2-13: *Oculimacula* spp (PSDCHE) in wheat – bridging data, summary

EPPO Zone		Untreated	BAS 765 00 F		BAS 765 AB F		Proline
			0.6 L/ha	1.0 L/ha	0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	aver	15.5	74.2	96.8	74.2	93.5	82.3
	min-max	-	-	-	-	-	-
	n	1	1	1	1	1	1
North-East	aver	28.9	-	84.7	-	85.5	85.2
	min-max	25.5-32.3	-	78.3-91.2	-	83.7-87.3	78.3-92.2
	n	2	-	2	-	2	2
South-East	aver	30.0	70.2	84.0	73.4	82.4	79.4
	min-max	21.0-49.5	59.6-95.2	76.2-100.0	60.0-92.9	74.2-98.8	68.2-100.0
	n	4	4	4	4	4	4
All zones	aver	27.6	-	86.1	-	84.9	81.5
	min-max	15.5-49.5	-	76.2-100.0	-	74.2-98.8	68.2-100.0
	n	7	-	7	-	7	7

Average levels of *Oculimacula* spp. control in wheat were similar for BAS 765 00 F and BAS 765 AB F applied at dose rate 1.0 L/ha (86% and 85% respectively). The same was recorded for products applied at dose rate 0.6 L/ha in Maritime zone (74% for both formulations) and South-East zone (70% for BAS 765 00 F and 73% for BAS 765 AB F). It is therefore evident that there is full equivalence of BAS 765 00 F and BAS 765 AB F in control of *Oculimacula* spp. in wheat.

***Pyrenophora teres* (PYRNTE), net blotch of barley**

Data on barley useful for bridging were generated in 13 trials in which efficacy against *Pyrenophora teres* was tested. Bridging data are available from North-East (9 trials) and South-East (4 trials) EPPO climatic zones. Moreover data for winter and spring barley were presented separately for North-East EPPO zone.

Table 3.2-14: *Pyrenophora teres* (PYRNTE) in barley – bridging data, summary

EPPO Zone		Untreated	BAS 765 00 F		BAS 765 AB F		Proline
			0.6 L/ha	1.0 L/ha	0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East HORVW	aver	7.8	-	94.0	-	93.7	92.3
	min-max	4.5-10.3	-	77.0-100.0	-	78.3-100.0	78.8-100.0
	n	7	-	7	-	7	7
North-East HORVS	aver	7.3	-	100.0	-	99.8	92.5
	min-max	6.5-8.0	-	100.0	-	99.7-100.0	88.5-96.6
	n	2	-	2	-	2	2
South-East	aver	17.9	73.5	86.6	75.4	88.0	77.0
	min-max	6.4-29.8	64.8-80.6	81.4-89.6	60.5-85.2	80.3-92.4	44.2-90.9
	n	4	4	4	4	4	4
All zones	aver	10.8	-	92.6	-	92.9	87.6
	min-max	4.5-29.8	-	77.0-100.0	-	78.3-100.0	44.2-100.0
	n	13	-	13	-	13	13

Average levels of *Pyrenophora teres* control in barley were the same for BAS 765 00 F and BAS 765 AB F applied at dose rate 1.0 L/ha (about 93%). The same was recorded for both formulations in South-East zone at dose rate 0.6 L/ha (74% and 75% respectively). It is therefore evident that there is full equivalence of BAS 765 00 F and BAS 765 AB F in control of *Pyrenophora teres* in barley.

***Puccinia hordei* (PUCCHD), brown rust of barley**

Data on barley useful for bridging were generated in 9 trials in which efficacy against *Puccinia hordei* was tested. All trials were conducted in North-East EPPO climatic zone. Data for winter and spring barley were presented separately.

Table 3.2-15: *Puccinia hordei* (PUCCHD) in barley – bridging data, summary

EPPO Zone		Untreated	BAS 765 00 F	BAS 765 AB F	Proline
			1.0 L/ha	1.0 L/ha	0.8 L/ha
North-East HORVW	aver	19.6	90.5	88.3	87.7
	min- max	6.4-37.7	69.8-100.0	59.1-100.0	46.5-100.0
	n	7	7	7	7
North-East HORVS	aver	13.8	91.3	90.4	94.2
	min- max	13.5-14.1	88.0-94.7	85.2-95.6	92.1-96.3
	n	2	2	2	2
North-East all	aver	18.3	90.7	88.8	89.1
	min- max	6.4-37.7	69.8-100.0	59.1-100.0	46.5-100.0
	n	9	9	9	9

Average levels of *Puccinia hordei* control in barley were very similar for BAS 765 00 F and BAS 765 AB F applied at dose rate 1.0 L/ha (91% and 89% respectively). It is therefore evident that there is full equivalence of BAS 765 00 F and BAS 765 AB F in control of *Puccinia hordei* in barley.

Conclusions

Bridging field data collected from many trials carried out in different European countries and concerning significant wheat and barley diseases show that BAS 765 00 F is equivalent to BAS 765 AB F in terms of biological activity. This confirms that changes in the tested formulations did not have any efficacy effects. It is thus concluded that data from the BAS 765 AB F formulations can be used in support of registration of BAS 765 00 F.

comments of zRMS: dRR point 3.2.1	1. For justification of the mixture and the ratio the Applicant presented 64 efficacy trials for wheat against major target diseases: SEPTTR, ERYSGR, PSDCHE and for barley against PYRNTE. Trials were conducted in Mediterranean, SE, NE, Maritime climatic EPPO zone. The tested formulation of product in trials was SC and was compared to the activity of both kresoxim-methyl at 100, 150 g a.i./ha and mefentrifluconazole at 100 and 150 g a.i./ha against the target diseases. The mixture of both actives performed better in comparison to efficacy of single active substances. The target dose rate of 1.0 l/ha BAS 765 00 F showed high efficacy - approx. 80% and better than dose rate 0,6 l/ha BAS 765 00 F. 2. The Applicant used in some reports very similar formulation to BAS 765 00 F. In the point "Bridging trials (KCP 6.1)" it is demonstrated the equivalence of BAS 765 00 F efficacy and the formulation BAS 765 AB F efficacy. The bridging data were presented: in 9 trials in wheat against SEPTTR (NE EPPO climatic zone - 7 trials and SE - 2 trials EPPO climatic zone); in 13 trials in wheat against PUCCRT (NE EPPO climatic zone - 7 trials and SE - 6 trials EPPO climatic zone); in 7 trials in wheat against PSDCHE (NE EPPO climatic zone - 2 trials and SE - 4 trials EPPO climatic zone, Maritime EPPO climatic zone – 1 trial); in 13 trials in barley against PYRNTE (NE EPPO climatic zone - 9 trials and SE - 4 trials EPPO climatic zone); in 9 trials in barley against PUCCHD (all trials conducted in NE EPPO climatic zone). Average levels of major target diseases control in wheat and barley were very similar for BAS 765 00 F and BAS 765 AB F applied at dose rate 0,6 l/ha and 1.0 L/ha. The presented results show equivalence of BAS 765 00 F and BAS 765 AB F. That is why data from trials from BAS 765 AB F product can be used to support the efficacy of BAS 765 00 F.

3.2.2 Minimum effective dose tests (KCP 6.2)

Many plant protection products are used to control a range of target diseases. In such situations, it would be impractical and unnecessary to provide evidence for the minimum effective dose for all recommendations. Information is required for a range of targets which are considered to be the most important, and for which control provides a major agricultural benefit. Therefore, to justify the minimum effective dose for BAS 765 00 F, data is presented on a number of key target diseases for which efficacy is claimed. In years 2018 - 2019 the minimum effective dose tests for BAS 765 00 F were conducted in 25 field trials throughout Europe. In North-East zone only dose rate 1.0 L/ha is proposed. In Maritime and South-East EPPO zones dose range 0.6 L/ha - 1.0 L/ha of BAS 765 00 F is requested. In countries like HU, SK, SL and RO the use of lower than registered dose rates is not permitted. This underlines the need for registered dose rate ranges in order to provide flexibility in use rate to farmers depending on disease pressure and weather conditions in these countries. In other countries the label gives the farmer guidance on the dose rates to be used and thus the explicit dose rate range on the label is a seen as a benefit. Therefore if it is considered justified, that dose rate range is proposed.
All trials were performed in accordance with the methodology set out in section 3.2.3 Efficacy tests (KCP 6.2).

Zymoseptoria tritici (SEPTTR) septoria leaf blotch of wheat

North-East EPPO zone
In 2019 product BAS 765 00 F was tested in 5 efficacy trials in order to determine the minimum effective dose for the control of SEPTTR in wheat. The application rate of 1.0 L/ha was compared with a reduced dose rate 0.6 L/ha. Both tested doses were compared to the standard product Proline containing prothioconazole (250 g a.i./L) and applied at the dose of 0.8 L/ha.

Table 3.2-16: *Zymoseptoria tritici* (SEPTTR) in wheat – minimum effective dose - North-East zone, summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East	average	19.5	63.6	85.9	61.9
	min-max	7.9-42.2	56.8-74.3	75.0-100.0	54.0-76.3
	n	5	5	5	5

In all cases, efficacy of BAS 765 00 F applied at the dose rate of 1.0 L/ha was higher than achieved with the 0.6 L/ha dose rate. Moreover, lower dose of product gave less consistent and more variable disease control. These data therefore justify that in order to achieve optimum activity of BAS 765 00 F it should be used at the 1.0 L/ha dose rate in North-East EPPO zone. Performance of BAS 765 00 F applied at dose rate 0.6 L/ha was on the level of Proline. Product at rate 1.0 L/ha outperformed significantly the standard.

South-East EPPO zone

In years 2018 and 2019 product BAS 765 00 F was tested in 5 efficacy trials in order to determine the minimum effective dose for the control of SEPTTR in wheat. The application rates of 0.6 L/ha and 1.0 L/ha were compared with a reduced dose rate 0.4 L/ha to prove the value of the dose rate range. All tested doses were compared to the standard product Proline containing prothioconazole (250 g. a. i./L), applied at a dose of 0.8 L/ha.

Table 3.2-17: *Zymoseptoria tritici* (SEPTTR) in wheat – minimum effective dose - South-East zone, summary

EPPO Zone		Untreated	BAS 765 00 F			Proline
			0.4 L/ha	0.6 L/ha	1.0 L/ha	0.8 L/ha
South-East	average	13.3	66.9	86.8	93.1	90.8
	min-max	7.9-19.4	56.0-80.6	79.3-100.0	85.0-100.0	82.3-100.0
	n	5	5	5	5	5

In all cases, efficacy of BAS 765 00 F applied at the dose rates 0.6 L/ha and 1.0 L/ha was higher than achieved with the 0.4 L/ha dose rate. Moreover, the lowest dose of product gave less consistent and more variable disease control. The difference of average efficacy between dose rate 0.4 L/ha and 0.6 L/ha was 20%. These data therefore justify, in order to achieve optimum activity of BAS 765 00 F it should be used at the dose range 0.6 L/ha - 1.0 L/ha. BAS 765 00 F at rate 1.0 L/ha outperformed the standard. Performance of BAS 765 00 F applied at dose rate 0.6 L/ha was only slightly worse than efficacy of Proline applied at full rate.

***Puccinia triticina* (PUCCRT) brown rust of wheat**

North-East EPPO zone

In 2019 the minimum effective dose for BAS 765 00 F was tested in 5 efficacy trials for brown rust in wheat. Product BAS 765 00 F was applied at rates of 0.6 L/ha and 1.0 L/ha. Both tested doses were compared to the standard product Proline applied at the dose of 0.8 L/ha.

Table 3.2-18: *Puccinia triticina* (PUCCRT) in wheat – minimum effective dose - North-East zone, summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East	average	16.6	73.0	87.5	74.9
	min-max	5.6-34.8	66.2-82.7	78.8-94.2	38.5-100.0
	n	5	5	5	5

Application of BAS 765 00 F at a dose rate of 1.0 L/ha provided more efficient control of the disease than 0.6 L/ha. The highest dose rate ensured on average 15% better control. The presented data therefore justify that in order to achieve optimum activity of BAS 765 00 F it should be used at the 1.0 L/ha dose rate. Nevertheless, also on brown rust the performance of the lower dose rate 0.6 L/ha was very close to the standard, whereas the full dose rate of 1.0 L/ha outperformed the standard.

South-East EPPO Zone

In 2018 and 2019 the minimum effective dose for BAS 765 00 F was tested in 5 efficacy trials for brown rust in wheat. Product BAS 765 00 F was applied at rates of 0.4 L/ha, 0.6 L/ha and 1.0 L/ha. All tested doses were compared to the standard product Proline applied at the dose of 0.8 L/ha.

Table 3.2-19: *Puccinia triticina* (PUCCRT) in wheat - minimum effective dose – South-East zone, summary

EPPO Zone		Untreated	BAS 765 00 F			Proline
			0.4 L/ha	0.6 L/ha	1.0 L/ha	0.8 L/ha
South-East	average	19.2	73.0	84.7	89.1	87.0
	min-max	7.2-28.1	66.7-78.9	83.1-87.1	87.2-91.6	84.7-91.0
	n	5	5	5	5	5

Application of BAS 765 00 F at dose range of 0.6 L/ha – 1.0 L/ha provided more efficient control of disease than 0.4 L/ha. The difference between dose rates 0.4 L/ha and 0.6 L/ha was 12%. For dose rate 0.4 L/ha both average efficacy and efficacy of all trials were below 80%. Presented data therefore justify that in order to achieve optimum activity of BAS 765 00 F it should be used at the 0.6 L/ha to 1.0 L/ha dose rate. Proline provided control of disease comparable to dose rates 0.6 L/ha and 1.0 L/ha of BAS 765 00 F.

***Pyrenophora teres* (PYRNTE) net blotch of barley**

North-East EPPO zone

In years 2018 and 2019 product BAS 765 00 F was tested in 5 efficacy trials in order to determine the minimum effective dose for the control net blotch in barley. The product was applied at rates of 0.6 L/ha and 1.0 L/ha. Both tested doses were compared to the standard product Proline at the dose of 0.8 L/ha. Additionally results for winter and spring barley are presented separately.

Table 3.2-20: *Pyrenophora teres* (PYRNTE) in barley – minimum effective dose - North-East zone, summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East HORVW	aver	8.1	77.6	87.1	85.5
	min-max	7.4-8.5	69.5-85.2	77.0-95.5	78.8-94.3
	n	3	3	3	3
North-East HORVS	aver	21.3	78.5	83.3	72.4
	min-max	6.6-36.0	78.1-79.0	83.2-83.4	69.3-75.5
	n	2	2	2	2
All	aver	13.4	78.0	85.6	80.2
	min-max	6.6-36.0	69.5-85.2	77.0-95.5	69.3-94.3
	n	5	5	5	5

Application of BAS 765 00 F at the lower rate of 0.6 L/ha dose rate gave lower control than achieved with the 1.0 L/ha dose rates. The efficacy at the full rate of BAS 765 00 F was more reliable compared to the lower dose rate. The same was observed for winter and spring barley. These data therefore justify that in order to achieve optimum activity of BAS 765 00 F it should be used at the 1.0 L/ha dose rate. The average values of spring and winter barley show that 1.0 L/ha BAS 765 00 F is superior to Proline, nevertheless efficacy of BAS 765 00 F at reduced rate of 0.6 L/ha is close to Proline.

South-East EPPO zone

In years 2018 and 2019 the product BAS 765 00 F was tested in 5 efficacy trials in order to determine the minimum effective dose for the control net blotch in barley. Product was applied at rates of 0.4 L/ha, 0.6 L/ha and 1.0 L/ha. All tested doses were compared to the standard product Proline at the dose of 0.8 L/ha.

Table 3.2-21: *Pyrenophora teres* (PYRNTE) in barley– minimum effective dose - South-East zone, summary

EPPO Zone		Untreated	BAS 765 00 F			Proline
			0.4 L/ha	0.6 L/ha	1.0 L/ha	0.8 L/ha
South-East	aver	19.3	62.8	72.6	87.2	80.3
	min-max	6.4-29.8	51.2-75.9	64.8-80.6	81.4-89.8	44.2-93.8
	n	5	5	5	5	5

Application of BAS 765 00 F at the lower rate of 0.4 L/ha dose rate gave lower control than achieved with the 0.6 L/ha and 1.0 L/ha dose rates. The average efficacy of dose 0.4 L/ha is 10% lower than efficacy of 0.6 L/ha. These data therefore justify that in order to achieve optimum activity of BAS 765 00 F it should be used at the 0.6 to 1.0 L/ha dose rate. Proline provided control of disease higher than 0.6 L/ha of BAS 765 00 F, however worse than the highest dose of the product.

Summary and conclusions on the minimum effective dose (KCP 6.2)

According to the presented 30 results from 25 trials, the 1.0 L/ha dose rate of BAS 765 00 F provided the optimum overall control and should be considered as an effective solution against the major cereal diseases, for which efficacy of BAS 765 00 F is claimed. As a result, the proposed rate of 1.0 L/ha should be considered the minimum effective dose to deliver broad spectrum control under a wide range of environmental conditions. In accordance with the EPPO standard PP1/225 (2) for minimum effective dose tests, situations were identified in Maritime and South-East EPPO zones where reduced dose rates provided satisfactory control, which was in several cases as good or very close to the performance of the standard Proline at 0.8 L/ha. It is therefore concluded, that in specific agroclimatic conditions or in situations of lower diseases pressure, a reduced dose rates of 0.6 L/ha of BAS 765 00 F may be sufficient under practical conditions, especially if the product is used in mixture with other chemistry.

North - East EPPO Zone

The application rate of 1.0 L/ha was tested in 12 field efficacy trials in comparison with a reduced dose rate of 0.6 L/ha. The application of 1.0 L/ha dose rate is fully justifiable based on data in control of Septoria leaf blotch and brown rust in wheat where 1.0 L/ha dose rate performed better than reduced rate about 20% and 15% respectively. The barley disease (net blotch) was also better controlled (8%) by 1.0 L/ha in comparison to the reduced rate.

Maritime and South – East EPPO Zones

In accordance with the EPPO standard PP1/225 (2) for minimum effective dose tests, situations were identified in Maritime and South-East EPPO zones where reduced dose rates provided satisfactory, similar or close to the standard, control of cereal diseases. The confirmation of dose range efficacy is especially important for South-East EPPO zone countries HU, SK, SL and RO. In these countries, use of lower than registered dose rates is not permitted. Therefore a dose rate range registration is proposed to provide flexibility to the farmers depending on the disease pressure and weather conditions in these countries. In other countries the label gives the farmer guidance on the dose rates to be used and thus the explicit dose rate on the label is a seen as a benefit (the Czech Republic).

The application rates of 0.6 L/ha and 1.0 L/ha were tested in 13 field efficacy trials in comparison with dose rate of 0.4 L/ha. The results from field trials, based on diseases of wheat (Septoria and brown rusts) and barley (net blotch) clearly show the dose response and validate the dose rates of 0.6 – 1.0 L/ha. The full dose rate confirmed the outstanding product performance being superior to the full rate of the standard product. The lower rate of 0.6 L/ha showed in most cases a similar performance or only slightly lower performance than the standard.

comments of zRMS: dRR point 3.2.2	**Minimum effective dose tests** The claimed dose rate is 1,0 L/ha for NE EPPO climatic zone and 0,6 – 1,0 L/ha for SE and Maritime EPPO climatic zones. The doses justification of SC formulation containing 100 g/l mefentrifluconazole and 150 g/l kresoxim-methyl are supported by data from 25 efficacy trials in the SE (13 trials) and NE EPPO zones (12 trials) in wheat and barley against the major cereal diseases, for which efficacy of BAS 765 00 F is claimed. In the trials dose rates were tested: for NE EPPO climatic zone - 0,6 l/ha; 1,0 l/ha; for SE EPPO climatic zone – 0,4 l/ha; 0,6 l/ha; 1,0 l/ha In the NE EPPO climatic zone efficacy trials BAS 765 00 F the rate of 1.0 L/ha showed a higher level of efficacy than reduced rate (0,6 l/ha). In the SE EPPO climatic zone efficacy trials BAS 765 00 F the rate of 0,6 L/ha and 1.0 L/ha showed a higher level of efficacy than reduced rate (0,4 l/ha). 0.6 L/ha showed a similar or only slightly lower control effect than the standard. This range of doses has demonstrated a good diseases control and was considered as the minimum effective dose.

3.2.3 Efficacy tests (KCP 6.2)

Table 3.2-22: Details on trial methodology

Guidelines	General guidelines	EPPO 1/135 (4) Phytotoxicity assessment EPPO 1/152 (4) Design and analysis of efficacy evaluation trials EPPO 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice EPPO 1/223 (2) Introduction to the efficacy evaluation of plant protection products EPPO 1/239 (2) Dose expression of plant protection products
	Specific guidelines	EPPO PP 1/26 (4) Foliar diseases of cereals EPPO PP 1/28 (3) Eyespot of cereals
Experimental design	Plot design	One - factorial randomized block design (113),
	Plot size	10.0-30.0 m²
	Number of replications	4 (113)
Crop	Trials per crop	Winter wheat (69) Winter barley (23) Spring barley (7) Rye (7) Triticale (7)
	Varieties per crop	Winter wheat: Delawar, Discus, Ezopus, Fidelius, Florian, Genius, GK Csillag, GK Körös, Hondia, Ilona, Ingenio, IS Laudis, Joker, KT Hasáb, Madejka, Murgavets, Nador, Opal, Pamir, Patras, Petur, Princeps, Renan, Sadovo, Sadovo 1, Sadovo 772, Skagen, Sorial, Stelarka, Tobak, Tonacja, Zeppelin, Zyta Winter barley: Antonella, Azrah, Bazant, Calypso, Galation Hybrid, Jalon, Jub, Kobuz, Kosmos, Obzor, Ordinale, Quadriga, Sandra, Veslets, Wotan, Zenek Spring barley: Hajduczek, Kucyk, KWS Harris, Malz, Olof Rye: Dankowskie Diament, Forsetti, Mephisto Triticale: Fredro, Grenado, KWS Aveo, Lombardo, Meloman, Rotondo
Application	Crop stage (BBCH)* at application	between 30 and 65 PSDCHE between 30 and 32
	Number of applications	1 in vast majority of trials, 2 trials on winter barley were carried with 2 application of tested product (and standards). In these trials number of days after second application is presented in column DAT of efficacy tables
	Spray volumes	190 - 300 L/ha
Assessment	Assessment types	Visual assessing of foliar disease as specified in PP1/26 (4) Visual assessing of haulm/tillers as specified in PP1/28 (3)
	Assessment dates	foliar and ear diseases: in majority of cases, the focus of this dossier was to target late assessment done about 40 days after treatment. In some exception, the considered assessment was done earlier (even 18 DAT), for example in case when the diseases level on untreated started to decline because of the challenging (to disease) weather conditions, while in other trials the considered assessment was done later, due to late diseases appearance (up to 52 DAT). PSDCHE: 40-84 DAT

Trial layout

Untreated plots were included in the trial layout.
The trial sites were chosen according to the disease presence or its probability to appear on a disease sensitive variety. The locations of the trials were chosen to present the performance of the product and its crop safety profile across requested climatic zones.
Statistical analysis
The yield values were subjected to analysis of the variance (ANOVA) and comparison of test measures obtained by Tukey test ($p \leq 0.05$).
Application equipment
All treatments with the exception of untreated controls were treated in the same way by plot sprayers. It is considered that the quality and quantity of product applied to the plant by the plot sprayers is representative of that achieved with commercial machinery.
The boom pressure varied between 1.5 and 5 bar, whilst the spray volume ranged between 190 and 300 L/ha.
More details on the applications can be found in BAD (BASF Doc ID 2020/2102791).
Treatments
Efficacy data with the final formulation, BAS 765 00 F, are available for trials conducted in 2019 and 2020. In 2018, the very similar formulation BAS 765 AB F was used. In order to demonstrate the equivalence in terms of fungicidal performance between these formulations and to relate the 2019 data with those from 2018 in many trials carried out in 2019 BAS 765 00 F was compared with BAS 765 AB F. Results of this comparison are presented in section 3.2.1 Preliminary tests (KCP 6.1).

In the efficacy section of this document most trials were carried with one application of the tested product (and standards). In only 2 trials on winter barley two applications were done. In such cases, number of days after last assessment is presented in efficacy tables.
Timing of Applications
Trials were designed to target disease at the onset of the attack, thus allowing the targeting of ideally one pathogen written in the protocol. In the practical world, the window of application might be narrow (3 days) what's more the disease stage – and the appropriate timing of the application - was assessed by a trialist and the precision of such a prediction was limited. For example, *Zymoseptoria tritici* (SEPTTR) has latent period from 14 up to 40 days. The disease, to be controlled must be hit not later than at half of the latent period, while the physical symptoms are not yet visible. In trials presented in this documentation, some of the lower efficacy figures might be explained by too late application, while the disease had already passed half of the latent period. This can be confirmed by the unsatisfactory performance of the standard.
In the trials, applications were done at a range of timings (BBCH 30 - 65), to represent usual farmer practice as well as target disease at onset. For barley most of trials were conducted up to BBCH 49, because this growth stage was set as a limit. However individual trials in which application was done at later growth stages are considered reliable and can definitely be used to support efficacy, especially that the limit was not set due to efficacy reasons.
The growth stages at the application time determined the protected leaves/plant part in the crop. Treatments at BBCH 30-33 target protection of leaf 3, while the application at BBCH 39 onwards target protection of the flag leaf and ear. Those application timings, depending on disease development, may offer protectant control on more leaf layers. The early application (T1) may supress disease in the canopy therefore the symptoms on the flag leaf could be diminished. Also in some cases, while the disease infection come late, the T1 application can offer protection of all top three leaves.

This is in response to fungicide treatment, which is dependable on the disease progress, therefore in efficacy tables in this document only some non-targeted leaf layers are presented.
Development trials are usually designed to evaluate control on only one disease. However in reality, a trial is usually infected by more than one disease, therefore the treatments may not appropriately target the infection of other disease as the spray time might be too late or too early to act preventatively.
BAS 765 00 F in the normal conditions even with high disease pressure provides long lasting efficacy at least comparable to standards. This advantage is confirmed in the vast majority of the field trials. However, in the situation of uncommon disease patterns as well as unusual disease pressure, the activity of mefentrifluconazole+kresoxim-methyl as well as standard lasted shorter than normally. These trials are described below each efficacy table.
The specificities of field trials allow products to be assessed in a wide range of practical situations. However, these trials are strongly dependent on weather conditions, disease development in the season and potential interruption from human error. All these factors can influence/ interfere with the final result of the trial.
Assessments
In the disease control trials, disease levels were usually assessed at application and at various intervals after application (from 18 to 52 days after treatment) as a visual percentage cover of infection on a particular plant part, where multiple diseases were present, each disease was assessed individually. This was carried out in accordance with EPPO standard PP1/26 (4) – 'Foliar Diseases of Cereals'.
In general, assessments were done based on single leaf layers or on ears (*Fusarium* spp.). In some countries, disease infection levels were recorded as a "leaf" rather than a specified plant part. This is a different method used compared to other countries, but is still relevant. The term 'leaf' is used, as it is an assessment of disease levels typically on 2 or 3 leaves having disease present. The levels of infection are expressed as the mean of the percentage of disease present on the assessed leaves. Trials where this assessment method is used present usually lower efficacy scores due to assessing leaves not targeted during application (ex. T2 spray at BBCH 39, assessed leaves: 1, 2 and 3).
Product efficacy figures are derived in most cases from the top three leaves or from ears (*Fusarium* spp.). This leaf layers, in particular in wheat were chosen because the top three leaves have the greatest contribution of leaf layer to yield. However the most important factor, which may limit lower leaves layer assessment to be consider is the late assessment timing. For example, some assessments presented in efficacy tables were done about 40 days after application, while applications were done at BBCH 32- 51 and as result, in many cases, the considered assessment was done in June at BBCH 69 -77. At such a late growth stage, the assessment done on lower leaves is not relevant. However in case earlier application and assessment at growth stages BBCH 32-55 results obtained for lower leaf layers may be still relevant. Therefore results for 4^{th} or 5^{th} leaf were used in some cases providing that assessment was done not later than BBCH 55. Disease intensity was calculated based on assessments.
On eyespot one assessment was performed 40 - 84 DAT. Twenty-five stems are randomly taken from each plot. The assessment is carried out on:

- The number of attacked stems
- The percentage of damaged area – an estimation is taken after a transversal cut of the stems in the main eye shape elliptical lesions forms. Based on assessments were calculated:

BEFWER: intensity of attack expressed in percentage (%), calculated from 4-classes assessment.

Trial Numbering/References
Full trial reference numbers are used in the data tables and the tables of site and application details. Taking the final trial from the site and application details as an example:
DEV-F-2018-PL-C22-A-03.0-PL-PLJ-001
“DEV” indicates that this is a development trial as distinct from other trial types
“F” indicates that this is a fungicide treatment trial
“2018” indicates the year in which the trial was conducted
“C22” is the trial protocol number (subsequent information detailing the version)
“PL” is the country code, in this case for Poland
“PLJ” is a specific local region in the country
“001” is a unique identifier for this trial taking into consideration the preceding information

Data summaries
In each section of the BAD, for example efficacy or yield, data are presented by crop (the efficacy section is split by target diseases).
In each table, percentage of evaluated factor (e.g. control of disease, yield) in relation to the untreated plot is presented. For the standard products, evaluated factor in relation to the untreated plots is generally placed in the last column.
Below each trials results table, a summary of the data is provided with the number of trials summarized with the average, minimum and maximum values. The average is calculated from one assessment timing from each trial, (if more than one leaf layer was assessed at assessment – mean of all values obtained is considered result of trial). Assessment timings were selected according to criteria described in Table 3.2-22.
Values are generally rounded to one decimal place. Figures for percentage control and summary means are generally calculated from within Microsoft Excel and due to rounding may be slightly different from a manual calculation of percentage control or summary means from the data presented in the tables.
Trials in which disease levels in untreated plots were insufficient to reliably demonstrate activity of the product are not presented in the dose response and efficacy sections.
Yield data are presented for both safety trials (without or with negligible level of disease) and for efficacy trials. Quality data are presented for efficacy trials.

***Zymoseptoria tritici* (SEPTTR), septoria leaf blotch of wheat (KCP 6.2)**

The efficacy of BAS 765 00 F against *Zymoseptoria tritici* in wheat was tested in 31 trials spread over EPPO zones. In the Maritime zone 4 trials were conducted, along with 11 trials in North-East and 16 trials in the South-East. The only standard used for this disease was Proline / Proline 275 at maximum dose rate. Additionally the RegPest model was used to justify comparability of trials across Europe. Many trials in North-East and South-East EPPO zones were conducted in regions with high (about 80% or higher) similarity to chosen Maritime region. Therefore, these trials fully confirm the efficacy of the product in Maritime EPPO zone. Details of this analysis are presented in section 3.2.3.1 Extrapolations.

Table 3.2-23: Control of *Zymoseptoria tritici* in wheat – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	aver.	19.6	82.3	87.8	75.6
	min-max	18.5-20.6	72.0-92.2	82.6-94.0	43.9-88.3
	n	4	4	4	4
North-East	aver.	16.0	-	88.4	79.0
	min-max	5.7-42.2	-	75.0-100.0	54.0-99.4
	n	11	-	11	11
South-East	average	14.5	-	93.4	91.8
	min-max	7.5-27.5	-	82.0-100.0	80.3-100.0
	n	16	-	16	16
South-East orthogonal	aver.	15.0	86.0	92.8	91.2
	min-max	7.9-27.5	76.0-100.0	82.0-100.0	80.3-100.0
	n	14	14	14	14
All zones	aver.	15.7	-	90.9	85.1
	min-max	5.7-42.2	-	75.0-100.0	43.9-100.0
	n	31	-	31	31
All zones orthogonal	aver.	16.1	85.2	91.7	87.8
	min-max	7.9-27.5	72.0-100.0	82.0-100.0	43.9-100.0
	n	18	18	18	18

BAS 765 00 F gave outstanding control of *Zymoseptoria tritici* with an average about 91% for dose rate 1 L/ha and about 85% for dose rate 0.6 L/ha. Infection in the untreated ranging from 6% to 42% (~16%). The efficacy of the product varied from 75% to 100% for dose rate 1 L/ha and from 72% to 100% for 0.6 L/ha. Average performance of standard was slightly better than efficacy of BAS 765 00 F at dose rate 0.6 L/ha and worse than full dose of BAS 765 00 F. The performance of the product was on a similar level in Maritime and North-East EPPO zones with slightly better average results in South-East zone.

***Puccinia triticina* (PUCCRT), brown rust of wheat (KCP 6.2).**

The efficacy of BAS 765 00 F against *Puccinia triticina* in wheat was tested in 32 trials spread over EPPO zones. In the Maritime zone 2 trials were conducted, along with 11 trials in the North-East and 19 trials in the South-East. Additionally the RegPest model was used to justify comparability of trials across Europe. Many trials in North-East EPPO and South-East zones were conducted in regions with high (about 80% or higher) similarity to chosen Maritime regions. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. Details of this analysis are presented in section 3.2.3.1 Extrapolations.

Table 3.2-24: Control of *Puccinia triticina* in wheat – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	23.1	78.2	84.2	63.6
	min-max	18.8-27.5	77.8-78.7	82.7-85.8	44.0-83.2
	n	2	2	2	2
North-East	average	14.4	-	91.2	82.8
	min-max	5.3-34.8	-	78.8-100.0	38.5-100.0
	n	11	-	11	11
South-East	average	15.4	-	93.7	90.9
	min- max	5.0-62.5	-	87.2-100.0	84.3-100.0
	n	19	-	19	19
South-East orthogonal	average	13.6	89.8	93.3	90.2
	min-max	6.3-28.1	83.1-96.6	87.2-100.0	84.3-96.0
	n	16	16	16	16
All	average	15.5	-	92.3	86.5
	min-max	5.0-62.5	-	78.8-100.0	38.5-100.0
	n	32	-	32	32
All orthogonal	average	14.6	88.5	92.3	87.2
	min-max	6.3-28.1	77.8-96.6	82.7-100.0	44.0-96.0
	n	18	18	18	18

BAS 765 00 F gave outstanding control of *Puccinia triticina* with an average 92% recorded for dose rate 1.0 L/ha and 89% for dose rate 0.6 L/ha. Infection in the untreated ranged from 5% to 62% (~16%). The efficacy of the product varied from 79% to 100% for full dose rate and from 78% to 100% for dose rate 0.6 L/ha. In most cases, BAS 765 00 F at full dose rate performed better than Proline with average efficacy 6% higher. BAS 765 00 F at dose rate 0.6 L/ha performed on the level of the standard. The performance of the product was similar in North-East and South-East EPPO zones. In the Maritime EPPO zone the efficacy was slightly lower. However the standard performed in these trials much below the average level. Therefore it is presumed that unfavourable conditions in these individual trials resulted in slightly lower efficacy.

***Blumeria graminis* (ERYSGR), powdery mildew of wheat (KCP 6.2)**

The efficacy of BAS 765 00 F against *Blumeria graminis* in wheat was tested in 11 trials spread over EPPO zones. In the Maritime zone 1 trial was conducted, along with 6 trials in the North-East zone and 4 trials in South-East zone. Additionally the RegPest model was used to justify comparability of trials across Europe. Many trials in North-East and South-East EPPO zones were conducted in regions with high (about 80% or higher) similarity to chosen Maritime regions. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. The same was confirmed for neighbouring countries which are located in North-East and South-East EPPO zones. Details of this analysis are presented in section 3.2.3.1 Extrapolations.

Table 3.2-25: Control of *Blumeria graminis* in wheat – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	17.5	82.9	74.3	57.1
	min-max	-	-	-	-
	n	1	1	1	1
North-East	average	10.5	-	78.9	82.5
	min-max	5.7-22.0	-	54.9-100.0	53.5-100.0
	n	6	-	6	6
South-East	average	14.9	76.6	90.8	87.0
	min-max	6.5-27.5	65.6-96.0	78.2-98.7	81.1-94.7
	n	4	4	4	4
All	average	12.7	-	82.8	81.8
	min-max	5.7-27.5	-	54.9-100.0	53.5-100.0
	n	11	-	11	11
All orthogonal	average	15.4	77.8	87.5	81.0
	min-max	6.5-27.5	65.6-96.0	74.3-98.7	57.1-94.7
	n	5	5	5	5

BAS 765 00 F gave good control of *Blumeria graminis* with an average of 83% recorded for dose rate 1.0 L/ha and 78% for dose rate 0.6 L/ha. Infection ranged from 6% to 28% (~13%). Generally control of *Blumeria graminis* was consistent. The only exception is one trial from Poland with the lowest efficacy. It should be underlined that in this trial, poor results for standard product confirm unfavourable conditions. The performance of the product slightly differs across EPPO zones. In the Maritime and North-East EPPO zones average efficacy is close to 80%. In South-East EPPO zone the product efficacy was recorded at the level of 91% for full dose rate. Efficacy of dose rate 0.6 L/ha was good in the South-East EPPO zone reaching 77% of efficacy.

***Pyrenophora tritici-repentis* (PYRNTR), tan spot of wheat (KCP 6.2)**

The efficacy of BAS 765 00 F against *Pyrenophora tritici-repentis* in wheat was tested in 10 trials spread over EPPO zones. In the Maritime zone 1 trial was conducted, along with 3 trials in the North-East zone and 6 trials in South-East zone. Since only registration in South-East EPPO zone is requested, results of trials from other zones are presented as supportive information.

Table 3.2-26: Control of *Pyrenophora tritici-repentis* in wheat –disease control (%) – summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	7.3	72.4	70.7	43.1
	min-max	-	-	-	-
	n	1	1	1	1
North-East	average	18.6	-	80.5	80.5
	min-max	5.9-27.5	-	55.5-95.8	62.7-90.0
	n	3	-	3	3
South-East	average	16.1	-	82.7	76.2
	min-max	10.6-30.8	-	69.5-100.0	56.8-94.7
	n	6	-	6	6
South-East orthogonal	average	12.7	74.2	85.7	82.1
	min- max	10.6-16.5	44.4-94.7	69.5-100.0	70.5-94.7
	n	4	4	4	4
All	average	16.0	-	80.8	74.2
	min-max	5.9-30.8	-	55.5-100.0	43.1-94.7
	n	10	-	10	10
All orthogonal	average	11.6	73.8	82.7	74.3
	min-max	7.3-16.5	44.4-94.7	69.5-100.0	43.1-94.7
	n	5	5	5	5

BAS 765 00 F gave good control of *Pyrenophora tritici-repentis* with an average of 81% recorded for dose rate 1.0 L/ha and 74% for dose rate 0.6 L/ha. Infection ranged from 6% to 31% (~16%). The efficacy of the product varied from 55% to 100% for full dose rate and from 44% to 95% for dose rate 0.6 L/ha. Standard products performed worse than full dose rate of BAS 765 00 F but slightly better than lower dose rate of the product. The performance of the product was similar in North-East and South-East EPPO zones. In Maritime EPPO zone the product efficacy was lower. However only one trial was conducted in this EPPO zone therefore this comparison may be considered not fully reliable.

***Oculimacula* spp. (PSDCHE), Cereal eyespot (KCP 6.2)**

The efficacy of BAS 765 00 F against *Oculimacula* spp. in wheat was tested in 17 trials spread over EPPO zones. In the Maritime zone 4 trials were conducted, along with 8 trials in the North-East and 5 trials in the South-East. Additionally the RegPest model was used to justify comparability of trials across Europe. Many trials in North-East and South-East EPPO zones were conducted in regions with high (about 80% or higher) similarity to chosen Maritime regions. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. Details of this analysis are presented in section 3.2.3.1 Extrapolations.

Table 3.2-27: Control of *Oculimacula* spp in wheat – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	14.0	77.5	88.3	75.7
	min-max	8.5-18.7	67.9-100.0	77.8-100.0	66.1-84.0
	n	4	4	4	4
North-East	average	34.3	-	82.6	79.4
	min- max	23.5-42.3	-	64.2-94.7	56.0-92.3
	n	8	-	8	8
South-East	average	28.1	-	87.2	75.9
	min-max	20.3-49.5	-	76.2-100.0	61.7-100.0
	n	5	-	5	5
South-East orthogonal	average	30.0	70.2	84.0	79.4
	min-max	21.0-49.5	59.6-95.2	76.2-100.0	68.2-100.0
	n	4	4	4	4
All	average	27.7	-	85.3	77.5
	min-max	8.5-49.5	-	64.2-100.0	56.0-100.0
	n	17	-	17	17
All orthogonal	average	22.0	73.8	86.2	77.6
	min-max	8.5-49.5	59.6-100.0	76.2-100.0	66.1-100.0
	n	8	8	8	8

BAS 765 00 F gave good control of *Oculimacula* spp. with an average 85% recorded for dose rate 1.0 L/ha and 74% for dose rate 0.6 L/ha. Infection ranged from 9% to 50% (~27%). The efficacy of the product at full dose rate varied from 64% to 100% and from 60% to 100% for dose rate 0.6 L/ha. The standard product performed on a slightly lower level than the full dose rate of BAS 765 00 F. The good performance of the product is very similar across all EPPO zones.

***Fusarium* spp. (FUSASP), Ear blight (KCP 6.2)**

The efficacy of BAS 765 00 F against *Fusarium* spp. in wheat was tested in 6 trials conducted in South-East EPPO zone (4 trials) and Maritime zone (2 trials). The registration is requested for South-East EPPO zone. Therefore only trials from this EPPO zone and supportive trials from other zones, from regions with similar agroclimatic conditions were presented. RegPest model was used to justify comparability of trials across Europe. Details of this analysis are presented in section 3.2.3.1 Extrapolations.

Table 3.2-28: Control of *Fusarium* spp. in wheat – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F	Proline
			1.0 L/ha	0.8 L/ha
All	average	44.0	65.8	65.4
	min-max	4.5-83.4	51.0-88.2	46.8-93.0
	n	6	6	6

BAS 765 00 F gave good control of *Fusarium* spp. with an average 66% recorded for dose rate 1.0 L/ha. The efficacy of the product at full dose rate varied from 51% to 88%. Infection ranged from 5% to 83% (~44%). The standard product performed on a similar level with average efficacy of 65%.

***Pyrenophora teres,* (PYRNTE), net blotch of barley (KCP 6.2)**

The efficacy of BAS 765 00 F against *Pyrenophora teres* in barley was tested in 27 trials spread over EPPO zones. In the North-East zone 14 trials were conducted, along with 13 trials in the South-East zone. Assessment of product performance for North-East EPPO zone is carried out separately on spring and winter cultivars. Therefore, trials carried out on winter cultivars (9 trials) and spring cultivars (5 trials) are presented separately in the summary table below. Additionally the RegPest model was used to justify comparability of trials across Europe. Results of analysis with use of RegPest tool indicate that many trials from North-East and South-East EPPO zones were conducted in regions with high (about 80% or higher) similarity to the chosen Maritime region, therefore results from these trials are relevant to Maritime EPPO Zone. Details of this analysis are presented in section 3.2.3.1 Extrapolations.

Table 3.2-29: Control of *Pyrenophora teres* in barley – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East HORVW	aver	7.6	-	94.9	92.6
	min-max	4.5-10.3	-	77.0-100.0	78.8-100.0
	n	9	-	9	9
North-East HORVS	aver	15.4	-	91.1	83.6
	min-max	6.5-36.0	-	83.2-100.0	69.3-96.6
	n	5	-	5	5
South-East	aver	27.1	-	86.1	84.6
	min-max	5.8-75.0	-	75.6-99.7	44.2-99.7
	n	13	-	13	13
South-East orthogonal	aver	33.1	80.6	90.1	87.4
	min-max	6.4-75.0	64.8-99.7	81.4-99.7	44.2-99.7
	n	8	8	8	8
All	aver	18.4	-	89.9	87.1
	min-max	4.5-75.0	-	75.6-100.0	44.2-100.0
	n	27	-	27	27

BAS 765 00 F gave outstanding control of *Pyrenophora teres* with an average of 90% recorded for dose rate 1.0 L/ha and 81% for dose rate 0.6 L/ha. Infection in the untreated ranged from 5% to 75% (~18%). The efficacy of the product varied from 76% to 100% for the full dose rate and from 65% to 100% for dose rate 0.6 L/ha. The standard performed on a slightly lower level than the full dose of BAS 765 00 F.
The very good performance of the product was on a similar level in both EPPO zones. The performance of the product was also on similar level when used in spring and winter cultivars of barley in North-East EPPO zone. This additionally confirms that extrapolation rules set by Polish Ministry of Agriculture and Rural Development in Extrapolation table for efficacy section1 can be used here. Therefore results from winter barley for which full set of data in available in North-East EPPO zone can be extrapolated to spring barley.
In two trials from South-East EPPO zone two applications were made with 9-10 days interval between applications. This is not fully according to GAP where minimum interval is set at 14 days. However these trials are considered reliable and can be used to support of efficacy in South-East EPPO zone. Therefore these trials are summarized in summary table.

[1] https://www.gov.pl/web/rolnictwo/ustalenia-dotyczace-sporzadzania-oceny-lub-uwag-w-zakresie-srodkow-ochrony-roslin-przez-podmioty-upowaznione

***Puccinia hordei* (PUCCHD), brown rust of barley**

The efficacy of BAS 765 00 F against *Puccinia hordei* in barley was tested in 10 trials conducted in North-East EPPO zone. Assessment of product performance for North-East EPPO zone is carried out separately on spring and winter cultivars. Therefore, trials carried out on winter cultivars (7 trials) and spring cultivars (3 trials) are presented separately in summary table below. Additionally results of one trial with slightly lower than required infection pressure were used as supportive. Results of this trial were not used in summary table. The RegPest model was used to justify comparability of trials across Europe. Results of analysis with use of RegPest tool indicate that trials from North-East zone were conducted in regions with high (about 80% or higher) similarity to chosen Maritime regions, therefore results from these trials are relevant to Maritime EPPO Zone. Details of this analysis are presented in section 3.2.3.1 Extrapolations.

Table 3.2-30: Control of *Puccinia hordei* in barley – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F	Proline
			1.0 L/ha	0.8 L/ha
North-East HORVW	average	19.6	90.5	87.7
	min-max	6.4-37.7	69.8-100.0	46.5-100.0
	n	7	7	7
North-East HORVS	average	12.0	85.4	90.2
	min-max	8.5-14.1	73.5-94.7	82.4-96.3
	n	3	3	3
All	average	17.3	88.9	88.4
	min-max	6.4-37.7	69.8-100.0	46.5-100.0
	n	10	10	10

BAS 765 00 F gave very good control of brown rust with an average of 89% recorded for dose rate 1.0 L/ha. Infection ranged between 6% and 38% (~17%) in the untreated. Standard performed similar to full rate of BAS 765 00 F. However BAS 765 00 F provided slightly more consistent control of brown rust.
The good performance of the product was on similar level when used in spring and winter cultivars of barley. This additionally confirms that extrapolation rules set by Polish Ministry of Agriculture and Rural Development in Extrapolation table for efficacy section can be used here. Therefore results from winter barley for which full set of data is available in North-East EPPO zone can be extrapolated to spring barley.

***Blumeria graminis* (ERYSGR), powdery mildew of barley (KCP 6.2)**

The efficacy of BAS 765 00 F against *Blumeria graminis* in barley was tested in 5 trials conducted in North-East EPPO zone (1 trial) and South-East zone (4 trials). These trials are intended to support registration of BAS 765 00 F in South-East EPPO zone. Since vast majority of trials is from this EPPO zone with 1 supportive trial from Poland, use of RegPest model is not considered necessary in this case.

Table 3.2-31: Control of *Blumeria graminis* in barley – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East	aver	5.2	76.7	80.6	77.7
	min-max	-	-	-	-
	n	1	1	1	1
South-East	aver	17.7	-	83.0	84.1
	min-max	8.2-31.0	-	75.8-90.0	73.5-98.7
	n	4	-	4	4
South-East orthogonal	aver	10.5	68.3	85.7	81.2
	min-max	8.2-12.8	62.4-74.2	81.3-90.0	73.5-89.0
	n	2	2	2	2
All	aver	15.2	-	82.5	82.8
	min-max	5.2-31.0	-	75.8-90.0	73.5-98.7
	n	5	-	5	5

BAS 765 00 F gave good control of powdery mildew with an average of 83% recorded for dose rate 1.0 L/ha. Lower dose rate - 0.6 L/ha gave quite good control of pathogen in two trials - 74% and 77%. In one trial the performance of lower dose rate was worse - 62%, however it should be underlined that this was trial with the lowest efficacy of standard. This indicates that conditions were challenging. The performance of higher dose was consistent, undependably on conditions. Generally standard performed worse than full rate of BAS 765 00 F, however better than reduced dose rate.

Generally there are forms of *Blumeria graminis* specific for individual crops which do not cross-infect. However results on other cereals can give idea about pathogen reaction to product. Therefore results of powdery mildew control on wheat can be considered supportive (4 trials from South-East EPPO zone with average efficacy of 91%). Moreover in dossier supporting solo application of mefentrifluconazole there are numerous trial indicating high efficacy against this pathogen on barley.

***Septoria* spp. (SEPTSP), septoria leaf blotch of triticale (KCP 6.2)**

The efficacy of BAS 765 00 F against *Septoria* spp. In triticale was tested in 2 trials conducted in Maritime zone and 4 trials in North-East EPPO zone. These trials are intended to support registration of BAS 765 00 F in all requested countries from three EPPO zones. Proline at dose rate 0.8 L/ha was used as standard in all trials.

Table 3.2-32: Control of *Septoria* spp. in triticale – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	38.8	86.5	89.4	90.1
	min-max	25.2-52.5	79.7-93.2	82.9-95.9	87.0-93.2
	n	2	2	2	2
North-East	average	21.2	-	89.5	88.2
	min-max	6.4-49.4	-	81.0-100.0	72.0-100.0
	n	4	-	4	4
All	average	27.1	-	89.5	88.9
	min-max	6.4-52.5	-	81.0-100.0	72.0-100.0
	n	6	-	6	6

BAS 765 00 F gave very good control of Septoria with an average of 90% recorded for dose rate 1.0 L/ha and 87% for dose rate - 0.6 L/ha. Efficacy was 80% or higher in all trials for both dose rates. The efficacy of standard was similar as for higher dose rate of BAS 765 00 F.

Additionally to above results, trials conducted on winter wheat can be used to support efficacy of BAS 765 00 F against Septoria leaf blotch. This is possible because direct extrapolation from winter wheat to triticale is acceptable. The rules of extrapolation are described in detail in document prepared by Polish Ministry of Agriculture and placed on its website. Results of 31 trials on wheat from three EPPO zones are described. BAS 765 00 F provided a mean level of control of 91% for dose rate 1 L/ha and 85% for dose rate 0.6 L/ha, so almost the same as presented above for triticale. Overall results of trials on wheat and triticale confirm high efficacy of BAS 765 00 F against Septoria leaf blotch.

No South-East zone trials on triticale were submitted. However results of 16 trials from this zone on wheat clearly demonstrate control of Septoria. Additionally for Maritime and North-East EPPO zones the same control of Septoria leaf blotch with BAS 765 00 F on both cereal crops wheat and triticale was proven. Therefore it is concluded that data on wheat are sufficient to claim control of Septoria leaf blotch on triticale in South-East EPPO zone.

***Puccinia recondita* (PUCCRE), brown rust of triticale (KCP 6.2)**

The efficacy of BAS 765 00 F against *Puccinia recondita* in triticale was tested in 2 trials; 1 conducted in Maritime zone and 1 in North-East EPPO zone.

Table 3.2-33: Control of *Puccinia recondita* in triticale – disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	15.5	87.6	89.7	87.9
	min-max	-	-	-	-
	n	1	1	1	1
North-East	average	6.3	-	100.0	100.0
	min-max	-	-	-	-
	n	1	-	1	1
All	average	10.9	-	94.9	94.0
	min-max	6.3-15.5	-	89.7-100.0	87.9-100.0
	n	2	-	2	2

BAS 765 00 F ensured very good control of brown rust on triticale undependably on dose rate used. The efficacy recorded for dose rate of 0.6 L/ha was 87% and for dose rate of 1 L/ha was 95%.

Additionally to presented above results, trials conducted on winter wheat can be used to support efficacy of BAS 765 00 F against brown rust. This is possible because direct extrapolation from winter wheat to triticale is acceptable. Results of 32 trials from three EPPO zones are described. BAS 765 00 F provided a mean level of control of 89% for dose rate 0.6 L/ha and 92% for dose rate 1 L/ha, so similar to presented above results for triticale. Overall results of trials on wheat and triticale confirm high efficacy of BAS 765 00 F against brown rust.

No South-East zone trials on triticale were submitted. However results of 19 trials from this zone on wheat clearly demonstrate control of brown rust. Additionally for Maritime and North-East EPPO zones very similar results of *Puccinia* spp. control with BAS 765 00 F on both cereal crops (wheat and triticale) were obtained. Therefore it is concluded that data on wheat are sufficient to claim control of brown rust on triticale in South-East EPPO zone.

***Puccinia recondita* (PUCCRE), brown rust of rye (KCP 6.2)**

The efficacy of BAS 765 00 F against *Puccinia recondita* in rye was tested in 4 trials conducted in Maritime EPPO zone and in 3 trials conducted in North-East zone. Proline at full dose rate was used as a standard in all trials.

Table 3.2-34: Control of *Puccinia recondita* in rye – disease control (%) - individual trial results

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	31.1	87.2	93.5	94.5
	min-max	5.0-95.8	75.7-100.0	86.6-97.7	87.9-100.0
	n	4	4	4	4
North-East	average	14.6	-	91.9	92.7
	min-max	5.8-25.0	-	89.1-94.1	86.4-99.1
	n	3	-	3	3
All	average	24.0	-	92.8	93.7
	min-max	5.0-95.8	-	86.6-97.7	86.4-100.0
	n	7	-	7	7

BAS 765 00 F ensured very good control of brown rust on rye undependably on dose rate used. The average efficacy recorded for dose rate of 0.6 L/ha was 87% and for dose rate of 1 L/ha was 93%.

Additionally to presented above results, trials conducted on winter wheat can be used to support efficacy of BAS 765 00 F against brown rust. This is possible because direct extrapolation from winter wheat to rye is acceptable for many diseases. The rules of extrapolation are described in detail in document prepared by Ministry of Agriculture and placed on its website. Results of 32 trials from three EPPO zones are described. BAS 765 00 F provided a mean level of control of 89% for dose rate 0.6 L/ha and 92% for dose rate 1 L/ha, so almost the same as presented above for rye. Overall results of trials on wheat and rye confirm high efficacy of BAS 765 00 F against brown rust.

No South-East zone trials on rye were submitted. However results of 19 trials on wheat from this zone clearly demonstrate control of brown rust. Additionally for Maritime and North-East EPPO zones very similar results of Puccinia spp. control with BAS 765 00 F on both cereal crops (wheat and rye) were obtained. Therefore it is concluded that data on wheat are sufficient to claim control of brown rust on rye in South-East EPPO zone.

3.2.3.1 Extrapolations

BAS 765 00 F was tested in the wide range of situation in 113 field trials. Nevertheless, efficacy in the some cases is not demonstrated by satisfying number of trials. Therefore various methods of extrapolations were used as a way to provide wide-range product information to the end user.
The most frequently used method of extrapolation is based on the assumption that results of trials conducted in countries which are located in other EPPO zones can be used as supportive data. However these trials can be used as supportive only when it is assured that their results (evaluation of plant protection product efficacy and the assessment of the environmental effects of their application) are relevant for areas which are intended to support. This is proven with use of RegPest Model. This software enables a comparison of the climatic and soil conditions and the structure of crops by visualization on a map of the similarity of areas in Europe. Areas where trials were conducted were compared to areas for which were used as supportive.
The further explanation about RegPest model can be found in the appended document - Expert report regarding division of Europe into regions characterized by homogenous soil and climatic conditions, within the boundaries of which the results of efficacy evaluation of pesticides can be relevant for the entire region (for more information please see BAD - BASF Doc ID 2020/2102791).
The second method of extrapolation is based on the assumption that product which can control a pathogen in a variety of situations, may control a related pathogen in a comparable situation. If a product can be used against a pathogen on one crop, it may perhaps be used against it on other crops. In some cases, it may be possible to extrapolate this way without supporting data or with limited set of data.
Rules of extrapolation based on this assumption are described in document Extrapolation table for efficacy section[2] prepared by Polish Ministry of Agriculture and Rural Development.
Even if some crops are not included in this document extrapolation is still possible providing that these crops (or uses) are minor. Minor uses are defined as: “those use of plant protection products (defined in relation to crops and pests) in which either the crop is considered to be of low importance at national level (minor crop), or the pest (minor pest) is not important on a major crop” or “does not occur routinely: its incidence would normally be localized and significant damage on high proportion of the crop would not normally be expected”. It is seen as important also to offer solutions for the segment of minor crops or against minor pests and to minimize the burden of efficacy trials. Therefore extrapolation in such situation is applicable. EPPO Guideline PP1/257 (2) “Efficacy and crop safety extrapolation for minor uses” introduces an extrapolation rules to decide if an extrapolation from one crop or disease to another crop or disease is justifiable.

[2] https://www.gov.pl/web/rolnictwo/ustalenia-dotyczace-sporzadzania-oceny-lub-uwag-w-zakresie-srodkow-ochrony-roslin-przez-podmioty-upowaznione

Table 3.2-35: Proposed extrapolations

Region	Crop	Disease	Basis of extrapolation
Maritime EPPO zone (Czech Republic)	Wheat	SEPTTR	Extrapolation based on Reg-Pest model - additional data presented below
		PUCCRT	
		ERYSGR	
		PSDCHE	
	Barley	PYRNTE	
		PUCCHD	
North-East EPPO zone (Poland)	Wheat	ERYSGR	Extrapolation based on Reg-Pest model - additional data presented below
	Spring barley	PYRNTE	Extrapolation based on data set for winter barley, done according to rules described in document Extrapolation table for efficacy section
		PUCCHD	
South-East EPPO zone	Wheat	FUSASP	Extrapolation based on Reg-Pest model - additional data presented below
		ERYSGR	
	Triticale	SEPTSP	Extrapolation based on data set for winter wheat, supported with data on triticale from other EPPO zones
		PUCCRE	
	Rye	PUCCRE	Extrapolation based on data set for winter wheat, supported with data on rye from other EPPO zones

Extrapolation based on use of RegPest model

The only country in Maritime EPPO zone for which registration is requested is Czech Republic. Regions of this country where cereal production (especially wheat and barley) is concentrated were selected for analysis. Regions Stredni Cechy and Jihovychod were selected for comparison with regions in nearby countries - Poland and Slovakia where trials were conducted.

Three regions Zapadne Slovensko, Stredne Slovensko and Vychodne Slovensko covering most area of this country and all trials locations were selected for analysis. In Poland vast majority of trials were located in South-West (close to Czech border) and West part of country. Individual trials were also located in North and East part of Poland. Therefore regions Dolnoslaskie, Kujawsko-Pomorskie, Lodzkie, Lubelskie, Opolskie, Pomorskie, Warminsko-Mazurskie and Wielkopolskie were selected for analysis. These regions cover all trials locations

Summary of these analysis is presented in Table 3.2-36 below.

Table 3.2-36: Summary of reports on comparison of regions (supporting efficacy in Maritime zone)

Region in Maritime EPPO zone	Region in other EPPO zone	EPPO zone	Similarity between regions
Jihovychod	Dolnoslaskie	North-East	88%, 87%
	Kujawsko-Pomorskie		85%, 84%
	Lodzkie		75%, 73%
	Lubelskie		82%, 81%
	Opolskie		84%, 83%
	Pomorskie		83%, 83%
	Warminsko-Mazurskie		91%, 91%
	Wielkopolskie		78%, 78%
	Stredne Slovensko	South-East	84%, 83%
	Vychodne Slovensko		88%, 87%
	Zapadne Slovensko		89%, 91%
Stredni Cechy	Dolnoslaskie	North-East	85%, 84%
	Kujawsko-Pomorskie		81%, 80%
	Lodzkie		71%, 70%
	Lubelskie		78%, 77%
	Opolskie		81%, 79%
	Pomorskie		80%, 80%
	Warminsko-Mazurskie		90%, 89%
	Wielkopolskie		75%, 74%
	Stredne Slovensko	South-East	86%, 85%
	Vychodne Slovensko		90%, 89%
	Zapadne Slovensko		88%, 89%

The level of similarity between the most regions where trials are conducted and regions for which are used as supportive is close to 80% or higher. This is considered high similarity and risk of different behaviour of the same plant protection product when applied in these regions is negligible. Therefore results of the trials are considered reliable for regions for which are used as supportive. The only region for which similarity is lower (about 70%) is Lodzkie. Therefore results of two trials located in this region are not considered in extrapolation.

***Zymoseptoria tritici* (SEPTTR), septoria leaf blotch of wheat (KCP 6.2)**

Trials supporting efficacy of BAS 765 00 F against *Zymoseptoria tritici* in Czech Republic were conducted in the Maritime, North-East (Poland) and South-East zone (Slovakia). Trials from Poland and Slovakia were conducted in regions with high (about 80% or higher) similarity to chosen regions of Czech Republic. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. The standard used for this disease was Proline / Proline 275 at maximum dose rate.

Table 3.2-37: Control of *Zymoseptoria tritici* in wheat – infection, diseases control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	aver.	19.6	82.3	87.8	75.6
	min-max	18.5-20.6	72.0-92.2	82.6-94.0	43.9-88.3
	n	4	4	4	4
North-East	aver.	14.4	87.2	92.0	94.2
	min-max	5.7-39.4	83.8-90.4	85.4-95.4	88.5-94.2
	n	5	5	5	5
South-East	average	14.1	88.5	91.9	89.2
	min-max	7.9-27.5	81.9-95.5	88.8-95.5	82.3-94.5
	n	5	5	5	5
All zones	aver.	15.8	86.3	90.8	87.1
	min-max	5.7-39.4	72.0-95.5	82.6-95.5	43.9-99.4
	n	14	14	14	14

BAS 765 00 F gave outstanding control of *Zymoseptoria tritici* with an average about 91% for dose rate 1 L/ha and about 86% for dose rate 0.6 L/ha. Infection in the untreated ranging from 6% to 40% (~16%). The efficacy of the product varied from 83% to 95% for dose rate 1 L/ha and from 72% to 96% for 0.6 L/ha. Average performance of standard was comparable to average efficacy of BAS 765 00 F at dose rate 0.6 L/ha and worse than full dose of BAS 765 00 F. The performance of the product in above trials fully supports dose range 0.6 L/ha - 1 L/ha in Czech Republic.

***Puccinia triticina* (PUCCRT), brown rust of wheat (KCP 6.2).**

Trials supporting efficacy of BAS 765 00 F against *Puccinia triticina* in Czech Republic were conducted in the Maritime, North-East (Poland) and South-East zone (Slovakia). Trials from Poland and Slovakia were conducted in regions with high (about 80% or higher) similarity to chosen regions of Czech Republic. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. The standard used for this disease was Proline at maximum dose rate.

Table 3.2-38: Control of *Puccinia triticina* in wheat – inf., diseases control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	23.1	78.2	84.2	63.6
	min- max	18.8-27.5	77.8-78.7	82.7-85.8	44.0-83.2
	n	2	2	2	2
North-East	average	12.7	90.7	94.2	91.1
	min-max	5.3-26.9	84.7-100.0	87.9-100.0	84.4-100.0
	n	5	5	5	5
South-East	average	11.3	91.3	95.9	91.9
	min- max	8.8-12.7	83.2-95.7	90.6-100.0	84.3-96.0
	n	3	3	3	3
All	average	14.4	88.4	92.7	85.8
	min-max	5.3-27.5	77.8-100.0	82.7-100.0	44.0-100.0
	n	10	10	10	10

BAS 765 00 F gave outstanding control of *Puccinia triticina* with an average 93% recorded for dose rate 1.0 L/ha and 88% for dose rate 0.6 L/ha. Infection in the untreated ranged from 5% to 28% (~14%). The efficacy of the product varied from 83% to 100% for full dose rate and from 78% to 100% for dose rate 0.6 L/ha. The performance of the product in above trials fully supports dose range 0.6 L/ha - 1 L/ha in Czech Republic.

***Blumeria graminis* (ERYSGR), powdery mildew of wheat (KCP 6.2)**

Trials supporting efficacy of BAS 765 00 F against *Blumeria graminis* in Czech Republic were conducted in the Maritime, North-East (Poland) and South-East zone (Slovakia). Trials from Poland and Slovakia were conducted in regions with high (about 80% or higher) similarity to chosen regions of Czech Republic. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. The standard used for this disease was Proline at maximum dose rate.

Table 3.2-39: Control of *Blumeria graminis* in wheat – infection, diseases control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	17.5	82.9	74.3	57.1
	min-max	-	-	-	-
	n	1	1	1	1
North-East	average	6.4	82.4	87.7	91.3
	min-max	5.7-7.3	63.1-100.0	72.1-100.0	85.1-100.0
	n	3	3	3	3
South-East	average	10.5	65.6	98.1	89.5
	min-max	-	-	-	-
	n	1	1	1	1
All	average	9.4	79.1	87.1	84.1
	min-max	5.7-17.5	63.1-100.0	72.1-100.0	57.1-100.0
	n	5	5	5	5

BAS 765 00 F gave good control of *Blumeria graminis* with an average 87% recorded for dose rate 1.0 L/ha and 79% for dose rate 0.6 L/ha. Infection ranged from 6% to 18% (~9%). The efficacy of the product varied from 72% to 100% for dose rate 1.0 L/ha and from 63% to 100% for dose rate 0.6 L/ha. The performance of the product in above mentioned trials fully supports dose range 0.6 L/ha - 1 L/ha in Czech Republic.

***Oculimacula* spp. (PSDCHE), Cereal eyespot (KCP 6.2)**

Trials supporting efficacy of BAS 765 00 F against *Oculimacula* spp. in Czech Republic were conducted in the Maritime, North-East (Poland) and South-East zone (Slovakia). Trials from Poland and Slovakia were conducted in regions with high (about 80% or higher) similarity to chosen regions of Czech Republic. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. The standard used for this disease was Proline / Proline 275 at maximum dose rate.

Table 3.2-40: Control of *Oculimacula* spp. in wheat – inf., diseases control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Maritime	average	14.0	77.5	88.3	75.7
	min-max	8.5-18.7	67.9-100.0	77.8-100.0	66.1-84.0
	n	4	4	4	4
North-East	average	27.1	73.2	84.1	87.0
	min- max	23.5-32.3	72.3-73.6	78.3-91.2	78.3-92.2
	n	3	3	3	3
South-East	average	23.0	78.4	88.1	87.0
	min-max	21.0-25.0	61.6-95.2	76.2-100.0	74.0-100.0
	n	2	2	2	2
All	average	20.4	76.3	86.9	82.0
	min-max	8.5-32.3	61.6-100.0	76.2-100.0	66.1-100.0
	n	9	9	9	9

BAS 765 00 F gave good control of *Oculimacula* spp. with an average 87% recorded for dose rate 1.0 L/ha and 76% for dose rate 0.6 L/ha. Infection ranged from 9% to 32% (~20%). The efficacy of the product at full dose rate varied from 76% to 100% and from 62% to 100% for dose rate 0.6 L/ha. Standard products performed on slightly lower level than full dose rate of BAS 765 00 F. The performance of the product in above mentioned trials fully supports a dose range 0.6 L/ha - 1 L/ha in Czech Republic.

***Pyrenophora teres,* (PYRNTE), net blotch of barley (KCP 6.2)**

Trials supporting efficacy of BAS 765 00 F against *Pyrenophora teres* in Czech Republic were conducted in the North-East (Poland) and South-East zone (Slovakia). Trials from Poland and Slovakia were conducted in regions with high (about 80% or higher) similarity to chosen regions of Czech Republic. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. The standard used for this disease was Proline at maximum dose rate.

Table 3.2-41: Control of *Pyrenophora teres* in barley – infection, diseases control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East	aver	8.8	95.6	97.9	94.4
	min-max	4.5-20.0	80.0-100.0	88.8-100.0	87.0-100.0
	n	9	9	9	9
South-East	aver	16.6	82.3	90.6	71.7
	min-max	8.6-24.6	64.8-99.7	81.4-99.7	44.2-99.1
	n	2	2	2	2
All	aver	10.2	93.2	96.6	90.3
	min-max	4.5-24.6	64.8-100.0	81.4-100.0	44.2-100.0
	n	11	11	11	11

BAS 765 00 F gave outstanding control of *Pyrenophora teres* with an average 97% recorded for dose rate 1.0 L/ha and 93% for dose rate 0.6 L/ha. Infection in the untreated ranged from 5% to 25% (~10%). The efficacy of the product varied from 81% to 100% for full dose rate and from 65% to 100% for dose rate 0.6 L/ha. Standards performed on a slightly lower level than full dose of BAS 765 00 F and similar to lower dose of the product.

The very good performance of the product was on a similar level in all trials. The exception was one trials from Slovakia with lower efficacy especially for dose rate 0.6 L/ha. The reason of this could be late application when first symptoms on L3 were visible. The performance of the standard which was worse than performance of dose rate 0.6 L/ha of BAS 765 00 F confirms unfavourable conditions. The performance of the product in above mentioned trials fully supports dose range 0.6 L/ha - 1 L/ha in Czech Republic.

***Puccinia hordei* (PUCCHD), brown rust of barley**

Trials supporting efficacy of BAS 765 00 F against *Puccinia hordei* in Czech Republic were conducted in the North-East EPPO zone (Poland). Trials from Poland were conducted in regions with high (about 80% or higher) similarity to chosen regions of Czech Republic. Therefore, those trials fully confirm the efficacy of the product in Maritime EPPO zone. The standard used for this disease was Proline at maximum dose rate.

Table 3.2-42: Control of *Puccinia hordei* in barley – infection, diseases control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
Norh-East	average	17.3	82.4	88.9	88.4
	min-max	6.4-37.7	60.0-100.0	69.8-100.0	46.5-100.0
	n	10	10	10	10

BAS 765 00 F gave very good control of brown rust with an average 89% recorded for dose rate 1.0 L/ha and 82% for dose rate 0.6 L/ha. Infection ranged between 6% and 38% (~17%) in the untreated. Standard performed similar to full rate of BAS 765 00 F. However BAS 765 00 F provided slightly more consistent control of brown rust. The performance of the product in above mentioned trials fully supports the dose range 0.6 L/ha - 1 L/ha in Czech Republic.
In North-East and South-East EPPO zones the majority of claimed uses, especially very important pathogens like *Zymoseptoria tritici* in wheat, are supported by sufficient number of trials. However efficacy against *Blumeria graminis* is supported with 6 trials in North-East zone and 4 trials in South-East EPPO zone. Therefore the same approach as for Maritime zone described above was used.

Data set from North-East EPPO zone meets the criterion of minimum number of trials. However this data set can be supported with results of trial from region Zapadne Slovensko of Slovakia (DEV-F-2019-SK-C24-A-02.0-SK-SK0-P04). To justify this, region was compared to regions of Poland where wheat production is the largest. Data available on the web page of the Polish Statistical Office indicates that Dolnośląskie, Lubelskie and Wielkopolskie are important regions of cereal production.

If agroclimatic conditions are similar in selected regions of Slovakia and Poland so trial(s) from Slovakia can be used to support efficacy in Poland, it is logical that trials from Poland can be used to support efficacy in Slovakia. However registration is requested also in other countries of South-East zone. Therefore some regions of Poland were compared to selected regions of Hungary and Romania to prove that Polish trials can be used to support efficacy of BAS 765 00 F against ERYSGR in whole South-East zone. Regions of these countries with high cereals production (according to Eurostat) were selected. Since Polish trials on powdery mildew are located mainly in Dolnoslaskie, Opolskie and Wielkopolskie, these regions were selected for comparison. Only trials in which both dose rates were tested were used as supportive.

Table 3.2-43: Summary of reports on comparison of regions (supporting efficacy in North-East and South-East EPPO zones)

Region in South-East EPPO zone	Region in North-East EPPO zone	Similarity between regions
Zapadne Slovensko	Dolnoslaskie	85%, 86%
	Lubelskie	81%, 82%
	Wielkopolskie	77%, 78%

Region in North-East EPPO zone	Region in South-East EPPO zone	Similarity between regions
Dolnoslaskie	Del-Dunantul (Hungary)	87%, 89%
	Sud (Romania)	80%, 84%
Wielkopolskie	Del-Dunantul (Hungary)	82%, 82%
	Sud (Romania)	77%, 79%
Opolskie	Zapadne Slovensko (Slovakia)	82%, 83%
	Del-Dunantul (Hungary)	85%, 87%
	Sud (Romania)	79%, 81%

The level of similarity between regions where trial is conducted and regions for which are used as supportive is 77%-89%. This is considered high similarity and risk of different behaviour of the same plant protection product when applied in these regions is negligible. Therefore results of the trial are considered reliable for regions for which are used as supportive.

***Blumeria graminis* (ERYSGR), powdery mildew of wheat (KCP 6.2)**

Presented above comparison of agroclimatic conditions in Poland and countries of the South-East EPPO zone justify relying on Polish and Slovak trial to support efficacy in the North-East zone and use of Polish trials to support efficacy in the South-East zone. Therefore the efficacy of BAS 765 00 F against *Blumeria graminis* in Poland is supported with was tested in 7 trials conducted in the North-East zone (6 trials) and South-East zone (1 trial). The efficacy of BAS 765 00 F against *Blumeria graminis* in the South-East EPPO zone is supported with 7 trials conducted in this zone (4 trials) and Poland - North-East zone (3 trials).

Table 3.2-44: Control of *Blumeria graminis* in wheat – North-East zone - disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F	Proline
			1.0 L/ha	0.8 L/ha
North-East	average	10.5	78.9	82.5
	min-max	5.7-22.0	54.9-100.0	53.5-100.0
	n	6	6	6
South-East	average	10.5	98.1	89.5
	min-max	-	-	-
	n	1	1	1
All	average	10.5	81.6	83.5
	min-max	5.7-22.0	54.9-100.0	53.5-100.0
	n	7	7	7

BAS 765 00 F gave good control of Blumeria graminis with an average 82% recorded for dose rate 1.0 L/ha. Infection ranged from 6% to 22% (~11%). The efficacy of the product varied from 55% to 100%. It should be underlined that in trials DEV-F-2019-PL-C23-A-02.0-PL-PLD-001 with the lowest efficacy was visible, results for standard product confirm unfavourable conditions. The performance of the product differs more due to specific conditions during the trials than localization in various EPPO zones. Therefore this data fully support efficacy of product in Poland (North-East EPPO Zone).

Table 3.2-45: Control of *Blumeria graminis* in wheat - South-East zone –disease control (%) - summary

EPPO Zone		Untreated	BAS 765 00 F		Proline
			0.6 L/ha	1.0 L/ha	0.8 L/ha
North-East	average	6.4	82.4	87.7	91.3
	min-max	5.7-7.3	63.1-100.0	72.1-100.0	85.1-100.0
	n	3	3	3	3
South-East	average	14.9	76.6	90.8	87.0
	min-max	6.5-27.5	65.6-96.0	78.2-98.7	81.1-94.7
	n	4	4	4	4
All	average	11.2	79.1	89.5	88.8
	min-max	5.7-27.5	63.1-100.0	72.1-100.0	81.1-100.0
	n	7	7	7	7

BAS 765 00 F gave in S-E and supporting trials good control of Blumeria graminis with an average 79% and 90% recorded for dose rates 0.6 L/ha and 1.0 L/ha respectively. Infection ranged from 6% to 28% (~11%). The performance of the product differs more due to specific conditions during the trials than localization in various EPPO zones. Therefore this data fully supports efficacy of product in South-East EPPO Zone.

Efficacy of BAS 765 00 F against FUSASP is claimed only in South-East EPPO zone. However claim about efficacy can be supported with 4 trials form South-East zone. Therefore additionally 2 trials from Czech Republic were used as supportive. Both trials were conducted in region Stredni Morava which is directly adjacent to Slovak border. However these trials are intendent to support efficacy against FUSASP in whole South-East zone. Therefore region Stredni Morava was compared to selected region of Slovakia, Hungary and Romania to fully prove that Czech trials can be used to confirm efficacy of BAS 765 00 F against FUSASP in South-East zone. Regions of these countries with high cereals production (according to Eurostat) were selected.

Table 3.2-46: Summary of reports on comparison of regions (supporting efficacy in South-East zone)

Region in Maritime EPPO zone	Region in South-East EPPO zone	Similarity between regions
Stredni Morava	Zapadne Slovensko (Slovakia)	84%, 85%
	Del-Dunantul (Hungary)	80%, 80%
	Sud (Romania)	76%, 78%

The level of similarity between regions where trials are conducted and regions for which are used as supportive is 76%-85%. This is considered high similarity and risk of different behaviour of the same plant protection product when applied in these regions is negligible. Therefore results of the trials are considered reliable for regions in South-East EPPO zone for which are used as supportive. This justifies of trials from both EPPO zones presented in Efficacy section.

Comments of zRMS:

The applicant submitted 113 reports showing the results in research into product efficacy carried out in 2018, 2019 and 2020 in NE, SE and Maritime EPPO climatic zones, on cultivars of:

- winter wheat (69 trials) against: (SEPTTR) *Zymoseptoria tritici*, (PUCCRT) *Puccinia triticina, (*ERYSGR) *Blumeria graminis, (*PYRNTR) *Pyrenophora tritici-repentis, (*FUSASP) - *Fusarium* spp., (PSDCHE) *Oculimacula* spp.;
- winter and spring barley (30 trials) against: (PYRNTE) *Pyrenophora teres*, (PUCCHD) *Puccinia hordei, (*ERYSGR) *Blumeria graminis*;
- winter triticale (7 trials) against (SEPTSP) *Septoria* spp., (PUCCRE) *Puccinia recondite*;
- rye (7 trials) against (PUCCRE) *Puccinia recondite*

to supports the registration of BAS 765 00 F in countries within the Central registration zone: PL, CZ, HU, RO, SI and SK.

In these trials, the efficacy of BAS 765 00 F was compared to Proline or Proline 275 (BAS 93141 F or BAS 93144 F) containing prothioconazole (250 and respectively 275 g. a. i./L) as reference products.

NE EPPO climatic zone (Poland)

Trials were conducted in several region in Poland. In all regions cereals were grown commercially with natural diseases infection. Trials were of randomized block design with a minimum of four replicates. Details on trial sites, applications are included in the Appendix 4 of BAD.
All trials were conducted by: University of Science and Technology in Bydgoszcz, Institute of Plant Protection-National Research Institute in Poznań, Agrostat Sp. z o.o., BASF Polska Sp. z o. o., SGS Polska Sp. z o. o., Biotek Agriculture Polska Sp. z o. o., AGRECO sp. z o. o., which are units with rights for performing investigation on efficacy of plant protection products. Investigations were performed according to principles of "Good Experimental Practice" (GEP), (List of Certificates includes Appendix 1 of BAD).

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:
- EPPO 1/135 (4) Phytotoxicity assessment

- EPPO 1/152 (4) Design and analysis of efficacy evaluation trials
- EPPO 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice
- EPPO 1/223 (2) Introduction to the efficacy evaluation of plant protec-tion products
- EPPO 1/239 (2) Dose expression of plant protection products
- PP 1/26(4) Foliar and ear diseases on cereals
- PP 1/28 (3) Eyespot of cereals

The product BAS 765 00 F was tested:

- in different varieties of winter wheat (Arkadia, Zeppelin, Aleksander, Fidelius, Delawar, Priceps, Skagen, Pamir, Tobak, Florian, Patras, Opal, Tonacja, Joker, Zyta, Hondia) at the dose rate of 1,0 L/ha and was applied one time (BBCH 30-69, for PSDCHE BBCH 30-32 - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: SEPTTR, PUCCRT, ERYSGR, PSDCHE; results were presented at the following time after treatment [days after treatments]: for SEPTTR – 21-51, for PUCCRT- 21-41, for ERYSGR- 27-41, for PSDCHE- 40-64;
- in different varieties of winter (Calypso, Ordinale, Kosmos, Kobuz, Bazant, Sandra, Kosmos, Zenek, Quadriga, Wotan) and spring barley (Kucyk, Hajduczek, Olof, Harris) at the dose rate of 1,0 L/ha and was applied one time (BBCH 32-55 (W), BBCH 31-49 (S), - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: PYRNTE, PUCCHD; results were presented at the following time after treatment [days after treatments]: for PYRNTE – 20-38 (s) and 21-40 (w), for PUCCHD – 18 (s) and 30-40 (w);
- in different varieties of winter triticale (Meloman, Fredro, Grenado, Rodonto) at the dose rate of 1,0 L/ha and was applied one time (BBCH 38-51 - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: SEPTSP, PUCCRE; results were presented at the following time after treatment [days after treatments]: for SEPTSP – 20-49, for PUCCRE – 31;
- in different varieties of winter rye (Su Forsetti, Dankowskie Diam, Mephisto) at the dose rate of 1,0 L/ha and was applied one time (BBCH 37-45 - target time at the onset of the disease attack, spray volume 200 – 250 l/ha) against PUCCRE, results were presented at the following time after treatment [days after treatments]: for for PUCCRE – 41-54;

The efficacy of BAS 765 00 F was compared to Proline (BAS 93141 F) containing prothioconazole (250 g. a. i./L) as the reference product. The results were presented as a pest severity. The recommended dose rate of product is 1,0 L/ha, applied one time or two times when required.

The effectiveness of the product was describe according to the following scale:
≥ 80% – Effectively controlled **(E)**
60 – 80% – Medium effectively controlled **(ME)**
0 – 60% – Limiting the number of pest **(R)**

Efficacy of one application of dose rate 1,0 L/ha

The effectiveness of dose rate 1,0L/ha of BAS 765 00 F on winter wheat:

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 11 trials. The tested product effectively controlled disease (88,4%) and superior to that provided by the reference product (79%) – **E**
  Infection in the untreated ranging from 5,7% to 42,2% (average 16%);
- against *Puccinia triticina* **PUCCRT** (brown rust of wheat) in 11 trials. The tested product effectively controlled disease (92,2%) and superior to that provided by the reference product (82,8%) – **E**
  Infection in the untreated ranging from 5,3% to 34,8% (average 14,4%);
- against *Blumeria graminis* **ERYSGR** (powdery mildew of wheat) in 6 trials. Additionally data from DE and SK (two trials) might be recognized as a supportive.The tested product effectively controlled disease (83,8%) and similarly to that provided by the reference product (76,7%) – **E**
  Infection in the untreated ranging from 5,7% to 22% (average 10,5%);
- against *Oculimacula* spp **PSDCHE** (cereal eyespot) in 8 trials. The tested product effectively controlled disease (82,6%,) and superior to that provided by the reference product (79,4%) – **E**
  Infection in the untreated ranging from 23,5% to 42,2% (average 34,3%).

In the GAP table, the Applicant asked for registration of the product also for protection of TRZAS, TRZDU, TRZSP. In accordance with the extrapolation rules set by Polish Ministry of Agriculture and Rural Development results from winter wheat (with full package of data for SEPTTR, PUCCRT, ERYSGR, PSDCHE) can be extrapolated to spring wheat. Nevertheless, according to the principles of extrapolation, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. Therefore, to support efficacy of spring wheat 1-2 trials for the above-mentioned diseases must be submitted.

Triticum durum and *Triticum spelta L.* are minor uses in Poland. The evaluation for these crops was not performed. In case of art. 33 of PPPR authorization the Applicant needs to present efficacy data. For the purpose of BAS 765 00 F authorization any efficacy data for minor uses was not presented by the Applicant.

At the stage of the product commenting, the Applicant asked about evaluation 2 additional trials for spring wheat carried out in North-East EPPO zone. Those two additional reports were evaluated and dRR was changed accordingly. The Applicant wrote:

"In 2021 two trials were conducted on spring wheat. Results of these trials indicate that the product BAS 765 00 F effectively controls diseases in spring wheat. Since a representative number of trials is provided for spring wheat to which we want to extrapolate, BASF believes that extrapolation rules can be used in this case. Therefore, we would like to ask for inclusion of available results in spring wheat and use of data on winter wheat to support efficacy in spring wheat.

Table 1. Control of diseases in spring wheat – infection, disease control (%) - individual trial results

Trial ID	Disease	Date of trt. GS crop water vol.	PP	DAT	Untr	BAS 76500 F				Proline	
						0.6 L/HA		1.0 L/HA		0.8 L/HA	
					inf.	inf.	eff.	inf.	eff.	inf.	eff.
DEV-F-2021-PL-C39-A-03.0-PL-PLB-B19	PYRNTR	10-JUN-2021 39 - 41 - 39 200 L/HA	L2	25	19.3	5.0	74.0	4.0	79.2	4.5	76.6
DEV-F-2021-PL-C39-A-03.0-PL-PLC-120	SEPTTR	08-JUN-2021 37 - 39 - 37 200 L/HA	L1	40	5.5	1.6	70.6	1.3	76.0	1.8	68.3
DEV-F-2021-PL-C39-A-03.0-PL-PLC-120	ERYSGT	08-JUN-2021 37 - 39 - 37 200 L/HA	L1	40	8.8	3.2	64.1	1.7	80.9	1.7	80.6

BAS 765 00 F gave good control of diseases in spring wheat. The performance of the target dose rate was close to 80% for all diseases and usually outperformed the standard. The dose response was visible in both trials confirming that dose rate of 1.0 L/ha should be used in North-East EPPO zone. The results are in line with results obtained for winter wheat, therefore confirm the validity of extrapolation rules and possibility of extrapolation."

The Evaluator's opinion:

Efficacy of one application of dose rate 1,0 L/ha

The effectiveness of dose rate 1,0L/ha of BAS 765 00 F on spring wheat (BBCH: 37-39, variety Goplana, water volume 200 l/ha):

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 1 trials. The tested product medium effectively controlled disease (76,0%) and superior to that provided by the reference product (68,3%) – **ME**

Infection in the untreated was 5,5%.

- against *Blumeria graminis* **ERYSGR** (powdery mildew of wheat) in 1 trial.The tested product effectively controlled disease (80,9%) and similarly to that provided by the reference product (80,6%) – **E**

Infection in the untreated was 8,8%;

Data against diseases on winter wheat might be extrapolated for spring wheat. According to the principles of extrapolation, the Applicant presented a representative number of trials (1 trial) for spring wheat against SEPTTR and ERYSGR. BAS 765 00 F effectively controlled ERYSGR and medium effectively controlled SEPTTR in spring wheat at dose rate 1,0 L/ha.

The Applicant submitted also data on spring wheat against PYRNTR. There is no possibility to recognize this result because, data against this disease had not been submitted for winter wheat.

The effectiveness of dose rate 1,0L/ha of BAS 765 00 F on winter and spring barley:

- against *Pyrenophora teres* **PYRNTE** (net blotch of barley) in 9 trials on winter barley and in 5 trails on spring barley. The tested product effectively controlled disease on winter barley (94,9%) and similarly to that provided by the reference product (92,6%) – **E;** The tested product also effectively controlled disease on spring barley (91,1%) and superior to that provided by the reference product (83,6%) – **E**
  Infection in the untreated: for winter barley ranging from 4,5% to 10,3% (average 7,6%) and for spring barley ranging from 6,5% to 36,0% (average 15,4%);

- against *Puccinia hordei* **PUCCHD** (brown rust of barley) in 7 trials on winter barley and in 3 trails on spring barley. The tested product effectively controlled disease on winter barley (90,5%) and superior to that provided by the reference product (87,7%) – **E;** The tested product also effectively controlled disease on spring barley (85,4,9%) and similarly to that provided by the reference product (90,2%) – **E;**
  Infection in the untreated: for winter barley ranging from 6,4% to 37,7% (average 19,6%) and for spring barley ranging from 8,5% to 14,1% (average 12,0%);

In accordance with the extrapolation rules set by the Polish Ministry of Agriculture and Rural Development results from winter barley (with full package of data for PYRNTE and PUCCHD) can be extrapolated to spring barley. The presented data for winter and spring barley meet all requirements.

The effectiveness of dose rate 1,0L/ha of BAS 765 00 F on winter triticale:

- against *Septoria* spp. **SEPTSP** (septoria leaf blotch of triticale) in 4 trials. The tested product effectively controlled disease (89,5%) and similarly to that provided by the reference product (88,2%) – **E**

  Infection in the untreated ranging from 6,4% to 49,4% (average 21,2%);
- against *Puccinia recondita* **PUCCRE** (brown rust of triticale) in 1 trial. The tested product effectively controlled disease (100%) and similarly to that provided by the reference product (100%) – **E**
  Infection in the untreated – 6,3;

In the GAP table, the Applicant asked for registration of the product also for protection of SECCS. In accordance with the extrapolation rules set by the Polish Ministry of Agriculture and Rural Development results from winter wheat (with full package of data for SEPTTR and PUCCRT) can be extrapolated to winter triticale and to spring triticale. Nevertheless, according to the principles of extrapolation, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. Therefore, the above results are appropriate for winter triticale and cannot be used for spring triticale. To support efficacy of spring triticale 1-2 trials for the above-mentioned diseases must be submitted.

The effectiveness of dose rate 1,0L/ha of BAS 765 00 F on winter rye:

- against *Puccinia recondita* **PUCCRE** (brown rust of rye) in 3 trials. The tested product effectively controlled disease (91,9%) and similarly to that provided by the reference product (92,7%) – **E**
  Infection in the untreated ranging from 5,8% to 25,0% (average 14,6%).

In accordance with the extrapolation rules set by the Polish Ministry of Agriculture and Rural Development results from winter wheat (with full package of data for PUCCRT) can be extrapolated to rye. The presented data for winter wheat and winter rye meet all requirements for winter and spring rye.

BAS 765 00 F effectively controlled diseases in cereals at dose rate 1,0 L/ha in Poland. Maximum number of applications in one season is 2, with a minimum of 14 days between applications and between growth stages 30-69. For wheat, triticale and rye, if first application is done after BBCH 49 a minimal spray interval has to be 21 days. For PSDCHE application time is BBCH 30-32 of wheat.

SE EPPO climatic zone (Hungary, Slovakia Slovenia, Romania)

Trials were conducted in several region in BG, HU, RO, SK. Additionally the applicant has presented document – „Reports on comparison of agroclimatic conditions generated automatically by the RegPest application developed in a collaboration of IUNG-PIB and PSOR" for SE, NE and Maritime EPPO climatic

zones to suport data from one zone with data from another. To suport the possibility of using data from different EPPO climatic zones to present efficacy, the Applicant has presented also document „Expert report regarding division of Europe into regions characterized by homogenous soil and climatic conditions, within the boundaries of which the results of efficacy evaluation of pesticides can be relevant for the entire region". In both document the information. Both documents have presented similarities in agronomic conditions (average 80%) to recognise efficacy data from one EPPO climatic zone as supportive for another EPPO climatic zone.
In all regions cereals were grown commercially with natural diseases infection. Trials were of randomized block design with a minimum of four replicates. Details on trial sites, applications are included in the Appendix 4 of BAD.
Trials were conducted by units with rights for performing investigation on efficacy of plant protection products. Investigations were performed according to principles of "Good Experimental Practice" (GEP) (List of Certificates includes Appendix 1 of BAD).

For following trials GEP certification (BASD Doc. ID: 2013/1423440) for Anadiag Bulgaria EOOD Patriarha Ewtimij 21/52, Sofia 1142 has expired:
DEV-F-2019-BG-C05-A-02.0-BG-BG0-068
DEV-F-2019-BG-C15-A-02.0-BG-BG0-070
DEV-F-2019-BG-C24-A-02.0-BG-BG0-072
DEV-F-2019-BG-C36-A-02.0-BG-BG0-073
DEV-F-2019-BG-C36-A-02.0-BG-BG0-074

For following trials GEP certification (BASD Doc. ID:2013/1399864) for SC AgroProspect Srl, Brasov, Romania has expired:
DEV-F-2018-RO-C18-A-03.0-RO-RO0-002
DEV-F-2018-RO-C18-A-03.0-RO-RO0-001

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:
- EPPO 1/135 (4) Phytotoxicity assessment
- EPPO 1/152 (4) Design and analysis of efficacy evaluation trials
- EPPO 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice
- EPPO 1/223 (2) Introduction to the efficacy evaluation of plant protec-tion products
- EPPO 1/239 (2) Dose expression of plant protection products
- PP 1/26(4) Foliar and ear diseases on cereals
- PP 1/28 (3) Eyespot of cereals

The product BAS 765 00 F was tested:

- in different varieties of winter wheat (Sadovo, Petur, Joker, Capo, Stelarka, Murgavets, Ingenio, Madejka, Hasab, Petur, Andrada, Avenue, Discus, Sadovo, Sorial, Anapurna, Is Laudis, Renan Ezopus, GK Csillag, GK Koros, Nador, Genius, Ilona, Tobak, Arkadia, Florian) at the dose rates of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 30-69, for PSDCHE BBCH 30-32 - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: SEPTTR, PUCCRT, ERYSGR, PYRNTR, PSDCHE, FUSASP; results were presented at the following time after treatment [days after treatments]: for SEPTTR – 20-41, for PUCCRT- 20-43, for ERYSGR- 27-41, for PSDCHE- 40-61, for PYRNTR – 27-38, for FUSASP- 29-40;

- in different varieties of winter (Veslec, Obzor, Jub, Jalon, Azrah, Bazant) and spring (Malz) barley at the dose rate of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 32-71 (W), BBCH 39 (S), - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: PYRNTE, ERYSGR; results were presented at the following time after treatment [days after treatments]: for PYRNTE – 24 (s) and 21-50 (w), for ERYSGR- 24 (s) and 28-40 (w);

- in different varieties of winter triticale (Meloman, Fredro, Grenado, Rodonto, KSW Aveo, Lombardo) at the dose rate of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 38-51 - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: SEPTSP, PUCCRE; results were presented at the following time after treatment [days after treatments]: for SEPTSP – 20-54, for PUCCRE- 31-49;

- in different varieties of winter rye (Su Forsetti, Dankowskie Diam, Mephisto) at the dose rate of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 37-59 - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against PUCCRE; results were presented at the

following time after treatment [days after treatments]: for PUCCRE- 41-54;

The efficacy of BAS 765 00 F was compared to Proline (BAS 93141 F) containing prothioconazole (250 g. a. i./L) as the reference product. The results were presented as a pest severity. The recommended dose rate of product is 0.6 L/ha and 1,0 L/ha, applied one time or two times when required.

The effectiveness of the product was describe according to the following scale:
≥ 80% – Effectively controlled **(E)**
60 – 80% – Medium effectively controlled **(ME)**
0 – 60% – Limiting the number of pest **(R)**

Efficacy of one application of dose rates: 0,6 and 1,0 L/ha

The effectiveness of dose rate 0,6 l/ha and 1,0L/ha of BAS 765 00 F on winter wheat:

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 16 trials (1L/ha) and in 14 trails (0,6 L/ha) The tested product effectively controlled disease: 86,0% (0,6 L/ha) and 92,8% (1L/ha). The product performed similarly to the reference product (91,2%) – **E**
  Infection in the untreated ranging from 7,9% to 27,5% (average 15,0%);
- against *Puccinia triticina* **PUCCRT** (brown rust of wheat) in 19 trials (1L/ha) and in 16 trails (0,6 L/ha). The tested product effectively controlled disease: 89,8% (0,6 L/ha) and 93,3% (1L/ha). The product performed similarly to the reference product (90,2%) – **E**
  Infection in the untreated ranging from 6,3% to 28,1% (average 13,6%);
- against *Blumeria graminis* **ERYSGR** (powdery mildew of wheat) in 4 trials (0, 6 l/ha and 1L/ha) in SE zone. What is more the comparison of agroclimatic conditions in Poland (Dolnoslaskie, Opolskie and Wielkopolskie) and countries of the South-East EPPO zone (Sud-Romania, Del Dunantul -Hungary, Zapadne Slovensko -Slovakia) has showed similarity on the level about 80% and allowed to support efficacy from the South-East zone with data from NE zone. That is why 3 trials (dose rate 1,0l/ha) from Poland regions were chosen to support data for SE EPPO climatic zone. As a result the tested product medium effectively controlled disease at dose rate 0,6 L/ha (76,6%, 4 trails) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (81,6%, 7 trials) – **E**. The product at dose rate 1,0L/ha performed similarly to the reference product (83,5%). At a dose rate 0,6L/ha it performed a bit worse in comparison to the reference product (87,0%).
  Infection in the untreated ranging: for 0,6 L/ha -from 6,5% to 27,5% (average 14,9%) and for 1,0 L/ha - from 5,7% to 22,0% (average 10,5%).
- against *Pyrenophora tritici-repentis* **PYRNTR** (tan spot of wheat) in 6 trials (0, 6 l/ha and 1L/ha) in SE zone. The tested product medium effectively controlled disease at dose rate 0,6 L/ha (74,2%) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (85,7%) – **E**. The product at dose rate 1,0L/ha performed similarly to the reference product and at a dose rate 0,6L/ha it performed a bit worse in comparison to the reference product (82,1%). What is more trials with 1,0L/ha showed more consistent control of the disease.
  Infection in the untreated ranging from 6,5% to 27,5% (average 14,9%).
- against *Oculimacula* spp **PSDCHE** (cereal eyespot) in 4 trials for dose rate 0,6 l/ha and in 5 trials for dose rate 1L/ha (SE zone). The tested product medium effectively controlled disease at dose rate 0,6 L/ha (70,2%) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (87,2%) – **E**. The product at dose rate 1,0L/ha performed superior to the reference product (75,9%). At a dose rate 0,6L/ha it performed a bit worse in comparison to the reference product (79,4%). 8 trials from Poland might supportive for countries of SE EPPO climatic zone since the Applicant showed similarity of agronomic conditions for regions: Dolnoslaskie, Opolskie and Wielkopolskie and Sud-Romania, Del Dunantul -Hungary, Zapadne Slovensko -Slovakia. In trials for Poland the product at dose rate of 1,0 L/ha controlled the disease on the level of 82,6%(**E**).
  Infection in the untreated ranging: for 0,6 L/ha -from 21,0% to 49,5% (average 30,0%) and for 1,0 L/ha - from 20,3% to 49,5,0% (average 28,1%).
- *against Fusarium spp* **FUSASP** (Ear blight) in 4 trials at dose rate 1L/ha in SE zone and 2 trails from Czech Republic (Maritime EPPO climatic zone). Stredni Morava where 2 trials were conducted in Maritime EPPO climatic zone was compared to region Sud-Romania, Del Dunantul - Hungary, Zapadne Slovensko -Slovakia to prove that these 2 trials can be used to confirm efficacy of BAS 765 00 F against FUSASP in South-East zone. The level of similarity between these

regions is 76 - 85%.
As a result the tested product medium effectively controlled disease at dose rate 1,0 L/ha (65,8%) – **ME.** The efficacy of the product was not consistent and varied from 51% to 88% and performed similarly to the reference product (65,4%).
Infection in the untreated ranging from 4,5% to 83,4% (average 44,0%).

In the GAP table, the Applicant asked for registration of the product also for protection of TRZAS, TRZDU, TRZSP. Results from winter wheat (with full package of data for SEPTTR, PUCCRT, ERYSGR, PYRNTR, PSDCHE, FUSASP) might be extrapolated to TRZAS, TRZDU, TRZSP. Nevertheless, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. The zRMS will leave it to the decision of SE EPPO climatic zones Member States (cMS).

The effectiveness of dose rate 0,6 l/ha and 1,0L/ha of BAS 765 00 F on winter and spring barley:

- against *Pyrenophora teres* **PYRNTE** (net blotch of barley) in 12 trials on winter barley and in 1 trail on spring barley. Into 2 trials a double dose rate was applied, that is why they were not taken under consideration during this assessment of efficacy. On the other hand results of these 2 trials showed a safety of the double dose rate for the crop. This is also important information, because product might be used two times in a season when required.
  In winter barley the product was tested in 5 trials for dose rate 0,6 l/ha and in 10 trials for dose rate 1L/ha. In spring barley the product was tested in 1 trial for dose rate 0,6 l/ha and in 1 trial for dose rate 1L/ha.
  For winter barley the tested product effectively controlled disease at dose rate 0,6 L/ha (81,6%) – **E** and effectively controlled disease at dose rate 1,0 L/ha (85,7%) – **E**. The product at dose rates 0,6 L/ha and 1,0L/ha performed similarly to the reference product (84,5%).
  For spring barley the tested product medium effectively controlled disease at dose rate 0,6 L/ha (64,8%) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (81,4%) – **E**. The product at dose rates 0,6 L/ha and 1,0L/ha performed superior to the reference product (44,2%).
  Infection in the untreated: for winter barley, dose rate 0,6 L/ha ranging from 6,4% to 75,0% (average 36,7%) and dose rate 1,0 L/ha ranging from 5,0% to 75,0% (average25,9%).
  Infection in the untreated for spring barley, dose rate 0,6 L/ha and dose rate 1,0 L/ha is 8,6%.

- against *Blumeria graminis* **ERYSGR** (powdery mildew of barley); trials were conducted only in one season (2019). Activity against ERYSGR was tested in 4 trials in SE EPPO climatic zone and additionally one trial was conducted in Poland in Malopolskie. The Applicant did not provide of RegPest, because he considered it is unnecessary in this case (since the majority of trials are from SE EPPO zone). The zRMS leave it to the decision of SE EPPO climatic zones Member States (zMS) whether this approach as well as one season trials and less than minimal number of trials (6) are acceptable. Nevertheless below efficacy results for this set of trials are presented:
  In winter barley the product was tested in 2 trials for dose rate 0,6 l/ha and in 4 trials for dose rate 1L/ha. In spring barley the product was tested in 1 trial for dose rate 0,6 l/ha and in 1 trial for dose rate 1L/ha.
  For winter barley the tested product medium effectively controlled disease at dose rate 0,6 L/ha (75,45%) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (82,9%) – **E.** The product at dose rates 0,6 L/ha performed a bit worse to the reference product (83,35) and at dose rates 1,0L/ha performed similarly to the reference product (85,2%).
  For spring barley the tested product medium effectively controlled disease at dose rate 0,6 L/ha (62,4%) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (81,3%) – **E**. The product at dose rate 0,6 L/ha performed worse to the reference product and at dose rate 1,0 L/ha performed superior to the reference product (73,5%).
  Infection in the untreated: for winter barley, dose rate 0,6 L/ha ranging from 5,2% to 8,2% (average 6,7%) and dose rate 1,0 L/ha ranging from 5,2% to 31,0% (average15,8%).
  Infection in the untreated for spring barley, dose rate 0,6 L/ha and dose rate 1,0 L/ha is 12,8%.

Results from winter barley (with full package of data for PYRNTE, **ERYSGR**) can be extrapolated to spring barley. The applicant presented a representative number of trials -1- for spring barley that is why results for winter and spring barley might be acceptable taking under consideration remarks made above for set of data for **ERYSGR**. What is more the performance of product on spring barley against **PYRNTE** might be expected the same like on winter barley, that is why it can be expected the same

effectiveness on both crops **(E)**. The zRMS will leave it to the decision of SE EPPO climatic zones Member States (zMS).

The effectiveness of dose rate 0,6 L/h and 1,0L/ha of BAS 765 00 F on winter triticale against: *Septoria* spp. **SEPTSP** (septoria leaf blotch of triticale) and *Puccinia recondita* **PUCCRE** (brown rust of triticale)

The efficacy of BAS 765 00 F against **SEPTSP** in triticale was tested in 6 trials: 2 in Maritime EPPO climatic zone and 4 in North-East EPPO climatic zone. The tested product effectively controlled disease at dose rate 0,6 L/ha (86,5%) – **E** and effectively controlled disease at dose rate 1,0 L/ha (89,5%) – **E**. The product at dose rate 0,6 L/ha and 1,0 L/ha performed similarly to the reference product.
The efficacy of BAS 765 00 F against and **PUCCRE** in triticale was tested in 2 trials: 1 in Maritime EPPO climatic zone and 1 in North-East EPPO climatic zone. The tested product effectively controlled disease at dose rate 0,6 L/ha (87,6%) – **E** and effectively controlled disease at dose rate 1,0 L/ha (94,0%) – **E**. The product at dose rate 0,6 L/ha and 1,0 L/ha performed similarly to the reference product.

For South-East zone no trials on triticale were submitted. However, results from winter wheat (with full package of data for Septoria and brown rust) might be extrapolated to winter and spring triticale. Results of 16 trials on winter wheat clearly demonstrate control of Septoria and 19 trials demonstrate control of brown rust. Nevertheless, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. The zRMS will leave it to the decision of SE EPPO climatic zones Member States (zMS) whether presented set of data for triticale is appropriate to confirm efficacy of the product against SEPTSP and PUCCRE.

The effectiveness of dose rate 0,6 L/ha and 1,0L/ha of BAS 765 00 F on winter rye against *Puccinia recondita* PUCCRE (brown rust of rye)

The efficacy of BAS 765 00 F against and **PUCCRE** in triticale was tested in 7 trials: 4 in Maritime EPPO climatic zone and 3 in North-East EPPO climatic zone. The tested product effectively controlled disease at dose rate 0,6 L/ha (87,2%, 4 trials) – **E** and effectively controlled disease at dose rate 1,0 L/ha (92,8%, 7 trials) – **E**. The product at dose rate 0,6 L/ha and 1,0 L/ha performed similarly to the reference product.

For South-East zone no trials on rye were submitted. However, results from winter wheat (with full package of data for brown rust) might be extrapolated to rye. Results of 19 trials demonstrate control of brown rust in winter wheat. Nevertheless, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. The zRMS will leave it to the decision of SE EPPO climatic zones Member States (zMS) whether presented set of data for rye is appropriate to confirm efficacy of the product against PUCCRE.

BAS 765 00 F effectively controlled diseases in cereals at dose rate 0,6 L/ha and 1,0 L/ha in SE EPPO climatic zone. For FUSASP the only tested dose rate was 1,0 L/ha. Maximum number of the product applications in one season is 2, with a minimum of 14 days between applications and between growth stages 30-69. For wheat, triticale and rye, if first application is done after BBCH 49 a minimal spray interval has to be 21 days. For PSDCHE application time is BBCH 30-32 of wheat.

Maritime EPPO climatic zone (Czech Republic)

Trials were conducted in several region in CZ, UK, FR, DE. Additionally the applicant has presented document – „Reports on comparison of agroclimatic conditions generated automatically by the RegPest application developed in a collaboration of IUNG-PIB and PSOR" for SE, NE and Maritime EPPO climatic zones to support data from one zone with data from another. To suport the possibility of using data from different EPPO climatic zones to present efficacy, the Applicant has presented also document Expert report regarding division of Europe into regions characterized by homogenous soil and climatic conditions, within the boundaries of which the results of efficacy evaluation of pesticides can be relevant for the entire region. In both document the information. Both documents have presented similarities in agronomic conditions (average 80%) to recognise efficacy data from one EPPO climatic zone as supportive for another EPPO climatic zone.
In all regions cereals were grown commercially with natural diseases infection. Trials were of randomized block design with a minimum of four replicates. Details on trial sites, applications are included in the

Appendix 4 of BAD.
All trials were conducted by units with rights for performing investigation on efficacy of plant protection products. Investigations were performed according to principles of "Good Experimental Practice" (GEP) (List of Certificates includes Appendix 1 of BAD).

The efficacy trials were designed, conducted and reported according to the following EPPO guidelines:
- EPPO 1/135 (4) Phytotoxicity assessment
- EPPO 1/152 (4) Design and analysis of efficacy evaluation trials
- EPPO 1/181 (4) Conduct and reporting of efficacy evaluation trials including good experimental practice
- EPPO 1/223 (2) Introduction to the efficacy evaluation of plant protection products
- EPPO 1/239 (2) Dose expression of plant protection products
- PP 1/26(4) Foliar and ear diseases on cereals
- PP 1/28 (3) Eyespot of cereals

The product BAS 765 00 F was tested:

- in different varieties of winter wheat (Pankratz, Monopol, KWS Siskin, Gravity, Arkadia, Skagen, Pamir, Tobak, Florian, Capo, Stelarka, Madejka, Chevron, Opal, Joker, Akteur, Monopol, Kerrin, Ezopus) at the dose rates of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 30-69, for PSDCHE BBCH 30-32 - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: SEPTTR, PUCCRT, ERYSGR, PSDCHE; results were presented at the following time after treatment [days after treatments]: for SEPTTR – 20-52, for PUCCRT- 21-32, for ER-YSGR- 23-41, for PSDCHE- 49-84;
- in different varieties of winter (Calypso, Ordinale, Kobuz, Sandra, Kosmos,) and spring (Kucyk, Harris, Malz) barley at the dose rate of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 45-55 (W), BBCH 37-49 (S), - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: PYRNTE, PUCCHD; results were presented at the following time after treatment [days after treatments]: for PYRNTE – 20-34 (s) and 21-34 (w), for PUCCHD – 18-34 (s) and 21-40 (w);
- in different varieties of winter triticale (KWS Aveo, Lombardo) at the dose rate of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 37-39 - target time at the onset of the disease attack, spray volume 200 – 300 l/ha) against: SEPTSP, PUCCRE; results were presented at the following time after treatment [days after treatments]: for SEPTSP – 46-54, for PUCCRE – 49;
- in different varieties of winter rye (Su Forsetti, Mephisto) at the dose rate of 0,6 L/ha and 1,0 L/ha and was applied one time (BBCH 39-59 - target time at the onset of the disease attack, spray volume 250 – 300 l/ha) against PUCCRE; results were presented at the following time after treatment [days after treatments]: for PUCCRE – 41 53;

The efficacy of BAS 765 00 F was compared to Proline/Proline 275 (BAS 93141 F/BAS 93144 F) containing prothioconazole (250/275 g. a. i./L) as the reference product. The results were presented as a pest severity. The recommended dose rate of product is 0.6 L/ha and 1,0 L/ha, applied one time or two times when required.

The effectiveness of the product was describe according to the following scale:
≥ 80% – Effectively controlled **(E)**
60 – 80% – Medium effectively controlled **(ME)**
0 – 60% – Limiting the number of pest **(R)**

Efficacy of one application of dose rates: 0,6 and 1,0 L/ha

The effectiveness of dose rate 0,6 l/ha and 1,0L/ha of BAS 765 00 F on winter wheat:

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 4 trials (1L/ha) and (0,6 L/ha) in Maritime EPPO climatic zones. What is more the comparison of agroclimatic conditions in Poland (regions: Dolnoslaskie, Kujawsko-Pomorskie, Lubelskie, Pomorskie, Opolskie, Warmińsko -Mazurskie and Wielkopolskie), regions in Slovakia (Stredne Slovensko,Vychodne Slovensko, Zapadne Slovensko -Slovakia) to regions in Czech Republic (Jihovychod and Stredni Cechy) has showed similarity on the level about 80% and allowed to support efficacy for Czech Republic with data from Poland and Slovakia. That is why 5 trials (dose rate 0,6 L/ha and 1,0

L/ha) from Polish regions and 5 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Slovak regions were chosen to support data for Czech Republic.
As a result the tested product effectively controlled disease at dose rate 0,6 L/ha (86,3%) – **E** and effectively controlled disease at dose rate 1,0 L/ha (90,8%) – **E**. The product at dose rate 1,0 L/ha performed superior to the reference product and at the dose rate 0,6 L/ha it performed similarly to the reference product (87,1 %).
Infection in the untreated ranging: from 5,7% to 39,4% (average 15,8%);

- against *Puccinia triticina* **PUCCRT** (brown rust of wheat) in 2 trials (1L/ha) and (0,6 L/ha) in Maritime EPPO climatic zones. What is more the comparison of agroclimatic conditions in Poland (regions: Dolnoslaskie, Kujawsko-Pomorskie, Lubelskie, Pomorskie, Opolskie, Warmińsko -Mazurskie and Wielkopolskie), regions in Slovakia (Stredne Slovensko,Vychodne Slovensko, Zapadne Slovensko -Slovakia) to regions in Czech Republic (Jihovychod and Stredni Cechy) has showed similarity on the level about 80% and allowed to support efficacy for Czech Republic with data from Poland and Slovakia. That is why 5 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Polish regions and 3 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Slovak regions were chosen to support data for Czech Republic.
  As a result the tested product effectively controlled disease at dose rate 0,6 L/ha (88,4%) – **E** and effectively controlled disease at dose rate 1,0 L/ha (92,7%) – **E**. The product at dose rate 1,0 L/ha performed superior to the reference product and at the dose rate 0,6 L/ha it performed similarly to the reference product (85,8 %).
  Infection in the untreated ranging: from 5,3% to 27,5% (average 14,4%);
- against *Blumeria graminis* **ERYSGR** (powdery mildew of wheat) in 1 trial (1L/ha) and (0,6 L/ha) in Maritime EPPO climatic zones. What is more the comparison of agroclimatic conditions in Poland (regions: Dolnoslaskie, Kujawsko-Pomorskie, Lubelskie, Pomorskie, Opolskie, Warmińsko -Mazurskie and Wielkopolskie), regions in Slovakia (Stredne Slovensko,Vychodne Slovensko, Zapadne Slovensko -Slovakia) to regions in Czech Republic (Jihovychod and Stredni Cechy) has showed similarity on the level about 80% and allowed to support efficacy for Czech Republic with data from Poland and Slovakia. That is why 3 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Polish regions and 1 trial (dose rate 0,6 L/ha and 1,0 L/ha) from Slovak regions were chosen to support data for Czech Republic.
  As a result the tested product medium effectively controlled disease at dose rate 0,6 L/ha (79,1%) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (87,1%) – **E**. The product at dose rate 1,0 L/ha performed similarly to the reference product and at the dose rate 0,6 L/ha it performed a bit worse to the reference product (84,1 %).
  Infection in the untreated ranging: from 5,3% to 27,5% (average 14,4%);
- against *Oculimacula* spp **PSDCHE** (cereal eyespot) in 4 trials (1L/ha) and (0,6 L/ha) in Maritime EPPO climatic zones. What is more the comparison of agroclimatic conditions in Poland (regions: Dolnoslaskie, Kujawsko-Pomorskie, Lubelskie, Pomorskie, Opolskie, Warmińsko -Mazurskie and Wielkopolskie), regions in Slovakia (Stredne Slovensko,Vychodne Slovensko, Zapadne Slovensko -Slovakia) to regions in Czech Republic (Jihovychod and Stredni Cechy) has showed similarity on the level about 80% and allowed to support efficacy for Czech Republic with data from Poland and Slovakia. That is why 3 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Polish regions and 2 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Slovak regions were chosen to support data for Czech Republic.
  As a result the tested product medium effectively controlled disease at dose rate 0,6 L/ha (76,3%) – **ME** and effectively controlled disease at dose rate 1,0 L/ha (86,9%) – **E**. The product at dose rate 1,0 L/ha superior performed to the reference product and at the dose rate 0,6 L/ha it performed a bit worse to the reference product (82,0 %).
  Infection in the untreated ranging: from 8,5% to 32,3% (average 20,4%);

In the GAP table, the Applicant asked for registration of the product also for protection of TRZAS, TRZDU, TRZSP. Results from winter wheat (with full package of data for SEPTTR, PUCCRT, ERYSGR, PSDCHE) might be extrapolated to TRZAS, TRZDU, TRZSP. Nevertheless, a representative number of trials (1-2) should be provided for the crops to which we extrapolate. The zRMS will leave it to the decision of SE EPPO climatic zones Member States (cMS).

The effectiveness of dose rate 0,6 L/ha and 1,0L/ha of BAS 765 00 F on winter and spring barley:

- against *Pyrenophora teres* **PYRNTE** (net blotch of barley) no trials were conducted in Maritime EPPO climatic zones. Trials were conducted in Poland and Slovakia. Applicant has presented the comparison of agroclimatic conditions in Poland (regions: Dolnoslaskie, Kujawsko-Pomorskie, Lubel-skie, Pomorskie, Opolskie, Warmińsko -Mazurskie and Wielkopolskie), regions in Slovakia (Stredne Slovensko,Vychodne Slovensko, Zapadne Slovensko -Slovakia) to regions in Czech Republic (Jihovychod and Stredni Cechy) has showed similarity on the level about 80% and al-lowed to support efficacy for Czech Republic with data from Poland and Slovakia. That is why 6 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Polish regions and 1 trial (dose rate 0,6 L/ha and 1,0 L/ha) from Slovak regions for winter barley were chosen to support data for Czech Republic. However Slovak trial was carried out with double dose rate that is why it was not taken under consideration during this assessment of efficacy. On the other hand results of this trial showed safety of the double dose rate for the crop. This is also important information, because product might be used two times in a season when required.
  As a result in the winter barley the tested product effectively controlled disease at dose rate 0,6 L/ha (95,9%) – **E** and effectively controlled disease at dose rate 1,0 L/ha (98,2%) – **E**. The product at dose rate 1,0 L/ha and 0.6 L/ha performed superior to the reference (88,9 %).
  Infection in the untreated ranging: from 4,5% to 42,5% (average 10,8%);
  For spring barley 5 trials (dose rate 0,6 L/ha and 1,0 L/ha) from Polish regions and 1 trial (dose rate 0,6 L/ha and 1,0 L/ha) from Slovak regions were chosen to support data for Czech Republic.
  As a result in the spring barley the tested product effectively controlled disease at dose rate 0,6 L/ha (86,1%) – **E** and effectively controlled disease at dose rate 1,0 L/ha (92,6%) – **E.** The product at dose rate 1,0 L/ha and 0.6 L/ha performed superior to the reference (79,35 %).
  Infection in the untreated ranging: from 6,5% to 20,0% (average 10,8%);

- against *Puccinia hordei* **PUCCHD** (brown rust of barley) no trials were conducted in Maritime EPPO climatic zones. Trials were conducted in Poland. Applicant has presented the comparison of agroclimatic conditions in Poland (regions: Dolnoslaskie, Kujawsko-Pomorskie, Lubel-skie, Pomorskie, Opolskie, Warmińsko -Mazurskie and Wielkopolskie) to regions in Czech Republic (Jihovychod and Stredni Cechy). The similarity of those regions on the level about 80% has been showed and it has allowed to support efficacy for Czech Republic with data from Poland. That is why 7 trials (dose rate 0,6 L/ha and 1,0 L/ha) for winter barley and 3 trials (dose rate 0,6 L/ha and 1,0 L/ha) for spring barley from Polish regions were chosen to support data for Czech Republic.
  On winter barley the tested product effectively controlled disease (90,5%) at the dose rate 1,0 L/ha **-E** and it effectively controlled disease (82,7%) at the dose rate 0,6 L/ha **-E.** The product performed similarly to the reference product (88,1%).
  On spring barley the tested product effectively controlled disease (85,4,9%) at the dose rate 1,0 L/ha **-E**-and it effectively controlled disease (82,7%) at the dose rate 0,6 L/ha **-E.** The product at the dose rate 0,6 L/ha and 1,0 L/ha performed a bit worse to the reference product (90,72%);
  Infection in the untreated: for winter barley was average 19,6% and 17,4% (for 1,0 L/ha and 0,6 L/ha respectively) and for spring barley was average 12,0% and 12,6% (for 1,0 L/ha and 0,6 L/ha respectively);

Results from winter barley (with full package of data for PYRNTE, PUCCHD) might be extrapolated to spring barley. The applicant presented a representative number of trials -3- for spring barley that is why results for winter and spring barley might be acceptable. The zRMS will leave it to the decision of the cMS.

The effectiveness of dose rate 0,6 L/ha and 1,0L/ha of BAS 765 00 F on winter triticale:

- against *Septoria* spp. **SEPTSP** (septoria leaf blotch of triticale) in 2 trials in Maritime EPPO climatic zone. The tested product effectively controlled disease (89,4%) at the dose rate 1,0 L/ha - **E** -and effectively controlled disease (86,5%) at the dose rate 1,0 L/ha - **E**. The product performed similarly to the reference product (90,1%)Infection in the untreated was average 38,8%;

- against *Puccinia recondita* **PUCCRE** (brown rust of triticale) in 1 trial in Maritime EPPO climatic zone. The tested product effectively controlled disease (89,4%) at the dose rate 1,0 L/ha - **E** -and effectively controlled disease (86,5%) at the dose rate 0,6 L/ha - **E**. The product performed similarly to the reference product (90,1%). Infection in the untreated was average 38,8%;

In the GAP table, the Applicant asked for registration of the product also for protection of SECCS. Results from winter wheat (with full package of data for SEPTTR and PUCCRT) might be extrapolated to winter triticale and to spring triticale. Nevertheless, a representative number of trials (1-2) should be

provided for the crops to which we extrapolate. Therefore, the above results are appropriate for winter triticale and cannot be used for spring triticale. To support efficacy of spring triticale 1-2 trials for the above-mentioned diseases must be submitted. The zRMS will leave it to the decision of the cMS.

The effectiveness of dose rate 1,0L/ha of BAS 765 00 F on winter rye:

against *Puccinia recondita* **PUCCRE** (brown rust of rye) in 4 trials. The tested product effectively controlled disease (93,5%) at the dose rate 1,0 L/ha - **E** -and effectively controlled disease (87,2%) at the dose rate 0,6 L/ha - **E**. The product performed similarly to the reference product (94,5%). Infection in the untreated was average 31,1%;

Results from winter wheat (with full package of data for PUCCRT) might be extrapolated to rye. The presented data for winter wheat and winter rye meet all requirements for winter and spring rye. The zRMS will leave it to the decision of the cMS.

BAS 765 00 F effectively controlled diseases in cereals at dose rate 0,6 L/ha and 1,0 L/ha in trials presented for Czech Republic. Maximum number of the product applications in one season is 2, with a minimum of 14 days between applications and between growth stages 30-69. For wheat, triticale and rye, if first application is done after BBCH 49 a minimal spray interval has to be 21 days. For PSDCHE application time is BBCH 30-32 of wheat.

At the stage of the product commenting, the Applicant asked about evaluation 1 additional trial to prove possibility of using the water volume range 100-300 l/ha. That 1 additional report was evaluated and dRR was changed accordingly.
The Applicant wrote: “There is a high interest for farmers to apply pesticides at lower water volumes, that’s why the water volume range for BAS 765 00 F was defined with 100-300 l/ha. However, with conventional replicated small plot trials used for regular efficacy evaluation, a practically relevant test of water volumes as low as 100 l/ha is difficult without compromising on trial quality. A specific trial has therefore been designed to evaluate the performance of BAS 765 00 F with different water volumes.
This special field trial has been summarized in the table below to compare the biological performance of BAS 765 00 F and the standard Proline with 100 l/ha water volume vs. 200 l/ha and 300 l/ha water volume. In conclusion of all results, it can be summarized that BAS 765 00 F shows high efficacy also with a low water volume of 100 l/ha. Low water volume does not induce any phytotoxicity symptoms. Water volume of 100 l/ha has no negative effect on yield and quality parameters.

Table 1. Application of BAS 765 00 F (1 L/ha) and Proline (0.8 L/ha) at different water volumes

Trial ID	Date of trt. GS crop	PP	DALT	Factor assessed	Untr.	100 L/ha		200 L/ha		300 L/ha	
						BAS 76500F	Proline	BAS 76500F	Proline	BAS 76500F	Proline
DEV-F-2020-EX-CW1-V-04.0-DE-VTF-440	22-APR-2020 31 - 32 - 32 08-MAY-2020 37 - 39 - 39	LEAF	38	**SEPTTR** efficacy	70.5	79.4	78.0	74.5	70.9	75.9	64.9
		GRAIN	74	**YIELD** DT	88.6	111.7	107.0	106.8	103.7	108.4	102.9
			125	**HEKLIT** KG	67.5	72.2	71.4	71.9	71.1	71.5	70.5
			125	**TAUKOG** G	32.6	38.4	36.4	37.4	36.8	37.9	35.9
		PLANT	-4	**PHYTOX**	0	0	0	0	0	0	0
			-1		0	0	0	0	0	0	0
			7		0	0	0	0	0	0	0
			11		0	0	0	0	0	0	0
			21		0	0	0	0	0	0	0

We would like to ask for inclusion of available results of product biological performance with different water volumes. “
Evaluator’s opinion: the trial was carried out in DE, in 2020 – results might be acceptable - efficacy against SEPTTR, yield and phytotoxicity on winter wheat (variety Riband/EU, BBCH 32-39) for 100l/ha, 200 l/ha and 300 l/ha are comparable. Nevertheless, the final opinion is leaving for decision of cMS, because it is only trial which was conducted only in one EPPO climatic zone – the Maritime EPPO climatic zone.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

The effect of BAS 765 00 F on cereal quality was assessed by measuring yield, hectoliter weight of harvested grain and thousand grain weight (TGW) in efficacy trials. Yield was assessed as the grain yield from a known harvested area corrected to an 86% dry matter (14% of moisture). The results are expressed in deci-tonnes per hectare (dt/ha) and as a percentage of untreated plots. Thousand grain weight (TGW) was determined using an electric counter to produce 1000-grain sample lots for weighing. Results are presented as the weight of 1000 grains in grams, corrected to 86% dry matter content, and expressed as a percentage of untreated plots. Hectolitre weights were obtained in a similar manner by weighing a relevant sample size from each treatment and corrected for moisture content. Results are expressed as the weight of 100 litres of grain in kg and as a percent of untreated plots. Yield, hectoliter weight and thousand grain weight were presented separately for every crop included into this document.

Table 3.2-47: Yield effect of BAS 765 00 F in efficacy trials

Grouping	Number of trials	Untreated control			BAS 765 00 F 1.0 l/ha			Proline 0.8 l/ha		
		Mean dt	Mean %	Min & Max %	Mean dt	Mean %	Min & Max %	Mean dt	Mean %	Min & Max %
wheat	68	62.9	100	-	71.3	114.6	97.2-219.9	70.5	113.5	95.9-218.0
barley	30	55.9	100	-	62.7	113.8	98.5-164.8	62.6	113.6	98.2-184.8
rye	7	91.3	100	-	101.8	111.5	105.3-117.9	99.2	108.5	104.2-114.5
triticale	7	84.3	100	-	94.8	112.6	102.8-124.0	95.2	113.1	101.3-126.4

Table 3.2-48: Hectoliter weight effect of BAS 765 00 F in efficacy trials

Grouping	Number of trials	Untreated control			BAS 765 00 F 1.0 l/ha			Proline 0.8 l/ha		
		Mean kg	Mean %	Min & Max %	Mean kg	Mean %	Min & Max %	Mean kg	Mean %	Min & Max %
wheat	68	73.6	100	-	74.8	101.6	98.6-109.0	74.7	101.5	93.5-112.8
barley	30	64.4	100	-	65.6	101.9	90.0-107.4	65.9	102.3	99.1-110.0
rye	6	73.2	100	-	73.4	100.2	96.2-102.6	73.7	100.6	98.1-103.2
triticale	7	67.1	100	-	68.9	102.8	101.0-106.9	68.5	102.1	98.5-108.8

Table 3.2-49: Thousand grain weight effect of BAS 765 00 F in efficacy trials

Grouping	Number of trials	Untreated control			BAS 765 00 F 1.0 l/ha			Proline 0.8 l/ha		
		Mean g	Mean %	Min & Max %	Mean g	Mean %	Min & Max %	Mean g	Mean %	Min & Max %
wheat	68	39.9	100	-	41.4	103.9	87.1-119.8	41.3	103.6	85.2-123.1
barley	30	42.4	100	-	44.2	104.7	98.8-129.5	44.5	105.5	97.9-128.9
rye	7	31.2	100	-	33.0	106.0	99.0-120.0	31.2	100.8	88.9-107.2
triticale	7	38.1	100	-	41.2	108.3	102.8-114.2	41.7	109.1	103.3-120.1

Comments of zRMS:	**Quality parameters of treated cereals in the presence of challenging pest populations** The effect of BAS 765 00 F on cereals was assessed in efficacy trails by measuring following parameters: 1. Yield- grain yield from a known harvested area corrected to 86% dry matter [dt/ha] and % of untreated plots, 2. Hectolitre weights of the harvested grains presented in [kg] and % of untreated plots, 3. Thousand grain weight corrected to 86% dry matter presented in [g] and % of untreated plots **NE EPPO climatic zone** Yield [% of untreated plots] in: • winter wheat- 110,5 (1,0 L/ha) • winter and spring barley-115,1 (w) and 111,7 (s) • rye-110,6 (1,0 L/ha) • winter triticale 107,4 (1,0 L/ha) Hectolitre weights of the harvested grains [% of untreated plots] of: • winter wheat 101,5 (1,0 L/ha) • winter and spring barley - 100,6 (w) and 102,4 (s) • rye- 98,3 (1,0 L/ha) • winter triticale- 102,3 (1,0 L/ha) Thousand grain weight [% of untreated plots] of: • winter wheat -102,5 (1,0 L/ha) • winter and spring barley -102,2 (w) and 104 (s) • rye - 105,1 (1,0 L/ha) • winter triticale -107,3 (1,0 L/ha) **SE EPPO climatic zone (Hungary, Slovakia Slovenia, Romania)** Yield [% of untreated plots] in: • winter wheat- 110 (0,6 L/ha) and 112,8 (1,0 L/ha) • winter and spring barley-111,6 (0,6 L/ha) and 114,4 (1,0 L/ha) Hectolitre weights of the harvested grains [% of untreated plots] of: • winter wheat – 101,0 (0,6 L/ha) and 101,1 (1,0 L/ha) • winter and spring barley - 101,8 (0,6 L/ha) and 102,7 (1,0 L/ha) Thousand grain weight [% of untreated plots] of: • winter wheat -102,5 (0,6 L/ha) and 103,7 (1,0 L/ha) • winter and spring barley -103,0 (0,6 L/ha) and 104,0 (1,0 L/ha) **NE EPPO climatic zone (Czech Republic)** Yield [% of untreated plots] in: • winter wheat- 106,7 (0,6 L/ha) and 109,2 (1,0 L/ha) • rye-109,9 (0,6 L/ha) and 112,1 (1,0 L/ha) • winter triticale – 115,3 (0,6 L/ha) and 119,5 (1,0 L/ha) Hectolitre weights of the harvested grains [% of untreated plots] of: • winter wheat – 101,5 (0,6 L/ha) and 101,7 (1,0 L/ha) • rye- 101,6 (0,6 L/ha) and 101,1 (1,0 L/ha) • winter triticale- 101,8 (0,6 L/ha) and 103,4 (1,0 L/ha) Thousand grain weight [% of untreated plots] of: • winter wheat -104,2 (0,6 L/ha) and 103,9 (1,0 L/ha) • rye - 105,3 (0,6 L/ha) and 106,8 (1,0 L/ha)

	• winter triticale -107,3 (0,6 L/ha) and 109,7 (1,0 L/ha) BAS 765 00 F showed no negative impact on yield and quality parameters at dose rates 0,6 l/ha and 1.0 L/ha of winter wheat (68 trials), winter and spring barley (30 trials), winter triticale (7 trials), rye (6-7 trials). It might be concluded that the product will not adversely affect winter and spring wheat, winter and spring barley, winter and spring triticale, winter and spring rye.

Summary and conclusion

The above presented results confirm the claim made in the introduction that BAS 765 00 F is a highly effective fungicide, offering a great opportunity for the control of important pathogens of cereals. The active ingredients contribute towards a rapid and particularly long-lasting fungicidal action against the most important cereal pathogens.

Yield, hectolitre weight and thousand grain weight were presented separately for every crop included into this document. In efficacy trials treated with 1.0 l/ha of BAS 765 00 F no negative impact on these parameters were seen. In the majority of the trials instead positive impact on yield, hectolitre weight and thousand grain weight was seen.

3.3 Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

BAS 765 00 F (100 g a.i. mefentrifluconazole + 150 g kresoxim-methyl per litre SC formulation) is intended for control of powdery mildew (*Blumeria graminis* f.sp. *tritici*), Septoria leaf blotch (*Zymoseptoria tritici*), brown rust (*Puccinia triticina*), yellow rust (*Puccinia striiformis*), tan spot (*Pyrenophora tritici-repentis*), eyespot (*Oculimacula yallundae and Oculimacula acuformis*) and Fusarium head blight (*Fusarium* spp.) in wheat.
In barley it is intended for control of powdery mildew (*Blumeria graminis* f.sp. *hordei*), net blotch *(Pyrenophora teres)* and leaf rust (*Puccinia hordei*).
In rye it is intended for control of powdery mildew (*Blumeria graminis* f.sp. *secalis*), leaf scald (*Rhynchosporium secalis*) and leaf rust (*Puccinia recondita*).
In triticale it is intended for control of powdery mildew, Septoria leaf and glume blotch (*Zymoseptoria tritici* and *Parastagonospora nodorum*), leaf rust (*Puccinia recondita*)

Mode of action
Mefentrifluconazole is a fungicide belonging to the group of the sterol biosynthesis inhibitors (SBI, mode of action class G). Within the SBIs, it belongs to the subgroup of demethylation inhibitors (DMI, G1, FRAC 2020) and the chemical group of triazoles.
The primary mode of action of DMIs is the blocking of ergosterol biosynthesis through inhibition of cytochrome P450 sterol 14α-demethylase (CYP51). The depletion of ergosterol and accumulation of non-functional 14α-methyl sterols results in inhibition of growth and cell membrane disruption.
Mefentrifluconazole is the first isopropanol azole: the triazole ‘head’ sits on the ‘neck’ of a slim isopropanol linker. This chemical constellation ensures a high degree of structural flexibility that is unique among the DMIs. This slim linker requires less energy to adjust compared to conventional DMIs. When mefentrifluconazole approaches the active site of its target enzyme, the flexible linker allows it to form a hook, which fits into the enzyme’s binding pocket, resulting in strong inhibition of enzyme activity. This might explain the high intrinsic activity of mefentrifluconazole on the target enzyme, which has been shown in studies with the cyp51 of *Zymoseptoria tritici* in comparison with other DMIs (Figure 3.3-1).

Binding constant (= association constant) $[mol/l]^{-1}$

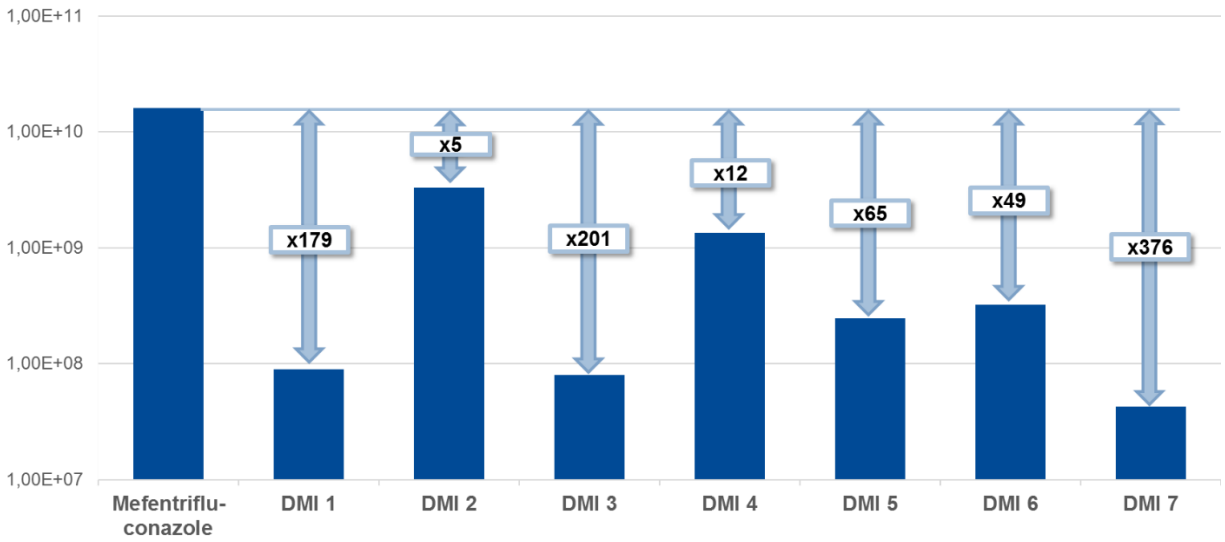


Figure 3.3-1: Binding constant (= association constant) of mefentrifluconazole and different DMIs [mol/l]-1 on the cytochrome P450 sterol 14α-demethylase (CYP51). The binding constant describes the affinity between a compound and its target. The higher the value, the stronger is the binding. Detailed method description in the chapter "Test Methods".

Kresoxim-methyl: According to the classification of the Fungicide Resistance Action Committee (FRAC), kresoxim-methyl belongs to the Mode of Action Group C (Respiration) and to the subgroup C3 (inhibition of complex III) with the target site cytochrome *bc*1 at QoI site and the FRAC code 11 with the group name QoI fungicides (Quinone outside inhibitors). The mode of action of QoI fungicides is the inhibition of mitochondrial respiration resulting from a blockage of the electron transport from ubihydroquinone to cytochrome *c* by means of a binding to the ubihydroquinone oxidation centre (Qo) of the cytochrome bc_1 complex (Complex III). This leads to a reduction of energy-rich ATP that is available to support a range of essential processes in the fungal cell.

Mechanism of resistance

Mefentrifluconazole: Three major mechanisms are associated with changes in DMI-sensitivity:

Mutations in the target gene (cyp51), as described e.g. for *Zymoseptoria tritici* (Leroux et al. 2006, Stammler et al. 2008, Huf et al. 2018), *Puccinia triticina* (Stammler et al. 2009) and *Phakopsora pachyrhizi* (Schmitz et al. 2014).

Overexpression of the target protein, as described e.g. for *Zymoseptoria tritici* (Cools et al. 2012), *Phakopsora pachyrhizi* (Schmitz et al. 2014), *Blumeriella jaapii* (Ma et al. 2006), *Puccinia triticina* (Stammler et al. 2009) and *Venturia inaequalis* (Schnabel and Jones 2001).

Reduced intracellular accumulation of DMIs by overexpression of efflux-pumps, as described e.g. for *Zymoseptoria tritici* (Leroux and Walker 2011) and *Botrytis cinerea* (Kretschmer et al. 2009, Grabke and Stammler 2015).

Various mutations in the target gene have different effects on different DMIs (Fraaije et al. 2007, Stammler et al. 2008, Huf et al. 2018, 2020). Target gene mutations might be combined and accumulate and can result in higher levels of resistance (Cools and Fraaije 2013, Huf et al. 2020). In addition, target site overexpression and/or enhanced efflux can also be found simultaneously in isolates (Stammler and Semar 2011, Cools and Fraaije 2013, Strobel et al. 2014, Huf et al. 2020). The accumulation of different resistance mechanisms results in a quantitative (directional) type of resistance and changes in the sensitivity of a population are gradual.

Kresoxim-methyl: There is evidence from studies with other inhibitors of the bc1 complex on the mechanism of resistance with baker's yeast (di Rago et al. 1989) and several non-pathogenic fungi (Kraiczy et al. 1996) that various target site mutations can lead to amino acid substitutions within the cytochrome b protein and that these changes can prevent the binding of a range of mitochondrial electron transport inhibitors to the cytochrome b protein. The main target site mutation in plant pathogens is the exchange from glycine to alanine at amino acid position 143 of the cytochrome b. This G143A mutation leads to high levels of resistance.

It is interesting to note that some fungal species do not show this mutation even after several years of intensive control by QoI fungicides, e.g. different rust species (*Puccinia* spp.), *Pyrenophora teres*, *Monilinia laxa, Monilinia fructicola, Guignardia bidwellii* and *Alternaria solani*. For these species this is connected with the presence of an intron (encoding a maturase, BASF internal studies) starting within or directly after the codon 143 (Grasso et al. 2006, Miessner and Stammler 2010, Miessner et al. 2011, Stammler et al. 2006). It is assumed that a mutation from a glycine- to an alanine-codon would lead to an incorrect splicing and consequently to a non-functional cytochrome b (Grasso et al. 2006).

A mutation at codon 129, which leads to the substitution of phenylalanine by leucine (F129L) is described for some of these "intron" species (e.g. *Pyrenophora teres* and *Alternaria solani*, Stammler et al. 2006, Pasche et al. 2005). The mutation F129L results generally in lower resistance factors (FRAC 2020, Semar et al. 2007).

Another mutation, the G137R has been rarely found in *Pyrenophora teres* and *Pyrenophora tritici-repentis* (BASF internal studies) and plays obviously only a minor role in the sensitivity response to QoI fungicides (FRAC 2020).

For the target pathogens in this resistance risk analysis an intron after the G143A is present in all *Puccinia species* and *Pyrenophora teres* (named "intron pathogens" in the following chapters) (Grasso et al. 2006 and BASF internal studies).

Evidence of resistance

Mefentrifluconazole: Some pathogens have shown a shift towards lower sensitivity in the period since DMI introduction. For most plant pathogenic fungi, the situation has stabilized after a period of adaptation (FRAC 2020).

European DMI sensitivity monitoring has been intensified for *Zymoseptoria tritici* since 2003, the year of the spreading of QoI resistance in this pathogen in Europe. A shift to a reduced sensitivity towards different DMIs has been determined with isolates taken from the most important cereal-growing regions in Europe (FRAC 2020, Strobel et al. 2014). Similar reports on stable sensitivity situations exist for *Puccinia triticina* (FRAC 2020, Stammler et al. 2009) and other *Puccinia* species (FRAC 2020), *Rhynchosporium secalis* (FRAC 2020), *Pyrenophora teres* (FRAC 2020), *Blumeria graminis* f.sp. tritici and *Blumeria graminis* f.sp. hordei (FRAC 2020).

Mutations and combinations of mutations in the target gene and to a lesser extent also enhanced efflux and target protein overexpression can be linked to the sensitivity changes observed (Cools and Fraaije 2013, Huf et al. 2020).

Isolates belonging to different cyp51-haplotypes showed variation in their sensitivity response to different DMIs, that means, correlation of sensitivity between various DMIs can be low or even negative (Stammler and Semar 2011). This is confirmed by frequency analyses of cyp51-haplotypes in the field after various DMI applications, which showed that DMIs select cyp51-haplotypes differently (Fraaije et al. 2007, Stammler et al. 2008). This is especially the case for mefentrifluconazole, which is highly active on many strains of *Zymoseptoria tritici*, which show lower sensitivity to other DMIs.

Hypothesis why mefentrifluconazole provides high efficacy of DMI shifted strains
Mutations in the cyp51 gene cause alterations of the binding site, often the binding site is widened, which affects the binding of conventional DMIs. The mefentrifluconazole molecule is more flexible in its structure than other DMIs and might therefore be able to bind even if the binding pocket shape is altered (Strobel et al. 2020) This flexibility comes from the fact that the triazole 'head' sits on the 'neck' of a slim isopropanol linker. This chemical constellation ensures a high degree of structural flexibility that is unique among the DMIs (Figure 3.3-2). This slim linker requires less energy to adjust compared to conventional DMIs. When mefentrifluconazole approaches the active site of the target enzyme C14-demethylase (cyp51), the flexible linker allows it to easily form a "hook", which fits perfectly into the enzyme's binding pocket, resulting in strong inhibition of enzyme activity. It easily adapts to different shapes and sizes of binding pockets caused by various target site mutations (Figure 3.3-3).

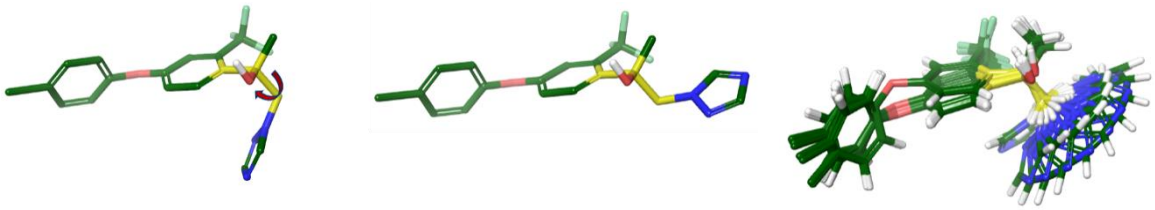


Figure 3.3-2: Flexibility of the mefentrifluconazole molecule

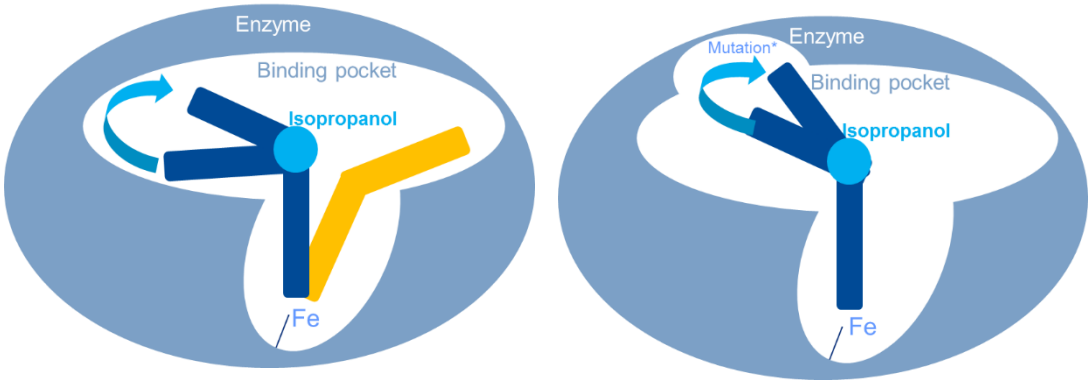


Figure 3.3-3: Adaption of mefentrifluconazole in a wildtype (left) and a mutated binding pocket (right), schematic. Blue: mefentrifluconazole, yellow: other DMI. The heme iron (Fe) of the cytochrome P450 is the major binding partner for the triazole ring of DMI fungicides.

Kresoxim-methyl: The evidence of resistance to QoIs comes from cases of field resistance shown by different plant pathogens. The pathogens have been isolated and found to be resistant to high concentrations of QoIs indicating a disruptive (single step) resistance (FRAC 2020).
The G143A mutation in the cytochrome *b* gene has been detected in several plant pathogenic fungi, including the target pathogens *Blumeria graminis, Zymoseptoria tritici, Parastagonospora nodorum and Pyrenophora tritici-repentis* of this resistance risk analysis, but not in *Puccinia* species or *Pyrenophora teres.* Only single cases are known for *Rhynchosporium secalis* from the last years monitoring's (FRAC 2020).
The mutation F129L has been found in *Pyrenophora teres* and *Pyrenophora tritici-repentis* and in these two pathogens also – but rarely - the mutation G137R mutation (BASF internal studies, FRAC 2020).
An actual list of plant pathogenic fungi where QoI resistance has been detected can be found on the FRAC webpage.

Cross resistance

Mefentrifluconazole: There are a lot of studies available on the sensitivity of plant pathogens, namely *Zymoseptoria tritici* towards DMIs. These studies indicated that a clear statement on DMI cross resistance is not possible. There are DMIs which show a good correlation for the sensitivity in *Zymoseptoria tritici*, but correlations for others are low, especially when sensitivities of imidazoles and triazoles are correlated. Obviously, there are mechanisms which might affect all DMIs to a more or lesser level, such as target site (cyp51) overexpression, enhanced efflux or some target site mutations. It has been shown for *Zymoseptoria tritici* in various studies that some target site mutations are more selective to the one than to another DMI. While cyp51-haplotypes containing I381V have higher EC_{50} values to some triazoles, such as tebuconazole and metconazole, EC_{50} values for prochloraz are on the wild type level or even lower (at least for the cyp51-haplotypes, where I381V is not combined with V136A and/or S524T, Leroux *et al.* 2011, Stammler e*t al.* 2008).
For mefentrifluconazole, this low correlation of sensitivity between DMIs is even more pronounced (Strobel *et al.* 2020). This is described in Figure 3.3-4, where sensitivity correlations of mefentrifluconazole and epoxiconazole and desthio-prothioconazole, respectively, are shown. The low correlation coefficients (R^2) indicate a low correlation with the sensitivity to other DMIs. Figure 3.3-5 shows that the current adaptation of *Z. tritici*, determined as EC_{50}, is in a smaller range for mefentrifluconazole than for other DMIs.

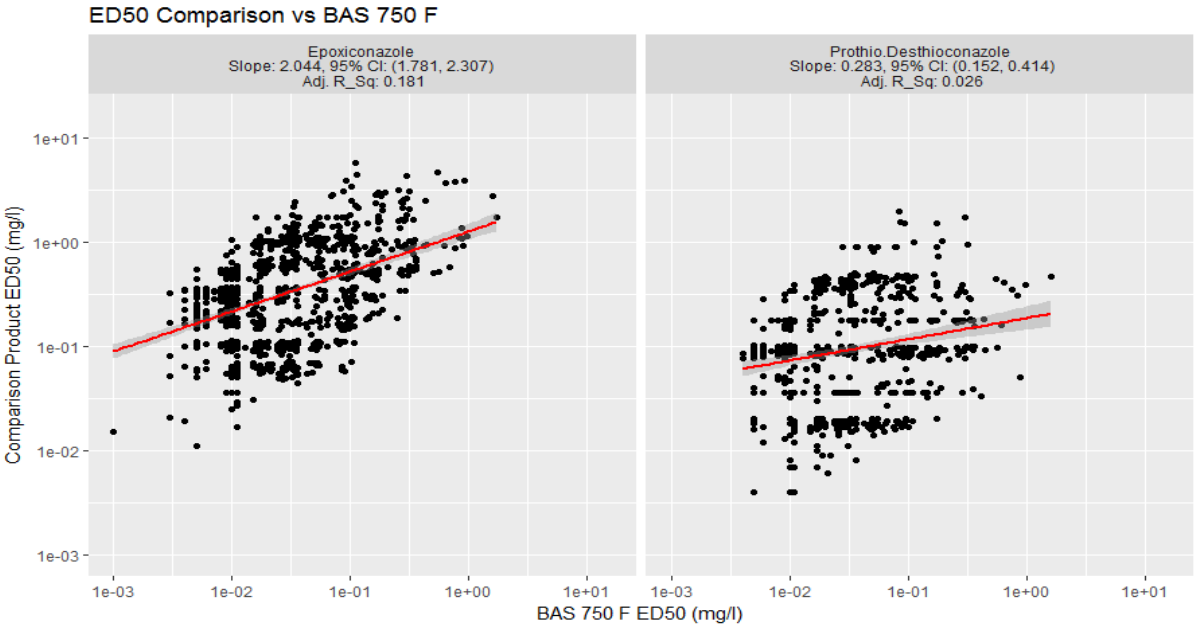


Figure 3.3-4: Correlation of the mefentrifluconazole sensitivity of *Zymoseptoria tritici* to epoxiconazole and desthio-prothioconazole, determined by microtiter assays (BASF, unpublished studies). R2 (Adj. R_Sq) are 0.181 and 0.026 for epoxiconazole and desthio-prothioconazole, respectively. Desthio-prothioconazole was used instead of prothioconazole due to its' recognized role in disease control (Parker et al. 2013).

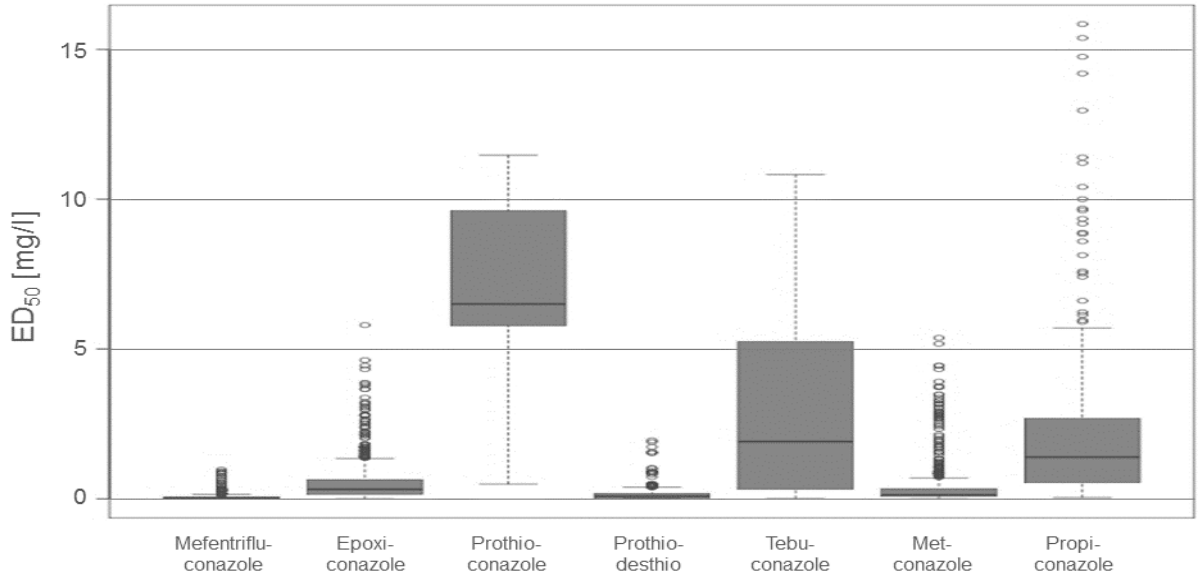
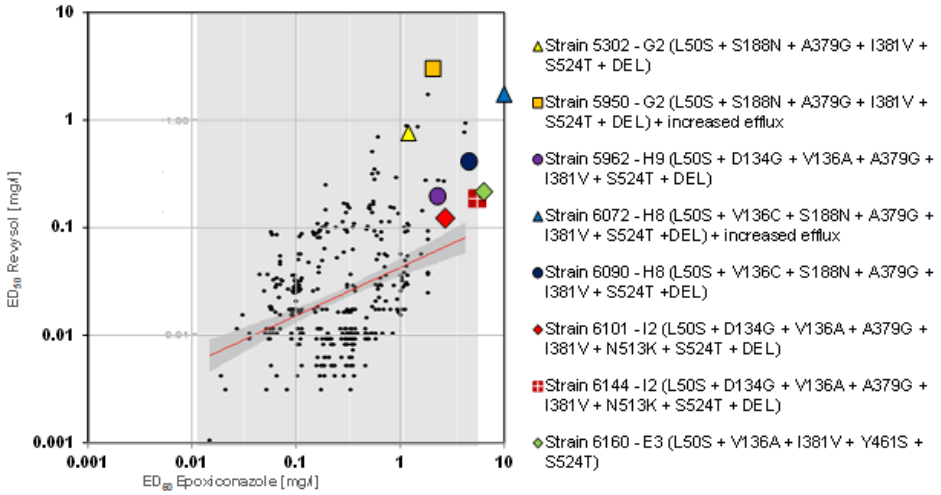
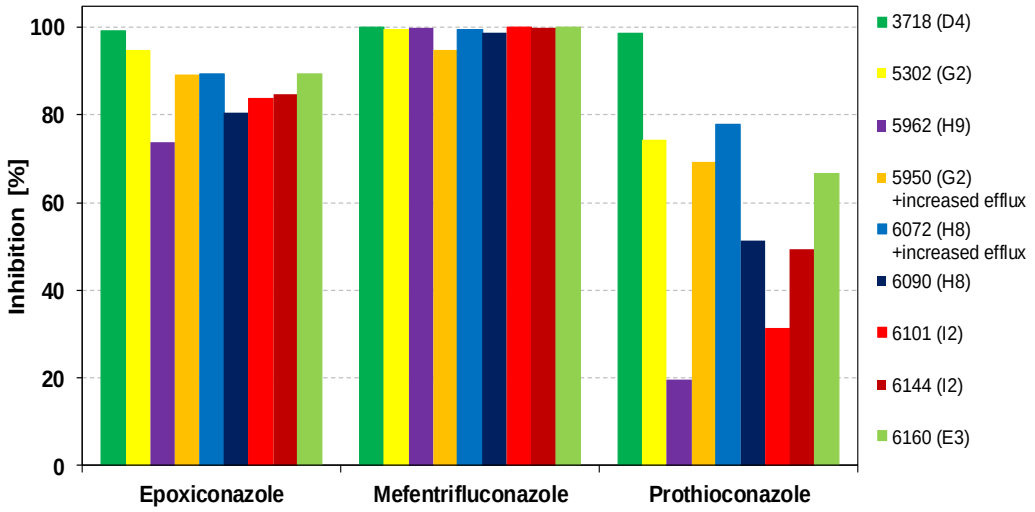


Figure 3.3-5: Range of sensitivity (ED50) determined in isolates from cross resistance studies with European populations from 2014-2016 (1272 isolates, BASF, unpublished studies). Lowest range was found for mefentrifluconazole.

A step closer to the field but running the disease cycle of defined isolates on the host plant under defined and controlled conditions, are *in vivo* trials in the greenhouse with a simulation of practical conditions. The latter is achieved by the use of wheat seedlings, market formulations and application equipment containing a spray bar with flat nozzles and fungicides rates, which are orientated on registered field rates (+ dilutions) and water volume of 400 l/ha. Greenhouse tests indicate that mefentrifluconazole provides excellent control of the most shifted strains, which could be detected in extensive monitoring programmes in the last years. Even pure populations of those most shifted isolates are efficiently controlled under severe infection conditions, where high spore load and optimal infection conditions concerning temperature, light exposure and humidity are provided. Both DMIs, which are leading in Europe for Septoria leaf blotch control, epoxiconazole and prothioconazole, were less active than mefentrifluconazole (Figure 3.3-6).





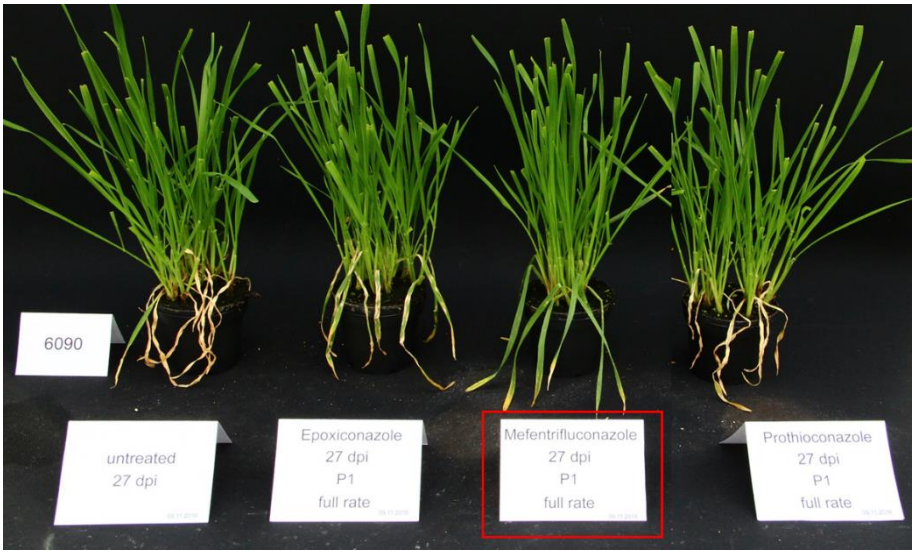


Figure 3.3-6: Efficacy of mefentrifluconazole, epoxiconazole and prothioconazole on selected, most shifted strains identified in the last years monitoring. Upper: Selection of isolates used for the tests by their EC50 values, cyp51 and efflux background. Middle: Efficacy of the three DMIs on the different strains (3718 is a low shifted reference strain). Lower: Example of plants diseased with strain 6090, untreated and treated with DMIs.

However, the current recommendation of the FRAC SBI Working Group is to consider all DMIs as one product group in which in general cross resistance exists.

Within the SBI-group, there is no cross resistance between morpholines (e.g. fenpropimorph) and DMI fungicides. There is no cross-resistance or a correlation of the sensitivity to SBI fungicides and other modes of action.

Kresoxim-methyl: Studies to date have shown that there is cross resistance between QoI fungicides (FRAC 2020), in particular when the mutation G143A in the cytochrome *b* gene is the cause of resistance. There is no indication of cross resistance with kresoxim-methyl and fungicides from outside the QoI group.

3.3.1.1 Baseline sensitivity / Monitoring data

In the following chapter, BASF baseline sensitivity data and the most recent BASF monitoring data are provided, followed by the latest statements of FRAC available on the FRAC website. Sensitivities to DMIs and mefentrifluconazole are described in subchapter A followed by sensitivities to QoIs and kresoxim-methyl in subchapter B.

3.3.1.2 A. Mefentrifluconazole

Baseline studies

More than 40 years ago the first DMI fungicides have been launched for control of various pathogens in a high number of crops. Many field populations of plant pathogens adapted to DMIs and therefore they do not reflect the “wild type” or “baseline” sensitivity, which a population had before DMI market launch.

Therefore, sensitivity studies nowadays cannot be seen as baselines, but show the actual sensitivity situation. Together with the sensitivity of old wild type isolates from internal or external fungal culture collections, the adaptation of isolates from current field populations compared to the baseline sensitivity can be estimated.

However, it is of most importance if the current field population is still sufficiently controlled with registered field rates. Annual sensitivity monitoring shows changes in populations over time, which might then lead to further studies on the field efficacy.

A1. Zymoseptoria tritici

Monitoring data

Broad European field monitoring for mefentrifluconazole started in 2014. Data from 2014 to 2019 were from the most intensive growing wheat regions in Europe, which are known for highest DMI adaptation worldwide. Box and whisker plots of EC_{50} values are provided in Figure 3.3-7. The variability of sensitivity is caused by mechanisms known to be responsible for DMI shifting. However, even isolates with the lowest sensitivity are still controlled by mefentrifluconazole as shown in the previous chapter (Figure 3.3-6). The data from 2014 to 2019 show a quite stable sensitivity situation.

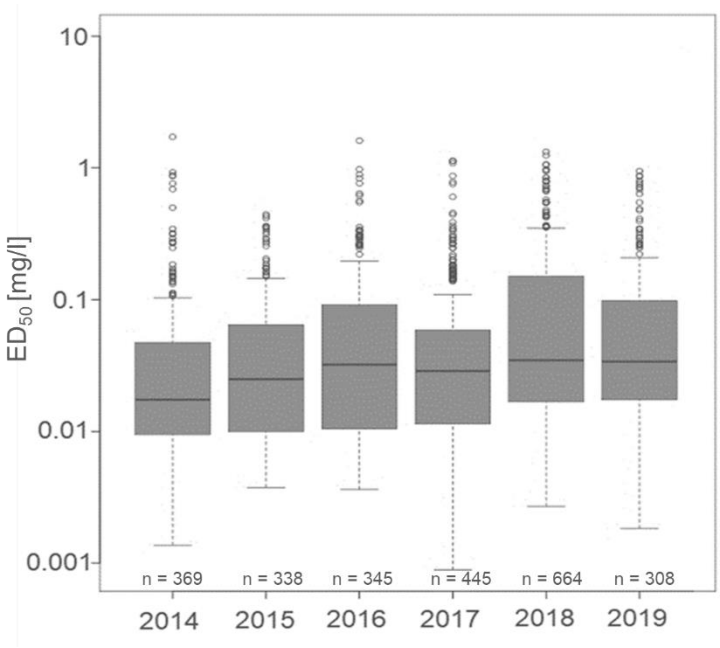


Figure 3.3-7: Sensitivity of European populations of *Zymoseptoria tritici* from 2014 to 2019 towards mefentrifluconazole. Method was a microtiter test, EC50 [mg/l] was determined by Probit analysis.

FRAC statement

FRAC summary of the status of DMI resistance in *Zymoseptoria tritici* based on all available data from the different members of the FRAC DMI Working Group (status webpage May 8th, 2020):

1.1. WHEAT

1.1.1. Septoria Leaf Blotch (*Mycosphaerella graminicola* / *Zymoseptoria tritici*)

Presentation of monitoring data 2019: ADAMA, BASF, Bayer, Corteva, Syngenta

- Disease pressure was moderate in most of the European countries but regionally variable in 2019.
- DMIs field performance was good when used according to the manufacturers and FRAC recommendations. No general field resistance has been reported.
- Monitoring 2019 was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Poland, Romania, Russia, Slovenia, Spain, Sweden, Switzerland, 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 ingredient 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 EC_{50} sensitivity values slightly higher compared to 2018 in some geographies but overall in the range of previous years.
- In *Z. 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.

www.frac.info

3

- Overall, DMI EC_{50} sensitivity values were somewhat higher in the UK 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.

3.3.1.3 A2. Puccinia triticina and other Puccinia species

Monitoring data

A broad European monitoring for mefentrifluconazole and *Puccinia triticina* was done in 2016 and 2018 (Figure 3.3-8). Isolates from different regions were made and investigated for their sensitivity to mefentrifluconazole. Mean ED_{50} were calculated from all isolates from a region. The data show that the situation from 2016 to 2018 is stable or even slightly more sensitive in most regions. Exception is the route Nickelsdorf-Györ-Sopron, which is now in the same range as all other European regions.

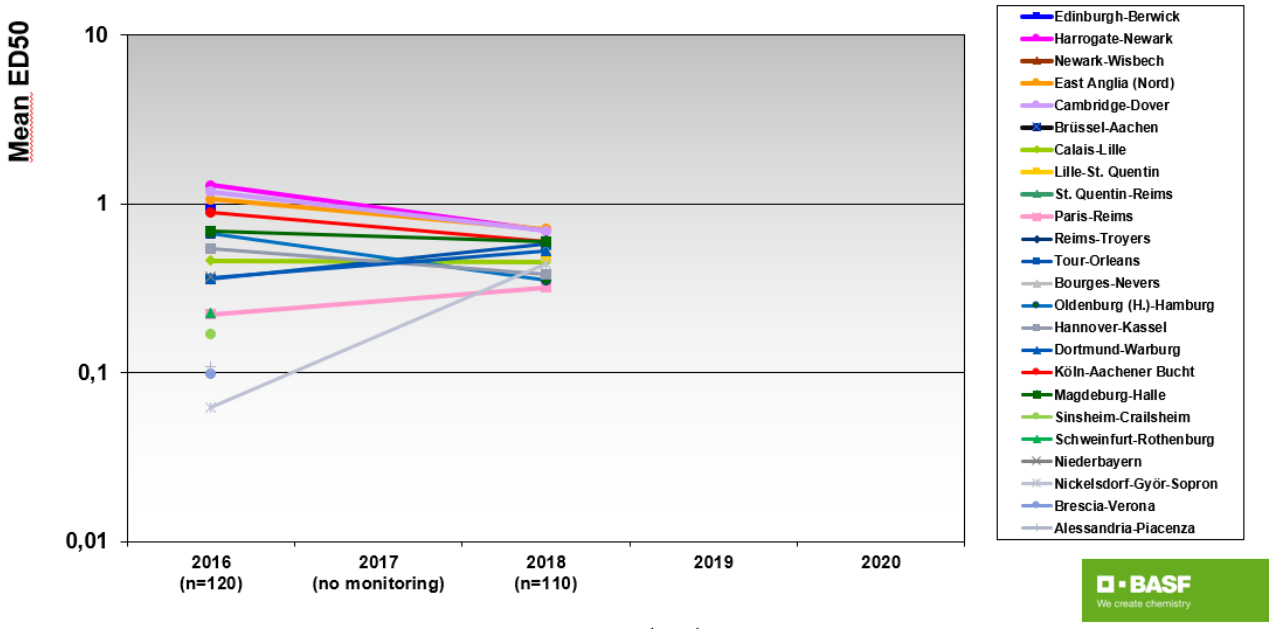


Figure 3.3-8: Mean ED50 values of isolates from different European regions. Ten isolates per region were tested for the sensitivity towards mefentrifluconazole. Monitoring started in 2016 and will be followed up every two years.

FRAC statement

FRAC summary of the status of DMI resistance in brown and yellow rust based on all available data from the different members of the FRAC DMI Working Group (status webpage May 20th, 2020):

1.1.3. Wheat brown rust (*Puccinia triticina*)

Presentation of monitoring data 2019: Sumitomo,

- 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 2019 has been carried out in Czech Republic, France, Germany, Poland, and United Kingdom.
- Sensitivity data from 2019 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

1.1.6. Yellow rust (*Puccinia striiformis*)

Presentation of monitoring data 2019: Bayer

- Disease pressure was moderate.
- Monitoring was carried out in Denmark, Germany, Latvia, Sweden and United Kingdom.

  The first monitoring in 2015 showed high sensitivity and low diversity, and from 2016 to 2019 a stable situation was reported.

A3. Pyrenophora teres

Monitoring data

Sensitivity of European isolates towards mefentrifluconazole from Ireland, France, Belgium, Germany, Denmark, Czech Republic and Italy isolated in 2015 showed a narrow distribution of EC_{50} values similar to the reference isolate isolated before 2000 with an EC_{50} median of 1.39 mg/l and a minimum values of 0.26 mg/l and a maximum value of 2.34 mg/l (Table 1).

This serves as the sensitivity situation before market introduction and further monitoring studies will show if there will be changes.

Table 3.3-1: Sensitivity of European isolates of *Pyrenophora teres* to mefentrifluconazole, determined in a MT test with YBA as medium

Isolate	Year of isolation	Country	EC_{50}
1013	1998	NZ	2.34
1741	2015	IE	1.02
1742	2015	IE	2.08
1762	2015	BE	1.53
1807	2015	DK	1.43
1849	2015	CZ	0.86
1867	2015	FR	1.36
1879	2015	FR	0,26
1966	2015	DE	1.18
1996	2015	IT	1.73

FRAC statement

FRAC summary of the status of DMI resistance in *Pyrenophora teres* based on all available data from the different members of the FRAC DMI Working Group (status webpage May 20th, 2020):

1.2.3. Net blotch (*Pyrenophora teres /Drechslera teres*)

Presentation of monitoring data 2019: Bayer, Syngenta

Monitoring 2019 still ongoing

- Disease pressure was generally low in 2019.
- Performance of SBI containing spray programmes was good.
- Monitoring was carried out in Belgium, Czech Republic, Denmark, France, Germany, Hungary, Ireland and United Kingdom.
- In 2017 in France significant shifts of sensitivity of populations have been observed. Highest EC_{50} 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.

A4. Rhynchosporium secalis (syn. Rhynchosporium commune)

Monitoring data

Sensitivity of European isolates towards mefentrifluconazole from Ireland, UK, France The Netherlands, Belgium, Denmark, Germany and Poland isolated in 2014-2017 showed a narrow distribution of EC_{50} values similar to the reference isolate from 2002 with an EC_{50} median of 3.14 mg/l, a minimum value of 1.62 mg/l and a max of 4.06 mg/l (Table 2).

This serves as the current sensitivity situation before market introduction and further monitoring studies will show if there will be changes.

Table 3.3-2: Sensitivity of European isolates of *Rhynchosporium secalis* to mefentrifluconazole, determined in a MT test with YBG as medium

Isolate	Year of isolation	Country	EC_{50}
1870	2002	UK	2.08
3469	2014	DK	4.06
3491	2015	DK	3.58
3494	2015	NL	2.24
3659	2015	BE	3.56
3664	2015	BE	3.38
3689	2016	FR	1.62
3700	2016	FR	3.04
3723	2016	DE	3.22
3736	2016	PL	2.97
3761	2016	PL	2.12
3766	2016	UK	2.17
3789	2016	DE	2.41
3808	2016	IE	2.61
3813	2016	IE	3.79
3838	2016	UK	3.70
3839	2017	FR	3.43
3863	2017	DE	3.07
3873	2017	UK	3.35
3889	2017	FR	3.29

FRAC statement

FRAC summary of the status of DMI resistance in *Rhynchosporium secalis* based on all available data from the different members of the FRAC DMI Working Group (status webpage May 20th, 2020):

1.2.2. Scald (*Rhynchosporium commune*)

Presentation of monitoring data 2019: BASF, Bayer,

- Disease pressure was extremely low in Europe in 2019.
- Field performance of DMIs was good.
- Monitoring was carried out in Belgium, France, Germany, Ireland, Poland and United Kingdom
- Stable situation. The sensitivity of the populations stayed in the range observed in the previous 15 years.

A5. Blumeria graminis

Monitoring data

No BASF data available

FRAC statement

FRAC summary of the status of DMI resistance in *Blumeria graminis* based on all available data from the different members of the FRAC DMI Working Group (status webpage May 20th, 2020):

1.1.2. Powdery mildew (*Blumeria graminis* f.sp. *tritici* / *Erysiphe graminis* f.sp. *tritici*)

Disease pressure in 2019 was low across Europe.

DMIs

Presentation of monitoring data 2019: Bayer, Sumitomo

- DMI field performance was good.
- In 2019, monitoring was carried out in Czech Republic, France, Germany, Poland, and United Kingdom.
- Sensitivity data presented for 2016 to 2019 confirmed that the situation was overall stable within the range of variability detected during the last 20 years.
- Differences in the sensitivity are significantly a.i. and regionally dependent. Higher resistance factors were observed only for particular DMIs especially in France, Germany and UK, but also to a lesser extend in Belgium.

1.2.1. Powdery Mildew (*Blumeria graminis* f.sp. *hordei* / *Erysiphe graminis* f.sp. *hordei*)

In 2019, disease pressure was low in Europe.

DMIs

Monitoring was carried out in Czech Republic, Denmark (2016), France, Germany, Latvia, Sweden (2016), Ukraine, and United Kingdom. Results from 2018 monitoring were presented by Bayer:

- DMI products performed well.
- The sensitivity of the populations stayed in the range observed for more than 15 years.

A6. Parastagonospora nodorum (formerly known as Leptosphaeria nodorum, Phaeosphaeria nodorum or Septoria nodorum)

Monitoring data

Sensitivity of European isolates towards mefentrifluconazole from Germany isolated in 2010 and 2012 showed low EC_{50} values <0.01 mg (Table 4)

This serves as the current sensitivity situation before market introduction and further monitoring studies will show if there will be any changes.

Table 3.3-3:: Sensitivity of European isolates of *Parastagonospora nodorum* to mefentrifluconazole, determined in a MT test with YBG as medium

Isolate	Year of isolation	Country	EC_{50}
Sn 7	Before 2000	Unknown, Reference	< 0.01
2000	Before 2000	Unknown, Reference	< 0.01
9	2010	DE	< 0.01
19	2012	DE	< 0.01

FRAC statement

No statement from last FRAC meeting available

A7. Pyrenophora tritici-repentis

Monitoring data

No BASF data available

FRAC statement

FRAC summary of the status of DMI resistance in *Pyrenophora tritici-repentis* based on all available data from the different members of the FRAC DMI Working Group (status webpage May 20th, 2020):

1.1.5. Tan spot (*Pyrenophora tritici-repentis, syn. Drechslera tritici-repentis*)

Presentation of monitoring data 2019: Syngenta

- Monitoring data from 2019 in Finland, Lithuania, and United Kingdom showed a narrow range of sensitivity in line with results from previous years.

A8. Fusarium spp.

Monitoring data

No BASF data available

FRAC statement

FRAC summary of the status of DMI resistance in *Fusarium* spp. based on all available data from the different members of the FRAC DMI Working Group (status webpage May 20th, 2020):

1.1.8. Fusarium Head Blight (*Fusarium graminearum*)

Presentation of monitoring data 2019: Bayer

- Monitoring was carried out in France.
- For the past 10 years, a stable sensitivity situation was observed.

A9. Oculimacula spp.

Monitoring data

No BASF data are so far available for mefentrifluconazole and *Oculimacula* spp.

FRAC statement

FRAC summary of the status of DMI resistance in *Oculimacula* spp. based on all available data from the different members of the FRAC SDHI Working Group (status March 20th, 2020):

1.1.4. Eyespot (*Tapesia* spp, *syn. Oculimacula* spp.)

Presentation of monitoring data 2019: Syngenta.

- Field performance was good.
- An analysis of samples from Czech Republic, Denmark, France, Germany, Poland, and United Kingdom from 2019 was presented.
- Between 2003 and 2012 there was no change in the sensitivity of W and R types, stable situation had been observed during that time. In 2013, some sensitivity change has been observed in the United Kingdom, but not in France or Germany. In 2014 further sensitivity decrease has been observed in the United Kingdom, and for the first time also in France and Germany. However, overall, resistance factors still remain low and performance was not affected.
- The 2018 data showed a homogenous and sensitive situation in all countries.
- In 2019, still comparable sensitivity ranges and medians were observed in all monitored countries without any geographical variations.

B. Kresoxim-methyl

Baseline studies

QoI were introduced in cereals in 1996. Many internal baseline studies are available and there is a high number of publications available on wild type sensitivity on many plant pathogenic fungi. The resistance mechanisms are elucidated, and genetic assays are established for efficient monitoring. Therefore, baseline sensitivity studies on the different pathogens are not provided but latest monitoring data.

B1. Zymoseptoria tritici

Monitoring data

High frequencies of G143A mutation have been detected in intensive wheat growing areas in North-Western Europe. The situation in Southern and Eastern European countries is much more favourable, where QoI resistance is still absent or present at lower levels (Figure 3.3-9).

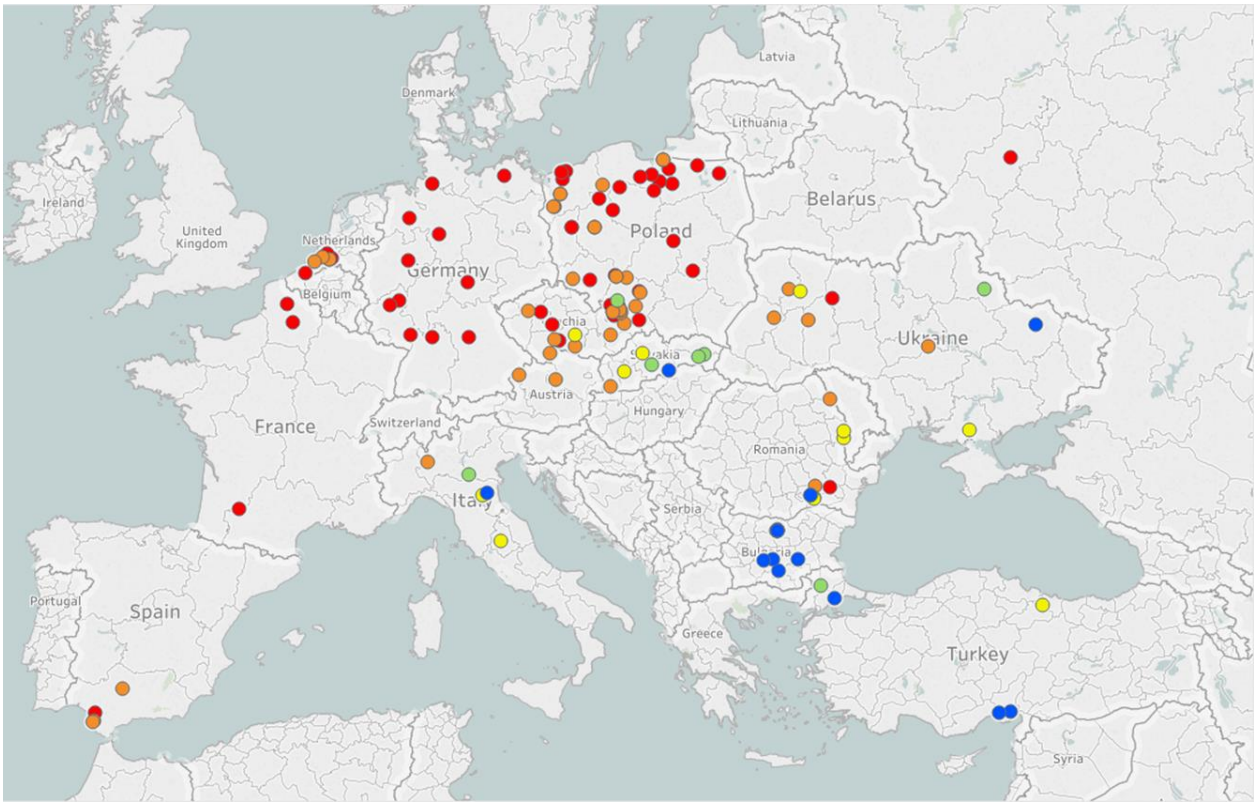


Figure 3.3-9: Monitoring of QoI sensitivity of *Zymoseptoria tritici* in 2019. Each dot represents a sample (N=136), which was analysed for frequency of G143A mutation by real-time PCR (blue: 0-2, green 3-10, yellow 11-30, orange 31-75, red 76-100% frequency of G143A).

FRAC statement

FRAC summary of the status of QoI resistance in *Zymoseptoria tritici* based on all available data from the different members of the FRAC QoI Working Group (status webpage May 20th, 2020):

Septoria leaf spot (*Septoria tritici* = *Mycosphaerella graminicola* = *Zymoseptoria tritici*), wheat

Companies: BASF, Syngenta

Disease information: Disease pressure was moderate in Europe in 2019.

The status at the end of the season 2019 is as follows:

Findings:

In Belgium, France, Germany, Ireland, Netherlands, Sweden, and United Kingdom: widespread resistance over all these countries at high levels were detected.

Medium to high resistance level was detected in Poland.

In Austria, Switzerland, Czech Republic, Lithuania, Spain: populations were showing in average moderate levels of resistance with high variability.

Low to moderate in: Italy Slovakia, Romania and Ukraine.

No to low levels of resistance were found in Bulgaria, Greece, Russia and Turkey.

Additional information for other countries is given in the 2018 minutes.

B2. Puccinia triticina and other Puccinia species.

Monitoring data

No reduced sensitivity has been detected for *Puccinia triticina* towards QoI in any sample in BASF monitoring studies since market introduction up to now. Latest data are from 2018 (Figure 3.3-10).

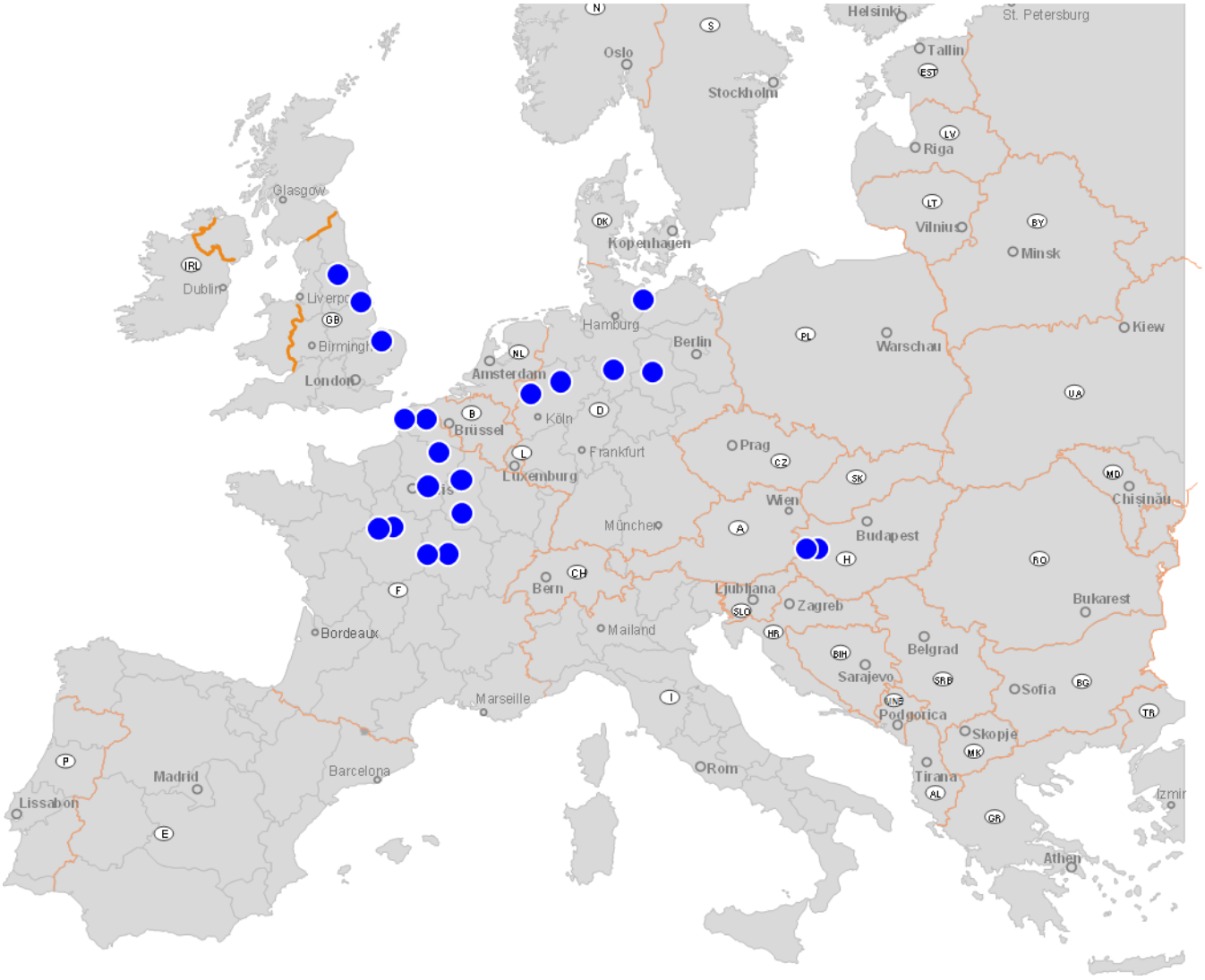


Figure 3.3-10: Monitoring of QoI sensitivity of *Puccinia triticina* in 2018. Each blue dot represents a sample from which 5 isolates (N=110 in total) were made and analysed for QoI sensitivity in detached leaf tests with a discriminatory dose of the QoI pyraclostrobin. All isolates from all samples were sensitive to QoIs.

FRAC statements

FRAC summary of the status of QoI resistance in *Puccinia* species based on all available data from the different members of the FRAC QoI Working Group (status webpage May 20th, 2020):

Brown rust (*Puccinia recondita* = *Puccinia triticina*), wheat

Companies: Syngenta

In 2019, performance of QoI fungicides against brown rust was good.

Findings:

No resistant isolates were detected in widespread monitoring studies in Europe in 2019, confirming the fully sensitive picture (Belgium, France, Germany and United Kingdom).

Additional information: These findings are consistent with the reported presence of a lethal intron in several fungi making the G143A mutation unlikely to occur (see FRAC QoI Intron Document).

Yellow rust (*Puccinia striiformis*), wheat

Companies: Bayer

Findings:

All isolates tested from Belgium, Germany, Denmark, Latvia, Sweden and United Kingdom were sensitive.

B3. Pyrenophora teres

Monitoring data

No G143A mutation in the cytochrome *b* was detected up to now in samples of *Pyrenophora teres*. The mutations F129L and/or G137R (G137R very seldom) are mainly found in UK, France, Germany and Denmark, and not or less frequent in other European countries in 2019 (Figure 3.3-11). The BASF method used was pyrosequencing of the cytochrome *b* gene.

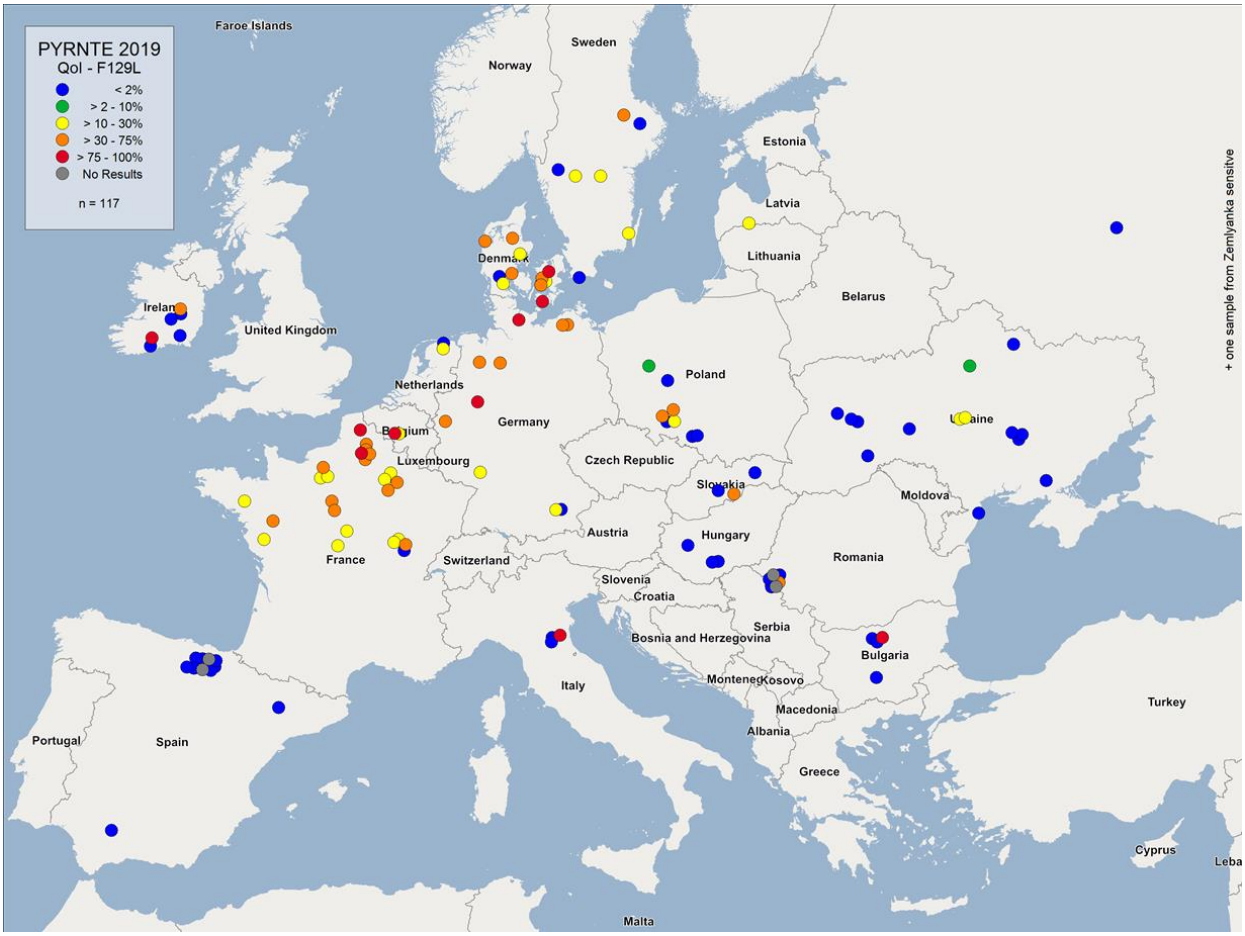


Figure 3.3-11: Monitoring of QoI sensitivity of *Pyrenophora teres* in 2019. Each dot represents a sample (N=117) which was analysed for frequency of F129L and G137R mutation by pyrosequencing (blue: 0-2, green 3-10, yellow 11-30, orange 31-75, red 76-100% frequency of F129L and/or G137R). Grey dots: no data obtained.

FRAC statement

FRAC summary of the status of QoI resistance in *Pyrenophora teres* based on all available data from the different members of the FRAC QoI Working Group (status webpage May 20th, 2020):

Net blotch (*Pyrenophora teres*), barley

Companies: BASF, Bayer, Syngenta

Disease information: Disease pressure was moderate within European countries in 2019. Field performance of QoI-containing fungicides against net blotch was good.

Monitoring: Data from 2019 was shared.

Additional information: Mainly the F129L mutation was found. As already observed with other pathogens, resistance factors are significantly lower in comparison with the G143A mutation and field performance of products used according to FRAC and

Manufacturers' recommendations remains good (for differences between QoI mutations see also the respective FRAC document titled "Mutations associated with QoI resistance" available on the FRAC website under QoI fungicides →Quick references).

These findings are consistent with the reported presence of a lethal intron in several fungi making the G143A mutation unlikely to occur.

Findings

The situation in 2019 is as follows:

Medium to high in: DK

Medium levels were detected in: Belgium, Germany, France and United Kingdom.

No to medium in: Ireland

Low in: Netherlands, Sweden and Switzerland

No to low levels in: Austria, Bulgaria, Czech Republic, Italy, Latvia, Poland, Romania, Russia, Slovakia, Spain and Ukraine

No resistance of mutation was found in: Greece and Hungary.

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 to the reported break-down of variety-resistance (variety ETINCEL) at significant cultivation areas and higher frequencies of mutated strains.

B4. Rhynchosporium secalis (syn. Rhynchosporium commune)

Monitoring data

Sensitivity monitoring (detection of G143A, F129L and G137R by pyrosequencing) on *Rhynchosporium secalis* did not show up any QoI-resistance in 2019 at any site analysed (Figure 3.3-12). Additionally, various isolates were made from the samples. Such isolates were tested in microtiter tests for their QoI sensitivity in order to identify if another mechanism, the AOX overexpression, is present, which is with our moleculargenetic methods used in *Rhynchosporium secalis* monitoring not detectable. In 2019 no isolate with AOX overexpression was found (data not shown).

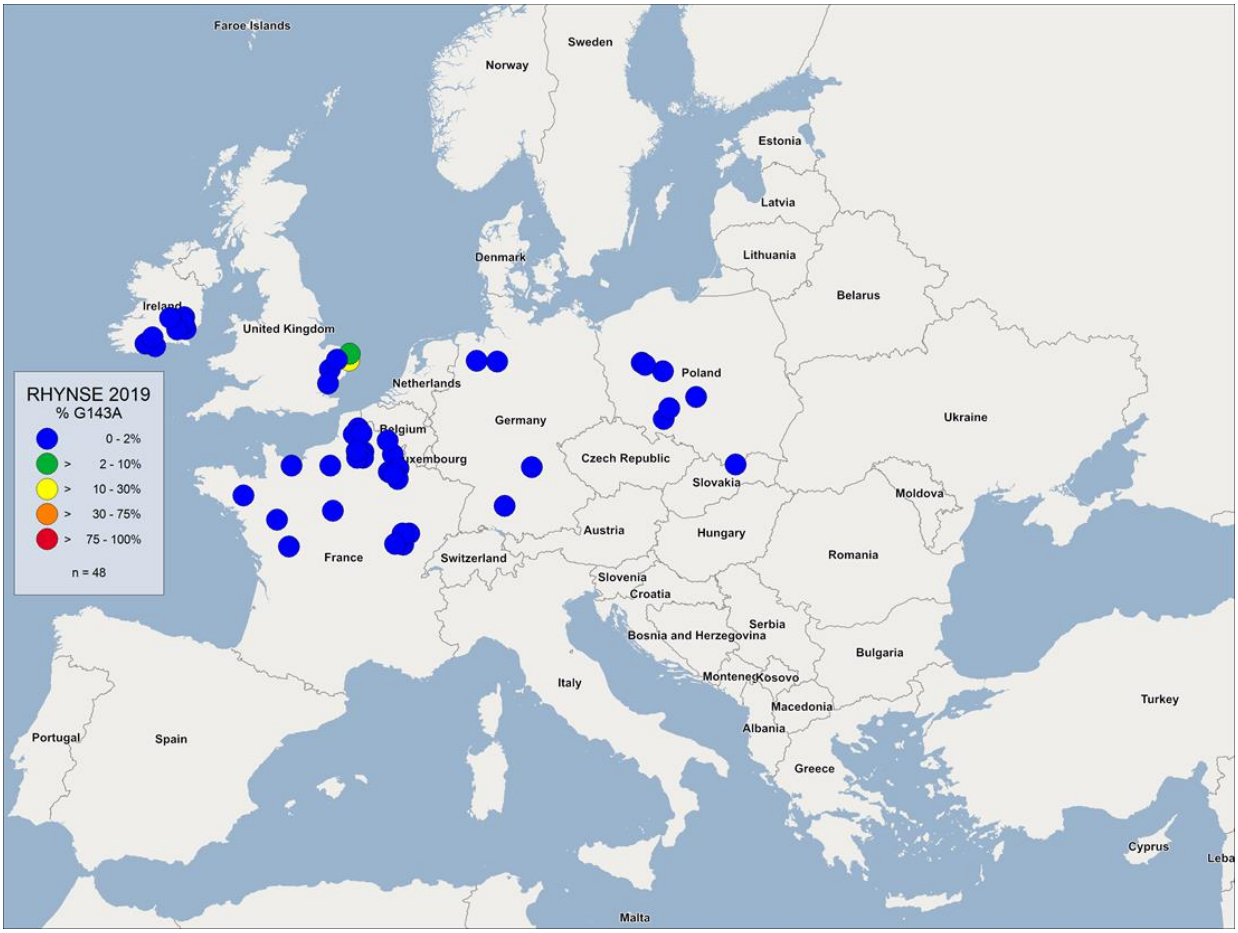


Figure 3.3-12: Monitoring of QoI sensitivity of *Rhynchosporium secalis* in 2019. Each blue dot represents a sample (N=48), which was analysed for QoI sensitivity by G143A, F129L and G137R analysis by pyrosequencing. All samples besides 2 from UK showed wild type sequences and were therefore classified as sensitive to QoIs. The 2 samples from UK were with low and medium frequency of G143A. From this sample no isolate could be made.

FRAC statement

FRAC summary of the status of QoI resistance in *Rhynchosporium secalis* based on all available data from the different members of the FRAC QoI Working Group (status webpage May 20th, 2020):

Leaf scald (*Rhynchosporium secalis* = *Rhynchosporium commune*), barley

Companies: BASF, Bayer,

Monitoring: Performance of QoI fungicides against Leaf scald was good.

Findings:

In 2019, samples were sensitive in: Belgium, Denmark, France, Germany, Ireland, Poland, Slovakia and United Kingdom.

Additional information: However, in some years since 2008 (e. g., 2012, 2013 France, 2014 UK, 2015 Spain, 2019 United Kingdom), occasionally isolates/samples have been found containing the G143A mutation. The frequency is always very low.

B5. Blumeria graminis

Monitoring data

No BASF data on QoI sensitivity are available.

FRAC statement

FRAC summary of the status of QoI resistance in cereal powdery mildews based on all available data from the different members of the FRAC QoI Working Group (status May 20th, 2020):

Powdery mildew (*Blumeria graminis* f. sp. *tritici* = *Erysiphe graminis* f.sp. *tritici*), wheat

Companies: Bayer

Monitoring has been carried out in Czech Republic, Latvia, Lithuania and Poland.

Findings:

Medium to high frequencies of resistance were found in Latvia, Lithuania and Poland.

Low to medium in: Czech Republic

Powdery mildew (*Blumeria graminis* f. sp. *hordei* = *Erysiphe graminis* f.sp. *hordei*), barley

Companies: Bayer

Monitoring: Overall, where monitoring was carried out, there was a similar situation in 2018 as compared to 2017.

Limited monitoring in 2019

Findings:

No to Low in: Latvia and Lithuania.

B6. Parastagonospora nodorum (formerly known as Leptosphaeria nodorum, Phaeosphaeria nodorum or Septoria nodorum)

Monitoring data

No data from the last years are available. The last monitoring for this fungal species was carried out in 2010. Most samples were full sensitive; only 6 out of 30 samples contained the G143A mutation at low to high frequency (Figure 3.3-13).

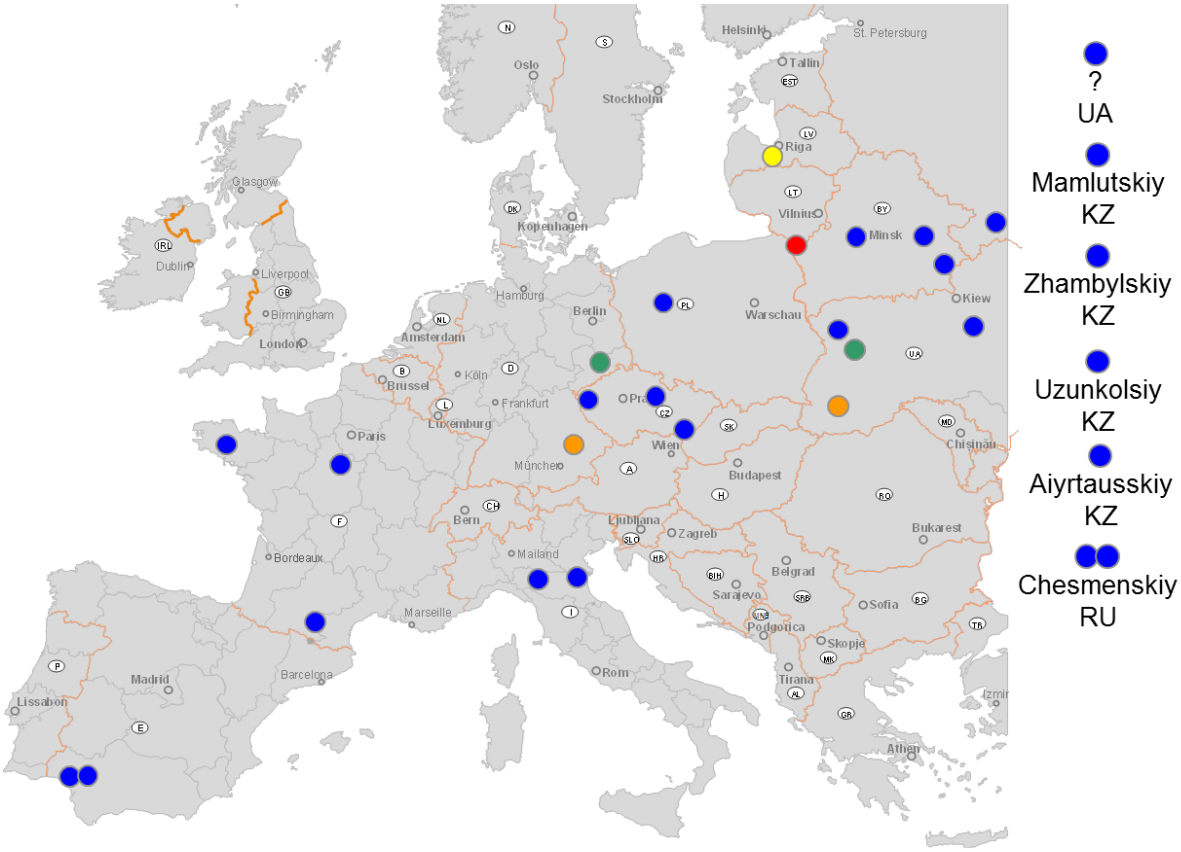


Figure 3.3-13: Monitoring of QoI sensitivity of *Parastagonospora nodorum* in 2010. Each dot represents a sample (N=30) which was analysed for frequency of G143A mutation by real-time PCR (blue: 0-2, green 3-10, yellow 11-30, orange 31-75, red 76-100% frequency of G143A). Dots on the right end are from samples outside the map segment.

FRAC statement

Parastagonospora nodorum is listed as a pathogen where the G143A mutation has been detected (FRAC 2020, Blixt *et al.* 2009). A current overview of the distribution and frequency of resistance is not available on the FRAC webpage.

B7. Pyrenophora tritici-repentis

Monitoring data

The G143A, F129L and (seldom) the G137R mutations were detected in Europe in the last years. The most important mutation is the G143A because of its higher frequency and higher impact on the sensitivity loss. The data on the current distribution over Europe in 2019 is shown in Figure 3.3-14. The G143A mutation was detected in different countries and fields with different levels.

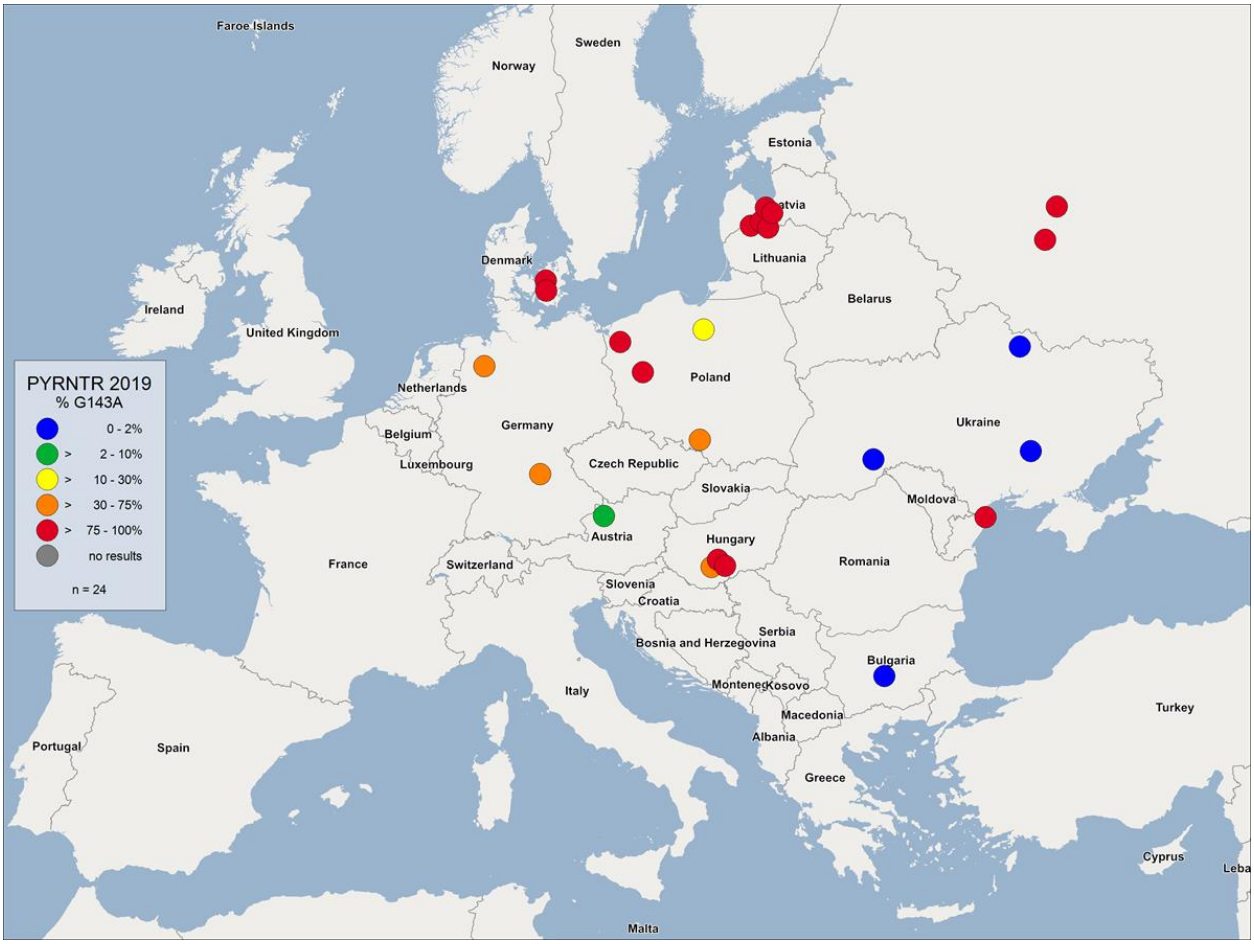


Figure 3.3-14: Monitoring of QoI sensitivity of *Pyrenophora tritici-repentis* in 2017. Each dot represents a sample (N=24) which was analysed for frequency of G143A mutation by pyrosequencing (blue: 0-2, green 3-10, yellow 11-30, orange 31-75, red 76-100% frequency of G143A).

FRAC statement

FRAC summary of the status of QoI resistance in *Pyrenophora tritici-repentis* based on all available data from the different members of the FRAC QoI Working Group (status webpage May 20th, 2020):

Tan spot (*Pyrenophora tritici-repentis*), wheat

Companies: BASF, Syngenta

Findings:

Samples distributed over countries containing the G143A mutation were found at the frequencies indicated below, partly based on limited number:

High frequency in: Denmark and Latvia

Medium to high in: Hungary and Poland

Medium resistance frequencies were found in: Germany

.

Low in: Austria

No in: Bulgaria and United Kingdom

Single resistant samples/isolates were found in: Finland, Latvia, Ukraine and Russia

Additional information: Although all three point mutations known for QoIs (G143A, F129L, G137R) have been detected in the past, and can occur in the same population, the G143A mutation is now dominant in this pathogen.

B8: Fusarium spp.

No BASF or FRAC data are available for *Fusarium* spp. sensitivity towards QoIs.

B9: Oculimacula spp.

No BASF or FRAC data are available for *Oculimacula* spp. sensitivity towards QoIs.

3.3.1.4 Use pattern

BAS 765 00 F is intended for registration for control of the above-mentioned diseases in cereals with up to 1.0 l product/ha in Poland and 0.6-1.0 l/ha in other EU countries. Maximum number of applications is 2, with a minimum of 14 days between applications and between growth stages 30-69.

Resistance risk assessment of unrestricted use pattern

Fungicide risk

Mefentrifluconazole: FRAC describes the DMI fungicides in general as *medium-risk* compounds (FRAC 2020) according to the principles described in FRAC Monographs 1 and 2 (Brent 2007, Brent and Hollomon 2007).

Kresoxim-methyl: FRAC describes the QoI fungicides in general as *high-risk* compounds (FRAC 2020) according to the principles described in FRAC Monographs 1 and 2 (Brent 2007, Brent and Hollomon 2007).

Pathogen risk

FRAC classified recently a high number of pathogens in species with a low, medium and high risk for fungicide resistance. This classification is based on experience and reported resistance claims over the last 45 years. It is updated yearly. Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high and the competitive ability of resistant individuals is high in the absence of selection pressure. Furthermore, the risk is considered as high when resistance evolved already after few years of product use.

High risk pathogens: *Blumeria graminis*

Medium risk pathogens: Zymoseptoria tritici, Parastagonospora nodorum, Pyrenophora tritici-repentis, Pyrenophora teres, Oculimacula spp.

Low risk pathogens: Puccinia spp., Rhynchosporium secalis, Fusarium spp.

Combined pathogen-fungicide risk

The combined risks of pathogens and fungicides are visualized in Figure 3.3-15 and Figure 3.3-16.

benzimidazoles dicarboximides phenylamides QoI	**high (x 3)**	3	6	9
SDHIs metrafenone DMIs MBIs phenylpyrroles anilinopyrimidines morpholines CAA	**medium (x 2)**	2	4	6
chlorothalonil dithianon copper dithiocarbamates phthalimides sulphur SAR-inducers	**low (x 0.5)**	0.5	1	1.5
basic fungicide risk		**low (1)**	**medium (2)**	**high (3)**
basic disease risk		***Fusarium* spp., *Rhynchosporium secalis*, *Puccinia* spp.**	***Zymoseptoria tritici*, *Parastagonospora nodorum*, *Pyrenophora tritici-repentis*, *Pyrenophora teres*, *Oculimacula* spp.**	***Blumeria graminis***

Figure 3.3-15: Combined risk analysis (modified after Brent and Hollomon 2007)

Score	Risk class
0.5-2	low risk
3-6	medium risk
9	high risk

An alternative model is suggested by Brent (2007) and a new and updated version of the original paper (EPPO 2003) is also published by EPPO (2015). The position of the fungicides and the different pathogens can be made in this model more differentiated and is shown in Figure 3.3-16. The positions were allocated considering the current knowledge and experience on the fungicides and pathogens.

1: DMI on *Puccinia* spp., *Fusarium* spp.

2: DMI on *Rhynchosporium secalis, Parastagonospora nodorum, Oculimacula* spp.

3: DMI on *Zymoseptoria tritici, Pyrenophora tritici-repentis, Pyrenophora teres*

4: DMI on *Blumeria graminis*

5: QoI on *Puccinia* spp.

6: QoI on *Pyrenophora teres*

7: QoI on Fusarium *spp.*

8: QoI on *Rhynchosporium secalis, Parastagonospora nodorum, Oculimacula* spp.

9: QoI on *Zymoseptoria tritici, Pyrenophora tritici-repentis,*

10: QoI on *Blumeria graminis*

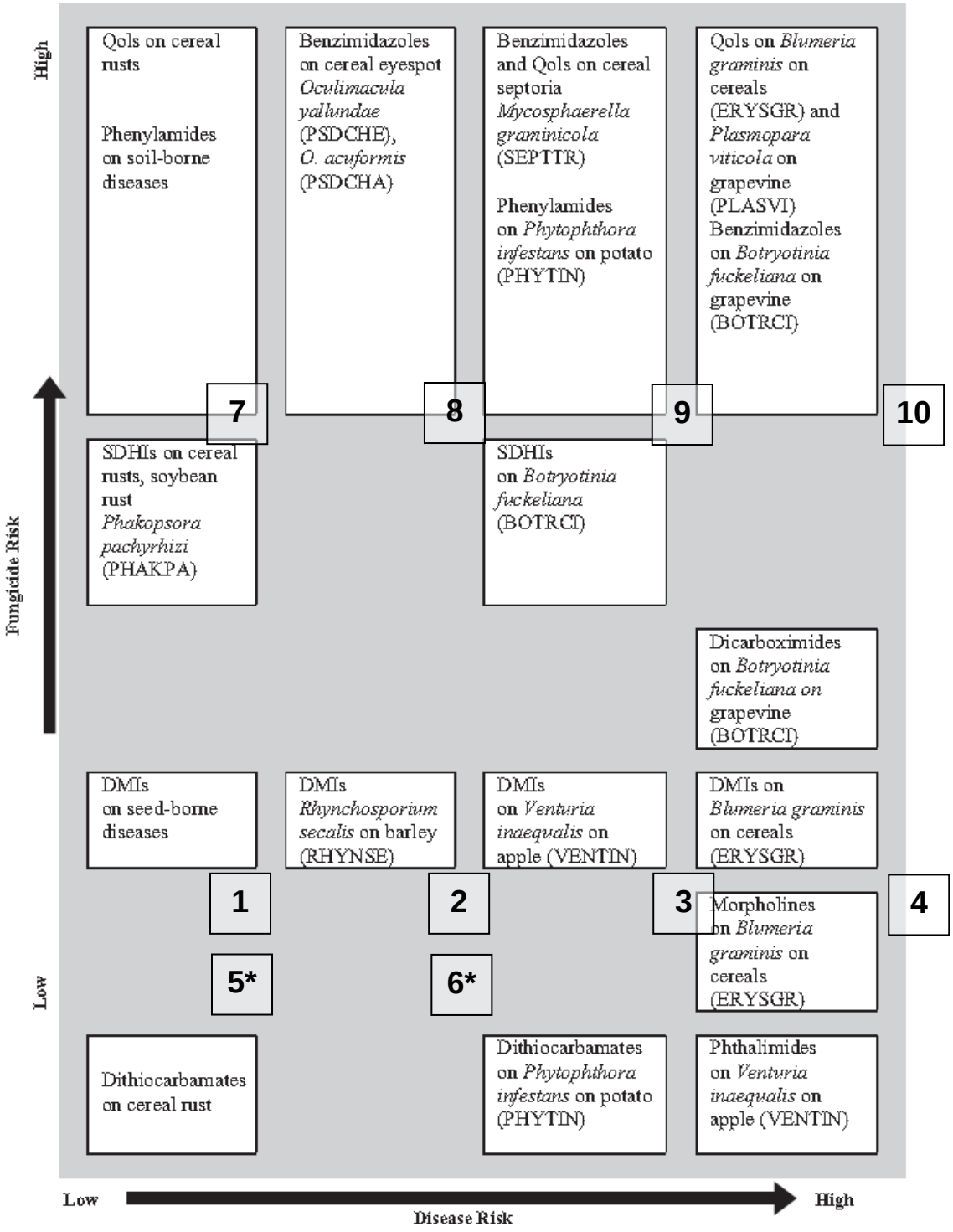


Figure 3.3-16: Scheme for visualizing the combined resistance risk (EPPO 2015). *5 and *6 are on a lower level, because *Puccinia* species and *Pyrenophora teres* have lower QoI resistance risk because of presence of an intron after codon 143 in the cyto-chrome b gene (please see chapter "Mechanism of resistance").

These diagrams exemplify interactions between inherent fungicide and pathogen risks of resistance development. The risk categorisation is approximate, and the scores are arbitrary. Nevertheless, these are probably the best estimates that can be made in the light of current knowledge. They represent risks under conditions of unrestricted fungicide use and severe, sustained disease pressure.

Taken the results of both analyses and the historical experience of resistance development together we classify the combined risks as follows:

DMI x pathogen …

- Puccinia spp., Fusarium spp.: low
- Rhynchosporium secalis, Parastagonospora nodorum, Oculimacula spp.: low to medium
- Zymoseptoria tritici, Pyrenophora tritici-repentis, Pyrenophora teres: medium
- Blumeria graminis: medium to high

QoI x pathogen …

- *Puccinia* spp.: low
- Pyrenophora teres, Fusarium spp.: low to medium
- Rhynchosporium secalis, Oculimacula spp: medium
  - *Zymoseptoria tritici, Parastagonospora nodorum, Pyrenophora tritici-repentis*: medium to high
  - *Blumeria graminis*: high

3.3.1.5 Test methods

A. Methods for Resistance risk assessment

Pathogen resistance risk

Classification of the pathogens was made according to FRAC

Fungicide risk

Classification of the fungicides was made according FRAC.

Combined pathogen x fungicide risk

Two different approaches can be found in the literature, the first one is a diagram by Brent and Hollomon (2007) and the other a diagram published in the EPPO document “Efficacy evaluation of plant protection products, Resistance risk analysis, PP 1/213(4), (EPPO 2015)”. We made the analyses with both approaches to evaluate if there are significant differences. The results, however, show that the assessments of the combined pathogen x fungicide risks are very similar.

B. Methods for sensitivity analysis

Methods for detection of sensitivity are described in the "Baseline sensitivity / Sensitivity monitoring" chapter. In general, sensitivity can be assessed by *in vivo* tests or *in vitro* tests or – if the genetic background (mutation) is known for the relevant resistance mechanism – by molecular genetic methods such as pyrosequencing or real-time PCR. All methods are established in the Fungicide Resistance Research Laboratory of BASF.

C. Method for determination of the cytochrome P450 binding constant

P450 enzymes show a typical absorbance spectrum in the visible range. The binding of substrates and the displacement of water cause a change in the active site geometry that can give rise to a spin change of the heme iron from low-spin to high spin. This gives rise to a change in spectral properties with an increase at 390 nm and a decrease at 420 nm absorbance. This change can be measured by difference spectroscopy as a "type I" spectrum (Figure 3.3-17). Inhibitors like azoles that directly bind to the heme iron (with the imidazole or triazole moiety) lead to "type II" difference spectra with a maximum at 430 nm and a minimum at 390 nm (Figure 3.3-17). In the absence of the reducing enzyme partner the binding affinity of an inhibitor can be determined from the type II difference spectra at increasing inhibitor concentrations.

The method used for measuring the absorbance spectra and for calculation of the dissociation constant (K_D in mol/l) was adapted from Parker *et al*. (2010).

The binding constant (= association constant) in $[mol/l]^{-1}$ was derived from the dissociation constant (K_D)

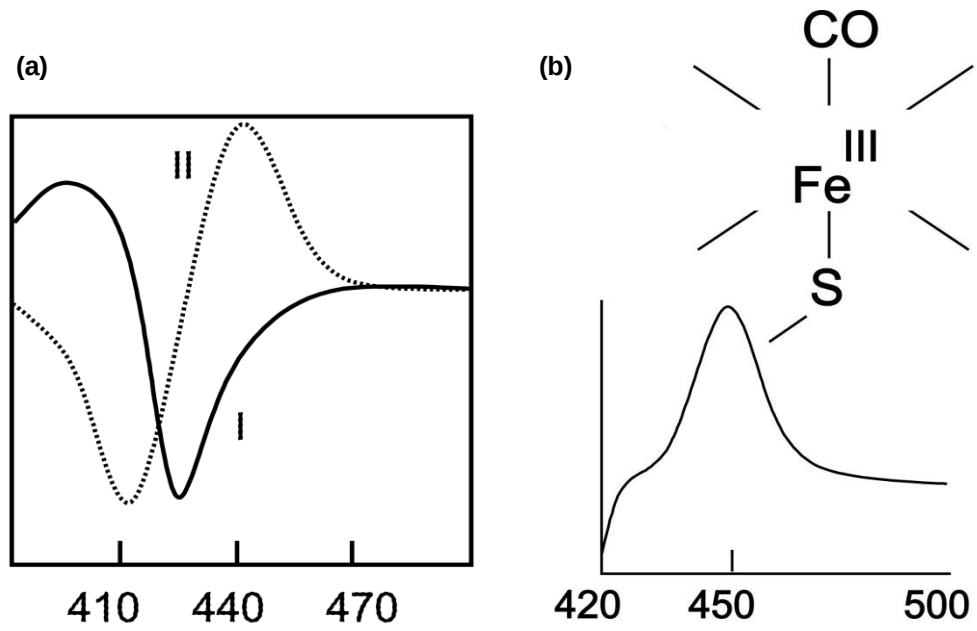


Figure 3.3-17: (a) Type I and Type II difference spectra of p450 enzymes and (b) CO difference spectrum of reduced CO bound p450 (adapted from Wikipedia)

Acceptability of the resistance risk

The analysis of the combined resistance risk showed that the risk is not acceptable for the medium-risk and high-risk pathogens under unrestricted use of BAS 765 00 F, therefore resistance management strategies need to be implemented.

Management strategies are necessary to reduce the risk of resistance development. The key of resistance management strategies is the reduction of selection pressure to a specific mode of action. Different modifiers that lead to such a reduction will be implemented in the resistance management strategy and are described in the next chapter.

Management strategy

The objective of resistance management strategies is the reduction of selection pressure to avoid or delay the occurrence of resistance or to keep the frequency of resistant isolates in a population low.

This can be achieved by good agricultural practice, which leads to less infection pressure (e.g. phytosanitary measurements, cultivation of less susceptible varieties, appropriate crop cultivation unfavourable for the target pathogens).

Limiting the number of sprays is also an important factor in delaying the build-up of resistant pathogen populations (van den Berg et al. 2016). The number of BAS 765 00 F applications will be restricted to 2 applications per season

A further tool is the use of fungicide mixtures. Recent studies showed that especially mixtures help in delaying the selection of resistance (Hobbelen *et al.* 2013, 2014, van den Bosch *et al.* 2014). BAS 765 00 F is already a mixture of two compounds with different modes of action, which are both active against most target organisms and provides therefore a build-in resistance management.

Since population size of pathogens is lower at disease onset than when already established in the field, selection pressure is less when using preventive applications rather than curative or eradicative spray schemes. Therefore, BAS 765 00 F should be applied in a preventive manner following the recommendations on the label. An optimal timing is also an effective resistance management (van den Berg *et al.* 2013).

BASF is a member of the FRAC DMI Working Group and will promote effective anti-resistance management strategies. The current FRAC recommendations for resistance management of DMI fungicides are:

SBI:

General guidelines for using SBI fungicides (all crops)

- Repeated application of SBI fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- For crop/pathogen situations where repeated spray applications (e.g. orchard crops/powdery mildew) are made during the season, alternation (block sprays or in sequence) or mixtures with an effective non cross-resistant fungicide are recommended.
- Where alternation or the use of mixtures is not feasible because of lack of effective or compatible non cross-resistant partner fungicides, then input of SBI's should be reserved for critical parts of the season or crop growth stage.
- If DMI's or "morpholine" performance should decline and sensitivity testing has confirmed the presence of less sensitive forms, SBI's should only be used in mixture or alternation with effective non cross-resistant partner fungicides.
- The introduction of the new classes of chemistry offers new opportunities for more effective resistance management. The use of different mode of actions should be maximised for the most effective resistance management strategies.
- Users must adhere to the manufacturers' recommendations. In many cases, reports of "resistance" have, on investigation, been attributed to cutting recommended rates of use, or to poor or miss-timed application.
- Fungicide input is only one aspect of crop management. Fungicide use does not replace the need for resistant crop varieties, good agronomic practice, plant hygiene/sanitation, etc.

Guidelines for using SBI fungicides on cereal crops

- Repeated application of DMI or "morpholine" fungicides alone should not be used on the same crop in one season against a high-risk pathogen in areas of high disease pressure for that particular pathogen.
- When used in mixture recommended effective rates of the SBI should be maintained.
- Split and reduced rate programmes, using multiple repeated applications at dose rates below Manufacturer's recommendations, provide continuous selection pressure and accelerate the development of resistant populations, and therefore must not be used.
- To ensure good performance in situations of high disease pressure it is of importance to adhere to dosages and spray timings as recommended by manufacturers. Highly curative late applications should be avoided. Mixing with a non-SBI fungicide at effective dose rates may contribute to a higher level of disease control.
- The "morpholine" fungicides are effective non-cross-resistant partner fungicides for DMI's on cereals for the control of powdery mildew.

QoI:

General guidelines for using QoI fungicides (all crops)

- Fungicide programs must deliver effective disease management. Apply QoI fungicide based products at effective rates and intervals according to manufacturer's recommendations. Effective disease management is a critical component to delay the build-up of resistant pathogen populations.
- The number of applications of QoI fungicide based products within a total disease management program must be limited whether applied straight or in mixtures with other fungicides. This limitation is inclusive to all QoI fungicides. Limitation of QoI fungicides within a spray programme provides time and space when the pathogen population is not influenced by QoI fungicide selection pressure.
- A consequence of limitation of QoI fungicide based products is the need to alternate them with effective fungicides from different cross-resistance groups.
- QoI fungicides, containing only the solo product, should be used in single or block applications in alternation with fungicides from a different cross-resistance group. Specific recommendation on size of blocks is given for specific crops.
- QoI fungicides applied as tank mix or as a co-formulated mixture with an effective mixture partner, should be used in single or block applications in alternation with fungicides from a different cross-resistance group. Specific recommendations on size of blocks are given for specific crops.
- Mixture partners for QoI fungicides should be chosen carefully to contribute to effective control of the targeted pathogen(s). The mixture partner must have a different mode of action, and in addition it may increase spectrum of activity or provide needed curative activity. Use of mixtures containing only QoI fungicides must not be considered as an anti-resistance measure.
- Where local regulations do not allow mixtures, then strict alternations with non-cross resistant fungicides (no block applications) are necessary.
- An effective partner for a QoI fungicide is one that provides satisfactory disease control when used alone on the target disease.
- QoI fungicides are very effective at preventing spore germination and should therefore be used at the early stages of disease development (preventive treatment).

Guidelines for using QoI fungicides on cereal crops

- Apply QoI fungicides always in mixtures with non-cross resistant fungicides to control cereal pathogens. At the rate chosen the respective partner(s) on its/ their own has/ have to provide effective disease control. Refer to manufacturers recommendations for rates.
- Apply a maximum of 2 QoI fungicide containing sprays per cereal crop. Limiting the number of sprays is an important factor in delaying the build-up of resistant pathogen populations.
- Apply QoI fungicides according to manufacturer's recommendations for the target disease (or complex) at the specific crop growth stage indicated.
- Apply the QoI fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of QoI fungicides.

Split / reduced rate programmes, using repeated applications, which provide continuous selection pressure, accelerate the development of resistant populations and therefore must not be used.

The responsible usage of all these different measurements provides under the current knowledge an effective anti-resistance management strategy.

3.3.1.6 Implementation of the management strategy

BASF promotes an awareness of fungicide resistance management in product leaflets and training sessions to sales personnel, distributors and growers' associations. The latest issues relating to fungicide resistance are discussed with the BASF technical managers from all regions of the world so that the information from individual countries can be passed on as quickly as possible to the other countries. In addition BASF actively participates in the FRAC meetings for all presently established Working Groups. In this way every attempt is made to formulate and promote resistance management strategies and the rational use of its fungicides.

3.3.1.7 Monitoring, reporting and reacting to changes in performance

The sensitivity of *Zymoseptoria tritici, Puccinia triticina, Pyrenophora teres,* and *Rhynchosporium secalis* to DMIs is monitored by BASF on an annual or biannual basis in extensive monitoring studies over all important European cereal growing areas.

The QoI sensitivity and/or presence of cytochrome *b* target site mutations (G143A, F129L, G137R) in *Zymoseptoria tritici, Puccinia triticina, Pyrenophora teres* and *Rhynchosporium secalis* are monitored by BASF on an annual or biannual basis in extensive monitoring studies over all important European cereal growing areas.

In case of field failure of BAS 765 00 F, which cannot be explained by other agronomic parameters, the sensitivity of the target pathogens of this Resistance Risk Analysis to mefentrifluconazole and kresoxim-methyl will be analysed.

Regulatory authorities will be informed at an early stage about all cases of field failure known to be due to resistance. Changes in sensitivity will be communicated in the FRAC working groups and may result in modifications to the recommended resistance management strategies.

Comments of zRMS:	Mefentrifluconazole belongs to the chemical group of triazolinthiones and it is an inhibitor of ergosterol biosynthesis (SBI – Sterol Biosynthesis Inhibitors). According to Fungicide Resistance Action Committee active substance mefentrifluconazole (DMI fungicides class, FRAC group – G1 DMI) belongs to the group of fungicides that present a medium risk for resistance development. Mefentrifluconazole inhibits of cytochrome P450 sterol 14α-demethylase and as a results inhibits ergosterol synthesis and finally cell membrane disruption and inhibition of mycelium growth. It is the new active substance which the molecule has a unique structure among DMI fungicides. It is the special isopropanol azole: the triazole 'head' sits on the 'neck' of a slim isopropanol linker. The extremely good performance of the substance might be explained by the fact that this slim linker requires less energy to adjust to the target enzyme binding pocket (cytochrome P450 sterol 14α-demethylase) compared to conventional DMIs. However the current recommendation of the FRAC SBI Working Group is to consider all DMIs to be cross-resistant with each other. In 2020, the sensitivity of the crop fungal pathogens populations for wheat and barley were overall stable on European level and for *Blumeria graminis* lover sensitivities have been detected in some geographies (France, UK, Germany) [Minutes from Virtual call on March 3rd, 2021, 11.15: - 12.05, Protocol of the discussions and recommendations of the SBI working group of the Fungicide Resistance Action Committee (FRAC);]. Kresoxim-methyl belongs to the Mode of Action Group C (Respiration) and to the subgroup C3 (inhibition of complex III) according to the classification of the Fungicide Resistance Action Committee (FRAC). The substance acts by blocking the transfer of electrons at the Quinone "outside" site of the bc1 complex (complex III in the electron transport chain) and as a results inhibit plant pathogens by blocking the pathogens ability to produce energy (ATP) and inhibit to growth. Resistance is known in various fungal species. Cross resistance shown between all members of the QoI group. Kresoxim-methyl belongs to the group of fungicides that present a hight risk for resistance development.

	In 2020, the following resistance of the crop fungal pathogens populations in cereal was presented (based on molecular data): - *Blumeria graminis* f. sp. *tritici*, wheat and rye: moderate in HU, CZ and high in PL; - *Zymoseptoria tritici*, wheat, medium to high resistance level detected in Croatia, CZ and PL, low to moderate levels in HU, RO, RU, SK and UA; - *Puccinia recondite/Puccinia triticina*, wheat, good performance of QoI fungicides; - *Puccinia striiformis*, wheat– all isolates sensitive (BE, DK, FR, DE, PL, ES, UK); - *Blumeria graminis f. sp. hordei*, barley - limited monitoring in 2019 was done, no to low resistance in LV and LT; - *Pyrenophora teres*, barley - medium to high levels of resistance in BE, DE, IE, NL and UK; medium levels in DK, FR, LT, SE, CH, PL; no to low levels in AT, HU, IT, LV, PL, RO, RU, SK, ES and UA, no resistance in BG, CZ and GR; - *Rhynchosporium secalis*, barley - full sensitivity in DK, DE, FR, HU, IE, LV, NL, PL, SK, ES and UK; - *Pyrenophora tritici-repentis*, wheat - high levels of resistance in DK, HU and LV, moderate to high in PL, moderate in DE, low in AT, CZ, RO and UA - *Puccinia hordei*, barley - full sensitivity in DE, FR, DE und UK [Meeting on January 25th and 26th, 2020, each 8:30 am - 12:30 am Protocol of the discussions and use recommendations of the QoI Working Group of the Fungicide Resistance Action Committee (FRAC)] Approved general resistance management tools for Mefentrifluconazole (SBI fungicides) are as follows: • use resistant crop varieties, good agronomic practice, plant hygiene/sanitation • use alternately fungicides with different modes of action, when fungicides is used more often than one treatment per season. • repeated application of fungicides alone should not be used on the same crop in one season against a high-risk pathogen (e.g. cereal powdery mildews, barley net blotch, scald) in areas of high disease pressure for that particular pathogen. • if the performance of SBIs should decline and sensitivity testing has confirmed the presence of less sensitive isolates, SBIs should only be used in mixture or alternation with effective non cross-resistant partner fungicides. • to ensure good performance and particularly resistance management in situations of even low disease pressure it is essential to adhere to dosages and spray timings as recommended by manufacturers. Curative applications should be avoided. Approved general resistance management tools for kresoxim-methyl (QoI fungicides) are as follows: ✓ apply fungicides always in mixtures with non-cross resistant fungicides to control cereal pathogens. ✓ apply a maximum of 2 QoI fungicide containing sprays per cereal crop ✓ apply fungicides according to manufacturers recommendations for the target disease (or complex) at the specific crop growth stage indicated ✓ apply fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of QoI fungicides Mefentrifluconazole: FRAC determined the DMI fungicides in general as medium-risk compounds Kresoxim-methyl: FRAC determined the QoI fungicides in general as high-risk compounds. Pathogen risk: High risk pathogens: *Blumeria graminis* Medium risk pathogens: *Zymoseptoria tritici, Parastagonospora nodorum, Pyrenophora tritici-repentis, Pyrenophora teres, Oculimacula spp.* Low risk pathogens: *Puccinia spp., Rhynchosporium secalis, Fusarium spp.* The Applicant presented combined risk analysis with two approaches – first is a diagram by Brent and Hollomon (2007) and the other a diagram published in the EPPO document "Efficacy evaluation of plant protection products, Resistance risk analysis, PP 1/213(4), (EPPO 2015)". The results show that the assessments of the combined pathogen x fungicide risks

	using both approaches are very similar. On the basis above mentioned analysis and data, the Applicant classified the combined risks as follows: DMI x pathogen: • **low**: *Puccinia* spp., *Fusarium spp.* • **low to medium:** *Rhynchosporium secalis, Parastagonospora nodorum, Oculimacula spp.* • **medium:** *Zymoseptoria tritici, Pyrenophora tritici-repentis, Pyrenophora teres* • **medium to high:** *Blumeria graminis* QoI x pathogen: • **low:** *Puccinia spp.* • **low to medium:** *Pyrenophora teres, Fusarium spp.* • **medium:** *Rhynchosporium secalis, Oculimacula spp.* • **medium to high:** *Zymoseptoria tritici, Parastagonospora nodorum, Pyrenophora tritici-repentis* • **high:** *Blumeria graminis* What is more the Applicant used method to determine the cytochrome P450 binding constant to show very high value mefentrifluconazole binding constant. Giving strong binding of the cytochrome P450 by the substance may provide excellent control of the most shifted isolates (resistant) under severe infection conditions. BAS 765 00 F is intended for control of diseases in cereals with up to 1.0 l product/ha in Poland and 0.6-1.0 l/ha in some SE and Maritime EPPO climatic zones countries. Maximum number of applications is 2, with a minimum of 14 days between applications and between growth stages 30-69. BAS 765 00 F is a mixture of two compounds with different modes of action, which are both active against most target organisms. This mixture (with all recommendation for using, with max application 2 times per season) will ensure maintenance of FRAC resistance management strategy. Nevertheless regulatory authorities should be informed about any new information which would change the resistance risk analysis.

3.4 Adverse effects on treated crops (KCP 6.4)

According to EPPO Guideline 1/135 data on phytotoxicity and yield is sufficient from efficacy trials at the maximum target dose rate for fungicides if no adverse phytoxic effects occur in the efficacy trials.
Since no phytotoxicity is seen in the efficacy trials in principle the same set of data from trials used for efficacy is also used for evaluation of adverse effects. Additionally results of 2 trials where no diseases were observed or infections were negligible are presented in sections 3.4.1 Phytotoxicity to host crop and 3.4.2 Effect on the yield of treated plants or plant products. These trials are described in Table 3.4-2. Since there are individual trials in which adverse effects were not tested the number of trials presented below is slightly lower than presented in efficacy section.

3.4.1 Phytotoxicity of product

Phytotoxicity was evaluated in a total of 111 efficacy trials and 2 trials free of disease. Trials were carried out on wheat, barley, rye and triticale in countries across Europe over three seasons from 2018 to 2020 on a wide range of commercially grown varieties. Assessments were at the same time carried out to determine whether the application of the test product or of the reference products caused damage to the treated crops. The assessments were performed in compliance with EPPO Guideline PP 1/135 (3/4) (Phytotoxicity assessment). Crop selectivity was assessed on a whole plot basis and any damage symptoms were recorded as the percentage relative to untreated plots. No phytotoxicity symptoms caused by BAS 765 00 F at the proposed use rate of 1.0 L/ha were recorded in assessed trials.
Details are provided in BAD (BASF Doc ID 2020/2102791).

Table 3.4-1 : Phytotoxicity of BAS 765 00 F – Efficacy trials (trials with and without disease)

Number of trials with…		Trials with phytotoxicity tested (113 trials)			
		with diseases (111 trials)		without disease (2 trials)	
		BAS 765 00 F 1.0 l/ha	Standard	BAS 765 00 F 1.0 l/ha	Standards
No of trials conducted for each rate or product					
Maximum of phytotoxicity recorded during the trials	0% to 5%	111	111	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0
Level of symptoms at the last assessments	0% to 5%	111	111	2	2
	>5% to 10%	0	0	0	0
	>10% to 15%	0	0	0	0
	>15 %	0	0	0	0

For crops and varieties assessed for phytotoxicity in efficacy trials please refer to Table 3.2-22: Details on trial methodology. For crops and varieties assessed for phytotoxicity in trials free of disease refer to Table 3.4-2 below.

Comments of zRMS:	The applicant submitted 111 efficacy reports (for winter wheat, winter and spring barley, winter triticale, rye) where phytotoxicity of the product was also carried out at the maximum target dose rate 1,0 L/ha. Additionally the phytotoxicity was tested in 2 trials free of disease. No phytotoxicity symptoms were observed in the efficacy tests.

3.4.2 Effect on the yield of treated plants or plant product (KCP 6.4.2)

Yields were assessed as the grain yield from a known harvested area corrected to an 86% dry matter (14% of moisture). The results are expressed in deci-tonnes per hectare (dt/ha) and as a percentage of untreated plots.

Table 3.4-2: Crop varieties included in trials free of disease and assessed for yield

Crop	No. trials	Varieties
winter wheat	2	Ariesan, Boregar

Results are available from 2 safety trials (where disease infection was below 5%). In these trials, BAS 765 00 F was compared to Proline. Summary is presented in Table 3.4-3 below, individual results in BAD (BASF Doc ID 2020/2102791).

Table 3.4-3: Yields in wheat - trials free of disease (dt/ha and % relative to untreated) – summary table

EPPO zone		Untreated	BAS 765 00 F 0.6 l/ha	BAS 765 00 F 1.0 l/ha	Standard
Maritime	**average**	97.0		101.4	96.6
	(%)	100.0		104.5	99.7
	min-max	-		-	-
	n	1		1	1
South-East	**average**	33.4	37.9	38.5	36.5
	(%)	100.0	113.5	115.4	109.3
	min-max	-	-	-	-
	n	1	1	1	1
All zones	**average**	65.2		69.9	66.6
	(%)	100.0		110.0	104.5
	min-max	-		104.5-115.4	99.7-109.3
	n	2		2	2

Good yield responses were seen after fungicidal application, with BAS 765 00 F increasing yield by a mean of 10% in free of disease trials (no or low disease values <5%) for the highest dose rate 1.0 L/ha. Standard offered an increase in yield about 5%. Based on the results it is concluded that no adverse effects on yield were seen from applications of BAS 765 00 F to wheat.

Comments of zRMS:	The effect of BAS 765 00 F on winter wheat was also assessed **in 2 trials free of diseases** by measuring: 1. Yield- grain yield from a known harvested area corrected to 86% dry matter [dt/ha] and % of untreated plots Yield in winter wheat amounted [% of untreated plots]: • in Maritime EPPO climatic zone: 104,5 (1,0 L/ha) • SE EPPO climatic zone: 113,5 (0,6 L/ha) and 115,4 (1,0 L/ha) It was observed an increased in yield about 10%. The standard gave the increased about 5 %. It can be concluded that BAS 765 00 F showed no negative impact on yield (at dose rates 0,6 l/ha and 1.0 L/ha) of winter wheat.

3.4.3 Effects on the quality of plants or plant products (KCP 6.4.3)

Since no adverse effects on yield were seen from applications of BAS 765 00 F, assessment of quality parameters in trials where no disease occurred or with low disease values is not considered necessary.

Comments of zRMS:	The applicant submitted 113 selectivity trials 68 for winter wheat and 30 for winter and spring barley, 7 for winter triticale ad 6-7 for rye carried out in 2018, 2019 and 2020 at dose rates: 0,6 and 1,0 L/ha. There were no negative effects on yield and quality parameters after the application of BAS 765 00 F. That is why no adverse effects on the quality of plants or plant products are expected.

3.4.4 Effects on transformation processes (KCP 6.4.4)

3.4.4.1 Bread-making – Wheat

Three trials have been processed with bread-making. Trial list is presented in Table 3.4-4.

Table 3.4-4: Trials used for bread-making process

Uses or crops (Number of trials)	Year	Trial n°	Test report	Testing facilities / Organisation	Guidelines	Trial Status	Comments
Winter wheat (3)	2019	F815/19-X-FR-FR2-229	DEV-F-2019-FR-815-A-02.0-FR-FR2-229	BASF	CEB N°218 - 2012	GEP	-
		F815/19-X-FR-FRB-B09	DEV-F-2019-FR-815-A-02.0-FR-FRB-B09	BASF	CEB N°218 - 2012	GEP	-
		F815/19-X-FR-FRE-E75	DEV-F-2019-FR-815-A-02.0-FR-FRE-E75	BASF	CEB N°218 - 2012	GEP	-

The impact of BAS 765 00 F on wheat processing procedure was performed in 3 French trials in 2019. These studies were carried out according the recommendations of the CEB n°218: method for the study of unintended effects of plant protection products on soft wheat quality and transformed products from wheat. BAS 765 00 F was applied at 1.0 L/ha in comparison with Proline at 0.8 L/ha.
At harvest, a representative sample from 5 to 10 kg of grains was taken in every plot (borders were eliminated) and kept in a linen bag at ambient temperature until its transportation at the laboratory.
After the measures of the protein content and the germination rate, the laboratory performed the usual tests: Hagberg, Zeleny, Chopin alveograph then bread-making.
● Description of the studies performed during the processing procedure Hagberg's falling time index:
The test measures the falling time of wheat, using ground wheat in suspension in water. A good milling wheat has a high falling time, and wheat with low falling times is not normally used in milling.
This index measures indirectly the activity of the amylases which can become excessive in the presence of grains which are germinated or in germination phase. It is expressed in seconds. The scale is the following one:

- hyperdiastasic flour (when wheat is germinated): the falling time is slow: 60 - 150 "; this wheat has to be rejected, their flour having a weak power of absorption of the water, the dough is fatty, sticky, the fermentation is fast; the crust is red, very colored, the crumb is sticky and sometimes comes loose from the crust.
- normal diastasic flour: the average falling time is ranging between 200 and 300 ".
- hypodiastasic flour: the falling time is greater than 300 "; the fermentation is very slow and laborious; these flours must be corrected by addition of malt.

A normal value of Hagberg must be superior to 180 and that differences lower than 10 % between 2 treatments is not significant (criteria GALYS).

Zeleny test

This test, specific in the soft wheat, is a quality test for the bread-making. It is based on the capacity of proteins of the flour to be inflated in acid environment. The Zeleny index corresponds to the height deposit obtained after stirring and sedimentation of a preparation of flour in suspension in a reagent. It is expressed in milliliters. Ten percent differences between 2 treatments are not significant.

Index	< 18	18 < < 28	28 < < 38	> 38
Quality	Not sufficient	Good baking quality	Very good baking quality	Excellent baking quality

Chopin alveograph

It allows predicting the capacity of wheat or flour to be used in the manufacturing of products of cooking. The principle of the measure consists of the study of the behaviour of a sample of dough during its deformation under the influence of a movement of air with constant flow. At first, a disk of dough resists to the pressure and does not deform, then it swells in the form of a more or less voluminous bubble according to its extensibility and bursts. The evolution of the pressure in the bubble is measured and transposed in the form of curve, called alveogram.

The alveogram is characterized by the following parameters:

- P = the height (in mm), corresponds to the moderate maximal pressure before the disk deforms. It is in connection with the tenacity of the dough (according to the laboratory GALYS, significant differences are superior to 15 %).
- L = the length (in mm) corresponds to the maximum inflation of the bubble. It is related to the extensibility of the dough.
- G = corresponds to the inflation and deducts by a formula according to L (significant differences superior to 10 %).
- P/L indicates the balance between the tenacity and the extensibility of the dough; it has to be of the order of 0,5 so that the qualities of the flour are balanced.
- W = surface of the alveogram; it represents the work of deformation of the dough until the break (expressed in 104 joules by gram of dough). Differences lower than 20 % are not significant.

Type of use	W	P/L
Biscuit production	120-150	0,3-0,5
French bread-making	200-250	0,5-0,7
Croissant - brioche	250-300	0,5-0,9
Sandwich bread	350	0,7-1

Source: Arvalis

Bread-making

Complete bread-making was done by the laboratory GALYS for the trials according to the previous criteria. Three marks are given:

- A dough index representing the characteristics of elasticity, viscosity, holding to the oven of the dough. A difference of 5 is considered as significant by the laboratory.
- The bread index (smell, color, texture, aspect of the crust) with differences lower than 10 considered as not significant.
- The sum of these two index added by a constant 100 (crumb index) represent the total bread-making index.

● Results: Yield and quality of the yield

The measures of yield and quality were performed in laboratory, after harvest. The results are presented in Table 3.4-5 and Table 3.4-6.

In terms of yield, BAS 765 00 F at 1.0 L/ha achieved a gain of 7,1 dT/ha in comparison with the untreated control, and + 3.5 dT/ha compared to Proline.

Regarding the other measures (grain moisture content, hectoliter weight, thousand grain weight and protein content), no negative impact was observed with the use of BAS 765 00 F nor the reference.

Table 3.4-5: Yield – bread-making trials

				UTC		BAS 765 00 F 1.0 L/ha			Proline 0.8 L/ha		
Trial	EPPO	Disease	Cultivar	value	Tukey	value	Tukey	%UTC	value	Tukey	%UTC
Yield (dt/ha)											
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	126,1	d	132,1	a	104,8	128,1	bcd	101,6
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	97,0	bc	101,4	abc	104,5	96,6	c	99,7
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	98,3	c	109,0	b	110,8	107,5	b	109,3
Mean value (3 trials)				107,1		114,2		106,7	110,7		103,5

Table 3.4-6: Moisture content, hectoliter weight, thousand grains weight, germination and protein rates – bread-making trials

				UTC		BAS 765 00 F 1.0 L/ha			Proline 0.8 L/ha		
Trial	EPPO	Disease	Cultivar	value	N&K	value	N&K	%UTC	value	N&K	%UTC
Moisture content (%)											
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	10,0	-	10,2	-	-	10,1	-	-
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	13,9	-	14,0	-	-	14,0	-	-
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	11,7	-	12,1	-	-	11,9	-	-
Mean value (3 trials)				11,9		12,1			12,0		
hectolitre weight (kg/hl)											
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	80,4	a	80,9	a	100,5	80,7	a	100,4
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	79,9	a	80,6	a	100,9	80,1	a	100,3
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	82,2	a	81,9	a	99,5	80,9	a	98,4
Mean value (3 trials)				80,9		81,1		100,3	80,6		99,7
Thousand grain weight (g)											
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	44,6	b	45,8	ab	102,8	45,5	ab	102,1
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	43,6	a	45,0	a	103,2	44,4	a	101,9
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	34,7	d	37,7	c	108,8	38,0	bc	109,5
Mean value (3 trials)				40,9		42,8		104,9	42,6		104,5
Protein content (%)											
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	11,6	a	11,6	a	99,7	11,7	a	100,3
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	13,3	b	13,5	ab	101,5	13,7	ab	103,0
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	11,8	a	11,5	ab	97,2	11,2	ab	94,9
Mean value (3 trials)				12,2		12,2		99,5	12,2		99,4
germination rate (%)											
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	98,0	-	98,0	-	100,0	98,0	-	100,0
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	99,0	-	98,0	-	99,0	99,5	-	100,5
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	99,0	-	100,0	-	101,0	100,0	-	101,0
Mean value (3 trials)				98,7		98,7		100,0	99,2		100,5

● Results of the processing procedure studies
The bread making results are presented in Table 3.4-7.

Results show that BAS 765 00 F does not lead to significant modifications of ZELENY index, Hagberg's falling time index or the Chopin alveograph. BAS 765 00 F at the dose rate of 1.0 L/ha does not show any significant difference in comparison to the references on the processing procedure for bread-making.
To conclude, all the studies and analysis confirm that BAS 765 00 F has no negative effect on wheat quality and processing procedures.

Table 3.4-7: Bread-making results

Trial	EPPO	Disease	Cultivar	UTC value	BAS 765 00 F 1.0 L/ha value	Proline 0.8 L/ha value	Difference BAS 765 00 F/ Proline	acceptable difference
Hagberg falling time (s)								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	378,0	388,3	385,7		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	423,0	419,3	421,7		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	373,7	372,0	374,0		
Mean value (3 trials)				391,6	393,2	393,8	-0,2%	< 10%
Sedimentation value (mm) - Zeleny								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	35	34	33		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	44	47	46		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	40	38	37		
Mean value (3 trials)				39,7	39,7	38,7	+2,6%	< 10%
Chopin alveograph G								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	24,5	21,8	22,9		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	17,9	17,8	15,6		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	21,1	19	19,8		
Mean value (3 trials)				21,2	19,5	19,4	+0,5%	< 10%
Chopin alveograph P								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	52	55	55		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	99	102	115		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	70	78	72		
Mean value (3 trials)				73,7	78,3	80,7	+3%	< 15%
Chopin alveograph P,L								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	0,43	0,57	0,52		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	1,52	1,59	2,35		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	0,78	1,07	0,91		
Mean value (3 trials)				0,9	1,1	1,3	-18%	
Chopin alveograph W								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	206	183	200		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	222	228	217		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	222	214	206		
Mean value (3 trials)				216,7	208,3	207,7	+0,3%	< 20%
Dough index								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	87	87	87		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	97	97	97		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	86	89	89		
Mean value (3 trials)				90,0	91,0	91,0	+0	< 5 points
Bread index								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	58	57	52		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	76	76	79		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	60	56	55		
Mean value (3 trials)				64,7	63,0	62,0	+1	< 15 points
Bread making index								
F815/19-X-FR-FR2-229	Ma	s	CHEVIGNON	245	244	239		
F815/19-X-FR-FRB-B09	Ma	-	BOREGAR	273	273	276		
F815/19-X-FR-FRE-E75	Ma	s	TERROIR	246	245	244		
Mean value (3 trials)				254,7	254,0	253,0	+1	< 15 points

3.4.4.2 Brewing study – Barley

The full study "**Malting and brewing trails** Evaluation of different barley varieties for brewing purposes" can be found in BAD (BASF Doc ID 2020/2102791).

Grains samples were taken from 2 trials conducted in 2019 on spring barley. Both trials received one applications of fungicide - full rate of BAS 765 00 F (1.0 l/ha) and other tested fungicides. The application timing followed the GAP table (one spray, fungicides diluted in 250 l/ha of water, applications conducted in BBCH from 61 to 69). The applications pattern also reflected the commercial practice. Trials were carried out under valid GEP certificate on field used for commercial production.
Grain samples were investigated at the chair of brewing and beverage technology-TUM/Weihenstephan (Lehrstuhl für Brau- und Getränketechnologie-BGT) with regard to brewing barley characteristics (specifications). The malting was done in the 1 kg micro malting system of the chair using the MEBAK standard method (45 % steeping degree, 5 steeping- and germination days, 18 °C down to 14.5 °C steeping- and germination temperature). The analyses were carried out using MEBAK standard methods by the laboratory of TUM-BGT.
The conclusion from the study is that results are similar between the untreated and the treated with various fungicides samples. Accordingly, no restrictions need apply for the use of BAS 765 00 F for barley grown for brewing. Details of results are presented in tables below.

Table 3.4-8: Malt analyses

		Check	BAS 76202F	BAS 76500F	BAS 758ARF	Check	BAS 76202F	BAS 76500F	BAS 758ARF
analysis	**unit**	**sample 1-1**	**sample 1-2**	**sample 1-3**	**sample 1-4**	**sample 2-1**	**sample 2-2**	**sample 2-3**	**sample 2-4**
water content	%	5.4	5.3	5.3	5.1	4.9	5.0	5.1	5.2
extract malt	%	76.8	76.4	76.5	77.7	76.4	76.1	76.3	77.4
extract malt d.m.	% d.m.	81.2	80.7	80.8	81.9	80.3	80.1	80.4	81.6
viscosity (related to 8,6 ww-%)		1.524	1.531	1.529	1.523	1.532	1.543	1.532	1.523
friability	%	73.9	76.8	73.2	75.3	74.1	73.9	72.3	75.8
1/1-steely	%	0.7	0.4	0.6	0.7	0.2	0.7	0.4	0.5
saccharification time	min.	5-10	5-10	5-10	5-10	5-10	5-10	5-10	5-10
final attenuation	%, app.	83.5	83.5	83.4	83.4	83.5	82.5	83.3	83.9
wort colour	EBC	2.8	3.2	2.9	3.2	2.9	3.1	3.2	3.0
pH		6.05	6.04	6.03	6.00	6.04	6.03	6.04	6.02
protein	%, d.m.	12.3	12.3	12.7	12.2	12.3	12.3	12.5	12.1
total soluble nitrogen	mg/100g malt d.m.	648	663	672	675	658	658	687	666
Kolbach index	%	32.9	33.7	33.1	34.6	33.4	33.4	34.4	34.4
free amino-N	mg/100g malt d.m.	111	107	99	97	117	112	113	103
beta-glucan 65 °C	mg/l	658	627	599	634	661	681	589	654
alpha amylase	DU, d.m.	52	53	53	48	54	48	61	53

Table 3.4-9: Wort analyses

sample		Check	BAS 76202F	BAS 76500F	BAS 758ARF	Check	BAS 76202F	BAS 76500F	BAS 758ARF
		sample 1-1	**sample 1-2**	**sample 1-3**	**sample 1-4**	**sample 2-1**	**sample 2-2**	**sample 2-3**	**sample 2-4**
gravity	GG %	11.14	11.15	11.2	11.08	11.28	11.45	11.31	11.15
gravity	GV %	11.61	11.63	11.69	11.55	11.77	11.95	11.81	11.63
app. degree of fermentation	%	77.1	76.7	77.1	77.6	78.4	79.4	80.1	79.5
pH		5.71	5.74	5.22	5.20	5.99	5.82	6.00	5.85
total nitrogen	mg/100 ml	90.6	93.2	92.1	93.7	95.0	97.1	96.8	92.6
total nitrogen (rel. to 12 GG %)	mg/100 ml	97.6	100.3	98.7	101.5	101.1	101.8	102.7	99.7
high molecular N	mg/100 ml	18.0	18.9	19.3	20.2	20.6	19.8	20.7	19.6
high molecular N (rel. to 12 GG %)	mg/100 ml	19.4	20.3	20.7	21.9	21.9	20.8	22.0	21.1
FAN	mg/100 ml	23.5	16.2	14.4	16.8	21.4	19.8	19.1	20.2
FAN (rel. to 12 GG %)	mg/100 ml	25.3	17.4	15.4	18.2	22.8	20.8	20.3	21.7
ß-Glucane	mg/l	460	503	504	541	546	553	551	516
ß-Glucane (rel. to 12 GG %)	mg/l	496	541	540	586	581	580	585	555
polyphenols	mg/l	207	204	203	208	189	209	206	194
polyphenols (rel. to 12 GG %)	mg/l	223	220	218	225	201	219	219	209
anthocyanogens	mg/l	106	107	107	104	104	105	112	113
anthocyanogens (rel. to 12 GG %)	mg/l	114	115	115	110	111	110	119	122
bitter units	EBC	49	45	46	48	44	43	46	45

Table 3.4-10: Beer analyses

			Check	BAS76202F	BAS76500F	BAS758ARF	Check	BAS76202F	BAS76500F	BAS758AR F
analysis			**KS065**	**KS066**	**KS067**	**KS068**	**KS069**	**KS070**	**KS071**	**KS072**
gravity (GG %)	MEBAK II 2.13.2.3	GG %	11.06	11.08	11.15	11.10	11.10	11.26	11.10	10.88
gravity (GV %	MEBAK II 2.13.2.3	GV %	11.53	11.55	11.63	11.57	11.57	11.75	11.57	11.33

Alcohol (GG %)	NIR; OIML	GG %	3.56	3.57	3.60	3.60	3.62	3.66	3.62	3.53
Alcohol (Vol %)	NIR; OIML	Vol %	4.54	4.56	4.60	4.59	4.62	4.67	4.62	4.51
degree of fermentation, app.	NIR; OIML	%	64.1	64.1	64.3	64.5	79.5	79.1	79.5	79.1
pH	MEBAK II 2.17		4.48	4.42	4.42	4.42	4.70	4.60	4.60	4.50
colour	MEBAK II 2.16.2	EBC	3.5	3.7	3.5	3.8	3.4	3.7	3.5	3.3
viscosity	MEBAK I 4.1.4.4	mPa*s	1.531	1.562	1.582	1.547	1.538	1.553	1.553	1.527
foam according to NIBEM	MEBAK II 2.23.3	s	167	173	215	218	183	212	229	225
bitter units	MEBAK II 2.22.1	EBC	25	25	26	26	24	25	28	28

Table 3.4-11: Tasting results

Brew number	product	AWM	date	**TUM-BGT**	DLG-grade
K065	Check			sample 1-1	34.0
K066	BAS 76202F	1.0	ES 59-61	sample 1-2	38.4
K067	BAS 76500F	1.0	ES 59-61	sample 1-3	35.2
K068	BAS 758ARF	1.5	ES 59-61	sample 1-4	34.5
K069	Check			sample 2-1	36.0
K070	BAS 76202F	1.0	ES 61-63	sample 2-2	36.2
K071	BAS 76500F	1.0	ES 61-63	sample 2-3	36.6
K072	BAS 758ARF	1.5	ES 61-63	sample 2-4	35.6

Comments of zRMS:	The impact of BAS 765 00 F on transformation processes was tested for winter wheat in three French trials in 2019 for bread – making and for spring barley in two German trials in 2020 for malting and brewing. The tested product was applied at the dose rate 1,0 L/ha. Bread – making – winter wheat: The studies were carried out according to the recommendations of the CEB n°218: method for the study of unintended effects of plant protection products on soft wheat quality and transformed products from wheat. The following parameters were measured: protein content, germination rate, Harberg factor, Zeleny factor, Chopin alveograph, dough index, bread index, bread -making index. It might be concluded that BAS 765 00 F at the dose rate of 1.0 L/ha does not show any significant difference in comparison to the references on the processing procedure for bread-making and as a result has no negative effect on wheat quality and processing procedures. Malting and brewing – spring barley: The following analyses were performed: Malt analyses Wort analyses Beer analyses Tasting results It might be concluded that BAS 765 00 F at the dose rate of 1.0 L/ha does not show any significant difference in comparison to the untreated and treated with the reference product, on the processing procedure for malting and brewing barley and as a result has no negative effect on barley quality and processing procedures.

Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

According to EPPO PP1/135 (4) the special study on propagation is not necessary for submission of BAS 765 00 F because after treatments in field trials practically no phytotoxic effects were seen. However, the specific case study was conducted. Results from glasshouse trials are presented in the attachment "Germination trials with harvested grains from wheat and barley treated with BAS 765 00 F" which is described in detail in BAD (BASF Doc ID 2020/2102791). Studies were conducted to establish the germination capacity of grain treated twice with BAS 765 00 F. A summary of results is presented below.
Six winter wheat trials located in various European countries were treated twice with 1.0 l./ha of BAS 765 00 F at crop growth stage BBCH 49 and 69. Then samples were collected and tested for germination capacity There were no differences seen in the germination of treated grain compared to the untreated.
Six winter barley trails located in various European countries were treated twice with 1.0 L/ha of BAS 765 00 F from which grain samples were collected and tested for germination capacity. There were no differences seen in the germination capacity of treated grain compared to untreated.
Summary and conclusion
Results of study indicate that previous foliar treatment with BAS 765 00 F does not have any impact on germination of harvested cereals. For more information, please refer to BAD (BASF Doc ID 2020/2102791).

Comments of zRMS:	In order to check the impact of the product on treated plants or plant products to be used for propagation, the Applicant presented 6 glasshouse trials for winter wheat and 6 glasshouse trials for winter barley from different countries. Wheat and barley were treated two times with 1.0 l./ha of BAS 765 00 F. After samples were collected the germination capacity of seeds were tested. The following varieties of wheat were tested: Ponticus, Szilard, Julius, Mistral, Oregrain, Marius. The germination of barley was tested for the following varieties: Avalon, Ella, Scarlet, Fairway, Memento, Idra. It might be concluded that BAS 765 00 F at the double dose rate of 1.0 L/ha does not show any significant difference differences in the germination capacity of treated grain compared to untreated. It might be concluded that BAS 765 00 F at the dose rate of 1.0 L/ha is safe for the germination of the grains of treated crops.

3.5 Observations on other undesirable or unintended side-effects (KCP 6.5)

3.5.1 Impact on succeeding crops (KCP 6.5.1)

3.5.2 Impact on succeeding crops (KCP 6.5.1)

3.5.2.1 Introduction

The influence of substrate contamination with BAS 765 00 F, a co-formulation of Mefentrifluconazole and Kresoxim-methyl, on the germination and growth of different crops has been tested in pot trials in the greenhouse.
The following 10 species were tested:

Beta vulgaris	Sugar beet	var. Danicia
Brassica napus	Oilseed rape	var. Licapo
Daucus carota	Carrot	var. LagunaF1
Helianthus annuus	Sunflower	var. Sunrich Orange F1
Hordeum vulgare	Winter barley	var. Astrid
Solanum tuberosum	Potatoe	var. Bintje
Pisum sativum	Pea	var. Livioletta
Triticum aestivum	Winter wheat	var. Monopol
Vicia faba	Broad bean	var. Taifun
Zea mays	Maize	var. Ronaldinio

Before cultivation of the crops, BAS 765 00 F was incorporated into the substrate. According to the PEC soil calculation, a dose rate of 2.0 L/ha BAS 765 00 F (= 500 g active ingredient/ha, i.e. 200g ai/ha Mefentrifluconazole + 300g ai/ha Kresoxim-methyl) was applied. This is the two-fold targeted registration rate.
Assessments:
Phytotoxicity was assessed as a percentage of injured plants at GS 12.
Germination was evaluated by counting the seedlings according to the ISTA-methods (Chapter 5: The Germination Test, 2004), at GS 12.
Plant height in cm (for monocots) and plant weight (fresh matter) in g/plant for all crops were measured at GS 12.
Results
Phytotoxicity
Neither of the tested crops showed crop injury, when grown in substrate treated with
BAS 765 00 F.

Germination
None of the tested crops grown in substrate treated with BAS 765 00 F exhibited a negative influence on germination rate in relation to the untreated substrate.
Plant weight
No negative effect on plant weight was observed between the crops grown in substrate treated with BAS 765 00 F and the crops grown in untreated substrate for all of the tested crops.

Plant height
No negative effect on plant height was observed between the crops grown in substrate treated with BAS 765 00 F and the crops grown in untreated substrate for all of the tested monocot crops.

Conclusion

As a conclusion of all studies conducted, BAS 765 00 F does not have any negative impact on the cultivation of the tested succeeding crops.
No signs are to be found in any glasshouse or field trials that BAS 765 00 F had negative effects on following crops. This indicates that the product BAS 765 00 F presents an extremely small risk of damage to any following crop. It may therefore be concluded that there are no grounds for expecting a risk of damage to following crops due to application of BAS 765 00 F.
There is no necessity for restrictions in the choice of following crops, even in the event of crop failure on a field which has been treated with BAS 765 00 F.

Comments of zRMS:	The impact of the product BAS 765 00 F on succeeding crops was conducted and reported according to the following guidelines: EPPO Guideline PP 1/207 (2) EPPO Guideline PP 1/135 (4) ISTA method, 2004, chapter 5 BBCH scale 2nd Edition 1997 BASF SOP Succeeding Crops August 2014 Germination and growth of different commercial varieties of crops were tested in greenhouse pot trials. Before cultivation of the crops a double dose rate of 2,0 L/ha BAS 765 00 F was applied. The following crops were tested: Sugar beet, Oilseed rape, Carrot, Sunflower, Winter barley, Potatoe, Pea,Winter wheat, Broad bean, Maize. There were no negative effects on germination, plant weight, and plant height. No phytotoxicity were also observed on the treated crops. It might be concluded that BAS 765 00 F at the dose rate of 1.0 L/ha has no risk of damage to above mentioned crops.

3.5.3 Impact on other plants including adjacent crops (KCP 6.5.2)

In a vegetative vigour test, six species of dicotyledonous plants (carrot, lettuce, oilseed rape, cabbage, soya bean, tomato) and four species of monocotyledonous plants (onion, rye grass, wheat, corn) were exposed to BAS 765 00 F to evaluate the phytotoxic potential. BAS 765 00 F was applied post-emergence at growth stage BBCH 12 – 14 at 1.0 l/ha. Five replicates were tested per plant species and treatment group, i.e. the test item and a control treatment (tap water only). After application, the plants were cultivated for 21 days under greenhouse conditions. Assessment for phytotoxicity and plant survival were done 7, 14 and 21 days after treatment (DAT); assessment for single plant length was done 21 days after application; plant dry weight was determined at study termination 21 DAT.

Results and conclusion

Based on the results of this study, conducted under greenhouse conditions, it can be concluded that BAS 765 00 F at 1.0 l/ha did not cause effects to plant phytotoxicity, plant survival, plant length and plant dry biomass for all tested plant species.

Post-emergence application of BAS 765 00 F under worst-case greenhouse conditions did not result in any treatment-related symptom of phytotoxicity for all tested species. The ER_{50} based on phytotoxicity, plant dry weight and height was > 1.0 L BAS 765 00 F/ha for all tested plant species (the highest rate tested). The NOER based on phytotoxicity for wheat was $\geq$ 1.0 L/ha.

The data presented within this Annex Point justifies the recommendation of **no restrictions on adjacent crops after the application of BAS 765 00 F.**

Comments of zRMS:	The impact of the product BAS 765 00 F on other plants including adjacent crops was conducted and reported according to the following guidelines: OECD Guideline 227 OCSPP 850.4150 The following dicotyledonous plants: carrot, lettuce, oilseed rape, cabbage, soya bean, tomato and monocotyledonous plants: onion, rye grass, wheat, corn were tested in a vegetative vigor test. BAS 765 00 F was applied at dose rate 1,0 L/ha, post-emergence, at growth stage BBCH 12 – 14 of the plants which were cultivated under greenhouse conditions for 21 days. Plant survival, plant length, plant dry weight were assessed as the factors of phytotoxicity symptoms for all tested plants. It can be concluded that BAS 765 00 F at 1,0 L/ha caused no negative effects basing on the factors phyto-toxicity symptoms for all tested plant species. Based on phytotoxicity, plant dry weight and height, ER50 amounted > 1.0 L/ha BAS 765 00 F/ha for all tested plant. NOER values was > 1.0 L/ha.

OECD Guideline 227

OCSPP 850.4150

3.5.4 Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

Tank cleaning
The document "Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing" - BAS 765 00 F" provides results that flushing with water will satisfactorily remove residues of the product without the need of a specific tank cleaner (for more information see BAD - BASF Doc ID 2020/2102791).

Physical and chemical compatibility
The physical and chemical compatibility of BAS 765 00 F together with 11 other mixtures of plant protection products were tested according to ASTM method E 1518-05. A static and dynamic tests of the mixtures were done. The mixtures were prepared with rates recommended for tank mixtures. A list with the 11 tested plant protection products is presented in Table 3.6-1: Products tested in mixture with BAS 765 00 F. below.
The physical properties of the tested aqueous mixture showed that BAS 765 00 F is physically compatible with the tank mix partners described in this report under normal tank mix conditions.
Based on the fact that no indications of any chemical reaction were observed between the mixed products, BAS 765 00 F is apparently chemically compatible with the tank mix partners described in table below.
Details of the report on physical and chemical compatibility of BAS 765 00 F can be found in BAD (BASF Doc ID 2020/2102791).

Table 3.6-1: Products tested in mixture with BAS 765 00 F.

Mixture number	BAS number	Trade name	Formulation	Content active ingredient	Comment
1	BAS 700 09 F	Imtrex	EC	62.5 g/l fluxapyroxad	
2	BAS 703 07 F	Priaxor	EC	75 g/l fluxapyroxad 150 g/l pyraclostrobin	
3	BAS 560 00 F	Flexity	SC	300 g/l metrafenone	Foaming occurs, use anti foam agent.
4	BAS 008 00 D	Turbo	GR		Fertilizer
	BAS 122 08 W	Medax Top	SC	300 g/l mepiquat chloride + 50 g/l prohexadione calcium	
	BAS 067 10 W	Camposan Extra	SL	660 g/l ethephon	
5	BAS 122 08 W	Medax Max	SC	5% prohexadione calcium + 7.5 % trinexapac ethyl	
6	BAS 044 26 H	Duplosan DP	SL	600 g/l dichloroprop-P	Foaming occurs, use anti foam agent.
7	BAS 812 00 H	Bitahlon Plus	WG	5,4% florasulam + 71.4 % tritosulfuron	Foaming occurs, use anti foam agent.
8	BAS 951 70 H	Ariane C	EC	80 g/l clopyralid + 2.5 g/l florasulam + 100 g/l fluroxypyr	
9	BAS 937 70 H	Atlantis	WG	0,6% iodosulfuron metyl natrium + 3% mesosulfuron methyl	Foaming occurs, use anti foam agent.
	BAS 910 10 S	Actirob B	EC		Adjuvant
10	BAS 900 50 I	Pirimor Granulat	GR	50% piromicarb	
11	BAS 314 03 I	Sumicidin Alpha	EC	50 g/l esfenvalerate	

Comments of zRMS:

Tank cleaning

The Applicant used a calculation method to estimate the effectiveness cleaning of spray application equipment after the use of BAS 765 00 F. The results showed that after a two-stage cleaning (each step with 10 % water in relation to the total tank capacity) the amount of the active ingredient is reduced to 1:1800 compared to the initial quantity. It means that the calculated amount of active substances carried over into a following application will be amounted 0,56 g a.s./ ha with an application rate of 400 L/ ha.

It might be concluded that the two-stage cleaning of field sprayer with water immediately after the use of BAS 765 00 F makes the contamination in the immediately following application negligible.

Because the formulation of the product is mixing with water protective clothing will be cleaned effectively when washed with usual laundry detergents.

Physical and chemical compatibility

The physical and chemical compatibility of BAS 765 00 F with 11 other mixtures of plant protection products was conducted and reported according to the ASTM method E 1518-05. Following products (different formulations and actives substances)were used to test:

Trade name	Formulation	Content active ing
Imtrex	EC	62.5 g/l fluxapyroxad
Priaxor	EC	75 g/l fluxapyroxad 150 g/l pyraclostrobin

	Flexity	SC	300 g/l metrafenone	
	Turbo	GR		
	Medax Top	SC	300 g/l mepiquat chloride + 50 g/l prohexadione calcium	
	Camposan Extra	SL	660 g/l ethephon	
	Medax Max	SC	5% prohexadione calcium + 7.5 % trinexapac ethyl	
	Duplosan DP	SL	600 g/l dichloroprop-P	
	Bitahlon Plus	WG	5,4% florasulam + 71.4 % tritosulfuron	
	Ariane C	EC	80 g/l clopyralid + 2.5 g/l florasulam + 100 g/l fluroxypyr	
	Atlantis	WG	0,6% iodosulfuron metyl natrium + 3% mesos methyl	
	Actirob B	EC		
	Pirimor Granulat	GR	50% piromicarb	
	Sumicidin Alpha	EC	50 g/l esfenvalerate	
	Based on the static test (where the following parameters homogeneity were examined: foaming, pH – value (once), creaming, flocculation, lumping, phase separation, sedimentation/sediment, re-dispersibility (after 2 hours), sieve residues/deposits) and dynamic test/Shear test (where the following parameters homogeneity were examined: pH - value (once), foaming, sieve residues/deposit), no indications of any chemical reaction were observed between the mixed products. It might be concluded that BAS 765 00 F is chemically compatible with the above mentioned tank mix partners.			

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Con.	Institute/ Organisation	Address	GEP Doc ID
AT	BASF Osterreich GmbH	Millenium Tower Handelskai 94-96 1200 Wien	2019/1029138
BG	Eurofins EOOD	Zar Kalojan 5 5570 Letniza	2015/1143221
	Anadiag Bulgaria EOOD	Patriarha Ewtimij 21/52 Sofia 1142	2013/1423440
CZ	InTec Agro Trials, s.r.o.	Blatnicka 179 687 24 Uhersky Ostroh	2019/2055093
	Zamedelsky vyzkumny ustav Kromeriz s.r.o.	Havlickova 2787/121 767 01 Kromeriz	2017/1192567
	Zkusebni Stanice Trut-nov	Volanovska 409 541 01 Trutnov	2017/1156065
DE	BASF SE	Agrarzentrum Limburgerhof Spreyerer Strasse 2 67117 Limburgerhof	2013/1412362
			2018/1238674
	Eurofis Agroscience Service GmbH	Carl Goerdeler Weg 5 21684 Stade	2016/1318743
FR	BASF Agro SAS	21 chemin des la sauvegarde 69134 Ecully	2017/1023856
			2019/1054949
HU	Agrofil SZMI Kft.	Petőfi S. u. 7. 9155 Püski	2017/1190271
	AGROPASS Hungária Kft.	Napóleon utca 10 9028 Győr	2019/2039801
	CPR Europe Kft.	Török Ignác u. 30 97 00 Szombathely	2020/2091439
	Syntech Research Hungary	Török Ignác 30. Szombathely	2016/1350307
PL	UTP in Bydgoszcz	ul. Ks. Kordeckiego 20 85-225 Bydgoszcz	2010/1226832
	IPP-NRI Sosnicowice	ul. Gliwicka 29 44-153 Sośnicowice	2010/1226834
	IOR PIB Poznań	ul. Władysława Węgorka 20 60-318 Poznań	2011/1269209
	Staphyt Sp. z o.o	ul. Ziębicka 2 60-164 Poznań	2011/1269203
	BASF Polska Sp. z o.o.	Al. Jerozolimskie 154 02-326 Warszawa	2011/1269204
	Biotek Agriculture Polska	Gać 64 55-200 Oława	2017/1230363
	SGS Polska Sp. z o.o.	Bema 83 01-233 Warsaw	2016/1350127
	Agreco Sp. z o.o.	Lipowa 21/1 53-124 Wrocław	2018/1181238

Con.	Institute/ Organisation	Address	GEP Doc ID
RO	AgroProspect SRL	Hoghiz Fantana Village nr. 1 Brasov country cod 507099	2013/1399864
	SGS Romania S.A.	Strada Bucovina 56 300668 Timisoara	2019/2038531
	BASF SRL	Morii, 21 917250 Tamadau Mare	2016/1135081
SK	UKSUP	Matuskova 21 833 16 Bratislava	2016/1352907
	Gemerprodukt Valice OVD	Okruzna 3771 979 01 Rimavska Sobota	2016/1273733
	Fyse, Ltd	Skolska 88 991 09 Kolare	2016/1056229
	Berberis s.r.o.	Boliarov 54 044 47 Boliarov	2017/1224930
	Blumeria Consulting s.r.o.	L. Okanika 590/4 949 01 Nitra	2016/1352169
	Vyskumny ustav ra-stlinnej vyroby Piestany	Bratislavska cesta 122 921 68 Piestany	2017/1226421
UK	BASF Plc	WINDMILL AVENUE WOOLPIT Suffolk GL7 5PU	2018/1015310

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6/1	Kryszczuk, A.	2020	Biological Assessment Dossier - Part K - BAS 765 00 F - Central Zone - zRMS Poland 2020/2102791 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	BASF
KCP 6.1/1	Valtin, M.	2020	Justification of the co-formulated mixture of BAS 765 00 F for cereals 2020/2087551 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/1	Klos, T.	2010	GEP Certificate - Uniwersytet Technologiczno - Przyrodniczy im. Jana i Jedrzeja Sniadeckich - Wydzial Rolnictwa i Biotechnologii - Katedra Fitopatologii i Mikologii Molekularnej, Bydgoszcz, Poland 2010/1226832 <none> no Unpublished	No	BASF
KCP 6.2/2	Wiraszka, D.	2010	GEP Certificate - Institute of Plant Protection - National Research Institute in Poznan - Sosnicowice Branch - Pesticide Efficacy Testing Department, Poland 2010/1226834 <none> no Unpublished	No	BASF
KCP 6.2/3	Anonymous	2011	GEP Certificate - Institut of Plant Protection - National Research Institute - Department of Plant Protection Products - Team for Fungicide Investigation, Poznan, Poland 2011/1269209 Institute of Plant Protection - National Research Institute, Poznan, Poland no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/4	Klos, T.	2011	GEP Certificate - Agrostat Sp. z.o.o., Poland 2011/1269203 Agrostat Sp. z o.o., Poznan, Poland no Unpublished	No	BASF
KCP 6.2/5	Klos, T.	2011	GEP Certificate - BASF Polska Sp. z.o.o., Warsaw, Poland 2011/1269204 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	BASF
KCP 6.2/6	Anonymous	2013	GEP Certificate - Anadiag Bulgaria EOOD (2013) 2013/1423440 Anadiag Bulgaria EOOD, Plovdiv, Bulgaria no Unpublished	No	BASF
KCP 6.2/7	Caspary, H.	2013	GEP Certificate: BASF SE Agrarzentrum Limburgerhof, Germany, 2013 2013/1412362 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/8	Leaota, E.	2013	GEP Certificate - SC AgroProspect SRL Brasov, Romania, 2013 2013/1399864 SC AgroProspect Srl, Brasov, Romania no Unpublished	No	BASF
KCP 6.2/9	Anonymous	2015	GEP Certicate: Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria - 2015 2015/1143221 Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria no Unpublished	No	BASF
KCP 6.2/10	Anonymous	2016	GEP Certificate - Eurofins Agroscience Service GmbH 2016 2016/1318743 Eurofins Agroscience Services GmbH, Stade, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.2/11	Baiculescu, D.	2016	GEP Certificate - S.C. BASF SRL Calarasi Romania - 2016 2016/1135081 S.C. BASF SRL, Calarasi, Romania no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/12	Krajmer, B.	2016	GEP Certificate: FYSE s.r.o., Kolare, Slovakia, 2016 2016/1056229 FYSE s.r.o., Kolare, Slovakia no Unpublished	No	BASF
KCP 6.2/13	Krajmer, B.	2016	GEP Certificate - UKSUP - Ustredny Kontrolny a Skusobny Ustav Polnohospodarsky, Kosice, Slovakia 2016 2016/1352907 UKSUP - Ustredny Kontrolny a Skusobny Ustav Polnohospodarsky, Kosice, Slovakia no Unpublished	No	BASF
KCP 6.2/14	Krajmer, B.	2016	GEP Certificate - Gemerprodukt Valice OVD, Rimavska Sobota, Slowakia 2016 - Translation 2016/1273733 Gemerprodukt Valice OVD, Rimavska Sobota, Slovakia no Unpublished	No	BASF
KCP 6.2/15	Laczynski, T.	2016	GEP Certificate - SGS Polska Sp. zo.o Warswa Poland - Translation 2016/1350127 SGS Polska Sp. zo.o., Warsaw, Poland no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/16	Oravecz, M.	2016	GEP Certificate - SynTech Research Hungary Kft. Szombathely Hungary - 2016 2016/1350307 SynTech Research Hungary Kft., Szombathely, Hungary no Unpublished	No	BASF
KCP 6.2/17	Anonymous	2016	GEP Certificate: Blumeria consulting sro, Nitra, Slovakia, 2016-2021 2016/1352169 Blumeria consulting s.r.o., Nitra, Slovakia no Unpublished	No	BASF
KCP 6.2/18	Anonymous	2017	GEP Certificate: Biotek Agriculture Polska Sp. z o.o., Olawa, Poland - 2017 2017/1230363 Biotek Agriculture Polska, Olawa, Poland no Unpublished	No	BASF
KCP 6.2/19	Minar, P.	2016	GEP Certificate: Zemedelsky Vyzkumny Ustav Kromeriz s.r.o., Poland 2016 2017/1192567 Zemedelsky Vyzkumny Ustav Kromeriz s.r.o., Kromeriz, Poland no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/20	Minar, P.	2016	GEP Certificate - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic - 2017 2017/1156065 ZST - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic no Unpublished	No	BASF
KCP 6.2/21	Anonymous	2017	GEP Certificate - NPPC - Vyskumny ustav rastlinnej vyroby Piestany, Piestany, Slovakia 2017 2017/1226421 VURV - Vyskumny Ustav Rastlinnej Vyroby Piestany, Piestany, Slovakia no Unpublished	No	BASF
KCP 6.2/22	Anonymous	2017	GEP Certificate - Berberis s.r.o., Boliarov, Slowakia 2017/1224930 Berberis s.r.o., Boliarov, Slovakia no Unpublished	No	BASF
KCP 6.2/23	Agoston, T.	2017	GEP Certificate - Agrofil-SZMI Kft. Pueski Hungary - 2017 2017/1190271 Agrofil-SZMI Kft., Pueski, Hungary no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/24	Tridon, A.	2017	GEP Certificate - BASF France SAS Ecully France - 2017 2017/1023856 BASF Agro SAS, Ecully, France no Unpublished	No	BASF
KCP 6.2/25	Anonymous	2018	GEP Certificate: BASF plc, United Kingdom, 2018 2018/1015310 BASF plc, Cheadle Cheshire SK8 6QG, United Kingdom no Unpublished	No	BASF
KCP 6.2/26	Anonymous	2018	GEP Certificate: AGRECO Sp. z o.o., Wroclaw, Poland 2018 2018/1181238 AGRECO Sp. z o.o., Wroclaw, Poland no Unpublished	No	BASF
KCP 6.2/27	Reineck, W.	2018	GEP Certificate - BASF SE Agrarzentrum Limburgerhof Germany - 2018 2018/1238674 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/28	Baiculescu, D.	2018	GEP Certificate - SGS Romania SA - AFL seed & Crop - 2018 2019/2038531 SGS Romania SA - AFL seed & Crop, Timisoara, Romania no Unpublished	No	SGS
KCP 6.2/29	Cotillon, A.	2019	GEP Certificate: BASF France SAS, Ecully, France, 2019 2019/1054949 BASF France SAS, Ecully, France no Unpublished	No	BASF
KCP 6.2/30	Hurt, S.	2019	GEP Certificate - BASF Oesterreich GmbH Wien Austria - 2018-2023 2019/1029138 BASF Oesterreich GmbH, Wien, Austria Rep. of no Unpublished	No	BASF
KCP 6.2/31	Minar, P.	2018	Rozhodnuti InTec Agro Trials spol sro, Uhersky Ostroh, Czech Republic 2019/2055093 InTec Agro Trials spol sro, Uhersky Ostroh, Czech Republic no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/32	Agoston, T.	2018	GEP Certificate - Agropass Hungaria Kft Gyoer Hungaria - 2018 2019/2039801 Agropass Hungaria Kft., Gyoer, Hungary no Unpublished	No	BASF
KCP 6.2/33	Tarnai, R.	2020	GEP certificate of CPR Europe Kft Szombathely Hungary, 2020 2020/2091439 CPR Europe Kft., Szombathely, Hungary no Unpublished	No	BASF
KCP 6.2/34	Lopatka, A., Koza, P., Siebielec, G., Lysiak, M.	2012	Expert report regarding division of Europe into regions characterized by homogenous soil and climatic conditions, within the boundaries of which the results of efficacy evaluation of pesticides can be relevant for the entire region 2012/1368202 IUNG - Institute of Soil Science and Plant Cultivation - State Research Institute, Pulawy, Poland no Unpublished	No	BASF
KCP 6.2/35	Anonymous	2020	Report on comparison of regions: Dolnoslaskie (Poland) and Del-Dunantul (Magyarorszag) 2020/2102320 IUNG - Institute of Soil Science and Plant Cultivation - State Research Institute, Pulawy, Poland no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/36	Anonymous	2020	BAS 765 00 F - single trial results 2020/2102319 <none> yes Unpublished	No	BASF
KCP 6.3/1	Stammler, G.	2020	BAS 765 00 F - Resistance Risk Analysis 2020/2081314 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 6.4.5/1	Erven, T.	2020	Malting and brewing trails - Evaluation of different barley varieties for brewing purposes 2020/2081315 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 6.4.5/2	Westphalen, A., Schuster, A.	2020	Germination trials with harvested grains from wheat and barley treated with BAS 765 00 F 2020/2006393 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.5.1/1	Brahm, L.	2019	Cultivation of different crops in Substrate treated with BAS 765 00 F (Succeeding crops study) 2019/1028203 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.5.2/1	Maleck, A.	2020	Effect of BAS 765 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2019/2034607 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 6.6/1	Nord, S.	2020	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 765 00 F 2020/2036308 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.6/2	Ott, C.	2019	Physical and chemical compatibility in aqueous tank mixtures of BAS 765 00 F 2019/1063195 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

BAS 765 00 F is a new product, no product studies have been evaluated previously