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FINAL REGISTRATION REPORT

Part B

Section 3

Efficacy Data and Information

Concise summary

Product code: BAS 768 00 F

Product name(s): Revytur

Chemical active substance(s):

Mefentrifluconazole 25 g/L

Sulfur 600 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: July 2023

MS Finalisation date: 02/04/2025

Version history

When	What
03/2023	Initial dRR – BASF DocID 2022/2030246
04/2023	Dossier sent for evaluation
06/2023	Updated version – BASF DocID 2023/2033009
07/2023	Updated verson – BASF DocID 2023/2034806
08/2023	zRMS evaluation of dRR
12/2023	Final version prepared by zRMS after Commenting period
04/2025	Updated the final version – BASF DocID 2023/2034806 – upon request of DE CMS

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

BAS 768 00 F is a new fungicide developed by BASF for the control of the major diseases in cereals, namely Septoria leaf blotch of wheat (*Zymoseptoria tritici*) and triticale (*Septoria* spp.), rusts (*Puccinia* spp.), powdery mildew (*Blumeria graminis*), ramularia leaf spot *(Ramularia collo-cygni)*, net blotch *(Pyrenophora teres)* and rhynchosporium leaf scald *(Rhynchosporium secalis)*.

BAS 768 00 F contains the following active ingredients:

- 25 g/L mefentrifluconazole
- 600 g/L sulfur

Mefentrifluconazole (BAS 750 F/Revysol) is an active substance and has been approved for inclusion in the Annex of the Implementing Regulation (EU) No 540/2011 on the on the 27th of February 2019 (Commission Regulation (EU) No 2019/337).

Sulfur was included into Annex I of Directive 91/414 (see Commission Directive 2009/70/EC) and has been approved by the Commission Implementing Regulation (EU) No 540/2011, as an active substance in accordance with the Regulation (EC) No. 1107/2009.

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

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 768 00 F in the Maritime EPPO climate zone and the sNE EPPO climate zone.

BAS 768 00 F contains 25 g/l of the active substance - mefentrifluconazole, 600 g/l of the active substance sulfur 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 4,0 l/ha with maximum 2 applications in season when required.

The applicant submitted 108 reports showing the results in research into product efficacy carried out in 2020, 2021 and 2022 in Maritime, NE and SE EPPO climate zones, on cultivars of:
- winter wheat (57 trials) against: (SEPTTR) *Zymoseptoria tritici*, (PUCCRT) *Puccinia triticina*, (PUCCST) *Puccinia striiformis*, (ERYSGR) *Blumeria graminis*;
- spring wheat (2 trials) against: (SEPTTR) *Zymoseptoria tritici;*
- winter and spring barley (winter barley 26 trials, spring barley 9 trlals) against: (PYRNTE) *Pyrenophora teres*, (PUCCHD) *Puccinia hordei*, (RHYNSE) *Rhynchosporium secalis*, (RAMUCC) *Ramularia collo - cygni*;
- winter triticale (13 trials) against: (SEPTSP) *Septoria spp*., (PUCCRE) *Puccinia recondite* ; (PUCCST) *Puccinia striiformis*, (ERYSGR) *Blumeria graminis;*

to support the registration of BAS 768 00 F in countries: DE, AT, IE, NL, PL, CZ.

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

NE EPPO climatic zone (Poland)

winter wheat at a dose rate 4,0 L/ha	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **ERYSGR** *Blumeria graminis* **(E)**
spring wheat at a dose rate 4,0 L/ha	• **SEPTTR** *Zymoseptoria tritici* **(ME)**
winter triticale at a dose rate 4,0 L/ha	• **SEPTTR** *Septoria tritici* **(E)** • **PUCCRE** *Puccinia recondita* **(E)** • **ERYSGR** *Blumeria graminis* **(E)**

Results from efficacy trials demonstrate that BAS 768 00 F at the dose rate 4,0 L/ha is a good alternative to standard fungicides for the control of several diseases in cereals. The product showed a rapid, preventative 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 30-59.

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 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. Therefore, the above results are appropriate for spring wheat against SEPTTR. To support efficacy of TRZAS against PUCCRT, ERYSGR and TRZDU, TRZSP against SEPTTR, PUCCRT, ERYSGR 2 trials for the above-mentioned diseases must be submitted.

Maritime EPPO climatic zone

winter wheat at a dose rate 4,0 L/ha	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **PUCCST** *Puccinia striiformis* **(E)** • **ERYSGR** *Blumeria graminis* **(ME)**
Winter/spring barley at a dose rate 4,0 L/ha	• **PYRNTE** *Pyrenophora teres* **(ME)** • **PUCCHD** *Puccinia hordei* **(ME)** • **RHYNSE** *Rhynchosporium secalis* **(ME)** • **RAMUCC** *Ramularia collo-cygni* **(E)**
winter triticale at a dose rate 4,0 L/ha	• **SEPTTR** *Septoria tritici* **(E)** • **PUCCRE** *Puccinia recondita* **(E)** • **PUCCST** *Puccinia striiformis* **(E)** • **ERYSGR** *Blumeria graminis* **(E)**

Results from efficacy trials demonstrate that BAS 768 00 F at the dose rate 4,0 L/ha is a good alternative to standard fungicides for the control of several diseases in cereals. The product showed a rapid, preventative 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 30-59.

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, PUCCST, ERYSGR might be extrapolated to TRZAS, TRZDU, TRZSP. Moreover, results from wheat (with full package of data) for SEPTTR, PUCCST, ERYSGR might be extrapolated to triticale. Therefore the number of trials for TTLWI is sufficient.

Additionally, in the GAP table for IE, the Applicant asked also for registration of the product also for protection of TRZAW, TRZAS, TRZDU, TRZSP against PYRNTR. However, the applicant has not submitted trials for the control of tan spot of wheat (PYRNTR) in wheat.

The applicant provided full information on the prevalence of resistance to two active substances. A robust risk analysis was performed to define a strategy for managing the risk of resistance to two active substances contained in the product BAS 768 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 768 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 and spring wheat, winter and spring barley, winter triticale in the presence of disease and in the absence of disease. (1 trial for winter wheat and 1 trial for winter triticale).

The product BAS 768 00 F had no negative effect on cereals quality, processing of bread -making (winter wheat), malting and brewing barley and was safe for the germination of the grains of treated wheat and barley.

No problems is going to be linked to BAS 768 00 F use on 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 768 00 F is a sufficient tank cleaning procedure.

BAS 768 00 F is chemically compatible with the tested tank mix partners.

According to the above, the plant protection product BAS 768 00 F is recommended to be approved to use according to the table of intended uses for BAS 768 00 F. The evaluation was carried out in accordance with the Uniform Principles.

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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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 Mefentrifluconazole / Sulfur	Water L/ha min / max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	DE, AT, IE, NL	wheat TRZAW, TRZAS TRZDU, TRZSP	F	*Zymoseptoria tritici* - SEPTTR *Blumeria graminis* - ERYSGR *Puccinia triticina* - PUCCRT *Puccinia striiformis* - PUCCST	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**		C CMS DE decision after commenting period: SEPTTR, PUCCST, ERYSGR, PUCCRT acceptable
2	IE	wheat TRZAW, TRZAS TRZDU, TRZSP	F	*P. tritici-repentis* - PYRNTR	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**	will be addressed by national addendum	C
3	PL	wheat TRZAW, ~~TRZAS~~ ~~TRZDU, TRZSP~~	F	*Zymoseptoria tritici* - SEPTTR *Blumeria graminis* - ERYSGR *Puccinia triticina* - PUCCRT	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**		A
4	PL	wheat TRZAS	F	*Zymoseptoria tritici* - SEPTTR ~~*Blumeria graminis* - ERYSGR~~ ~~*Puccinia triticina* - PUCCRT~~	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**		A

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No.	**Member state(s)**	**Crop and/ or situation** (crop destination / purpose of crop)	**F, Fn, Fnp G, Gn, Gnp or I ***	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. 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 applications (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 Mefentrifluconazole / Sulfur	Water L/ha min / max			
5	PL	wheat TRZDU, TRZSP	F	*Zymoseptoria tritici* - SEPTTR *Blumeria graminis* - ERYSGR *Puccinia triticina* - PUCCRT	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**		N
~~4~~ 6	DE, AT, IE, NL	barley HORVW, HORVS	F	*Ramularia collo-cygni* - RAMUCC *Pyrenophora teres* - PYRNTE *Puccinia hordei* – PUCCHD *Rhynchosporium secalis* - RHYNSE	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**		C CMS DE decision after commenting period: RAMUCC, PYRNTE, RHYNSE acceptable; PUCCHD ~~not~~ acceptable CMS NL decision after commenting period: max. number a) per use b)per crop/season: a) 1 b) 1
~~5~~ 7	DE, AT, IE, NL	triticale TTLWI	F	*Septoria species* - SEPTSP *Blumeria graminis* - ERYSGR *Puccinia triticina* -	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**		C CMS DE decision after commenting period:

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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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 Mefentrifluconazole / Sulfur	Water L/ha min / max			
				PUCCRT *Puccinia striiformis* - PUCCST										SEPTSP, ERYSGR, PUCCRE acceptable; PUCCST not acceptable
~~6~~ 8	PL	triticale TTLWI	F	*Septoria species* - SEPTSP *Blumeria graminis* - ERYSGR *Puccinia triticina* - PUCCRT	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 4 b) 8	a) 0.100 / 2.400 b) 0.200 / 4.800	100 - 300	F**		A
~~7~~ 9	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP	F	*Zymoseptoria tritici* - SEPTTR *Blumeria graminis* - ERYSGR *Puccinia triticina* - PUCCRT *Puccinia striiformis* - PUCCST	Spraying (SP)	30 - 59	a) 1 b) 1		a) 3 - 4 b) 3 - 4	a) 0.100 / 2.400 b) 0.100 / 2.400	100 - 300	F**		C
~~8~~ 10	CZ	barley HORVW, HORVS	F	*Ramularia collo-cygni* - RAMUCC *Pyrenophora teres* - PYRNTE *Puccinia hordei* – PUCCHD *Rhynchosporium secalis* - RHYNSE	Spraying (SP)	30 - 59	a) 1 b) 1		a) 3 - 4 b) 3 - 4	a) 0.100 / 2.400 b) 0.100 / 2.400	100 - 300	F**		C
~~9~~ 11	CZ	triticale TTLWI	F	*Septoria species* - SEPTSP *Blumeria graminis* - ERYSGR	Spraying (SP)	30 - 59	a) 1 b) 1		a) 3 - 4 b) 3 - 4	a) 0.100 / 2.400 b) 0.100 / 2.400	100 - 300			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: developmental stages of the pest or pest group)	**Application**				**Application rate**			**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max)	**zRMS Conclusion (efficacy)**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	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 Mefentrifluconazole / Sulfur	Water L/ha min / max			
				Puccinia triticina - PUCCRT *Puccinia striiformis* - PUCCST										

* 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
** Defined by latest application timing. Fixed by professional use

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 Biological Assessment Dossier (BAD) supports the registration of BAS 768 00 F in countries within the Central registration zone (AT, CZ, DE, IE, NL, PL). Poland has been selected as zRMS. A separate submission will be done in the United Kingdom.
BAS 768 00 F is a fungicide to be used in cereals (wheat, barley and triticale). The targets for the use of BAS 768 00 F are the diseases: *Zymoseptoria tritici, Septoria* spp., *Puccinia* spp., *Blumeria graminis, Ramularia collo-cygni, Pyrenophora teres and Rhynchosporium secalis.*

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 subgroup 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 768 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.

Sulfur is an abundant, naturally occurring inorganic element present in different forms within the soil, and is a major essential nutrient required for many cellular biochemical processes that contribute towards optimal plant growth, root nodule formation of legumes, and induced anti-fungal defense in nascent plant protection mechanisms. When used as a plant protection product, sulfur acts as a broad-spectrum, non-systemic, contact and protectant fungicide for the control of a range of fungal pathogens, including those causing Powdery mildew, in a wide variety of different crop types. Sulfur also has useful secondary role as an acaricide controlling mites on various crops.
Elemental sulfur was one of the earliest and most commonly used fungicides for the protection of crops and was particularly important for the treatment of fruit diseases in the early 20th century. The first report of an application of sulfur on fruit trees is dated in 1803, with further studies documenting the effects of sulfur against powdery mildew in peaches and in grapevines in 1841 and 1857, respectively. Earlier still, the cleansing properties of sulfur were known by the Greeks 2800 years ago as depicted in Homer’s ‘The Odyssey’ when Odysseus says, "Bring sulfur, old nurse, that cleanses all pollution, and bring me fire, that I may purify the house with sulfur...".

Actual contact of the sulfur particle with the fungus is necessary before fungicidal activity can occur. It is also considered that vapour activity may inhibit spore germination.

Many theories have evolved regarding the mode of action of sulfur against fungi, and despite approximately 200 years of use in agriculture the exact details remain an active area of research. Particle size appears to be an important factor in fungicidal efficacy and phytotoxic effects, and it has been reported that physical contact between the sulfur particle and the fungus is necessary for activity. The multi-site nature of sulfur activity against fungi has been observed to inhibit respiration, disrupt proteins and form heavy metal chelates within fungal cells resulting in the inhibition of spore germination and hyphal growth. Two different theories on the molecular mode of action have been described to explain how sulfur, as a practically insoluble and hydrophobic element, exerts its effects on fungal cells: The oxidised sulfur theory attributes toxicity to oxidation products such as sulfur dioxide, sulfur trioxide, sulfuric acid, thiosulfuric acid and pentathionic acid caused by the action of heat, light, oxygen and atmospheric humidity on sulfur, although this is now thought to be a general effect of pH rather than a fungitoxic effect on specific cellular targets. The reduced sulfur theory ascribed toxicity to the generation of hydrogen sulfide by fungal action on sulfur; however, colloidal sulfur is 5-50 times more toxic to fungal spores than an equivalent quantity of hydrogen sulfide. The most widely accepted theory is that the fungicidal activity must be the result of a direct effect of sulfur contact with fungal cells. A proposal based on the sulfur treatment of *Monilinia fructicola* conidia suggests that the reduction of sulfur instead of oxygen occurs at cytochrome c in the electron transport chain of fungal metabolism resulting in the inhibition of ATP synthesis and a catabolic metabolism that leads to the inhibition of DNA and RNA synthesis and a decrease in lipids, free fatty acids and amino acids, and ultimately cell death. Further cellular toxicity could result from cross-linking of proteins, enzymes or other cellular components by sulfur free radicals, or from extensive oxidation of thiol groups on cellular proteins and enzymes. The Fungicide Resistance Action Committee (FRAC) classifies sulfur as Mode of Action Group M2 with multi-site contact activity.

The differential sensitivity of fungal species to hydrophobic sulfur could be explained by the fat content in spores and the solubility of sulfur in different phospholipids, perhaps demonstrated by the fact that sulfur is efficient against drought-resistant fungi such as powdery mildew and rusts, while it is not so effective against water-borne fungi such as *Peronospora* and *Botrytis* spp.

Elemental sulfur, and many sulfur-containing compounds are produced by plants directly or indirectly in defense against microbial pathogens. Supplementation of soil with sulfur could enhance innate host defences and increase the resistance of plant species to fungal attack.

The multi-site activity of sulfur is a useful tool in the phytopathogen resistance management of systemic fungicides with more specific single-site modes of action, as the combination of sulfur with these types of products might not only increase their spectrum of activity but also decreases the chances of pathogen resistance.

As an essential nutrient, sulfur is required in considerable amounts to avoid deficiencies in a wide range of agricultural and horticultural crops as a shortage of sulfur during plant growth and development can affect both yield and quality. Sulfur deficiency has become widespread in many countries in Europe and because atmospheric inputs of sulfur from burning coal and petroleum will continue to decrease, the deficit in the sulfur is likely to increase unless fertilizers are used. The application of sulfur-based fungicides on sulfur deficient soils can help to alleviate deficiencies.

Sulfur is the most important fungicide with action against powdery mildew diseases for organic producers and it is the only fungicide available for use against Apple scab in colder conditions and for organic grape and soft fruit production. Specific sulfur fungicides are therefore permitted for certified organic production in EU countries and can be an essential part of disease control strategies in many crops grown for this market.

Sulfur poses very little if any risk to human and animal health. Short-term studies show that sulfur has very low acute oral toxicity, does not irritate the skin and is not a skin sensitizer, however it can cause some eye irritation, dermal toxicity and inhalation hazards.

More information about sulfur as an a.i. and references to documents supporting above information can be found in BAD for Sulfur 80% WG (BASF DocID 2012/1218514**).**

Table 3.2-1: Details of the active substances

Active ingredient	Mefentrifluconazole	Sulfur
CAS number:	1417782-03-6	7704-34-9
IUPAC name:	2-[4-(4-chlorophenoxy)-2-(trifluoromethyl)phenyl]-1-(1H-1,2,4-triazol-1-yl)propan-2-ol	sulfur
Molecular weight:	397.8 g/mol	32.1 g/mol
Chemical formula:	$C_{18}H_{15}ClF_3N_3O_2$	S_8 the most common allotrope
Chemical group:	Triazoles / Isopropanol-azoles	Inorganic
Mode of action:	**D**e**M**eththylation **I**nhibitor (DMI) – sterol biosynthesis in membranes	Multi-site contact activity
Resistance group:	G1/DMI-fungicides	inorganic (electrophiles)-fungicides

Description of the plant protection product

BAS 768 00 F is a novel fungicide containing 25 g/l mefentrifluconazole and 600 g/l sulfur as an suspension concentrate (SC). BAS 768 00 F is intended for use as a foliar spray in wheat, barley and triticale against the diseases *Zymoseptoria tritici*, *Septoria* spp., *Puccinia* spp., *Blumeria graminis, Ramularia collo-cygni, Pyrenophora teres and Rhynchosporium secalis.*

The applications should be made between growth stages 30-59 BBCH of cereal crops. Two applications could be made in the crop with a maximum dose rate per treatment of 4.0 L/ha.

Table 3.2-2: Simplified table of currently registered uses and requested uses for BAS 768 00 F

Uses		Member State	Requested rate(s)	Comments / Other relevant details on GAPs
Crop(s)	**Target(s)**			
Wheat	*Zymoseptoria tritici - SEPTTR* *Puccinia triticina - PUCCRT* *Blumeria graminis - ERYSGT*	DE, AT, IE, NL, CZ, PL	4.0 L/ha 3.0-4.0 L/ha (CZ)	
Wheat	*Puccinia striiformis - PUCCST*	DE, AT, IE, NL, CZ		
Barley	*Ramularia collo-cygni* *Pyrenophora teres* *Rhynchosporium secalis* *Puccinia hordei*	DE, AT, IE, NL, CZ		
Triticale	*Septoria spp. - SEPTSP* *Puccinia recondita - PUCCST* *Blumeria graminis - ERYSGT*	DE, AT, IE, NL, CZ, PL		
Triticale	*PUCCRE* *Puccinia striiformis -*	DE, AT, IE, NL, CZ		

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
PUCCRT	*Puccinia triticina*	Brown rust of wheat
PUCCST	*Puccinia striiformis*	Yellow rust of wheat
SEPTTR	*Zymoseptoria tritici*	Septoria leaf blotch of wheat
RAMUCC	*Ramularia collo-cygni*	Ramularia leaf spot of barley
PYRNTE	*Pyrenophora teres*	Net blotch of barley
RHYNSE	*Rhynchosporium secalis*	Rhynchosporium leaf scald of barley
PUCCHD	*Puccinia hordei*	Brown rust of barley
ERYSGR	*Blumeria graminis*	Powdery mildew of triticale
PUCCRE	*Puccinia recondita*	Brown rust of triticale
PUCCST	*Puccinia striiformis*	Yellow 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	AT, CZ, DE, NL, IE, PL	-	*Zymoseptoria tritici*	AT, CZ, DE, NL, IE, PL	-
			Puccinia triticina		
			Puccinia striiformis		
			Blumeria graminis		
Barley	AT, CZ, DE, NL (HORVS), IE	NL (HORVW)	*Ramularia collo-cygni*	AT, CZ, DE, NL (HORVS), IE	NL (HORVW)
			Pyrenophora teres		
			Rhynchosporium secalis		
			Puccinia hordei		
Triticale	AT, CZ, DE, PL	NL, IE	*Septoria* spp.	AT, CZ, DE, PL	NL, IE
			Puccinia recondita		
			Puccinia striiformis		
			Blumeria graminis		

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 108 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 efficacy trials

Crop(s)	Country	Years	Number of trials			GEP, non-GEP
			Maritime	North-East	South-East	
Winter wheat	Denmark	2021	4			GEP
	Germany	2020	4			GEP
		2021	13			GEP
		2022	5			GEP
	France	2020	2			GEP
		2021	2			GEP
		2022	1			GEP
	UK	2021	3			GEP
		2022	2			GEP
	Latvia	2021		3		GEP
	Lithuania	2021		1		GEP
	Poland	2020		4		GEP
		2021		9		GEP
		2022		2		GEP
	Hungary	202			2	GEP
	TOTAL	**2019-2020**	**36**	**19**	**2**	**57**
Spring wheat	Latvia	2021		2		
	TOTAL	**2021**		**2**		**2**
Spelt	Germany	2022	1			
		2022	**1**			**1**
Winter barley	Austria	2021	2			GEP
	Germany	2020	4			GEP
		2021	3			GEP
		2022	7			GEP
	France	2020	1			GEP
		2021	3			GEP
		2022	1			GEP
	UK	2021	2			GEP
		2022	2			
	Poland	2022		1		
	TOTAL	**2020-2021**	**25**	**1**	**0**	**26**
Spring barley	Czech Republic	2021	1			GEP
	Denmark	2021	2			GEP
	France	2022	1			GEP
	UK	2021	1			GEP
	Poland			4		
	TOTAL	**2021**	**5**	**4**	**0**	**9**

Crop(s)	Country	Years	Number of trials			GEP, non-GEP
			Maritime	North-East	South-East	
Triticale	Denmark	2021	2			GEP
		2022	1			GEP
	Germany	2021	3			GEP
		2022	1			GEP
	France	2022	1			GEP
	Lithuania	2021		1		GEP
		2022		1		GEP
	Poland	2021		3		GEP
	TOTAL	**2021-2022**	**8**	**5**		**13**
GRAND TOTAL		**2019-2020**	**75**	**31**	**2**	**108**

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

Crop(s)	Reference standard	Country(ies) where the product is registered	Authorization number	Active substance	Formulation		Registered application rate	Application rate in trials (per treatment)
					Type	Concentration of a.s.		
TRZAX HORVX TTLWI	Proline BAS 93141 F	Austria Belgium Czech Republic Germany Ireland Lithuania Romania Slovakia	3771/0 9805P/B 4523-1 025287-00 03786 AS2-6F(2018) 457PC 06-02-0768	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 0.8 L/ha 0.8 L/ha 0.6-0.8 L/ha	0.5 -0.8 L/ha
TRZAW	Flexity BAS 560 00 F	Belgium Czech Rep. Germany Lithuania Poland	3974/0 5627-0 025311-00 AS2-50F(2019) R- 244/2019	metrafenone	SC	300 g/L	0.5 L/ha 0.5 L/ha 0.5 L/ha 0.5 L/ha 0.5 L/ha	0.5 L/ha
	Balaya BAS 751 00 F	Belgium Denmark Germany Latvia Lithuania Poland	11061P/B 19-240/72478 00A286-00 0750 AS2-1F(2020) R-174/2019	mefentrifluconazole pyraclostrobin	EC	100 g/L 100 g/L	1.5 L/ha 0.75-1.5 L/ha 1.5 L/ha 0.5-1.5 L/ha 0.5-1.5 L/ha 1.5 L/ha	1.0-1.5 L/ha
	Input Triple BAS 9643 0 F	Czech Rep. Germany Lithuania Poland	5549-0V 008930-00 AS2-103F(2019) R-13/2020	spiroxamine prothioconazole proquinazid	EC	200 g/L 160 g/L 40 g/L	1.25 L/ha 1.25 L/ha 0.75 L/ha 1.25 L/ha	1.25 L/ha
	Ascra XPRO BAS 9770 0 F	Belgium Czech Rep. Germany Lithuania Poland	10783P/B 5649-0 008219-00 AS2-4F(2017) R-172/2018	bixafen fluopyram prothioconazole	EC	65 g/L 65 g/L 130 g/L	1.5 L/ha 1.2-1.5 L/ha 1.5 L/ha 0.6-1.5 L/ha 1.0-1.5 L/ha	1.5 L/ha

3.2.1 Preliminary tests (KCP 6.1)

Rationale for the co-formulation BAS 768 00 F

BAS 768 00 F consists of mefentrifluconazole and sulfur.

Mefentrifluconazole is a relatively new active substance in Europe. It is a Sterol Biosynthesis Inhibiting fungicide and the primary mode of action is a DeMethylation inhibitor (DMIs), thus belonging to the sub-group of the Demethylation-Inhibitors (DMIs).

Sulfur is an abundant, naturally occurring inorganic element present in different forms within the soil and is a major essential nutrient required for many cellular biochemical processes that contribute towards optimal plant growth, root nodule formation of legumes, and induced anti-fungal defense in induced plant protection mechanisms. When used as a plant protection product, sulfur acts as a broad-spectrum, non-systemic, contact and protectant fungicide for the control of a range of fungal pathogens, including those causing powdery mildew, in a wide variety of different crop types.

The mode of action of mefentrifluconazole and sulfur are completely different, and their activity spectrums are different and complementary. The strengths of mefentrifluconazole are its very high activity on *Zymoseptoria tritici* in wheat and *Ramularia collo-cygni* in barley. Sulfur is an effective active substance used against pathogens causing powdery mildew including *Blumeria graminis* but also with known activity against *Zymoseptoria tritici*.
Thus, BAS 768 00 F is designed to allow a broad-spectrum disease control by association of both active substances in a ready-mix and consequently, a complete and powerful cereal fungicide for farmers.

Moreover, the multi-site activity of sulfur is a useful tool in the phytopathogen resistance management of systemic fungicides with more specific single-site modes of action (e.g., mefentrifluconazole), as the combination of sulfur with these types of products might not only increase their spectrum of activity but also decreases the selection of pathogen resistance. Thus, the concept of BAS 768 00 F was designed to protect mefentrifluconazole and the sulfur will help to delay evolution of DMI resistance.

As of today, the active ingredients are registered as solo-formulations and co-formulations in a broad range of countries. A detailed overview of the registrations of solo formulations in European countries can be found in BAD (BASF DocID 2023/200094) in part 3.2.0.4 Overview on existing uses of the active ingredient (KCP 6).
Currently in Europe a few products in cereals with sulfur as a mixture are available in the market. The table below presents approved products.

Table 3.2-7: Cereal products containing sulfur in mixture

Country	Trade name	Registration number	A.i. combination	Formul.	Concentration	Dose rate	Company
AT	Tebusul	4137/0	Sulfur + Tebuconazole	WG	693+43.37 g/kg	5 kg/ha	Nufarm
FR	Rotate SC	2160749	Sulfur + Tebuconazole	SC	700+45 g/L	5 L/ha	Sulphur-Mills
FR	Startwin Unicorn DF	2160705	Sulfur + Tebuconazole	WG	700+45 g/kg	5 kg/ha	Sulphur-Mills Nufarm
HU	Bordoile + Ken Nano SC	16081/2003	Cu + Sulfur	SC	215+290 g/L	4-5 L/ha	Agroterm
HU	Tebusul	6300/1819-1/2020	Sulfur + Tebuconazole	WG	700+45 g/kg	5 kg/ha	Nufarm
IT	Folicur Combi WG	15222	Sulfur + Tebuconazole	WG	70+4.5%	5-5.5 kg/ha	Bayer-Crop-science
IT	Tebusip Combi	14474	Sulfur + Tebuconazole	WG	70+4.5%	5-5.5 kg/ha	Ital-Agro
IT	Tridan Combi T	13691	Sulfur + Tebuconazole	SC	600+40 g/L	6 L/ha	Sulphur-Mills
SP	Unicorn DF	ES-00019	Sulfur + Tebuconazole	WG	70+4.5%	5 kg/ha	Nufarm Sulphur-Mills

Justification of BAS 768 00 F

The BAS 768 00 F concept was tested in a robust data set of efficacy trials conducted in 2021 and 2022. Efficacy trials set up in wheat and barley were performed across Europe in the Maritime and the North-East EPPO zones. Efficacy trials were conducted according to EPPO guidelines and in testing facilities with GEP certificate.
The efficacy data shows efficacy of single and combined active ingredients of BAS 768 00 F. The table with the tested products as well as the reference standard can be found below.

Table 3.2-8: Tested items and standard used in efficacy trials with solo active ingredients of BAS 768 00 F

	Active ingredient	g ai/l	g ai /ha	Formulation	Commercial name/ Dose rate	BAS code
Tested items	mefentrifluconazole	400	100	SC	Belanty / 0.25 l/ha	BAS 750 02 F
	sulfur	600	2400	SC	- / 4 l/ha	BAS 175 AH F
	mefentrifluconazole + sulfur	25+ 600	100 + 2400	SC	- / 4 l/ha	BAS 768 00 F
Standards	prothioconazole	250	200	EC	Proline / 0.8 l/ha	BAS 9314 1 F
	bixafen fluopyram prothioconazole	65 65 130	97.5 97.5 195	EC	Ascra XPRO/1.5 l/ha	BAS 9770 0 F
	spiroxamine prothioconazole proquinazid	200 160 40	250 20 50	EC	Input Triple/1.25 l/ha	BAS 9643 0 F

All trials were set up as randomized blocks with four replicates. The disease was assessed visually by estimating the percentage of leaf or ear area infected by the disease. This is expressed as severity of attack (P% INF). The assessments were conducted at different times after the application. A minimum of 5% of intensity of attack in the untreated plot is required to validate the assessment. One assessment per trial was chosen for evaluation (most pertinent per disease). It was usually an assessment between 20-56 days after the treatment. Product efficacy figures are derived mainly from the top three leaves (flag leaf, leaf 2 and leaf 3). If more leaf layers were assessed on one assessment, an average of the results was calculated. In one trial disease infection levels were recorded as a "leaf". 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. In one trial intensity of powdery mildew was assessed on stem.
Individual results used for the summaries can be found in Document BASF DocID 2022/2062261.

Efficacy of BAS 768 00 F against foliar diseases of wheat and barley

Zymoseptoria tritici
The efficacy of mefentrifluconazole, sulfur and BAS 768 00 F against *Zymoseptoria tritici* in wheat was tested in 20 trials located in the Maritime and the North-East EPPO zones. BAS 768 00 F gave very good control of *Zymoseptoria tritici* with an average of 83%. The efficacy of BAS 768 00 F was clearly higher than the efficacy of the solo active ingredients mefentrifluconazole (74%) and sulfur (64%). BAS 768 00 F also outperformed the standard product - Proline. The performance of BAS 768 00 F was almost the same in both EPPO zones.

Blumeria graminis
The efficacy of BAS 768 00 F and its active substances against *Blumeria graminis* in wheat was tested in 8 trials located in the Maritime and the North-East EPPO zones. BAS 768 00 F ensured good control of the disease (79%). The efficacy of BAS 768 00 F was higher than the efficacy of the solo active ingredients mefentrifluconazole (67%) and sulfur (73%). BAS 768 00 F almost matched the efficacy of the standard product - Proline. This should be considered as a good result as Proline is known to control powdery mildew very well.

Puccinia striiformis
The efficacy of mefentrifluconazole, sulfur and BAS 768 00 F against *Puccinia striiformis* in wheat was tested in 4 trials carried out in the Maritime EPPO zone. BAS 768 00 F gave very good control of *Puccinia striiformis* with an average of 83%. The efficacy of BAS 768 00 F was clearly higher than the efficacy of the solo active ingredients mefentrifluconazole (56%) and sulfur (55%). The efficacy of BAS 768 00 F and Proline was at the same level in these trials.

Ramularia collo-cygni
The control of *Ramularia collo-cygni* in barley with BAS 768 00 F was tested in 5 trials from the Maritime EPPO zone. BAS 768 00 F gave very good control of *Ramularia collo-cygni* with an average of 82%. The efficacy of BAS 768 00 F was clearly higher than the efficacy of the solo active ingredients mefentrifluconazole (67%) and sulfur (47%). BAS 768 00 F slightly outperformed the standard product - Proline.

Table 3.2-9: Efficacy of sulfur, mefentrifluconazole and their mixture on important leaf diseases of wheat and barley, infection and intensity in %; summary

Disease	EPPO zone	Number of trials	DAT		Untr. inf.	BAS 175 AH F 4.0 L/HA eff.	BAS 750 02 F 0.25 L/HA eff.	BAS 768 00 F 4.0 L/HA eff.	Proline 0.8 L/HA eff.
SEPTTR	Both zones	20	29-43	average	18.6	63.9	73.7	83.3	76.2
				min-max	5.0-76.3	13.8-87.2	43.7-100.0	62.2-100.0	54.7-100.0
	Maritime	10	29-43	average	26.3	60.8	67.9	82.1	73.2
				min-max	5.0-76.3	13.8-87.2	43.7-78.1	71.8-94.4	54.7-89.7
	North-East	10	29-43	average	11.0	67.0	79.5	84.6	79.2
				min-max	6.8-26.9	51.4-77.5	62.2-100.0	62.2-100.0	56.8-100.0
ERYSGT	Both zones	8	10*-56	average	13.3	73.3	66.5	78.8	83.9
				min-max	5.5-37.9	46.2-100.0	16.6-94.3	50.0-100.0	39.3-100.0
	Maritime	4	10*-56	average	14.1	67.1	51.4	69.7	76.4
				min-max	5.5-37.9	46.2-84.1	16.6-70.8	50.0-81.8	39.3-100.0
	North-East	4	10*-42	average	12.5	79.5	81.6	88.0	91.5
				min-max	8.6-17.5	52.5-100.0	72.4-94.3	70.1-100.0	84.5-100.0
PUCCST	Maritime	4	29-43	average	29.3	55.4	56.1	82.8	84.9
				min-max	16.6-59.8	16.1-84.6	28.9-85.1	72.5-94.4	78.2-89.8
RAMUCC	Maritime	5	20-42	average	35.7	47.0	66.7	82.1	79.5
				min-max	9.2-74.4	28.2-72.8	38.1-87.9	76.2-86.1	57.3-91.0

* In these trials, products were applied twice, therefore assessment was carried out 10 days after second application (32-34 days after first application)

Summary of the efficacy of the single active ingredients at rates as used in BAS 768 00 F and its ready mixture.

To summarize, each of the shown active substances has certain strength which are combined in BAS 768 00 F to achieve a broad-spectrum fungicide which shows efficacy against diseases in wheat and barley. In addition, although, sulfur and mefentrifluconazole at rates used in BAS 768 00 F showed only reduction to moderate control for *Puccinia striiformis* and *Ramularia collo-cygni*, the combination of both in BAS 768 00 F led to an excellent control of both diseases (83% and 82% respectively). The same excellent result BAS 768 00 F provides for *Zymoseptoria tritici* (83%). Sulfur itself provides good control of *Blumeria graminis*, although the efficacy of BAS 768 00 F is better and reaches 79%. An overview can be found below in Table 3.2-11.

Table 3.2-10: Summary of the efficacy of SC formulated products containing single active ingredients and its ready mixture - BAS 768 00 F

Disease	sulfur 2400 g/ha	mefentrifluconazole 100 g/ha	BAS 768 00 F 4 L/ha
Zymoseptoria tritici	moderate	good	excellent
Blumeria graminis	good	moderate	good
Puccinia striiformis	disease limitation	disease limitation	excellent
Ramularia collo-cygni	disease limitation	moderate	excellent

Comparison of BAS 768 00 F (SC) and BAS 750 01 F (EC) efficacy

Vast majority of products containing mefentrifluconazole are formulated as emulsifiable concentrate (for details see table with selected registration of mefentrifluconazole in European countries). However, it is technically impossible to completely dissolve both, mefentrifluconazole and sulfur, in a practical usable emulsifiable concentrate. The majority of sulfur liquid mixtures, including BAS 768 00 F, are suspension concentrates (see Table 3.2-8 in this section). The great performance of mefentrifluconazole applied in EC formulation was extensively tested and unequivocally confirmed. To confirm that the change of the formulation to SC and that addition of the partner sulfur was beneficial, trials were selected in which both formulations were tested. Results of these trials and presented below in Table 3.2-12, details in Document BASF DocID 2022/2062261.

Table 3.2-11: Comparison of BAS 768 00 F (SC) and BAS 750 01 F (EC) efficacy

Crop Disease	EPPO zone	Number of trials	DAT		Untr. inf.	BAS 768 00 F 4.0 L/HA eff.	BAS 750 01 F 1.0 L/HA eff.	Standard product eff.
TRZAW SEPTTR	Maritime	4	39-64	average	23.0	78.8	66.8	44.0
				min-max	11.5-44.4	66.7-89.1	53.3-80.4	0-75.9
HORVX RAMUCC	Maritime	3	22-29	average	9.7	79.9	79.7	54.2
				min-max	5.8-15.0	68.3-92.6	65.1-89.1	26.1-69.7

The results indicate that BAS 768 00 F controls *Zymoseptoria tritici* better than BAS 750 01 F. Both products are equally efficient against *Ramularia collo-cygni.* Therefore, it is assumed that the addition of sulfur, despite the formulation change, was beneficial for the performance of the product.

BAS 768 00 F as resistance management tool

Increased performance of BAS 768 00 F in comparison with the single active ingredient - mefentrifluconazole is an important advantage of the product. However, just as important, is the possibility to use BAS 768 00 F as resistance management tool compared to a solo application of BAS 750 01 F. The use of fungicide mixtures is an essential tool to delay the selection of fungicide resistance. The concept of BAS 768 00 F was designed to protect mefentrifluconazole and the sulfur will help to delay evolution of DMI resistance. According to FRAC sulfur is a contact and preventive fungicide, which controls fungi through multiple sites of action and classified as a low-risk compound for fungicide resistance development. Sulphur is one of the last remaining multi-site fungicides available to growers in the EU since the loss of approval for chlorothalonil and mancozeb. Therefore, products containing sulfur i.e. BAS 768 00 F could help to replace these active ingredients in resistance management.

Conclusions

- The efficacy of both active ingredients mefentrifluconazole and sulfur was tested at the dose rates as used in the ready-mix BAS 768 00 F in comparison with a standard.
- Solo, mefentrifluconazole achieves the highest performance on Septoria in wheat and sulfur provided good control of powdery mildew. The association of both active ingredients into BAS 768 00 F offers a broad-spectrum, effective product which can be regarded as complete solution for users.
- Data showed a significantly increased performance of the mixture mefentrifluconazole + sulfur in comparison with the single active ingredients.
- It could be concluded that BAS 768 00 F containing 600 + 25 g/L sulfur + mefentrifluconazole provides a consistent and reliable control of major diseases in cereal crops.
- BAS 768 00 F for tested diseases matched efficacy of the standard product - Proline or outperformed it.
- BAS 768 00 F could be an important resistance management tool because it contains sulfur, one of the last remaining multi-site fungicides approved for use in EU.

Bridging trials

Efficacy data with the final formulation, BAS 768 00 F, are available from trials conducted in years 2021 and 2022. In 2020, the very similar formulation BAS 768 AJ F was used. The detailed comparison of both formulations is given in the confidential document of this submission. In order to demonstrate the equivalence in terms of fungicidal performance between these formulations and to relate the 2021/22 data with those from 2020 in many trials carried out in 2021 BAS 768 00 F was compared to BAS 768 AJ F. The efficacy results generated from these trials are reported in the following tables of this section. Registration of the dose rate 4 L/ha is proposed in the Maritime and the North-East EPPO zones. Therefore, results for efficacy of that dose are presented for the Maritime and the North-East zones. For more information, please see GAP table.

Zymoseptoria tritici (SEPTTR) septoria leaf blotch of wheat

Data on wheat useful for bridging were generated in 15 trials in which efficacy against *Zymoseptoria tritici* was tested. Bridging data are available from the Maritime (7 trials) and the North-East (8 trials) EPPO climatic zones.

Table 3.2-12: *Zymoseptoria tritici* (SEPTTR) in wheat – bridging data in Maritime and North-East zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	BAS 768 AJ F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	30.3	83.9	83.8	75.9
	min- max	5.0-76.3	76.2-94.4	70.0-95.2	66.6-84.6
	n	7	7	7	7
North-East	average	11.5	89.9	87.4	84.2
	min- max	6.8-26.9	81.7-100.0	80.8-100.0	71.2-100.0
	n	8	8	8	8
Both zones	average	20.3	87.1	85.7	80.3
	min- max	5.0-76.3	76.2-100.0	70-100.0	66.6-100.0
	n	15	15	15	15

Average levels of *Zymoseptoria tritici* control in wheat were similar for BAS 768 00 F and BAS 768 AJ F applied at full dose rate 4.0 L/ha (87% and 86% respectively). It is therefore evident that there is full equivalence of BAS 768 00 F and BAS 768 AJ F in control of *Zymoseptoria tritici* in wheat.

Blumeria graminis (ERYSGT), powdery mildew of wheat

Data on wheat useful for bridging were generated in 7 trials in which efficacy against *Blumeria graminis* was tested. Bridging data are available from the Maritime (4 trials) and the North-East (3 trials) EPPO climatic zones.

Table 3.2-13: *Blumeria graminis* (ERYSGT) in wheat – bridging data in Maritime and North-East zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	BAS 768 AJ F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	13.6	68.1	65.7	76.7
	min- max	5.5-35.9	50.0-81.8	37.5-81.8	39.3-100.0
	n	4	4	4	4
North-East	average	10.9	84.0	82.7	88.7
	min- max	8.6-12.3	70.1-100.0	70.1-100.0	84.5-91.8
	n	3	3	3	3
Both zones	average	12.4	74.9	73.0	81.8
	min- max	5.5-35.9	50.0-100.0	37.5-100.0	39.3-100.0
	n	7	7	7	7

Average levels of *Blumeria graminis* control in wheat were similar for BAS 768 00 F and BAS 768 AJ F applied at full dose rate 4.0 L/ha (75% and 73% respectively). In individual trials some variability is visible, however it related mainly to trials with low disease pressure and moderate efficacy. In these trials even small difference in recorded results might mean large percentage difference. Overall, it is evident that there is full equivalence of BAS 768 00 F and BAS 768 AJ F in control of *Blumeria graminis* in wheat.

Ramularia collo-cygni (RAMUCC) Ramularia leaf spot of barley

Data on barley useful for bridging were generated in 4 trials in which efficacy against *Ramularia collo-cygni* was tested. Trials were conducted in the Maritime EPPO climatic zone.

Table 3.2-14: *Ramularia collo-cygni* (RAMUCC) in barley – bridging data in Maritime zone, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	BAS 768 AJ F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	42.3	78.4	81.9	71.5
	min- max	9.2-84.6	72.7-84.6	76.2-86.5	57.3-87.5
	n	4	4	4	4

Average levels of *Ramularia collo-cygni* control in barley were similar for BAS 768 00 F and BAS 768 AJ F applied at dose rate 4.0 L/ha (78% and 82% respectively). It is therefore evident that there is full equivalence of BAS 768 AJ F and BAS 768 00 F in control of *Ramularia collo-cygni* in barley.

<table>
<tr>
<td>comments of zRMS: dRR point 3.2.1</td>
<td>
dRR point 3.2.1.1 Ratio and Co - formulation justification

<u>Rationale for the co-formulation BAS 768 00 F</u>

BAS 768 00 F consists of mefentrifluconazole and sulfur as active substances. The both actives have different mode of action. Mefentrifluconazole, (a DMI fungicide), provides a high level of protection against Zymoseptoria tritici, Puccinia triticina and Puccinia striiformis as well as Ramularia collo-cygni. It protects efficiently or medium efficiently also crops against powdery mildew. On the other hands sulfur is mainly used against pathogens causing powdery mildew including Blumeria graminis. The activity of both substances are different and complementary.

What is more, the choice of sulfur as the multi – site active is also justified as a tool in the managing resistance with the use of systemic fungicides with specific single-site modes of action, which belongs mefenthrifluconazole to.

In zRMS opinion, a combination of these two active substances substances in BAS 768 00 F is rational.

<u>Justification of BAS 758 00 F</u>

For justification of the mixture and the ratio the Applicant presented:

1. Efficacy of the single active ingredients of BAS 768 00 F to compare efficacy of the solo actives and the final mixture BAS 768 00 F. Efficacy of the single active ingredients was presented at rates as used in BAS 768 00 F. Efficacy was compared to the reference product.

<u>Martime EPPO climate zone</u>
Efficacy of two solo active substances at the dose rates used in BAS 768 00 F, the efficacy of final mixture BAS 768 00 F and the efficacy of the reference product were compared.
on following cereals:
• wheat against: SEPTTR (10 trials), ERYSGT (4 trials), PUCCST (4 trials),
• barley against: RAMUCC (5 trials)

SEPTTR
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</table>

	The efficacy of BAS 768 00 F was higher (82%) than the efficacy of the solo active substances mefentrifluconazole (68%) and sulfur (61%). The product performed also better than the standard product – Proline (73%). ERYSGT The efficacy of BAS 768 00 F was higher (70%) than the efficacy of the solo active substances mefentrifluconazole (51%) and sulfur (67%). The product performed comparable to the standard product – Proline (76%). PUCCST The efficacy of BAS 768 00 F was higher (83%) than the efficacy of the solo active substances mefentrifluconazole (56%) and sulfur (55%). The product performed comparable to the standard product – Proline (85%). RAMUCC The efficacy of BAS 768 00 F was higher (82%) than the efficacy of the solo active substances mefentrifluconazole (67%) and sulfur (47%). The product performed also better than the standard product – Proline (73%). To sum up, efficacy of the final mixture BAS 758 00 F was better than particular two – inredient (a.s) what confirms that 2 active substnaces in one mixture will guaratee wider spectrum crop protection against different diseases in comparison to solo products and two – inredient (a.s) mixtures. The Applicant did not tested different ratio of actives substances in the product. Only efficacy of the single active ingredients was presented at rates as used in the final product BAS 768 00 F. The tested dose rates of solo products showed medium efficacy (60%-80%) or limiting the number of pest (40% - 60%). Generaly mefentrifluconazole and sulfur as solo products are used in higher doses than these ones testes in presented trials, showing excellent results against diseases. Both actives together in chosen dose rates, presented good or very good efficacy, in most cases 80 or more percent. What is more in accordance with PP 1/306 (1) General principles for the development of co-formulatedmixtures of plant protection products, where some overlap of activity against the target pests existsthen the contribution of each component in the ratio should be demonstrated (preliminary data may be sufficient). Two active substnces contained in BAS 768 00 F do not have the overlapping activity, so presented results without wider demontation of actives substances ratio can be acceptable. **<u>NE EPPO climate zone</u>** Efficacy of two solo active substances at the dose rates used in BAS 768 00 F, the efficacy of final mixture BAS 768 00 F and the efficacy of the reference product were compared. on wheat against: SEPTTR (10 trials), ERYSGT (4 trials) SEPTTR The efficacy of BAS 768 00 F was higher (85%) than the efficacy of the solo active substances mefentrifluconazole (80%) and sulfur (67%). The product performed also a little better than the standard product – Proline (79%). ERYSGT

The efficacy of BAS 768 00 F was higher (88%) than the efficacy of the solo active substances mefentrifluconazole (82%) and sulfur (82%). The product performed comparable to the standard product – Proline (92%).

To sum up, efficacy of the final mixture BAS 758 00 F was better than particular two – inredient (a.s) what confirms that 2 active substnaces in one mixture will guaratee wider spectrum crop protection against different diseases in comparison to solo products and two – inredient (a.s) mixtures.

The Applicant did not tested different ratio of actives substances in the product. Only efficacy of the single active ingredients was presented at rates as used in the final product BAS 768 00 F. The tested dose rates of solo products showed medium efficacy (60%-80%) or a little better. Generaly mefentrifluconazole and sulfur as solo products are used in higher doses than these ones testes in presented trials, showing excellent results against diseases.
Both actives together in chosen dose rates, presented very good efficacy, more than 85%.
What is more in accordance with PP 1/306 (1) General principles for the development of co-formulatedmixtures of plant protection products, where some overlap of activity against the target pests existsthen the contribution of each component in the ratio should be demonstrated (preliminary data may be sufficient). Two active substnces contained in BAS 768 00 F do not have the overlapping activity, so presented results without wider demontation of actives substances ratio can be acceptable.

Comparison of BAS 768 00 F (SC) and BAS 750 01 F (EC) efficacy
The Applicant presented data proving that the change of the formulation to SC and addition of sulfur was not effect negatively on mefentrifluconazole performance (which the best activity was confirmed in EC formulation). Data was conducted in the Maritime EPPO climate zone.
The results were compared for two disease SEPTTR on TRZAW and RAMUCC on HORVX for which the main activity is presented by mefentrifluconazole. In trials two product were used: the final formulation BAS 768 00 F (SC formulation) and BAS 750 01 F (EC formulation with mefentrifluconazole as the active substance).
The addition of sulfur and changing of formulation did not affect negatively on efficacy mefentrifluconazole against both diseases.

dRR point 3.2.1.1 3.2.1.2 Bridging trials (KCP 6.1)
The Applicant used in some reports very similar formulation to BAS 768 00 F. In the point "Bridging trials (KCP 6.1)" it is demonstrated the equivalence of BAS 768 00 F efficacy and the formulation BAS 768 AJ F efficacy.

Maritime EPPO climate zone
The bridging data were presented: in 7 trials on wheat against SEPTTR; in 4 trials on wheat against ERYSGT; in 4 trials on barley against RAMUCC; carried out in 2021.

Average levels of major target diseases control in wheat and barley were very similar for BAS 768 00 F and BAS 768 AJ F applied at dose rate 4,0 l/ha.

Disease/crop	Efficacy [%]		
	BAS 768 00 F	BAS 768 AJ F	reference product

SEPTTR/wheat	83,9	83,8	75,9
ERYSGT/wheat	68,1	65,7	76,7
RAMUCC/barley	78,4	81,9	71,5

The presented results show equivalence of BAS 768 00 F and BAS 768 AJ F. That is why data from trials using the BAS 768 AJ F product can be used to support the efficacy of the BAS 768 00 F product.

NE EPPO climate zone

The bridging data were presented: in 8 trials on wheat against SEPTTR; in 3 trials on wheat against ERYSGT; carried out in 2021.

Average levels of major target diseases control in wheat and barley were very similar for BAS 768 00 F and BAS 768 AJ F applied at dose rate 4,0 l/ha.

Disease/crop	Efficacy [%]		
	BAS 768 00 F	BAS 768 00 F	reference product
SEPTTR/wheat	89,9	87,4	84,2
ERYSGT/wheat	84,0	82,7	88,7

The presented results show equivalence of BAS 768 00 F and BAS 768 AJ F. That is why data from trials using the BAS 768 AJ F product can be used to support the efficacy of the BAS 768 00 F product..

Data from two EPPO climate zones confirmed that changes in the tested formulations did not have any impact on the efficacy. It might be concluded that the BAS 768 AJ F formulation can be used to support the authorization of the BAS 768 00 F formulation.

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 768 00 F, data is presented on a number of key target diseases for which efficacy is claimed. In the years 2021 - 2022 the minimum effective dose tests for BAS 768 00 F were conducted in 36 field trials throughout Europe. In the Maritime and the North-East EPPO zones the target dose rate 4.0 L/ha is proposed. Therefore performance of BAS 768 00 F applied at dose rates 3.0 L/ha and 4.0 L/ha was analysed in this section.
All trials were performed in accordance with methodology explained in section 3.2.0.7 Compliance with the Uniform Principles. Information on trials submitted, materials and methods (KCP 6.2).

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

In the years 2021 - 2022 the product BAS 768 00 F was tested in 23 efficacy trials in order to determine the minimum effective dose for the control of septoria leaf blotch in wheat. The application rate of 4.0 L/ha was compared with a reduced dose rate of 3.0 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 3.2-15: *Zymoseptoria tritici* (SEPTTR) in wheat – minimum effective dose - Maritime and North-East zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F		Proline
			3.0 L/ha	4.0 L/ha	0.8 L/ha
Maritime	average	29.1	79.9	82.7	70.0
	min- max	5.0-76.3	67.1-100.0	71.8-94.4	32.2-89.7
	n	12	12	12	12
North-East	average	11.1	84.5	89.7	79.1
	min- max	6.8-26.9	74.4-100.0	81.7-100.0	21.9-100.0
	n	11	11	11	11
Both zones	average	20.5	82.1	86.1	74.4
	min- max	5.0-76.3	67.1-100.0	71.8-100.0	21.9-100.0
	n	23	23	23	23

In most cases, efficacy of BAS 768 00 F applied at the dose rate of 4.0 L/ha was higher than achieved with the 3.0 L/ha dose rate. Moreover, the lower dose of the product gave less consistent and more variable disease control. These data therefore justify that in order to achieve optimum activity of BAS 768 00 F it should be used at the 4.0 L/ha dose rate. BAS 768 00 F applied at both dose rates outperformed the standard product - Proline.

Puccinia striiformis (PUCCST), yellow rust of wheat

Maritime EPPO zone

In the years 2021 - 2022 the product BAS 768 00 F was tested in 4 efficacy trials in order to determine the minimum effective dose for the control of yellow rust in wheat. The application rate of 4.0 L/ha was compared with a reduced dose rate of 3.0 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. Results of 1 trial on spelt were presented as supportive data. These results were greyed out in table with individual results and not included in average values calculation.

Table 3.2-16: *Puccinia striiformis* (PUCCST) in wheat – minimum effective dose - Maritime zone, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F		Proline
			3.0 L/ha	4.0 L/ha	0.8 L/ha
Maritime	average	29.3	78.4	82.8	84.9
	min- max	16.6-59.8	61.6-91.0	72.5-94.4	78.2-89.8
	n	4	4	4	4

In most cases, efficacy of BAS 768 00 F applied at the dose rate of 4.0 L/ha was higher than achieved with the 3.0 L/ha dose rate. Moreover, the lower dose of the product gave less consistent and more variable disease control. These data therefore justify that in order to achieve optimum activity of BAS 768 00 F it should be used at the 4.0 L/ha dose rate. BAS 768 00 F applied at target dose rate match the performance of the standard product - Proline. Result of trial on spelt are fully consistent with results of trials on winter wheat.

Blumeria graminis (ERYSGT), powdery mildew of wheat

Maritime and North-East EPPO zone

In the years 2021 and 2022 product BAS 768 00 F was tested in 10 efficacy trials in order to determine the minimum effective dose for the control of powdery mildew in wheat. The application rate of 4.0 L/ha was compared with a reduced dose rate of 3.0 L/ha. Both tested doses were compared to the standard product Proline, applied at a dose of 0.8 L/ha.

Table 3.2-17: *Blumeria graminis* (ERYSGT) in wheat–minimum effective dose - Maritime and North-East zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F		Proline
			3.0 L/ha	4.0 L/ha	0.8 L/ha
Maritime	average	12.8	63.1	69.4	77.0
	min- max	5.5-35.9	50.1-90.9	50.0-81.8	39.3-100.0
	n	5	5	5	5
North-East	average	8.9	76.7	82.0	86.8
	min- max	5.5-12.3	50.2-100.0	58.0-100.0	67.7-100.0
	n	5	5	5	5
Both zones	average	10.9	69.9	75.7	81.9
	min- max	5.5-35.9	50.1-100.0	50.0-100.0	39.3-100.0
	n	10	10	10	10

In most cases, efficacy of BAS 768 00 F applied at the dose rate of 4.0 L/ha was higher than achieved with the 3.0 L/ha dose rate. Moreover, the lower dose of the product gave less consistent and more variable disease control. These data therefore justify that in order to achieve optimum activity of BAS 768 00 F it should be used at the 4.0 L/ha dose rate.

Ramularia collo - cygni, (RAMUCC), ramularia leaf spot of barley

Maritime EPPO zone

In 2021 the product BAS 768 00 F was tested in 6 efficacy trials in order to determine the minimum effective dose for the control ramularia leaf spot of barley. The product was applied at rates of 3.0 L/ha and 4.0 L/ha. Both tested doses were compared to the standard product Proline at the dose of 0.8 L/ha.

Table 3.2-18: *Ramularia collo - cygni* in barley – minimum effective dose - Maritime zone, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F		Proline
			3.0 L/ha	4.0 L/ha	0.8 L/ha
Maritime	average	42.9	74.6	80.5	77.2
	min- max	9.2-84.6	64.8-85.1	72.7-86.1	57.3-91.0
	n	6	6	6	6

Application of BAS 768 00 F at the rate of 3.0 L/ha dose rate gave lower control than achieved with the 4.0 L/ha dose rate. The efficacy at the full rate of BAS 768 00 F was more reliable compared to the lower dose rate. These data therefore justify that in order to achieve optimum activity of BAS 768 00 F it should be used at the 4.0 L/ha dose rate. The average efficacy values show that BAS 768 00 F applied at full dose rate is superior to Proline.

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

According to the presented results from 36 trials, the 4.0 L/ha dose rate of BAS 768 00 F in the Maritime and the North-East EPPO zones provided the optimum overall control and should be considered as an effective solution against the major cereal diseases, for which efficacy of BAS 768 00 F is claimed. The application of 4.0 L/ha dose rate is justifiable based on data in control of Septoria leaf blotch, yellow rust and powdery mildew, where 4.0 L/ha dose rate performed better than reduced rate 4%-6%. The barley disease (ramularia leaf spot) was also better controlled (6%) by 4.0 L/ha in comparison to the reduced rate. As a result, the proposed dose rates should be considered the minimum effective dose to deliver broad spectrum diseases 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 where reduced dose rates provided satisfactory control, which was in several cases better or very close to the performance of the standard Proline. It is therefore concluded, that in specific agroclimatic conditions or in situations of lower diseases pressure, a reduced dose rate of BAS 768 00 F - 3.0 L/ha may be sufficient under practical conditions, especially if the product is used in mixture with other chemistry. This issue is further discussed in section Dose rate range justification (KCP 6.2).

Table 3.2-19: Minimum Effective Dose in Maritime and North-East zones, summary results for all crops presented as disease intensity in untreated control and products efficacy (%)

EPPO climatic Zone	Crop	Disease	No. of trials		Untreated infect	BAS 768 00 F 3.0 L/ha efficacy	BAS 768 00 F 4.0 L/ha efficacy	Standard efficacy
Maritime and North-East	Wheat	SEPTTR	n = 23	mean	20.5	82.1	86.1	74.3
				(min-max)	5.0-76.3	67.1-100.0	71.8-100.0	21.9-100.0
		PUCCST	n = 4	mean	29.3	78.4	82.8	84.9
				(min-max)	16.6-59.8	61.6-91.0	72.5-94.4	78.2-89.8
		ERYSGT	n = 10	mean	10.9	69.9	75.7	81.9
				(min-max)	5.5-35.9	50.1-100.0	50.0-100.0	39.3-100.0
	Barley	RAMUCC	n = 6	mean	42.9	74.6	80.5	77.2
				(min-max)	9.2-84.6	64.8-85.1	72.7-86.2	57.3-91.0

comments of zRMS: dRR point 3.2.2

Minimum effective dose tests

The claimed dose rate is 4,0 l/ha for NE and Maritime EPPO climate zones.

Maritime EPPO climate zone

The dose justification of BAS 768 00 F has been supported by data from efficacy trials on: wheat against SEPTTR (12 trials), PUCCST (4 trials), ERYSGT (5 trials) and barley against RAMUCC (6 trials) for which efficacy of BAS 768 00 F is claimed. Efficacy of the claimed dose rate 4,0 l/ha was compared with the reduced (75% of the claimed dose rate) dose rate of 3,0 l/ha. Trials were conducted in 2021 and 2022 in FR, DE, DK, UK.

Disease/crop	Efficacy of BAS 768 00 F [%]		
	3,0 l/ha	4,0 l/ha	reference product
SEPTTR/wheat	79,9	82,7	70,0
PUCCST/wheat	78,4	82,8	84,9
ERYSGT/wheat	63,1	69,4	77,0
RAMUCC/barley	74,6	80,5	77,2

In the Maritime EPPO climatic zone efficacy trials, BAS 768 00 F at the dose rate of 4,0 l/ha showed more consistent and higher level of efficacy than the reduced dose rate ~~0,3~~ 3,0 l/ha).

4,0 l/ha dose rate of BAS 768 00 F demonstrated a very good or good diseases control at similar or better level of efficacy in comparison to the reference product. Only for ERYSGT efficacy of the reference was better than dose 4,0 l/ha.

The dose rate 4,0 l/ha was considered the minimum effective dose rate.

NE EPPO climate zone

The doses justification of BAS 768 00 F are supported by data efficacy trials on: wheat against SEPTTR (11 trials), ERYSGT (5 trials) for which efficacy of BAS 768 00 F is claimed. Efficacy of the claimed dose rate 4,0 l/ha was compared with the reduced (75% of the claimed dose rate) dose rate of 3,0 l/ha. Trials were conducted in 2021 and 2022 in LT, LV, PL.

Disease/crop	Efficacy of BAS 768 00 F [%]		
	3,0 l/ha	4,0 l/ha	reference product
SEPTTR/wheat	84,5	89,7	79,1
ERYSGT/wheat	76,7	82,0	86,8

In the Maritime EPPO climatic zone efficacy trials, BAS 768 00 F at the dose rate of 4,0 l/ha showed more consistent and higher level of efficacy than the reduced dose rate 0,3 l/ha).

4,0 l/ha dose rate of BAS 768 00 F demonstrated a very good diseases control and better than the reference product for SEPPTR and a little worse than the reference product for ERYSGT.

The dose rate 4,0 l/ha was considered the minimum effective dose rate.

3.2.3 Efficacy tests (KCP 6.2)

Table 3.2-20: 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, 5) 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, 3) Dose expression of plant protection products EPPO 1/214 (3) Principles of acceptable efficacy PP 1/226 Number of efficacy tests
	Specific guidelines	EPPO PP 1/26 (4) Foliar diseases of cereals
Experimental design	Plot design	One - factorial randomized block design (108)
	Plot size	5.25 (1), 10.5-100.0 m² (107)
	Number of replications	4 (107), 3 (1)
Crop	Trials per crop	Winter wheat (57) Spring wheat (2) Spelt (1) Winter barley (26) Spring barley (9) Triticale (13)
	Varieties per crop	Winter wheat: Akteur, Arkadia, Arktis, Asory, Avenue, Balaton, Bataja, Benchmark, Bergamo, Bermude, Biscay, Boss, Costello, Crusoe, Dinosor, Emil, Fox, Hereford, Hydrock, Kerrin, KWS Barrel, KWS Extase, KWS Firefly, Legenda, LG Skyscraber, Lukullus, Mv Tallér, Nemo, Patras, Rgt Reform, Riband, Sailor, Skagen, Talent, Tobak, Torp, Zyta Spring wheat: Calixo Spelt: Zollernperle Winter barley: Adalina, California, Cassia, Esterel, Etincel, Finita, Finola, Flagon, Joy, Ketos, Maltesse, Pixel, Quadriga, Sandra, Su Vireni, Sy Kingsbarn, Viola, Wallace Spring barley: Kosmos, KWS Irina, Laureate, Malz, Planet, Propino, Runner, Soldo Triticale: Cappricia, Dinaro, Fredro, Kitesurf, Lombardo, Neogen, Trapero, Trimaxus,Trismart

Application	Crop stage (BBCH) at application	between 30 and 59
	Number of applications	1 in vast majority of trials, 10 trial on wheat were carried with 2 application of tested product (and standards) to confirm product performance and safety. In these trials number of days after second application is presented in column DAT of efficacy tables
	Spray volumes	100 - 300 L/ha
Assessment	Assessment types	Visual assessing of foliar disease as specified in PP1/26 (4)
	Assessment dates	foliar diseases: in majority of cases, the focus of this dossier was to target late assessment done about 35-40 days after treatment. In some exception, the considered assessment was done earlier (even 14 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 72 DAT). These assessments are considered reliable and relevant. In one trial assessment was done 10 days after second application. The results of second application might be not visible, however trial is considered relevant.

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.

In one trial plot size was slightly below requirements of EPPO guidance. Plot size can be particularly important for sprays applied to tall crops. In this trial products were applied early in growing season to wheat at BBCH GS 30-32. Therefore, this deviation is considered minor.

Statistical analysis
The observed or calculated variables were subjected to an analysis of variance (ANOVA). When the result of the analysis was significant, a multiple comparison of treatments was performed as follows:
- efficacy and germination data: Student-Newman-Keuls-Test (SNK) with an automatic transformation of assessed data
- yield and quality data: Tukey-Test without transformation of data.

The statistical tests show which treatments are different with a 95% probability. The averages are divided into homogeneous groups (A, B, C …). Statistically significant difference exists, if the letters beside the results for two treatments are different. Values followed by the same letter are not significantly different ($P<0.05$).
Statistics of efficacy is available on the individual leaf layer level. No statistics have been made on these mean values as they were calculated additionally.

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 1.4 and 3.7 bar, whilst the spray volume ranged between 100 and 300 L/ha.
More details on the applications can be found in Appendixes 4 and 10 of BAD (BASF DocID 2023/2000942).

Treatments

In all trials either formulation BAS 768 AJ F or final formulation BAS 768 00 F were used. These formulations are very similar. The detailed comparison of both formulations is given in the confidential document of this submission. In order to demonstrate the equivalence in terms of fungicidal performance between these formulations in many trials BAS 768 00 F was compared to BAS 768 AJ F. The results of this comparison can be found in section 3.2.1.2 Bridging trials (KCP 6.1) of BAD (BASF DocID 2023/2000942).
Most trials presented in the efficacy section of this document were carried with one application of the tested product (and standards). However, in several trials products were applied twice to assess product performance and application safety.

Timing of Applications

Trials were designed to target the 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)[1] 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 a 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 - 59), to represent usual farmer practice as well as target disease at onset. Individual trials in which the application was done at later growth stages are considered reliable, because disease occurred late and can definitely be used to support the efficacy.

Assessments

In the disease control trials, disease levels were usually assessed at application and at various intervals after application (from 14 to 72 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 some cases, in single trial several diseases occurred, were assessed and described in this document. Since each disease was assessed individually, some trials are presented several times for different pathogens. Therefore, the actual number of conducted trials is lower than the summary of trial numbers indicated for every disease per crop.
In general, assessments were done based on single leaf layers. In some countries, disease infection levels were recorded as a "leaf" rather than a specified plant part. This is a different method used in some 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 also 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. These leaf layers, in particular in wheat were chosen because the top three leaves have the greatest contribution 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 may be not relevant.

[1] AHDB, Wheat disease management guide, Feb 2016, https://cereals.ahdb.org.uk/media/176167/g63-wheat-disease-management-guide-february-2016.pdf

However, in case earlier application and assessment at growth stages BBCH 32-59 results obtained for lower leaf layers may be still relevant. Therefore, results for 4th or 5th leaf were used in some cases providing that assessment was done not later than BBCH 55. Disease intensity (severity) was calculated based on the assessments and presented in all efficacy tables.

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-2021-DE-C25-A-05.0-DE-D04-026
"DEV" indicates that this is a development trial as distinct from other trial types
"F" indicates that this is a fungicide treatment trial
"2021" indicates the year in which the trial was conducted
"C25" is the trial protocol number (subsequent information detailing the version)
"DE" is the country code, in this case for Germany ~~Czech Republic~~
"D04" is a specific local region in the country
"026" 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, the percentage of the evaluated factor (e.g. control of disease, yield) in relation to the untreated plot is presented. For the standard products, the 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 the assessment – the mean of all values obtained is considered the result of trial). The assessment timings were selected according to the 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 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. For clarity of the presented results, trials/assessments which were not used to support efficacy for other reasons than described in this chapter are presented in tables with individual trials results, greyed out and the reasons for not considering these trials/assessments are explained.
Yield and quality data are presented for efficacy trials.

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

The efficacy of BAS 768 00 F against *Zymoseptoria tritici* in wheat was tested in 46 trials spread over two EPPO zones. In the Maritime zone 30 trials were conducted, along with 16 trials in the North-East. In North-East zone trials in winter wheat (14 trials) and spring wheat (2 trials) are analysed separately. The main standard used for this disease was Proline at maximum dose rate.

Table 3.2-21: Control of *Zymoseptoria tritici* in wheat – Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	27.7	82.1	68.5
	min- max	5.0-76.3	65.6-97.4	0.0-89.7
	n	30	30	30
North-East TRZAW	average	10.8	91.2	82.8
	min- max	6.8-26.9	81.7-100.0	21.9-100.0
	n	14	14	14
North-East TRZAS	average	9.3	63.5	59.5
	min- max	9.3-9.3	62.2-64.9	56.8-62.2
	n	2	2	2
Both zones	average	22.3	85.0	73.1
	min- max	5.0-76.3	66.7-100.0	0.0-100.0
	n	44	44	44
Both zones incl. TRZAS	average	21.7	84.1	72.5
	min- max	5.0-76.3	62.2-100.0	0.0-100.0
	n	46	46	46

BAS 768 00 F gave good control of *Zymoseptoria tritici* with an average of 82% for the dose rate 4.0 L/ha in the Maritime EPPO zone. The infection in the untreated control is ranging from 5% to 76% (~28%). The efficacy of the product varied from 67% to 97%. The average performance of the standard was about 15% worse than the full dose of BAS 768 00 F.

BAS 768 00 F gave very good control of *Zymoseptoria tritici* in the North-East zone with an average about 91% for the dose rate of 4.0 L/ha. The infection in the untreated is ranging from 7% to 27% (~11%). The efficacy of the product varied from 82% to 100%. BAS 768 00 F performed superior to the standard product. The efficacy of BAS 768 00 F was 7% better in the North-East zone than efficacy in the Maritime zone. The reason for this might be much higher infection pressure in the Maritime zone. The rule applies also for the standard product - Proline.

Performance of standard Proline was below expectations in some of the trials. Generally, it was concluded that poor performance of the standard product in these trials is result of challenging condition rather than any mistakes in conducted trial. Therefore results were used to calculate average efficacy values.

There are 5 trials in which disease intensity was sufficient, however results of these trials (or individual assessments) were not used. Symptoms of Septoria leaf blotch were observed at application in most of these trials. The disease developed rapidly during the growing season. This caused challenging conditions. Performance of the standard in these trials/assessments, which was on the level of BAS 768 00 F or worse, confirms this. This indicates as important is proper application timing. Curative application, especially when conditions during season are challenging often is less effective than preventive one.

In two trials, assessments presented in tables above were made quite a long time after application (64 and 72 DAT). It is not expected that products in these trials were active so long. However, effects of inhibiting development of the disease are obvious. Therefore, results of these trials are used.
In 9 trials tested and standard products were applied twice. The performance of the product was good up to 41 days after the second application. This confirms that double application of the product prolongs the period of protection against diseases and also is safe for treated plants (for more details see section 3.4 Adverse effects on treated crops (KCP 6.4)).

Puccinia striiformis (PUCCST), yellow rust of wheat (KCP 6.2).

The efficacy of BAS 768 00 F against *Puccinia striiformis* in wheat was tested in 9 trials conducted in the Maritime EPPO zone. Results of 1 trial on spelt were presented as supportive data. These results were greyed out in table with individual results and not included in average values calculation.

Table 3.2-22: Control of *Puccinia striiformis* in wheat – Maritime EPPO zone, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	21.8	82.0	82.2
	min- max	5.0-59.8	72.5-94.4	67.6-90.0
	n	9	9	9

BAS 768 00 F gave good control of *Puccinia striiformis* with an average of 82% efficacy recorded for the dose rate 4.0 L/ha in the Maritime zone. The infection in the untreated control ranged from 5% to 60% (~22%). The efficacy of the product varied from 73% to 94%. In average BAS 768 00 F at 4.0 L/ha showed efficacy similar to the standard product Proline. Results of trial on spelt are consistent with results of trials on winter wheat.

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

The efficacy of BAS 768 00 F against *Puccinia triticina* in wheat was tested in 10 trials spread over EPPO zones. In the Maritime zone 5 trials were conducted, along with 5 trials in the North-East zone. Additionally results of two supportive trials from South-East zone were presented.
The RegPest model was used to justify comparability of trials across Europe. Two trials were conducted in the South-East EPPO zone in regions with high (more than 75%) similarity to chosen Maritime zone and North-East zone regions. Therefore, those trials can be used to support the efficacy of the product in other EPPO zones. These trials are presented separately in the tables below. Trial from Germany was conducted in agroclimatic conditions similar to those prevailing in Poland. Therefore, German trials can be used to support efficacy in Poland. The rule also works the other way around and Polish trials can be used to support efficacy in most of the Maritime zone countries. For more information, please see section 3.6.3 RegPest model analysis.

Table 3.2-23: Control of *Puccinia triticina* in wheat –Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	13.3	90.3	91.4
	min- max	6.2-33.8	80.0-100.0	72.5-100.0
	n	5	5	5
North-East	average	8.4	93.6	93.0
	min- max	6.0-10.6	83.3-100.0	84.7-97.5
	n	5	5	5
South-East	average	53.1	89.1	94.9
	min- max	25.5-80.8	87.0-91.2	94.1-95.7
	n	2	2	2
All zones	average	17.9	91.5	92.7
	min- max	6.0-80.8	80.0-100.0	72.5-100.0
	n	12	12	12

BAS 768 00 F gave outstanding control of *Puccinia triticina* in the Maritime zone with an average of 90% efficacy, recorded for the dose rate 4.0 L/ha. Infection in the untreated control ranged from 6% to 34% (~13%). The efficacy of the product varied from 80% to 100%. BAS 768 00 F at the full dose rate performed on average at the level of standard. In the North-East zone both average and min-max efficacy values were similar to values in the Maritime zone. BAS 768 00 F gave excellent control of *Puccinia triticina* with an average of 94% efficacy, recorded for the full dose rate, the efficacy of the product varied from 83% to 100%. The supportive trials from Hungary (South-East EPPO zone) also confirm great performance of BAS 768 00 F against brown rust in wheat.

In 2 trials tested and standard products were applied twice. The performance of the product was good up to 34 days after the second application. This confirms that double application of the product prolongs the period of protection against diseases and also is safe for treated plants (for more details see section 3.4 Adverse effects on treated crops (KCP 6.4)).

Blumeria graminis (ERYSGT), powdery mildew of wheat (KCP 6.2)

The efficacy of BAS 768 00 F against *Blumeria graminis* in wheat was tested in 16 trials spread over EPPO zones. In the Maritime zone 8 trials were conducted, along with 8 trials in the North-East zone.

Table 3.2-24: Control of *Blumeria graminis* in wheat –Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	11.3	74.8	81.6
	min- max	5.5-37.9	50.0-97.1	39.3-100.0
	n	8	8	8
North-East	average	8.6	81.6	83.7
	min- max	5.5-12.3	58.0-100.0	53.8-100.0
	n	8	8	8
Both zones	average	10.0	78.2	82.7
	min- max	5.5-37.9	50.0-100.0	39.3-100.0
	n	16	16	16

BAS 768 00 F gave good control of *Blumeria graminis* in the Maritime zone with an average of 75% recorded for the dose rate 4.0 L/ha. The infection ranged from 6% to 38% (~11%). The efficacy of the product varied from 50% to 97%. BAS 768 00 F at the full dose rate was inferior to the standard product.
BAS 768 00 F gave very good control of *Blumeria graminis* in the North-East zone with an average of 82% efficacy, recorded for the dose rate 4.0 L/ha. Infection ranged from 6% to 12% (~9%). The efficacy of the product applied at dose rate 4.0 L/ha varied from 58% to 100%.

Ramularia collo - cygni, (RAMUCC), ramularia leaf spot of barley (KCP 6.2)

The efficacy of BAS 768 00 F against *Ramularia collo - cygni* in barley was tested in 19 trials conducted in the Maritime EPPO zone.

Table 3.2-25: Control of *Ramularia collo - cygni* in barley – Maritime EPPO zone, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	41.4	80.2	74.1
	min- max	8.3-84.6	68.3-95.3	46.2-94.1
	n	19	19	19

BAS 768 00 F gave very good control of Ramularia leaf spot in the Maritime EPPO zone with an average of 80% efficacy, recorded for the dose rate 4.0 L/ha. Infection in the untreated ranged from 8% to 85% (~41%). The efficacy of the product varied from 68% to 95%. The performance of BAS 768 00 F was better than the performance of the standard product.

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

The efficacy of BAS 768 00 F against *Pyrenophora teres* in barley was tested in 10 trials spread over two EPPO zones. In the Maritime zone 5 trials were conducted, along with 5 trials in the North-East zone which were used as supportive. The RegPest model was used to justify comparability of trials across Europe. Trials were conducted in North-East EPPO zone in regions with high (more than 75%) similarity to chosen Maritime zone regions. Therefore, those trials can be used to support the efficacy of the product in the Maritime zone.

Table 3.2-26: Control of *Pyrenophora teres* in barley – Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	12.1	71.1	73.9
	min- max	4.5-25.9	47.1-100.0	22.2-100.0
	n	5	5	5
North-East	average	14.5	74.8	75.8
	min- max	5.8-45.6	59.8-91.0	50.4-92.0
	n	5	5	5
Both zones	average	13.3	73.0	74.9
	min- max	4.5-45.6	47.1-100.0	22.2-100.0
	n	10	10	10

BAS 768 00 F gave quite good control of net blotch in the Maritime EPPO and North-East zones with an average of 73% efficacy, recorded for the dose rate 4.0 L/ha. Infection in the untreated ranged from 5% to 46% (~13%). The efficacy of the product varied from 47% to 100%. The infection of untreated and efficacy of BAS 768 00 F was similar in both EPPO zones. The performance of BAS 768 00 F was at the level of the standard product.

Rhynchosporium secalis (RHYNSE), rhynchosporium leaf scald of barley

The efficacy of BAS 768 00 F against *Rhynchosporium secalis* in barley was tested in 9 trials spread across EPPO zones. In the Maritime zone 7 trials were conducted, along with 2 trials in the North-East zone. The RegPest model was used to justify comparability of trials across Europe. Trials were conducted in North-East EPPO zone in regions with high (more than 75%) similarity to chosen Maritime zone regions. Therefore, those trials can be used to support the efficacy of the product in the Maritime zone.

Table 3.2-27: Control of *Rhynchosporium secalis* in barley – Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	27.8	70.2	84.8
	min- max	7.0-98.0	40.0-93.7	54.6-98.8
	n	7	7	7
North-East	average	6.9	90.3	93.7
	min- max	6.9-6.9	89.6-91.0	93.6-93.9
	n	2	2	2
Both zones	average	23.2	74.7	86.8
	min- max	6.9-98.0	40.0-93.7	54.6-98.8
	n	9	9	9

BAS 768 00 F gave quite good control of rhynchosporium leaf scald in the Maritime EPPO and the North-East zones with an average of 75% efficacy, recorded for the dose rate 4.0 L/ha. Infection in the untreated ranged from 7% to 98% (~23%). The efficacy of the product varied from 40% to 94%. The efficacy of BAS 768 00 F was better in the North-East EPPO zone. The most likely reason of that was much lower infection pressure in the North-East EPPO zone. The standard product outperformed BAS 768 00 F.

Puccinia hordei (PUCCHD), brown rust of barley

The efficacy of BAS 768 00 F against *Puccinia hordei* in barley was tested in 10 trials conducted in the Maritime (7 trials) and the North-East (3 trials) EPPO zones. The RegPest model was used to justify comparability of trials across Europe. Trials were conducted in the North-East EPPO zone in regions with high (more than 75%) similarity to chosen Maritime zone regions. Therefore, those trials can be used to support the efficacy of the product in the Maritime zone.

Table 3.2-28: Control of *Puccinia hordei* in barley – Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	20.7	66.4	95.6
	min- max	5.0-74.6	42.1-100.0	86.9-100.0
	n	7	7	7
North-East	average	8.7	93.3	94.2
	min- max	5.9-14.4	90.0-100.0	90.2-100.0
	n	3	3	3
Both zones	average	17.1	74.5	95.2
	min- max	5.0-74.6	42.1-100.0	86.9-100.0
	n	10	10	10

BAS 768 00 F gave quite good control of brown rust in the Maritime EPPO and the North-East zones with an average of 75% efficacy, recorded for the dose rate 4.0 L/ha. Infection in the untreated ranged from 5% to 75% (~17%). The efficacy of the product varied from 42% to 100%. The efficacy of BAS 768 00 F was better in the North-East EPPO zone. The most likely reason of that was much lower infection pressure in this EPPO zone. The standard product outperformed BAS 768 00 F.

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

The efficacy of BAS 768 00 F against *Septoria* spp. in triticale was tested in 4 trials conducted in the Maritime zone and 3 trials in the North-East EPPO zone. These trials are intended to support registration of BAS 768 00 F in all requested countries from two EPPO zones. Proline at dose rate 0.8 L/ha was used as standard in all trials.

Table 3.2-29: Control of *Septoria* spp. in triticale – Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	14.1	90.8	89.7
	min- max	6.8-27.8	81.5-95.6	83.3-95.6
	n	4	4	4
North-East	average	7.8	90.0	86.3
	min- max	5.8-10.8	76.7-100.0	60.5-100.0
	n	3	3	3
Both zones	average	11.4	90.5	88.3
	min- max	5.8-27.8	76.7-100.0	60.5-100.0
	n	7	7	7

BAS 768 00 F gave very good control of Septoria in the Maritime EPPO zone with an average of 91% efficacy, recorded for the dose rate 4.0 L/ha. The infection in the untreated ranged from 7% to 28% (~14%). The efficacy of the product varied from 82% to 96%. The efficacy of BAS 768 00 F was at the level of the standard. The efficacy of BAS 768 00 F in the North-East zone was very similar to results in the Maritime zone. An average of efficacy, recorded for the dose rate 4.0 L/ha was 90%. The infection in the untreated ranged from 6% to 11% (~8%). The efficacy of the product varied from 77% to 100%. BAS 768 00 F outperformed the standard product - Proline.

Additionally, to above mentioned results, trials conducted on winter wheat, presented in section 3.2.3.1 can be used to support efficacy of BAS 768 00 F against septoria leaf blotch. Direct extrapolation from winter wheat to triticale is acceptable in many countries. As an example, can be used rules of extrapolation prepared by Polish Ministry of Agriculture and placed on its website. Similar guideline is available in UK. In section 3.2.3.1 results of 44 trials from two EPPO zones are described. BAS 768 00 F provided a mean level of control of 83% efficacy for the dose rate 4.0 L/ha in the Maritime and 91% in the North-East zone. The comparison of available trials indicates that results for wheat are similar to presented above for triticale. Therefore, it is concluded that data on triticale and wheat are sufficient to claim control of septoria leaf blotch on triticale in the Maritime and the North-East EPPO zones.

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

The efficacy of BAS 768 00 F against *Puccinia recondita* in triticale was tested in 2 trials conducted in the Maritime EPPO zone and 3 trials conducted in the North-East one. Proline at dose rate 0.8 L/ha was used as standard in these trials.

Table 3.2-30: Control of *Puccinia recondita* in triticale – Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	5.7	90.8	93.3
	min- max	5.5-5.8	81.8-99.9	86.6-100.0
	n	2	2	2
North-East	average	6.9	95.7	91.5
	min- max	5.3-9.3	92.0-100.0	82.4-100.0
	n	3	3	3
Both zones	average	6.4	93.8	92.2
	min- max	5.3-9.3	81.8-100.0	82.4-100.0
	n	5	5	5

BAS 768 00 F ensured very good control of brown rust on triticale. The efficacy recorded for the dose rate 4.0 L/ha was 94%. It was slightly better than the efficacy of the standard product.
Additionally, to above presented results, trials conducted on winter wheat, presented in section 3.2.3.2 can be used to support efficacy of BAS 768 00 F against brown rust. Direct extrapolation from winter wheat to triticale is acceptable in many countries. As an example can be used rules of extrapolation prepared by Polish Ministry of Agriculture and placed on its website. Similar guideline is available in UK. In section 3.2.3.2 results of 11 trials are described. BAS 768 00 F provided a mean level of control of 93% in the Maritime zones, 89% in the North-East zone. The efficacy against brown rust for BAS 768 00 F in trials on both cereal crops is similar. Therefore, it is concluded that data on triticale and supportive on wheat are sufficient to claim control of brown rust on triticale.

Puccinia striiformis (PUCCST), yellow rust of triticale

The efficacy of BAS 768 00 F against *Puccinia striiformis* in triticale was tested in 3 trials conducted in the Maritime EPPO zone. The additional supporting evidence is mentioned in 3.2.3.3 where yellow rust was evaluated on wheat. It is very unlikely that same pathogen (*Puccinia striiformis*) will have different behaviour on two cereals – wheat and triticale.

Table 3.2-31: Control of *Puccinia striiformis* in triticale – Maritime EPPO zone, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F 4.0 L/ha	Proline 0.8 L/ha
Maritime	average	15.8	93.2	92.5
	min- max	5.3-22.3	83.4-100.0	85.6-96.6
	n	3	3	3

BAS 768 00 F ensured very good control of yellow rust on triticale. The efficacy recorded for the dose rate of 4.0 L/ha was 93%. The infection in the untreated ranged from 5% to 22% (~16%). The efficacy of the product varied from 83% to 100%. The efficacy of BAS 768 00 F was at the same level of efficacy as standard product.

Additionally to above presented results, trials conducted on winter wheat, presented in section 3.2.3.3 can be used to support the efficacy of BAS 768 00 F against yellow rust. Direct extrapolation from winter wheat to triticale is acceptable in many countries. As an example can be used rules of extrapolation prepared by Polish Ministry of Agriculture and placed on its website. Similar guideline is available in UK. In section 3.2.3.3 results of 8 trials from Maritime EPPO zone are described. BAS 768 00 F provided a mean level of control of 84% for the dose rate 4.0 L/ha in the Maritime zone. Overall slightly better efficacy against yellow rust for BAS 768 00 F was presented in trials on triticale than in trials for wheat. However these trials could be conducted in different location, partially in different growing seasons. Therefore, it is concluded that data on both cereal crops (wheat and triticale) are sufficient to claim control of yellow rust on triticale.

Blumeria graminis (ERYSGT), powdery mildew of triticale

The efficacy of BAS 768 00 F against *Blumeria graminis* in triticale was tested in 3 trials conducted in the Maritime EPPO zone and in 3 trials conducted in the North-East zone. These trials are intended to support registration of BAS 768 00 F in all requested countries from two EPPO zones. Proline at dose rate 0.8 L/ha was used as standard in all trials.

Table 3.2-32: Control of *Blumeria graminis* in triticale – Maritime and North-East EPPO zones, summary results presented as disease intensity in untreated control and products efficacy (%)

EPPO Zone		Untreated	BAS 768 00 F	Proline
			1.5 L/ha	0.8 L/ha
Maritime	average	23.8	84.3	89.3
	min- max	10.5-43.3	76.7-90.5	73.8-98.3
	n	3	3	3
North-East	average	28.5	85.8	96.0
	min- max	7.0-69.6	82.1-93.1	93.1-98.6
	n	3	3	3
All zones	average	26.1	85.0	92.7
	min- max	7.0-69.6	76.7-93.1	73.8-98.6
	n	6	6	6

BAS 768 00 F ensured good control of powdery mildew on triticale in the Maritime EPPO zone. The efficacy recorded for the dose rate of 4.0 L/ha was 84%. The infection in the untreated ranged from 11% to 43% (~24%). The efficacy of the product varied from 77% to 91%. The average efficacy of BAS 768 00 F in trials conducted in the North-East zone was almost at the same level as efficacy in the Maritime zone. Performance of standard product was better than performance of BAS 768 00 F in both EPPO zones.
Additionally, to the above presented results, trials which were conducted on wheat are presented in section 3.2.3.4. These trials can be used to support the efficacy of BAS 768 00 F against powdery mildew in triticale. Direct extrapolation from wheat to triticale is acceptable in many countries. As an example can be used rules of extrapolation prepared by Polish Ministry of Agriculture and placed on its website. Similar guideline is available in UK. In section 3.2.3.4 results of 15 trials from two EPPO zones are described. Overall, slightly better efficacy against powdery mildew for BAS 768 00 F was presented in trials on triticale than in trials for wheat. However, these trials could be conducted in different location, partially in different seasons. Therefore, it is concluded that presented data are sufficient to claim control of powdery mildew on triticale.

Dose rate range justification (KCP 6.2)

A dose rate range is requested for Czech Republic to allow farmers to use the product as part of an Integrated Pest Management approach and adapt the application rate of the Plant Protection Product as needed. Crop variety, crop vigour, disease pressure and the prevailing climatic conditions are all potential factors that could affect the application rate.
Across the results, it is demonstrated that lower dose rates of BAS 768 00 F can be effective under certain agricultural conditions. A number of trials carried out on different cereal crops support this. Trials are presented mainly for the Maritime EPPO climatic zone. Additionally, trials form the North-East zone can be considered supportive in this case.
Based on fact that the Czech Republic needs a dose rate range and that the overall principles of efficacy of a lower dose rate has been demonstrated with data from two EPPO climatic zones, it is proposed to allow a dose rate range of 3.0 – 4.0 L/ha of BAS 768 00 F for Czech Republic.

Data from altogether 21 trials from the Maritime EPPO zone and 14 trials from the North-East zone following application of BAS 768 00 F at reduced dose rate of 3.0 L/ha compared to the full dose rate of 4.0 L/ha were presented in the Minimum Effective Dose chapter. As the reduced dose rate tested in MED chapter is the same as the lower limit of the dose rate range proposed for Czech Republic, no additional results are presented here. It is referred to section 3.2.2 Minimum effective dose tests (KCP 6.2).
Dose response in wheat was justified on SEPTTR, PUCCST and ERYSGT, in barley on RAMUCC. The benefit of the full dose rate of 4.0 L/ha is obvious, it provided clearly superior efficacy on average usually higher than 80% and more consistent. On the other hand, it is observed that in many trials the reduced dose rate achieved quite high efficacy, in some cases above 80%. Therefore for all assessed diseases the average efficacy for reduced dose rate is equal or higher than 70%. In addition, the efficacy of the lower rate was, for some diseases, comparable to standard Proline. Therefore it is concluded that the results demonstrate that under certain conditions reasonable efficacy can be achieved with the reduced dose rate of 3.0 L/ha.

Conclusion

The proposed dose range of 3.0-4.0 L/ha of BAS 768 00 F in the Czech Republic provide the farmer reasonable frame to adapt the dose rate to actual situation and is considered as justified for use in all cereals crops.

Comments of zRMS:

The applicant submitted 108 reports showing the results in research into product efficacy carried out in 2020, 2021 and 2022 in Maritime, NE EPPO climate zones, on cultivars of:
- winter wheat (57 trials) against: (SEPTTR) *Zymoseptoria tritici*, (PUCCRT) *Puccinia triticina*, (PUCCST) *Puccinia striiformis*, (ERYSGR) *Blumeria graminis*;
- spring wheat (2 trials) against: (SEPTTR) *Zymoseptoria tritici;*
- winter and spring barley (winter barley 26 trials, spring barley 9 trlals) against: (PYRNTE) *Pyrenophora teres*, (PUCCHD) *Puccinia hordei*, (RHYNSE) *Rhynchosporium secalis*, (RAMUCC) *Ramularia collo - cygni*;
- winter triticale (13 trials) against: (SEPTSP) *Septoria spp*., (PUCCRE) *Puccinia recondite* ; (PUCCST) *Puccinia striiformis*, (ERYSGR) *Blumeria graminis;*

to support the registration of BAS 768 00 F in countries: DE, AT, IE, NL, PL, CZ.

In these trials, the efficacy of BAS 768 00 was compared mainly to Proline (BAS 93141 F, containing prothioconazole) but in a few trials also to: Flexity (BAS 560 00 F, containing metrafenon), Balaya (BAS 751 00 F, containing mefentrifluconazole, pyraclostrobin), Input Triple (BAS 9643 0 F, containing spiroxamine, prothioconazole, proquinazid) and Ascra XPRO (BAS 9770 0 F, containing bixafen, fluopyram, prothioconazole) as reference products.

Maritime EPPO climatic zone

Trials were conducted in several regions in CZ, UK, DE, DK, NL, AT. 2 supportive trials on winter wheat were conducted in HU (SE EPPO Climate 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, 3) Dose expression of plant protection products

- PP 1/26 (4) Foliar and ear diseases on cereals

The product BAS 768 00 F was tested:

- in different varieties of winter wheat (varieties: Akteur, Asory, Balaton (HU trial), Benchmark, Bergamo, Bermude, Biscay, Boss, Costello, Crusoe, Dinosor, Fox, Hereford, Hydrock, Kerrin, KWS Barrel, KWS Firefly, LG Skyscraber, Lukullus, Mv Tallér (HU trial), Nemo, Rgt Reform, Riband, Talent, Tobak, Torp, Zyta) at the dose rates of 3,0 l/ha and 4,0 l/ha and was applied one time in most trials (BBCH 30-55, spray volume 120 – 300 l/ha) against: SEPTTR, PUCCRT, PUCCST, ERYSGR, PYRNTR; results were presented at the following time after treatment [days after treatments]: for SEPTTR – 27-64, for PUCCRT- 32-43, for PUCCST -29 – 51, for ERYSGR-19 -41;
- in one variety of spelt - Zollernperle at the dose rates o of 3,0 l/ha and 4,0 l/ha and was applied one time (BBCH 39-49, spray volume 250 l/ha) against: PUCCST; results were presented at the following time after treatment [days after treatments]: for PUCCST - 34;
- in different varieties of winter and spring barley (varieties of winter barley: Adalina, California, Cassia, Esterel, Etincel, Finita, Finola, Flagon, Joy, Ketos, Maltesse, Pixel, Sandra, Su Vireni, Sy Kingsbarn, Viola, KWS Wallace) and spring barley (varieties: KWS Irina, Laureate, Malz, RGT Planet) at the dose rates o of 3,0 l/ha and 4,0 l/ha and was applied one time in most trials (BBCH 30-51, spray volume 150 – 300 l/ha) against: RAMUCC, PYRNTE, PUCCHD, RHYNSE; results were presented at the following time after treatment [days after treatments]: RAMUCC – 18-43, for PYRNTE – 27-42, for PUCCHD – 22-25, RHYNSE – 27-43,
- in different varieties of winter triticale (Cappricia, Kitesurf, Lombardo, Neogen,) at the dose rates of 3,0 l/ha and 4,0 l/ha and was applied one time (BBCH 37- 58, spray volume 150 – 300 l/ha) against: SEPTSP, PUCCRE, PUCCST, ERYSGT; results were presented at the following time after treatment [days after treatments]: for SEPTSP – 17-44, for PUCCRE – 46, PUCCST – 31 - 75, ERYSGT – 26-42;

The results were presented as a pest severity. The recommended dose rate of product is 4,0 l/ha applied one time or two times when required (the second application min. 14 days after the first application).

<u>The effectiveness of the product was described according to the proposed by the evaluator, following scale:</u>
≥ 80% – Effectively controlled **(E)**
60 – 80% – Medium effectively controlled **(ME)**
0 – 60% – Limiting the number of pest **(R)**

<u>**The effectiveness of dose rate 4,0 l/ha of BAS 768 00 F on wheat/spelt (1 trial):**</u>

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 30 trials. The tested product effectively controlled disease at dose rate 4,0 l/ha (82,1%) – **E** and performed superior to the reference product (68,5%).
  Infection in the untreated ranging: from 5,0% to 76,3% (average 27,7%);

  In 6 trials efficacy of the product was assessed 30 – 43 days after the second application.

  In 21 trials after one application, the efficacy of the product was on the level 81,4% - **E** and efficacy of the reference product was on the level 68,4%. In 6 trials after the second application, the product protected the crop on the level of 87,3% - **E** and efficacy of the reference product was on the level 76,39%. Those results show that the second application prolonged performance of the product up to 43 days after the second application.
- against *Puccinia triticina* **PUCCRT** (brown rust of wheat) in 5 trials. The tested product effectively controlled disease (90,3%) – **E** and performed similarly to the reference product (91,4 %).
  Infection in the untreated ranging: from 6,2% to 33,8% (average 13,3%);

  In 1 trial efficacy of the product was assessed 35 days after the second application. As mentioned above this result showed that the second application prolonged performance of the product.

The number of trials against PUCCRT on winter wheat as a major crop/major disease is insufficient. Using the RegPest model, the Applicant presented an example comparison of agro-climatic conditions for a region of Hunhgary (Del-Dunantul) and region of Germany (Sachsen- Anhalt); and Wielkopolskie, Opolskie, Kujawsko – Pomorskie, Slaskie provinces and regions in Germany. The similarity of agro-climatic conditions of the regions was shown to be about 80% (some regions about 75%), which, according to the model, indicates a very low/low risk of different behaviour of the same product in these regions. Taking into account presented results from Report on comparison of different regions (BASF DocID 2022/2062260) data from SE (HU) and NE (PL) EPPO climate zone can be supportive for DE or other MS of the Maritime zone. Nevertheless zRMS will leave it to the final decision of cMS whether the number of trials and supportive data are sufficient.

- against *Puccinia striiformis* **PUCCST** (yellow rust of wheat) in 9 trials on winter wheat and in one trial on spelt. The tested product effectively controlled disease (82,0%) – **E** and on the same level as the reference product (82,2%).
  Infection in the untreated ranging: from 5,0% to 59,8% (average 21,8%);

In one trial on spelt, the product achieved efficacy against PUCCST 79%.The reference product performed better and achieved 100% of efficacy.

- against *Blumeria graminis* **ERYSGR** (powdery mildew of wheat) in 8 trials. The tested product effectively controlled disease (74,8%) – **ME** and performed a little worse than the reference product (81,6 %).
  Infection in the untreated ranging: from 5,5% to 37,9% (average 11,3%);

  In 1 trial efficacy of the product was assessed 10 days after the second application. As mentioned above those results showed that the second application prolonged performance of the product.

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, PUCCST, ERYSGR might be extrapolated to TRZAS, TRZDU, TRZSP.

What is more, in the GAP table for IE, the Applicant asked also for registration of the product also for protection of TRZAW, TRZAS, TRZDU, TRZSP against PYRNTR. However, the applicant has not submitted trials for the control of tan spot of wheat (PYRNTR) in wheat.

<u>The effectiveness of dose rate 4,0 l/ha of BAS BAS 768 00 F on winter and spring barley:</u>

- against *Ramularia collo-cygni* **RAMUCC** (ramularia leaf spot of barley) in 19 trials. On barley the tested product effectively controlled disease (80,2%) **- E** and performed a little better than the reference product (74,1%).
  Infection in the untreated ranging: from 8,3% to 84,6% (average 41,4%);
- against *Pyrenophora teres* **PYRNTE** (net blotch of barley) in 5 trials. On barley the tested product medium effectively controlled disease (71,1%) – **ME** and performed comparable to the reference (73,9 %).
  Infection in the untreated ranging: from 12,1% to 68,8% (average 12,1%);

  The number of trials against PYRNTE on winter ~~wheat~~ barley as a major crop/major disease is insufficient. Using the RegPest model, the Applicant presented an example comparison of agro-climatic conditions for regions: Wielkopolskie, Opolskie, Kujawsko – Pomorskie, Slaskie provinces and regions in Germany. The similarity of agro-climatic conditions of the regions was shown to be about 80% (some regions about 75%), which, according to the model, indicates a very low/low risk of different behaviour of the same product in these regions. Taking into account presented results from the Report on comparison of different regions (BASF DocID 2022/2062260) data from NE (PL) EPPO climate zone can be supportive for DE or other MS of the Maritime zone. Efficacy data conducted in PL presented similar level of the product activity against PYRNTE (74,8%) to the performance of the product in Maritime EPPO climate zone. Nevertheless zRMS will leave it to the final decision of cMSs, whether the number of trials and supportive data are sufficient.

- against *Rhynchosporium secalis* **RHYNSE** (rhynchosporium leaf scald of barley) in 7 trials. On winter the tested product medium effectively controlled disease (70,2%) - **ME** and performed a worse than the reference product (84,4%).
  Infection in the untreated ranging: from 7,0% to 98,0% (average 27,8%);

  Additionally two trials conducted in PL were presented as supportive. Product showed better efficacy in PL, (90,3%) what could be linked with lower disease pressure. The product should be applied as a preventive measure, so perhaps PL trials in which the product was applied at low disease pressure provide noteworthy information for product evaluation. Nevertheless zRMS will leave it to the final decision of cMSs whether supportive data are relevant for cMSs.

- against *Puccinia hordei* **PUCCHD** (brown rust of barley) in 7 trials. On barley the tested product medium effectively controlled disease (66,4%) - **ME** and performed worse than the reference product (95,6%).
  Infection in the untreated ranging: from 5,0% to 74,6% (average 20,7%);

  With stronger disease pressure, the product showed weaker disease control, confirming the importance of proper timing of product application and its preventive rather than curative effect.

  Additionally ~~two~~ three trials conducted in PL were presented as supportive. Product showed better efficacy in PL, (93,3%) what could be linked with lower disease pressure. The product should be applied as a preventive measure, so perhaps PL trials in which the product was applied at low disease pressure provide noteworthy information for product evaluation. Nevertheless zRMS will leave it to the final decision of cMSs whether supportive data are relevant for cMSs.

The effectiveness of dose rate 4,0 l/ha of BAS BAS 768 00 F on winter triticale:

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 4 trials (in one trial a species of *Zymoseptoria* was not presented). The tested product effectively controlled disease (90,8%) – **E** and performed comparable to the reference product (89,7%)
  Infection in the untreated ranging: from 6,8% to 27,8% (average 14,1%);

- against *Puccinia recondita* **PUCCRE** (brown rust of triticale) in 2 trials. The tested product effectively controlled disease (90,8%) – **E** and performed comparable to the reference product (93,3%)
  Infection in the untreated ranging: from 5,5% to 5,8% (average 5,7%);

- against *Puccinia striiformis* **PUCCST** (yellow rust of triticale) in 3 trials. The tested product effectively controlled disease (93,2%) – **E** and performed comparable to the reference product (92,5%);
  Infection in the untreated ranging: from 5,3% to 22,3% (average 15,8%);

- against *Blumeria graminis* **ERYSGR** (powdery mildew of triticale) in 3 trials. The tested product effectively controlled disease (84,3%) - **E** and performed comparable to the reference product (89,3%).
  Infection in the untreated ranging: from 10,5% to 43,3% (average 23,8%);

Results from wheat (with full package of data) for SEPTTR, PUCCST, ERYSGR might be extrapolated to triticale. Therefore the number for TTLWI and above mentioned trials are sufficient.

BAS 768 00 F effectively controlled diseases in cereals at dose rate 4,0 l/ha applied one or two times in season, in trials presented for the Maritime EPPO climate zone. In trials on wheat against ERYSGR and in trials on barley against PYRNTE, RHYNSE, PUCCHD, the product performed medium effectively (74,8%; 71,1%; 70,2%; 66,4% respectively).
The Applicant is requesting 2 applications of the product per season, with a minimum of 14 days between applications and between growth stages 30-59.

To confirm the efficacy of BAS 768 00 F at different application dates, the Applicant has submitted an extensive package of efficacy trials, with treatments carried out at a wide range of developmental stages of crops, taking into account the different requirements of individual pathogens as to the developmental stages of plants at which they are usually infected. Two applications may prove necessary in practice, for example, at the onset of pressure from another disease when the long-term efficacy of the first fungicide dose has come to an end.

The Applicant has submitted trials with two applications for the Maritime zone (in DE- 1 trial, in DK – 3 trials, in FR – 2 trials and in UK – 2 trials). The effectiveness of the product was evaluated after 2 applications at the dose rate 4,0 l/ha: on wheat (against: SEPTTR, PUCCTR, PUCCST, ERYSGR) into 8 trials.
The results in trials with two applications indicated that effectiveness of the product was prolonged as a result of the second application. The product maintained high efficacy after both 1 and 2 applications. What is more twice application of the product was safe for wheat as there were no symptoms of phytotoxicity and no impact of yield, hectolitre weight of harvested grain and thousand grain weight. Triticale is closely related botanically to wheat, so it can be assumed that 2 applications will also safe for triticale. However, the applicant did not presented trials with 2 applications for barley.
The final decision on whether to allow 2 applications of the product per season based on the trials presented is up to the cMSs.

The Applicant has also proposed to allow a dose rate range of 3,0 – 4,0 l/ha of BAS 768 00 F, applied once, for Czech Republic in order to adapt the application rate of the product to crop variety, crop vigour, disease pressure and the prevailing climatic conditions as potential factors that could affect the application rate. The results of the reduce dose rate - 3,0 l/ha were presented in the section 3.2.2 Minimum effective dose tests (KCP 6.2) showing sufficient control of some diseases. The dose rate 3,0 l/ha obtained high efficacy comparable to the refence product in many trials. It might justified to use the lower dose rate when i.e. diseases pressure is low, unfavourite weather conditions for diseases development. ZRMs will leave this decision to the cMS.

NE EPPO climatic zone (PL)

Trials were conducted in several regions in PL, LT, LV.
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, 3) Dose expression of plant protection products
- PP 1/26 (4) Foliar and ear diseases on cereals

The product BAS 768 00 F was tested:

- in different varieties of winter wheat (varieties: Arkadia, Sailor, Zyta, Legenda, KWS Emil, Skagen, Arktis, Tobac, Bataja, Patras, Avenue), at the dose rates of 3,0 l/ha and 4,0 l/ha and was applied one time in most trials (BBCH 30-55, spray volume 200 – 300 l/ha) against: SEPTTR, PUCCRT, ERYSGR; results were presented at the following time after treatment [days after treatments]: for SEPTTR – 32-52, for PUCCRT- 20-72, for ERYSGR- 20 -53;
- in one variety of spring wheat – Calixo, at the dose rates o of 3,0 l/ha and 4,0 l/ha and was applied one time (BBCH 39-41, spray volume 200 l/ha) against: PUCCST; results were presented at the following time after treatment [days after treatments]: for SEPTTR - 31;
- in different varieties of winter triticale (varieties: Trimaxus, Fredro, Trapero, Trismart, Dinaro) at the dose rates of 3,0 l/ha and 4,0 l/ha and was applied one time (BBCH 37- 59, spray volume 200 – 300 l/ha) against: SEPTTR, PUCCRE, ERYSGT; results were presented at the following time

after treatment [days after treatments]: for SEPTTR – 30-42, for PUCCRE – 40-42, ERYSGT – 31-40;

The results were presented as a pest severity. The recommended dose rate of product is 4,0 l/ha applied one time or two times when required (the second application min. 14 days after the first application).

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

The effectiveness of dose rate 4,0 l/ha of BAS 768 00 F on winter wheat:

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 14 trials. The tested product effectively controlled disease at dose rate 4,0 l/ha (91,2%) – **E** and performed superior to the reference product (82,8%).
  Infection in the untreated ranging: from 6,8% to 26,9% (average 10,8%);

  In 3 trials efficacy of the product was assessed 29 – 36 days after the second application.

  In 3 trials after the second application, the product protected the crop on the level of 86,4% **- E** and efficacy of the reference product was on the level 78,2%. Those results show that the second application prolonged performance of the product up to 36 days after the second application.
- against *Puccinia triticina* **PUCCRT** (brown rust of wheat) in 5 trials. The tested product effectively controlled disease (90,3%) – **E** and performed similarly to the reference product (93,6 %).
  Infection in the untreated ranging: from 6,0% to 10,6% (average 8,4%);

The number of trials against PUCCRT on winter wheat as a major crop/major disease is insufficient. Moreover BAS 768 00 F is a new mixture of existing substances, registered for use in Poland and taking into account Guidelines of the Ministry of Agriculture and Rural Development, for new mixtures only trials conducted in NE EPPO climate zone are relevant to evaluate efficacy of the product. Nevertheless, the product showed very high and consistent efficacy in those 5 trials. Therefore, the evaluator proposes conditional approval of this use with the need to submit 3-5 additional trials to confirm the product efficacy against PUCCRT on wheat.

- against *Blumeria graminis* **ERYSGR** (powdery mildew of wheat) in 8 trials. The tested product effectively controlled disease (81,6%) – **E** and performed comparable to the reference product (83,7 %).
  Infection in the untreated ranging: from 5,5% to 12,3% (average 8,6%);

The effectiveness of dose rate 4,0 l/ha of BAS 768 00 F on spring wheat:

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 2 trials. The tested product medium effectively controlled disease at dose rate 4,0 l/ha (63,5%) – **ME** and performed a little better than the reference product (59,5%).
  Infection in the untreated ranging was on the average level of 9,3%);

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 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. Therefore, the above results are appropriate for spring wheat against SEPTTR. To support efficacy of TRZAS against PUCCRT, ERYSGR and TRZDU, TRZSP against SEPTTR, PUCCRT, ERYSGR 2 trials for the above-mentioned diseases must be submitted.
On the other hand TRZDU, TRZSP are minor crop in PL and the procedure of art. 51 is applicable in this case.

The effectiveness of dose rate 4,0 l/ha of BAS BAS 768 00 F on winter triticale:

- against *Zymoseptoria tritici* **SEPTTR** (septoria leaf blotch of wheat) in 3 trials. The tested product effectively controlled disease (90,0%) – **E** and performed a little better than the reference product (86,3%)
  Infection in the untreated ranging: from 5,8% to 10,8% (average 7,8%);
- against *Puccinia recondita* **PUCCRE** (brown rust of triticale) in 3 trials. The tested product effectively controlled disease (95,7%) – **E** and performed a little better than the reference product (91,5%)
  Infection in the untreated ranging: from 5,3% to 9,3% (average 6,9%);
- against *Blumeria graminis* **ERYSGR** (powdery mildew of triticale) in 3 trials. The tested product effectively controlled disease (85,5%) **- E** and performed a little worse than the reference product (96,0%).
  Infection in the untreated ranging: from 7,0% to 69,6% (average 28,5%);

Results from wheat (with full package of data) for SEPTTR, PUCCRT, ERYSGR might be extrapolated to triticale. Therefore the number for TTLWI against SEPTTR, ERYSGR above mentioned trials are sufficient. Extrapolation from PUCCRT in winter wheat on PUCCRE in winter triticale is also possible taking into account the condition mentioned above concerning number of trials for use PCCRT/winter wheat.

BAS 768 00 F effectively controlled diseases in cereals at dose rate 4,0 l/ha applied one or two times in season, in trials presented for the NE EPPO climate zone.
The Applicant is requesting 2 applications of the product per season, with a minimum of 14 days between applications and between growth stages 30-59.

To confirm the efficacy of BAS 768 00 F at different application dates, the Applicant has submitted an extensive package of efficacy trials, with treatments carried out at a wide range of developmental stages of crops, taking into account the different requirements of individual pathogens as to the developmental stages of plants at which they are usually infected. Two applications may prove necessary in practice, for example, at the onset of pressure from another disease when the long-term efficacy of the first fungicide dose has come to an end.

The Applicant has submitted trials with two applications for the NE zone (in LV- 1 trial, in PL – 2 trials). The effectiveness of the product was evaluated after 2 applications at the dose rate 4,0 l/ha on wheat (against: SEPTTR) into 3 trials.
The results in trials with two applications indicated that effectiveness of the product was prolonged as a result of the second application. The product maintained high efficacy after both 1 and 2 applications. What is more twice application of the product was safe for wheat as there were no symptoms of phytotoxicity and no impact of yield, hectolitre weight of harvested grain and thousand grain weight. Triticale is closely related botanically to wheat, so it can be assumed that 2 applications will also safe for triticale.

Additionally in the Maritime zone the effectiveness of the product was evaluated after 2 applications at the dose rate 4,0 l/ha: on wheat (against: SEPTTR, PUCCTR, PUCCST, ERYSGR) into 8 trials. Data from Maritime EPPO climate zone showed also clearly that there is no negative effect of double application of BAS 7~~5~~68 00 F on protected plants.

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

The effect of BAS 768 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 3.2-33: Yield effect of BAS 768 00 F in efficacy trials - Maritime and North-East zones - summary

Grouping	Number of trials	Untreated control			BAS 768 00 F 4.0 l/ha			Standard product(s)		
		Mean dt	Mean %	Min & Max %	Mean dt	Mean %	Min & Max %	Mean dt	Mean %	Min & Max %
wheat	58	82.2	100.0	-	89.7	109.6	99.1-142.9	89.3	109.1	99.8-135.4
barley	32	82.8	100.0	-	88.1	106.8	96.6-120.5	89.5	108.4	97.2-136.9
triticale	13	79.4	100.0	-	88.0	113.2	102.3-140.7	87.3	111.0	101.8-118.5

Table 3.2-34: Hectoliter weight effect of BAS 768 00 F in efficacy trials - Maritime and North-East zones - summary

Grouping	Number of trials	Untreated control			BAS 768 00 F 4.0 l/ha			Standard product(s)		
		Mean kg	Mean %	Min & Max %	Mean kg	Mean %	Min & Max %	Mean kg	Mean %	Min & Max %
wheat	49	73.0	100.0	-	74.0	101.7	97.5-111.5	73.7	101.0	88.1-109.2
barley	22	612.5	100.0	-	63.3	101.4	95.7-110.0	63.8	102.3	99.0-108.7
triticale	13	69.0	100.0	-	70.2	101.7	99.0-105.3	69.7	101.1	97.4-105.0

Table 3.2-35: Thousand grain weight effect of BAS 768 00 F in efficacy trials - Maritime and North-East zones - summary

Grouping	Number of trials	Untreated control			BAS 768 00 F 4.0 l/ha			Standard product(s)		
		Mean g	Mean %	Min & Max %	Mean g	Mean %	Min & Max %	Mean g	Mean %	Min & Max %
wheat	45	38.9	100.0	-	40.2	103.8	96.8-116.0	39.8	103.0	87.6-120.0
barley	19	45.4	100.0	-	46.6	102.9	97.5-118.3	47.2	104.2	100.1-108.7
triticale	12	37.7	100.0	-	39.2	104.0	96.5-113.1	39.6	105.0	99.0-111.2

Summary and conclusion

The result presented from altogether 108 efficacy trials in wheat, barley and triticale confirm the claim that BAS 768 00 F is a highly effective fungicide offering a great opportunity for the control of important cereal pathogens. Performance of BAS 768 00 F against most key diseases matched that of the standard(s) or exceeded it. An overall summary in Table 3.2-35 recapitulates the results organized in a different order than in the efficacy chapter. Here they are ordered first by pathogen and then within the pathogen by the target crop. The aim is to visualize that the product is similarly efficient on the same pathogens across the different crops and to support the extrapolation claims made within the efficacy chapter.
Beside the efficacy of the product, the results demonstrated a yield increase after application of BAS 768 00 F and confirmed no negative impact of the product on the parameters such as thousand grain weight and hectolitre weight in wheat, barley and triticale.
The submitted data together with the argumentation provided support the claim for registration of BAS 768 00 F as requested in the GAP.

Table 3.2-36: Efficacy summary

Disease	Crop	EPPO Zone	No. of trials		Untreated	BAS 768 00 F 4.0 L/ha	Standard
SEPTTR/SEPTSP	**Wheat**	**Maritime**	**n = 30**	mean (min-max)	27.7 5.0-76.3	82.1 65.6-97.4	68.5 0.0-89.7
		North-East TRZAW	**n = 14**	mean (min-max)	10.8 6.8-26.9	91.2 81.7-100.0	82.8 21.9-100.0
		North-East TRZAS	**n = 2**	mean (min-max)	9.3 9.3-9.3	63.5 62.2-64.9	59.5 56.8-62.2
	Triticale	**Maritime**	**n = 4**	mean (min-max)	14.1 6.8-27.8	90.8 81.5-95.6	89.7 83.3-95.6
		North-East	**n = 3**	mean (min-max)	7.8 5.8-10.8	90.0 76.7-100.0	86.3 60.5-100.0
PUCCRT/PUCCRE/ PUCCHD	**Wheat**	**Maritime**	**n = 5**	mean (min-max)	13.3 6.2-33.8	90.3 80.0-100.0	91.4 72.5-100.0
		North-East	**n = 5**	mean (min-max)	8.4 6.0-10.6	93.6 83.3-100.0	93.0 84.7-97.5
		South-East	**n = 2**	mean (min-max)	53.1 25.5-80.8	89.1 87.0-91.2	94.9 94.1-95.7
	Triticale	**Maritime**	**n = 2**	mean (min-max)	5.7 5.5-5.8	90.8 81.8-99.9	93.3 86.6-100.0
		North-East	**n = 3**	mean (min-max)	6.9 5.3-9.3	95.7 92.0-100.0	91.5 82.4-100.0
	Barley	**Maritime**	**n = 7**	mean (min-max)	20.7 5.0-74.6	66.4 42.1-100.0	95.6 86.9-100.0
		North-East	**n = 3**	mean (min-max)	8.7 5.9-14.4	93.3 90.0-100.0	94.2 90.2-100.0
PUCCST	**Wheat**	**Maritime**	**n = 9**	mean (min-max)	21.8 5.0-59.8	82.0 72.5-94.4	82.2 77.8-90.0
	Triticale	**Maritime**	**n = 3**	mean (min-max)	15.8 5.3-22.3	93.2 83.4-100.0	92.5 85.6-96.6

Disease	Crop	EPPO Zone	No. of trials		Untreated	BAS 768 00 F 4.0 L/ha	Standard
ERYSGR	**Wheat**	**Maritime**	**n = 8**	mean (min-max)	11.3 5.5-37.9	74.8 50.0-97.1	81.6 39.3-100.0
		North-East	**n = 8**	mean (min-max)	8.6 5.5-12.3	81.6 58.0-100.0	83.7 53.8-100.0
	Triticale	**Maritime**	**n = 3**	mean (min-max)	23.8 10.5-43.3	84.3 76.7-90.5	89.3 73.8-98.3
		North-East	**n = 3**	mean (min-max)	28.5 7.0-69.6	85.8 82.1-93.1	96.0 93.1-98.6
RAMUCC	**Barley**	**Maritime**	**n = 19**	mean (min-max)	41.4 8.3-84.6	80.2 68.3-95.3	74.1 46.2-94.1
PYRNTE	**Barley**	**Maritime**	**n = 5**	mean (min-max)	12.1 4.5-25.9	71.1 47.1-100.0	73.9 22.2-100.0
		North-East	**n = 5**	mean (min-max)	14.5 5.8-45.6	74.8 59.8-91.0	75.8 50.4-92.0
RHYNSE	**Barley**	**Maritime**	**n = 7**	mean (min-max)	27.8 7.0-98.0	70.2 40.0-93.7	84.8 54.6-98.8
		North-East	**n = 2**	mean (min-max)	6.9 6.9-6.9	90.3 89.6-91.0	93.7 93.6-93.9

Comments of zRMS:

Quality parameters of treated cereals in the presence of challenging pest populations

The effect of BAS 768 00 F on cereals was assessed in efficacy trials 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 corrected to 86% dry matter presented in [kg] and % of untreated plots,
3. Thousand grain weight corrected to 86% dry matter presented in [g] and % of untreated plots

Maritime EPPO climate zone

Yield [% of untreated plots] in:

- winter wheat – 110,8%
- winter barley – 106,1%
- winter triticale – 111,3%

Hectolitre weights of the harvested grains [% of untreated plots] of:

- winter wheat - 102,4%
- winter barley – 101,4%
- winter triticale – 102,4%

Thousand grain weight [% of untreated plots] of:

- winter wheat – 106,0%
- winter barley – 102,9%
- winter triticale – 105,1%

In the Maritime EPPO climate zone, the effect of BAS 768 00 F was assessed in trials with one and two applications on winter wheat/one application on barley and triticale showing no negative effect on yield treated cereals.

	BAS 768 00 F showed no negative impact on yield and quality parameters at dose rate 4,0 l/ha of winter wheat, winter barley, winter triticale. **NE EPPO climate zone** Yield [% of untreated plots] in: • winter wheat – 107,9% • winter barley - 110,4% • winter triticale – 116,3% Hectolitre weights of the harvested grains [% of untreated plots] of: • winter wheat – 100,6% • winter triticale – 100,6% Thousand grain weight [% of untreated plots] of: • winter wheat -101,6% • winter triticale – 102,4% In the NE EPPO climate zone, the effect of BAS 768 00 F was assessed in trials with one and two applications on winter wheat/one application on barley and triticale showing no negative effect on yield treated cereals. BAS 768 00 F showed no negative impact on yield of barley and yield and other quality parameters of winter wheat and triticale at dose rate 4,0 l/ha of winter wheat, winter triticale. **SE EPPO climate zone** Yield [% of untreated plots] in: • winter wheat – 105,4% Thousand grain weight [% of untreated plots] of: • winter wheat -101,2% In the Maritime EPPO climate zone, the effect of BAS 768 00 F was assessed in trials with one application on winter wheat and triticale showing no negative effect on yield treated cereal. BAS 768 00 F showed no negative impact on yield of winter wheat, triticale and thousand grain weight of winter wheat at dose rate 4,0 l/ha of.

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

BAS 768 00 F (25 g a.i. mefentrifluconazole and 600 g a.i. sulfur per litre SC formulation) is intended for control of the following diseases.
In wheat it is intended for control of Septoria leaf blotch (*Zymoseptoria tritici*), brown rust (*Puccinia triticina* syn. *Puccinia recondita*), yellow rust (*Puccinia striiformis*) and powdery mildew (*Blumeria graminis* f.sp. *tritici*).
In barley it is intended for control of Ramularia leaf spot *(Ramularia collo-cygni)*, Net blotch *(Pyrenophora teres)*, Brown rust of barley *(Puccinia hordei)* and Rhynchosporium leaf scald *(Rhynchosporium secalis)*.
In triticale it is intended for control of Septoria leaf and glume blotch (*Zymoseptoria tritici* and *Parastagonospora nodorum*), brown rust (*Puccinia recondita*), yellow rust (*Puccinia striiformis*) and powdery mildew (*Blumeria graminis* f.sp. *tritici*).

Mode of action

Mefentrifluconazole is a fungicide belonging to the group of the sterol biosynthesis inhibitors (SBI, FRAC Group G) according to the classification of the Fungicide Resistance Action Committee (FRAC). Within the SBIs, it belongs to the subgroup of demethylation inhibitors (DMI, G1, FRAC 2022) 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 14a-methyl sterols results in inhibition of growth and cell membrane disruption.

Sulfur is one of the oldest fungicides in agricultural history and is classified by FRAC into the group of chemicals with multi-site activity (FRAC Group M) and in the subgroup of inorganics M02. Despite its long-term use, the precise mechanism of action is not fully elucidated. Some hypotheses describe a reduction in the electron transport system in the inner mitochondrial membrane between cytochrome b and c, where electrons are used to reduce sulfur instead of oxygen, with the result that no ATP is produced. Additionally, sulfur might act in general like oxygen, as a hydrogen (electron) acceptor and disturbs biochemical processes within the cell. Free radicals of sulfur might also crosslink proteins in a relative unspecific manner (Kuklinska et al. 2013, Williams and Cooper 2004). An indirect effect via systemic acquired resistance has also been described for sulfur (Williams and Cooper 2004).

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), *Phakopsora pachyrhizi* (Schmitz *et al.* 2014) and *Venturia inaequalis* (Hoffmeister *et al.* 2021).
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, Huf 2020) 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 (Ziogas and Malandrakis 2015, Mehl *et al.* 2019).

Sulfur: There is no evidence of acquired resistance to sulfur described and consequently no resistance mechanisms are known.

Evidence of resistance

Evidence of DMI-resistance in general: Many pathogens exposed to DMIs have shown a shift towards lower sensitivity in the period after DMI introduction for their control. The level of the sensitivity shifts are monitored more than 20 years for the most important pathogens in different crops and are summarized in the meeting minutes of the FRAC SBI Working Group (FRAC 2022). There are species which show a stabilization of such sensitivity shifts after some years and others where field performance at least for some DMIs is impacted. 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, Ziogas and Malandrakis 2015, Mehl *et al.* 2019, Huf *et al.* 2020).
Main factors influencing the level and stability of sensitivity shifts in a population are the pathogenic species, the active ingredient, the disease and selection pressure, the resistance mechanism and fitness penalties accompanied with resistance phenotypes (Ziogas and Malandrakis 2015, Mehl *et al.* 2019).
Evidence of DMI-resistance for the target pathogens: 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 2022, Strobel *et al*. 2014). The DMI sensitivity of *Zymoseptoria tritici* is still under evolution and intensively monitored. For *Puccinia triticina,* multi-year monitoring studies indicate an adaptation after DMI market launch in many European regions with a stabilization on a certain level (FRAC 2022, Stammler *et al*. 2009). Similar reports on stable sensitivity situations exist also for other *Puccinia* species (FRAC 2022) and *Pyrenophora teres* (FRAC 2022). For *Ramularia collo-cygni* DMI adaptation has been reported in Europe and mechanisms for this adaptation have been elucidated (Rehfus *et al.* 2019). More details on recent sensitivity data are provided in chapter “Baseline sensitivity / Monitoring data”.

Differences in evidence of resistance for different DMIs: After many years of DMI sensitivity monitoring, many publications and intensive discussions in scientific conferences and in the DMI FRAC Working Group, it is obvious that there is no complete cross resistance and sensitivity correlation between DMIs. Isolates of *Zymoseptoria tritici* 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, Huf 2020). For new introduced DMIs this is even more pronounced since they have been developed on the current DMI-shifted population. Therefore, mefentrifluconazole is highly active on many strains of *Zymoseptoria tritici*, which show lower sensitivity to other DMIs (Strobel *et al*. 2020, Jorgensen *et al.* 2020, 2021). This might also explain the smaller range of sensitivity (EC_{50} values) compared to most other DMIs (Figure 3.3-1). More details on sensitivity correlation and cross resistance are provided in the next chapter.

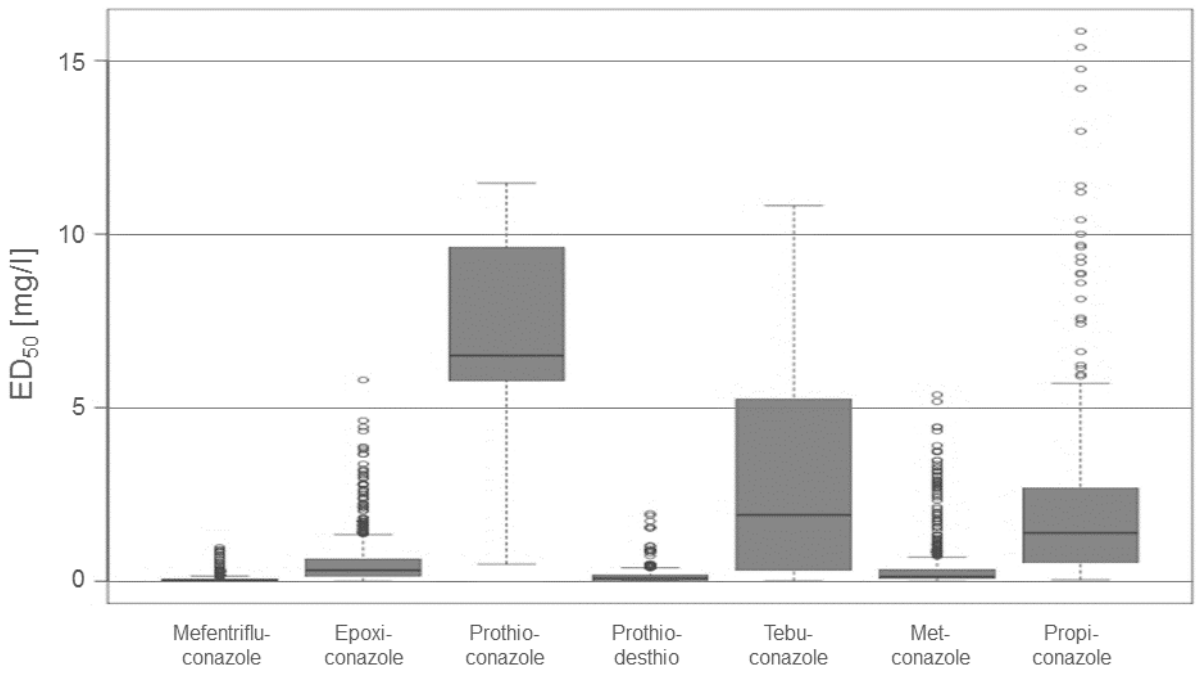

Figure 3.3-1: Range of sensitivity (ED_{50}) determined in isolates from cross resistance studies with European populations from 2014-2016 (1272 isolates, BASF, unpublished studies). Lowest range was found for mefentrifluconazole.

Sulfur: Sulfur is a multi-site fungicide. Despite its use in agriculture since more than 150 years against various diseases, there is no evidence of acquired resistance to sulfur described.

Cross resistance

There are a lot of studies available on the sensitivity of plant pathogens, namely *Zymoseptoria tritici* towards DMIs. To the authors knowledge, *Zymoseptoria tritici* has underwent the most advanced DMI evolution of cereal pathogenic fungi, resulting in more than 100 different cyp51 haplotypes (Huf 2020). Studies show that 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, but also within triazoles, cross resistance is incomplete (Leroux *et al.* 2006, Stammler *et al.* 2008, Leroux and Walker 2011, Heick *et al.* 2020, Jorgensen *et al.* 2020). 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 (Cools and Fraaije 2013, Huf 2020). 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. Especially mutations at codon 136 (mainly V136A) or 137 (e.g. Y137F) have different effects on various DMIs, but also other haplotypes lead to different sensitivities to various DMIs. This is most intensively investigated for *Zymoseptoria tritici*, but also valid for other plant pathogenic fungi (Hoffmeister *et al.* 2021). Studies on the selection of different cyp51 haplotypes after different treatment with different DMIs in the field confirm the relevance of different effects of cyp51 haplotypes also on a field level (BASF internal studies, Huf 2020).

Correlation studies were performed for mefentrifluconazole with different DMIs (Strobel *et al.*, 2020, Heick *et al.* 2020). The sensitivity correlation of mefentrifluconazole and desthio-prothioconazol is low (Figure 3.3-2), while the correlation between mefentrifluconazole and difenoconazole and tebuconazole is higher (Figure 3.3-3). Desthio-prothioconazole (or prothioconazole-desthio) is the active metabolite of prothioconazole (Parker *et al.* 2013) and provides from our experience more stable and sustainable results in our sensitivity test system and is therefore used instead of prothioconazole.

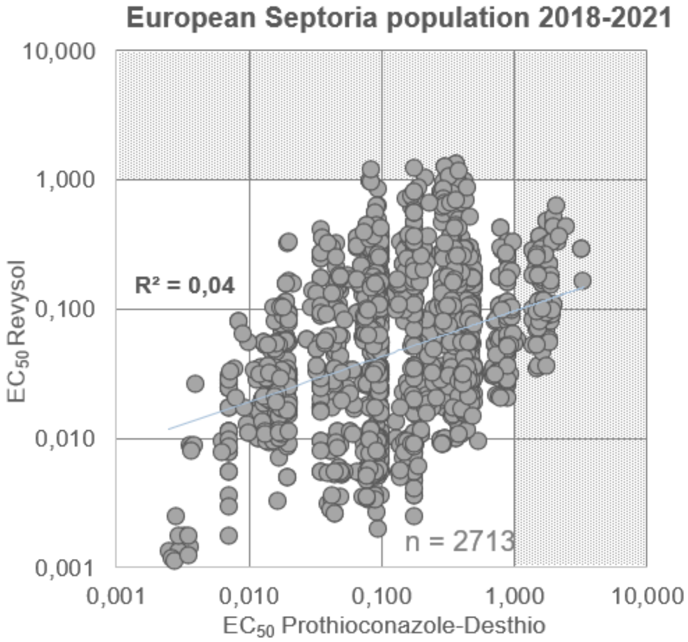

Figure 3.3-2: Correlation of the mefentrifluconazole (Revysol) sensitivity of *Zymoseptoria tritici* to desthio-prothioconazole, determined by microtiter assays (BASF, unpublished studies). R^2 (Adj. R_Sq) are 0.04 for mefentrifluconazole and desthio-prothioconazole, respectively. Desthio-prothioconazole was used instead of prothioconazole due to its' recognized role in disease control (Parker *et al.* 2013).

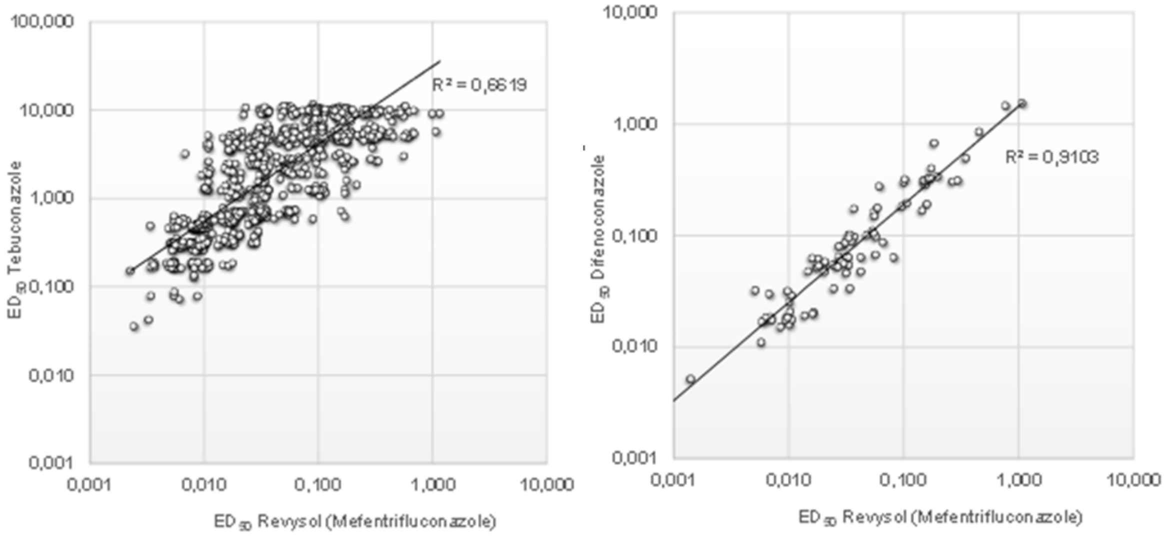

Figure 3.3-3: Correlation of the sensitivity of mefentrifluconazole with tebuconazole and difenoconazole in *Zymoseptoria tritici*. The data are based on microtiter tests performed by the company Epilogic by order of BASF. Isolates used for the tebuconazole studies are from 2016 and 2017 (n=1077) and for the difenoconazole studies from 2017 (n=100).

The paper of Heick *et al.* (2020) provides an overview about the correlation of the most important DMIs used for *Zymoseptoria tritici* control in Europe. Figure 3.3-4 shows the cross-resistance patterns provided in this paper for mefentrifluconazole and difenoconazole, tebuconazole, epoxiconazole and desthio-prothioconazole.

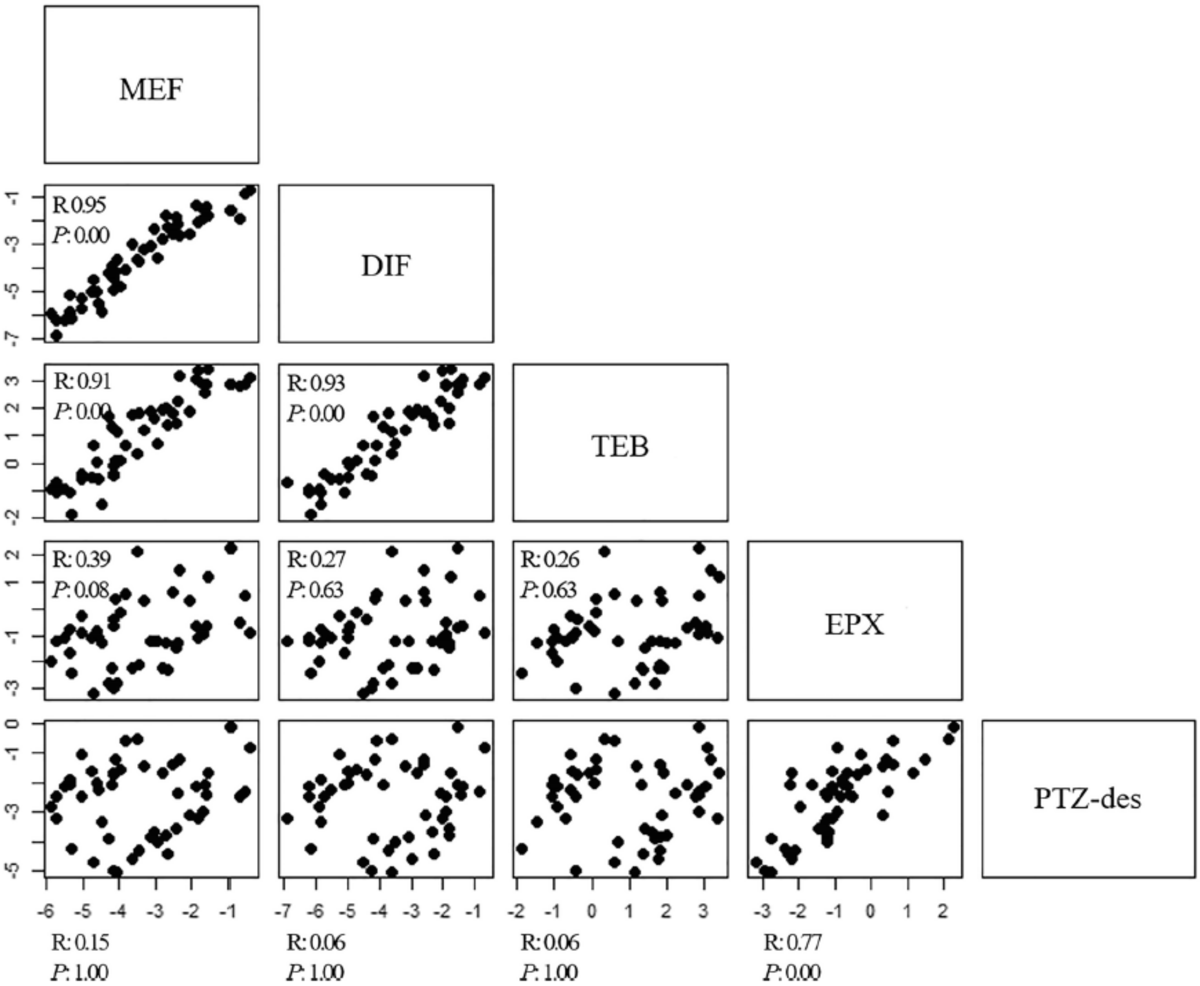

Fig. 4 Scatter plot matrix of sensitivity log(EC_{50} ppm) of *Z. tritici* 2019 sub-collection to five azoles. MEF (mefentrifluconazole), DIF (difenoconazole), TEB (tebuconazole), EPX (epoxiconazole), and PTZ-des (prothioconazole-desthio)

Figure 3.3-4: Cross-resistance studies made by Heick *et al.* (2020). It shows the Fig. 4 included in their paper.

Their study confirms BASF findings on the low correlation of mefentrifluconazole and prothioconazole sensitivity and that the correlation between mefentrifluconazole and difenoconazole and tebuconazole is higher.

Heick *et al.* (2020) concluded that the DMI group can be divided by their cross-resistance patterns. On the one side, epoxiconazole and prothioconazole and on the other side tebuconazole, difenoconazole and mefentrifluconazole form a group with a similar cross-resistance pattern.

Additionally, based on own analysis and findings described by Jorgensen *et al.* (2020, 2021), they stated that mefentrifluconazole performs significantly better in field trials against *Zymoseptoria tritici* than other DMIs. Figure 3.3-5 (= Fig. 3 of the paper of Heick *et al.* (2020)) shows that mefentrifluconazole controlled Septoria leaf blotch over three years with efficacy rates >80%, while the efficacy rates of other DMIs were much lower and could in these years not reach efficacy rates higher than 70%.

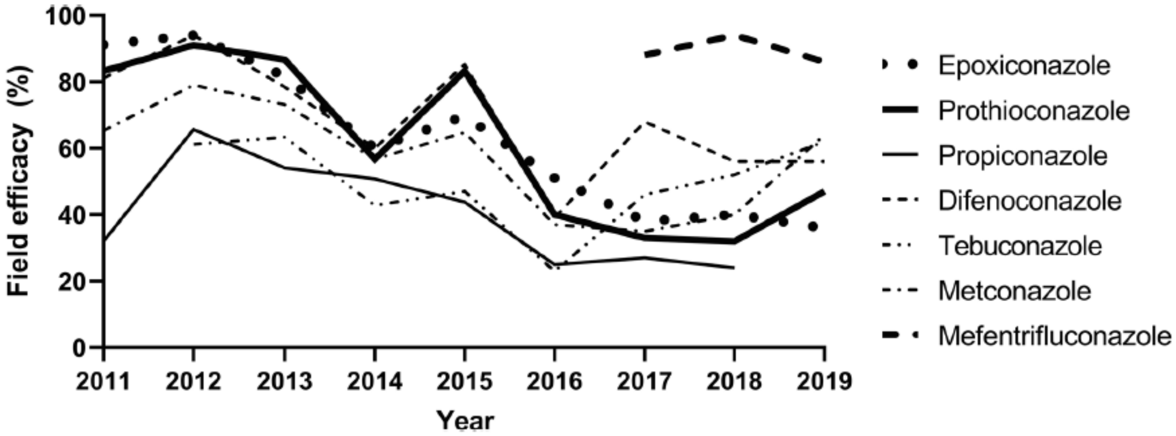

Fig. 3 Field efficacy of DMI fungicides in the Danish field trials from 2011 to 2019. The efficacy was calculated on the basis of two treatments with half the label rate at GS 32–33 and 51–55

Figure 3.3-5: Field efficacy data provided by Heick *et al.* (2020). It shows the Figure 3 included in their paper.

These findings indicate that also other properties than *in vitro* sensitivity correlation determines efficacy of DMI compounds against *Zymoseptoria tritici* in the field.

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.

<u>Sulfur:</u> Since there is no resistance to sulfur known, there is no cross resistance to any mode of action.

Baseline sensitivity / Monitoring data

In the following chapter, sensitivity data and the most recent monitoring data by BASF are provided, followed by the latest statements of FRAC available on the FRAC website.

Sensitivity data are available for mefentrifluconazole, not for sulfur.

The target pathogens of this RRA are listed in the following order:

1: *Zymoseptoria tritici*
2: *Puccinia* spp.
3. *Pyrenophora teres*
4. *Parastagonospora nodorum*
5. *Ramularia collo-cygni*
6. *Blumeria graminis*
7. *Rhynchosporium secalis*

In this chapter the term EC_{50} is used when sensitivity was evaluated with *in vitro* test systems (*e.g.* microtiter tests) and the term ED_{50} is used when the data are based on *in vivo* test systems (*e.g.* detached leaf tests).

Comment to baseline studies

A sensitivity baseline describes the natural sensitivity of a population never exposed to the specific mode of action. 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 towards a newly introduced DMI, 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. Annual or biannual monitoring studies provide also information on the dynamic of DMI adaptation over the time.

However, it is of high interest if the current field population is still sufficiently controlled with registered field rates. Therefore, sensitivity monitoring studies are accompanied by field trials targeting DMI efficacy on current populations.

Mefentrifluconazole has been developed on the current fungal populations and shows high field efficacy on these. It is common knowledge that the current population of *e.g. Zymoseptoria tritici* is significantly shifted towards DMIs compared to wildtype isolates, which are very rarely found in Europe nowadays. Resistance factors (RF values) of current isolates are calculated on wildtype strains and reach high values for various DMIs, including mefentrifluconazole. Since mefentrifluconazole was developed on such shifted field populations with high RF values the use of RF values based on wildtype isolates is of limited value for description of an adaptation of current isolates towards mefentrifluconazole.

1. *Zymoseptoria tritici*

Monitoring data

Broad European field monitoring for mefentrifluconazole started before market launch. Data from 2018 to 2022 were mainly 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 for mefentrifluconazole from the last five years are provided in Figure 3.3-6. The data from the last years show a quite stable sensitivity situation. Sensitivity studies on *Zymoseptoria tritici* were performed by the external company EpiLogic (Freising, Germany).

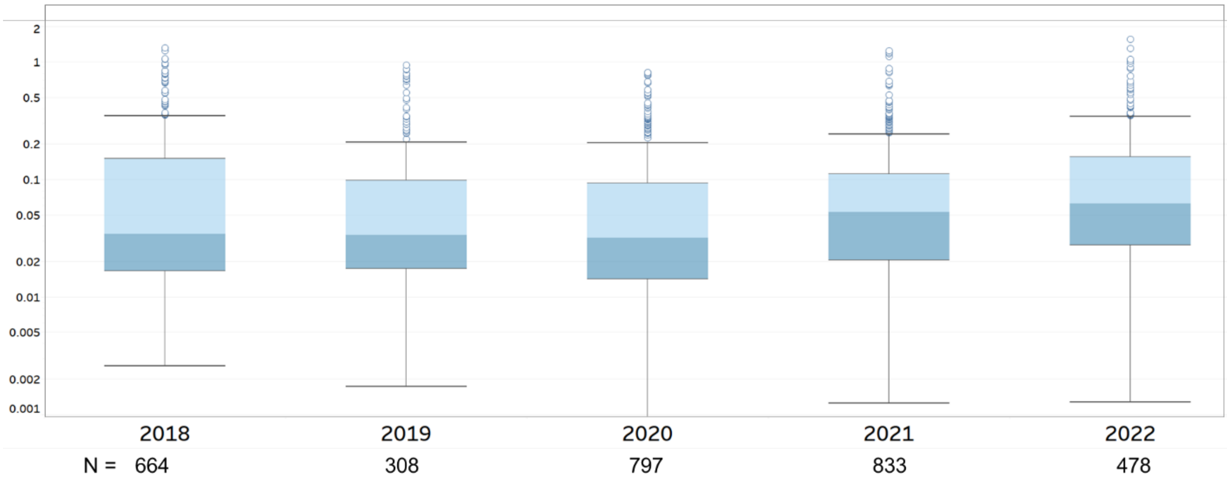

Figure 3.3-6: Sensitivity of European populations of *Zymoseptoria tritici* from 2018 to 2022 towards mefentrifluconazole. Method was a microtiter test, EC_{50} [mg/l] values were determined by Probit analysis. Data for 2022 are preliminary as analysis is still ongoing at the timepoint of writing this RRA.

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 FRAC webpage, November 2022):

1.1. WHEAT

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

Presentation of monitoring data 2021: BASF, Bayer, Corteva, FMC, Sumitomo, Syngenta

- Disease pressure in 2021 was moderate with a later onset in some wheat growing regions in Europe. Field performance of DMI-containing fungicides was good when used according to the manufacturers and FRAC recommendation. The overall sensitivity levels were stable and comparable to previous years.

- In 2021, monitoring was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Spain, Sweden, The Netherlands, Turkey, Ukraine, and the United Kingdom.

- In 2020, disease pressure was low to moderate with very dry conditions in some countries. DMIs field performance was good when used according to the manufacturers and FRAC recommendations. No general field resistance has been reported.

- In 2020, monitoring was carried out in Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Turkey, Ukraine and United Kingdom

- In 2020, the sensitivity of populations was overall stable on European level with EC_{50} sensitivity values in the range of previous years.

- Overall, as already reported in 2019, DMI EC50 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 *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.

- 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 2018, the sensitivity of the populations was overall stable on the European level.

- In 2016 and 2017, the sensitivity of 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 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).
- 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 were 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 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.

2. *Puccinia triticina* and other *Puccinia species*

<u>Monitoring data</u>

A broad European monitoring for mefentrifluconazole and Puccinia triticina was done in 2016, 2018, 2020 and 2022 (Figure 3.3-7) in the company EpiLogic (Freising, Germany) with a bioassay using detached leaves treated with different concentrations of mefentrifluconazole and subsequent ED_{50} calculation. The frequency diagram including the 4 years of monitoring is provided in Figure 3.3-7. The data indicate that there is a stable situation for mefentrifluconazole over the seasons.

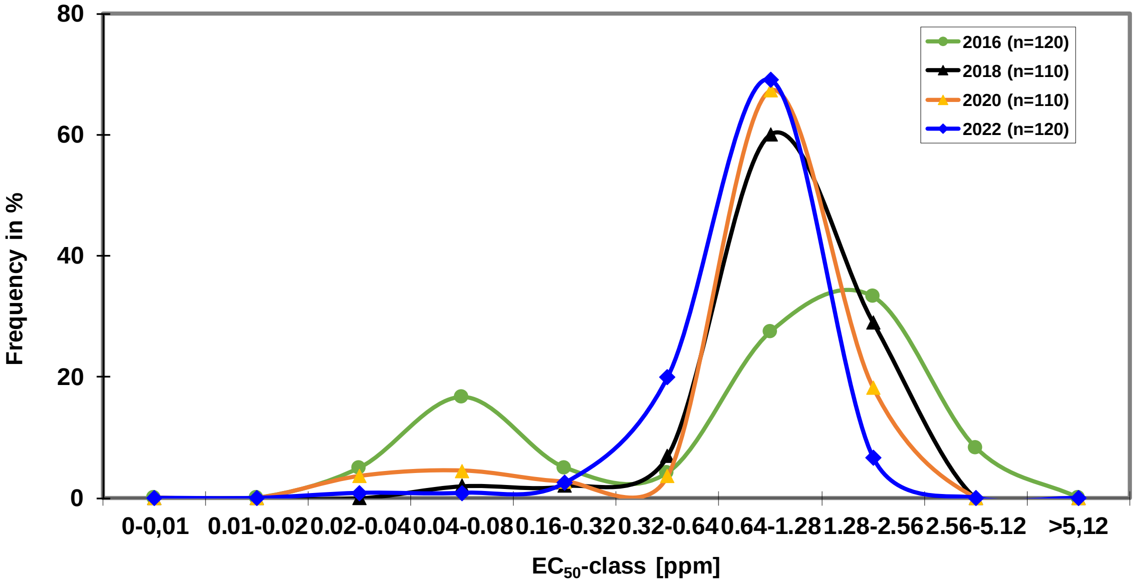

Figure 3.3-7: Frequency distribution of ED_{50} values of European isolates towards mefentrifluconazole. Monitoring started in 2016 and has been followed up every two years.

Previous studies show that the mutation Y134F has been found in isolates of *Puccinia triticina* (Stammler et al. 2009) and *Puccinia striiformis* (Cook *et al*. 2021). Homologous mutations are known to influence DMI sensitivity in other fungal species (Schmitz *et al.* 2014, Huf *et al.* 2018, Hoffmeister *et al.* 2021) and the mutation is seen as an acquired resistance mechanism. However, effects on DMI sensitivity in both rust species were reported to be low (Stammler *et al*. 2009, Cook *et al.* 2021).

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 FRAC webpage, November 2022):

1.1.3. Wheat brown rust (*Puccinia triticina*)

Presentation of monitoring data 2020: BASF, Bayer, Sumitomo,

- In 2020, brown rust disease pressure was low to moderate in most of the countries in Europe.
- Good field performance of DMIs against rust has been maintained.
- Monitoring in 2020 has been carried out in Belgium, Czech Republic, Denmark, France, Germany, Hungary, Italy, Poland, Romania, Slovakia, Spain and United Kingdom.
- Sensitivity data from 2020 for wheat brown rust showed that sensitivities were in the range of those of the last 20 years as observed in monitoring from other FRAC member companies

1.1.6. Yellow rust (*Puccinia striiformis*)

Presentation of monitoring data 2021: Sumitomo

- In 2021, monitoring was carried out in Belgium, Czech Republic, France, Germany, Italy, Poland, and Romania.
- Disease pressure was low in 2021.
- The first monitoring in 2015 showed high sensitivity and low diversity, and from 2016 to 2021 a stable situation was reported.

3. *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 value of 0.26 mg/l and a maximum value of 2.34 mg/l (Table 3.3-1).
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 November, 2022):

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

Presentation of monitoring data 2021: Bayer, Corteva, Syngenta (ongoing)

- In 2021, monitoring was carried out in Austria, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Russia, Slovakia, Spain, Sweden, The Netherlands, Ukraine, and the United Kingdom.
-
- In 2020, monitoring was carried out in Austria, Belgium, Bulgaria, Czech Republic, Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Poland, Romania, Russia, Slovakia, Spain, Sweden, Switzerland, Ukraine, and United Kingdom.

- Overall, the sensitivity of populations monitored in 2021 stayed in the range observed in previous years, without any major geographical differences across Europe.

- 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.

- 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 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.

4. *Parastagonospora nodorum* (formerly known as *Stagonospora nodorum, Leptosphaeria nodorum, Phaeosphaeria nodorum* or *Septoria nodorum*)

<u>Monitoring data</u>

Sensitivity of European isolates towards mefentrifluconazole from Germany isolated in 2010 and 2012 showed low EC_{50} values <0.01 mg/l (Table 3.3-2).
These data provide a limited data set on the sensitivity situation of *Parastagonospora nodorum* towards mefentrifluconazole before market introduction. Future monitoring studies will show if there will be any changes.

Table 3.3-2: 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

FRAC summary of the status of DMI resistance in *Parastagonospora nodorum* based on all available data from the different members of the FRAC DMI Working Group (status FRAC webpage, November 2022):

1.1.9. Glume blotch (*Stagnospora nodorum*)

Presentation of monitoring data 2020 & 2021: Syngenta

- In 2020 & 2021, a limited monitoring was carried out in countries like Czech Republic, Germany, Hungary, Latvia and Sweden.
- A very narrow sensitivity range with high sensitivity levels was observed in both years

5. *Ramularia collo-cygni*

Monitoring data

Monitoring studies with mefentrifluconazole and European isolates of *Ramularia collo-cygni* were performed by the company Agrotest fyto (Kromeriz, Czech Republic) from 2017 to 2022. Test system is a Petri dish assay with pure isolates growing on different fungicide concentrations with subsequent EC_{50} calculation. The data showed a broad range of sensitivity, which indicate an acquired adaptation (Figure 3.3-8). Obviously, the adaptation started before 2017 and is since then on a stable level.

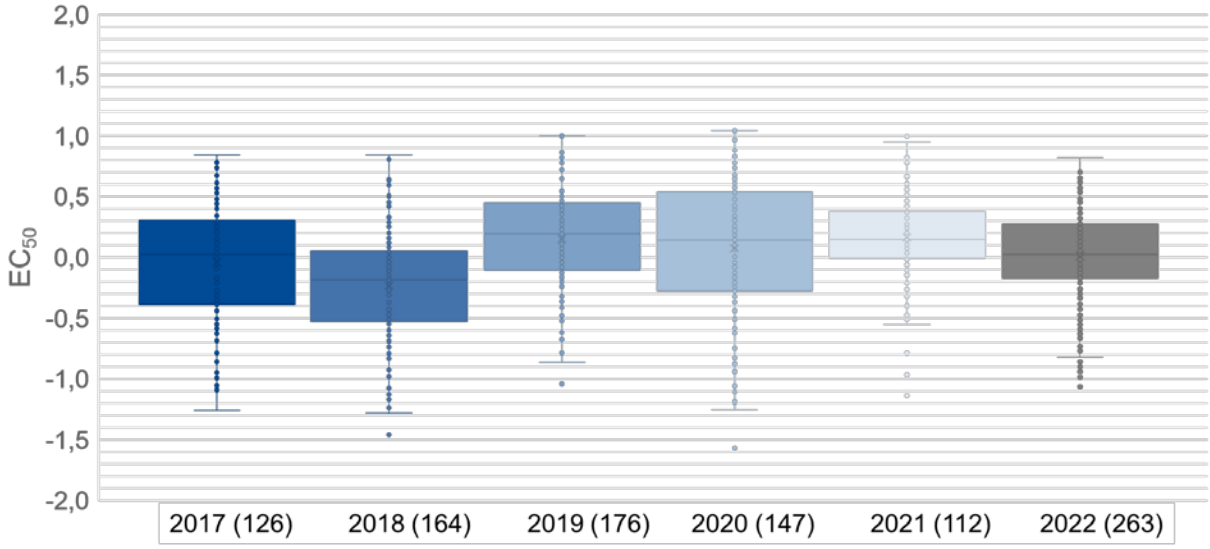

Figure 3.3-8: Distribution of EC_{50} values of European isolates of *Ramularia collo-cygni* towards mefentrifluconazole from 2017 to 2021 in a box and whisker format.

Previous studies showed that this shift to lower sensitivities is caused by various target site mutations (Rehfus *et al.* 2019, FRAC 2022). The isolates can be classified in 3 types according to their numbers of mutations (Table 3.3-3). In Figure 3.3-9 the effects of the haplotypes are provided, which show that there are differences in the effects of cyp51 haplotypes towards DMIs and that mefentrifluconazole is less affected.

Table 3.3-3: Classification of cyp51 haplotypes of *Ramularia collo-cygni* according to Rehfus *et al.* (2019).

V136A	Y137F	A311S	I381T	I384L	D458G	Y459C	Y459N	G460D	G460V	Y461N	Y461H	Kodierung
-	-	-	-	-	X	-	-	-	-	-	-	*Rcc*A1
-	-	-	-	-	-	X	-	-	-	-	-	*Rcc*A2
-	-	-	-	-	-	-	X	-	-	-	-	*Rcc*A3
-	-	-	-	-	-	-	-	X	-	-	-	*Rcc*A4
-	-	-	-	-	-	-	-	-	X	-	-	*Rcc*A5
-	-	-	-	-	-	-	-	-	-	X	-	*Rcc*A6
-	-	-	-	-	-	-	-	-	-	-	X	*Rcc*A7
-	X	-	-	-	-	-	-	-	-	-	-	*Rcc*A8
X	-	-	-	-	X	-	-	-	-	-	-	*Rcc*B1
X	-	-	-	-	-	-	-	-	-	X	-	*Rcc*B2
X	-	-	-	-	-	-	-	-	-	-	X	*Rcc*B3
-	-	X	-	-	X	-	-	-	-	-	-	*Rcc*B4
-	-	-	X	X	-	-	-	-	-	-	-	*Rcc*B5
-	-	-	X	X	-	X	-	-	-	-	-	*Rcc*C1
-	-	-	X	X	-	-	-	X	-	-	-	*Rcc*C2
-	-	-	X	X	-	-	-	-	-	-	X	*Rcc*C3

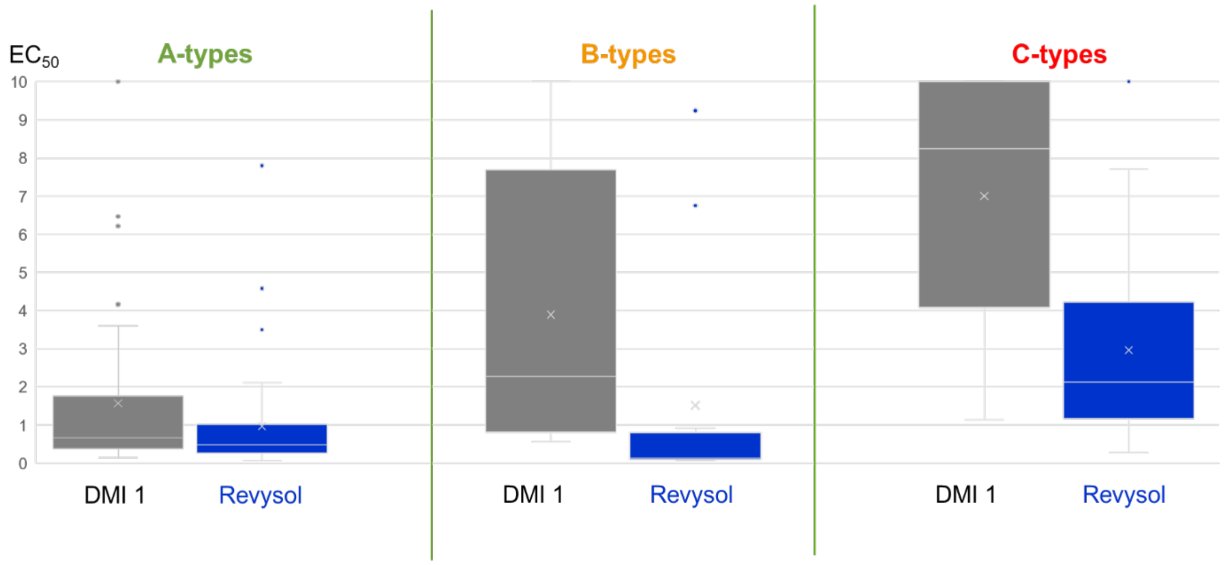

Figure 3.3-9: Sensitivity of *Ramularia collo-cygni* towards 2 DMIs (Revysol = mefentrifluconazole) separated by their cyp51 haplotypes (A, B and C). Test system was a Petridish assay performed at Agrotest fyto.

FRAC statement

FRAC summary of the status of DMI resistance in *Ramularia collo-cygni* based on all available data from the different members of the FRAC DMI Working Group (status FRAC webpage, November 2022):

1.2.4. Ramularia leaf spot (*Ramularia collo-cygni*)

Presentation of monitoring data 2021: Bayer (ongoing), BASF, Corteva (ongoing), Syngenta (partially still ongoing)

- In 2021, monitoring was carried out in Austria, Croatia, Czech Republic, Denmark, France, Germany, Ireland, Italy, Netherlands, Spain, Sweden, and United Kingdom
- In 2020, monitoring was carried out in Denmark France, Germany, Hungary, Ireland, Italy, Lithuania, Poland, Slovakia, Spain, Sweden, Switzerland, and United Kingdom.
- Isolates were detected showing significant loss of sensitivity. Relevant CYP51-mutations explaining the effects have been identified (I325T, I328L, Y403C/Y405H).

In 2021, the results from bioassay and molecular analysis focusing on the most relevant mutations are:

- no resistance in Italy
- low frequencies of resistance in Spain & Croatia
- moderate frequencies of resistance in Austria and The Netherlands
- moderate to high frequencies of resistance in Czech Republic, France, Germany, Ireland, Sweden, and the United Kingdom
- high frequencies of resistance in Denmark
- On the European continent, a gradient in terms resistance frequencies can be observed from north to south. Overall, the frequency of relevant CYP51-mutations was comparable to 2020.
-
- The field performance of DMI-containing products remains still relatively good in 2021.

In 2020, the results from bioassay and molecular analysis focusing on the most relevant mutations are:

- no to low frequencies of resistance in Italy, Switzerland, and Spain
- no to high frequencies of resistance in France
- moderate to high frequencies of resistance in Germany and Sweden,

- high frequencies of resistance in Czech Republic, Denmark, France, Hungary, Ireland, Lithuania, Slovakia, and United Kingdom.

In 2019 the results are:

- no isolates/samples with the above-mentioned mutations were detected in Spain & Italy
- no to low frequencies in Slovenia and Croatia
- low frequencies of DMI resistance allele were detected in Switzerland and Slovakia
- in Austria, low to moderate frequencies were observed
- moderate to high frequencies in Belgium, Germany and Sweden
- high frequencies in Ireland, United Kingdom and France

In 2018 the results are:

- no isolates with the above-mentioned mutations detected in Switzerland, Spain and Italy, and Sweden.
- no to high frequency in Denmark,
- low to moderate frequency in single samples from Austria, France, Hungary,
- low to high frequency in Germany,
- moderate to high frequency in Belgium, Netherlands, United Kingdom, Ireland, and Latvia.

Data from 2017 showed high frequency of resistant strains in Denmark, Ireland, and United Kingdom, moderate frequency in Estonia, low to moderate frequency in Sweden, and no resistant strains were detected in Finland.

In 2016, a broad sensitivity range has been identified with very high frequency of high resistant strains in southern Germany, with moderate frequency in Denmark, Ireland, Belgium, Northwestern Germany, and low frequency detected in France, Austria, Sweden, and United Kingdom. No detection of resistance in Estonia.

6. *Blumeria graminis*

Monitoring data

There are no current BASF monitoring data available. In FRAC, data for wheat powdery mildew (*Blumeria graminis* f.sp. *tritici*) and barley powdery mildew (*Blumeria graminis* f.sp. *hordei*) were provided.

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, November 2022):

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

Disease pressure in 2020 was low across Europe.

DMIs

Presentation of monitoring data 2020: Bayer, Sumitomo, Syngenta

- DMI field performance was good.
- In 2019, monitoring was carried out in Czech Republic, France, Germany, Poland, and United Kingdom.
- A limited monitoring in New Zealand in 2019 showed sensitivity ranges comparable to European populations.
- In 2020, monitoring was carried out in Belgium, Czech Republic, Denmark, France, Germany, Hungary, Italy, Poland and United Kingdom.
- Sensitivity data presented for 2016 to 2020 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 2020, 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 & 2020 monitoring in France, Germany and United Kingdom were presented by Bayer.

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

7. *Rhynchosporium secalis* (syn. *Rhynchosporium commune*)

Monitoring data

Sensitivity of European isolates towards mefentrifluconazole from Ireland, UK, France, Netherlands, Belgium, Denmark, Germany and Poland isolated in 2002-2017 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 3.3-4). Monitoring studies from 2019, 2020 and 2021 showed a similar distribution with single outliers in 2021 (Figure 3.3-10).
Method is a microtiter test performed in BASF laboratory.

Table 3.3-4: 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

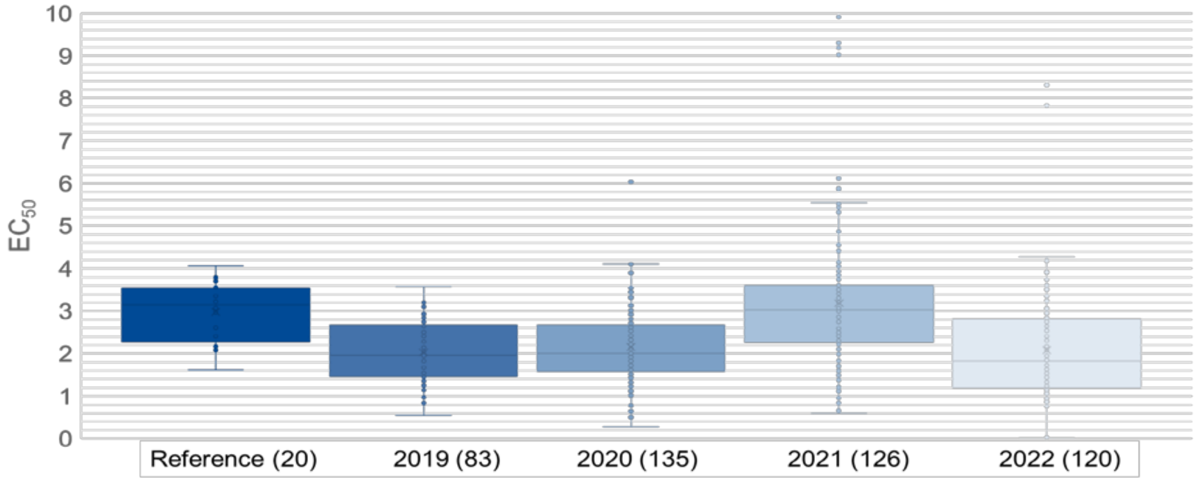

Figure 3.3-10: Box and Whisker distribution of mefentrifluconazole EC_{50} values of European isolates from last seasons (2019-2022) including the reference isolates from 2002-2014 of Table 3.3-1.

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 FRAC webpage, August 2022):

1.2.2. Scald (*Rhynchosporium commune*)

Presentation of monitoring data 2021: Bayer (ongoing), Syngenta

- In 2021, monitoring was carried out in Denmark, France, Germany, Hungary, Ireland, Italy, Poland, Spain and United Kingdom
- Field performance of DMIs was good.
- In 2020, monitoring was carried out in Denmark, France, Germany, Hungary, Ireland, Italy, Latvia, The Netherlands, Poland, Slovakia, Spain and United Kingdom

- Stable situation. The sensitivity of the populations stayed in the range observed in Europe in the previous 16 years.

Use pattern

BAS 768 00 F is intended for registration for control of the above-mentioned diseases in cereals with a maximum of 2 applications between growth stages 30-59 (33-40 in Denmark) and a maximum rate of 4.0 l/ha per application.

Resistance risk assessment of unrestricted use pattern

Fungicide risk

Mefentrifluconazole: FRAC describes the DMI fungicides in general as *medium-risk* compounds (FRAC 2022) according to the principles described in FRAC Monographs 1 and 2 (Brent 2007, Brent and Hollomon 2007).

Sulfur: FRAC describes the multisite fungicides in general as *low-risk* compounds (FRAC 2022) 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: *Ramularia collo-cygni, Blumeria graminis*

Medium risk pathogens: *Zymoseptoria tritici, Pyrenophora teres*

Low risk pathogens: *Parastagonospora nodorum, Puccinia* spp., *Combined pathogen-fungicide risk*

The combined risks of pathogens and fungicides are visualized in **Figure 3.3-11** and **Figure 3.3-12**.

benzimidazoles dicarboximides phenylamides QoI +B3:F9	**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 Sulfur SAR-inducers	**low (x 0.5)**	0.5	1	1.5
basic fungicide risk	**basic disease risk**	**low (1)**	**medium (2)**	**high (3)**
		Parastagonospora nodorum Puccinia hordei Puccinia striiformis Puccinia triticina	***Zymoseptoria tritici Pyrenophora teres***	***Blumeria graminis Ramularia collo-cygni***

Figure 3.3-11: 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 3.3-12. The positions were allocated considering the current knowledge and experience on the fungicides and pathogens.

1: DMI on *Puccinia* spp.
2: DMI on *Parastagonospora nodorum*
3: DMI on *Zymoseptoria tritici, Pyrenophora teres*
4: DMI on *Ramularia collo-cygni, Blumeria graminis*

5: Sulfur on *Puccinia* spp.
6: Sulfur on *Parastagonospora nodorum*
7: Sulfur on *Zymoseptoria tritici, Pyrenophora teres*
8: Sulfur on *Ramularia collo-cygni, Blumeria graminis*

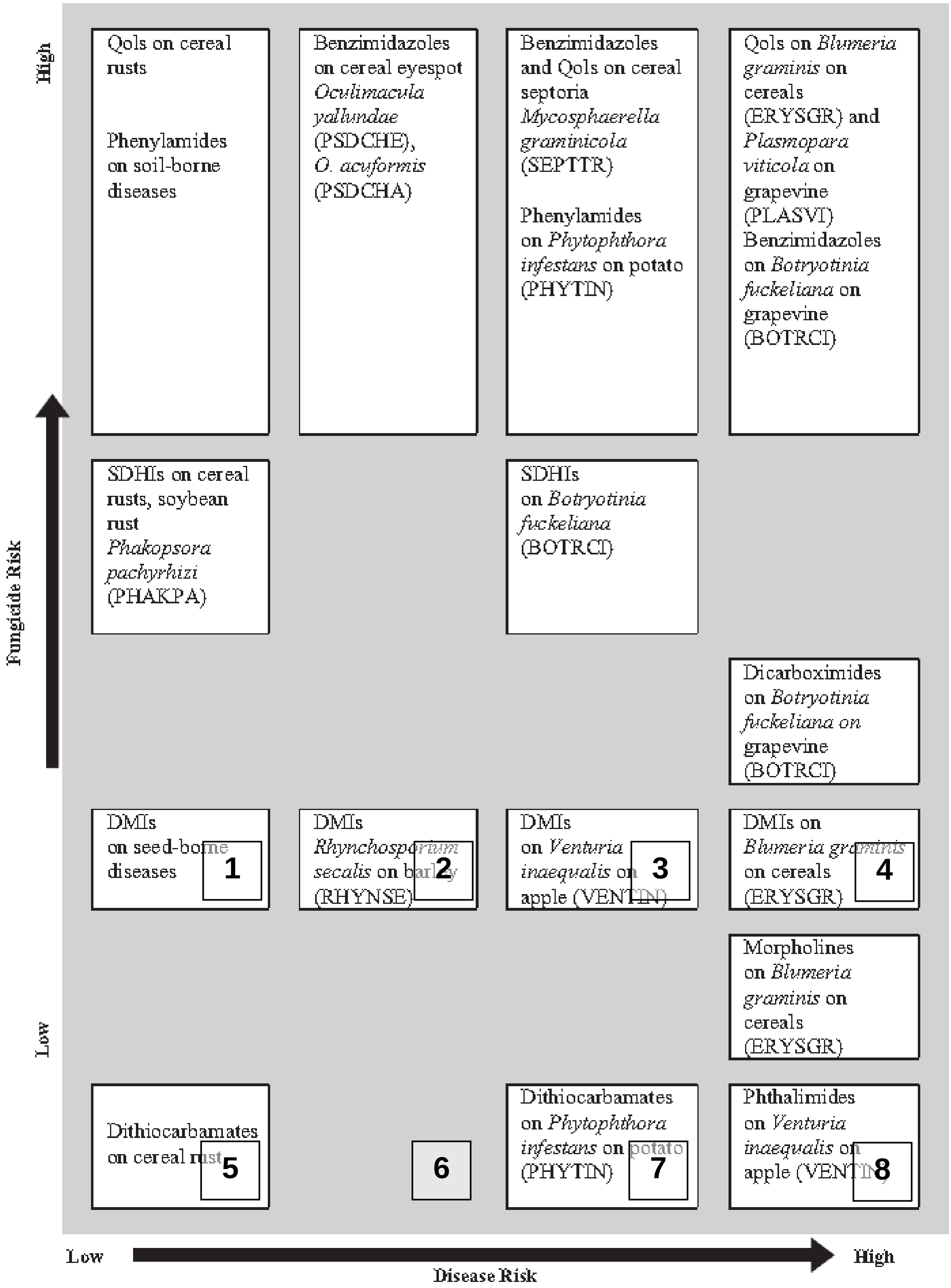

Figure 3.3-12: Scheme for visualizing the combined resistance risk (EPPO 2015).

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.: low
Parastagonospora nodorum: low to medium
Zymoseptoria tritici, *Pyrenophora teres*: medium
Ramularia collo-cygni, *Blumeria graminis*: medium to high

Sulfur x pathogen …

Puccinia spp., *Parastagonospora nodorum*, *Zymoseptoria tritici*, *Pyrenophora teres*, *Ramularia collo-cygni*, *Blumeria graminis*: low

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 sensitivities 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 Management Laboratory of BASF.

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 and the use of the solo compound mefentrifluconazole, 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). The principals of Integrated Pest Management (IPM) should be implemented.

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 768 00 F applications will be restricted to a maximum of 2 applications per season.

A further tool is the use of fungicide mixtures. Various studies showed that especially mixtures help in delaying the selection of resistance (Hobbelen *et al.* 2013, 2014, van den Bosch *et al.* 2014). BAS 768 00 F is a mixture of two compounds with the different mode of action. This fact helps to slow down the evolution of DMI resistance.

BAS 768 00 F will be used in spray programmes with the inclusion of other modes of action, which reduces selection pressure and provides effective resistance management (Hobbelen *et al.* 2011, 2013, 2014; van den Bosch *et al.* 2014).

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 768 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 SBI Working Group and will promote effective anti-resistance management strategies. The current FRAC recommendations for resistance management of SBI fungicides are:

"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."

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

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 most presently established Working Groups. In this way every attempt is made to formulate and promote resistance management strategies and the rational use of fungicides.

Monitoring, reporting and reacting to changes in performance

The sensitivity of *Zymoseptoria tritici, Puccinia triticina* and *Ramularia collo-cygni* to DMIs is monitored by BASF on an annual or biannual basis in broad monitoring studies over all important European cereal growing areas.
In case of field failure of BAS 768 00 F, which cannot be explained by other agronomic parameters, the sensitivity of the target pathogens of this Resistance Risk Analysis to mefentrifluconazole 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:	BAS 768 00 F is intended for control of diseases in cereals with 4,0 l product/ha in the Maritime and NE EPPO climate zones. Maximum number of applications is 2, with a minimum of 14 days between applications and between growth stages 30-59. BAS 768 00 F is a mixture of two compounds with different modes of action. 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. Sulfur is classified by FRAC into the group of chemicals with multi-site activity (FRAC Group M) and in the subgroup of inorganics M02. The mechanism of action is not fully explained. Mefentrifluconazole: FRAC determined the DMI fungicides as medium-risk compounds. Sulfur: Generally considered as a low risk group without any signs of resistance developing to the fungicides. Pathogen risk: High risk pathogens: *Blumeria graminis, Ramularia collo-cygni* Medium risk pathogens: *Zymoseptoria tritici, Pyrenophora tritici-repentis, Pyrenophora teres* Low risk pathogens: *Puccinia spp., Rhynchosporium secalis* 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. • low to medium: *Rhynchosporium secalis,* • medium: *Zymoseptoria tritici, Pyrenophora tritici-repentis, Pyrenophora teres,* • medium to high: *Blumeria graminis, Ramularia collo-cygni* Sulfur x pathogen: • low: *Puccinia* spp., *Rhynchosporium secalis, Zymoseptoria tritici, Pyrenophora tritici-repentis, Pyrenophora teres, Blumeria graminis, Ramularia collo-cygni* 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. For medium-risk and hihg risk pathogens under unrestricted use of BAS 768 00 F, risk is not acceptaptable, therefore the applicant proposed to implement resistance management strategies to obtain the reduction of selection pressure. Good agricultural practice leads to less infection pressure and limiting number of application is also important factor in preventing the build-up of resistant pathogen populations. That is why the use of the product is restricted to 2 application per season. What is more BAS 768 00 F should be applied in a preventive manner following the recommendations on the label, when population size of pathogens is lower and selection pressure is less (preventive applications, not curative or eradicative applications). 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)

Adverse effects on treated crops were studied in efficacy trials (disease trials) as well as in 2 trials free of disease (where disease infection was below 5%). Crops and varieties assessed in free of diseases trials are summarized in Table 3.4-1 below and in Table 3.2-22 for efficacy trials. The detailed report of these trials can be seen in Appendix 5 and Appendix 7 of BAD (BASF DocID 2023/2000942). All principles mentioned in the section Materials and methods were followed and also relate to the trials presented below.

Table 3.4-1: Crop/varieties included in free of diseases trials

Crop	No. trials	Varieties
winter wheat	1	Oregrain
triticale	1	Brehat

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Phytotoxicity was evaluated in a total of 105 efficacy trials and 2 trials free of disease. Trials were carried out on wheat, barley and triticale in countries across Europe over three seasons from 2020 to 2022 on a wide range of commercially grown varieties. This set of trials includes trials with double application (which is considered the worst case). 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. Generally, no phytotoxicity symptoms caused by BAS 768 00 F at the proposed maximum use rate of 4.0 L/ha were recorded in assessed trials.
Details are provided in Appendix 7: Summary of phytotoxicity data (KCP 6) of BAD (BASF Doc ID 2023/2000942.

Table 3.4-2 : Phytotoxicity of BAS 768 00 F – Efficacy trials (trials with and without disease)

Number of trials with…		Efficacy trials (107 trials)			
		with diseases (105 trials)		without diseases (2 trials)	
		BAS 768 00 F 4.0 l/ha	Standard	BAS 768 00 F 4.0 l/ha	Standard
No of trials conducted for each rate or product					
Maximum of phytotoxicity recorded during the trials	0% to 5%	105	105	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%	105	105	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. For crops and varieties assessed for phytotoxicity in trials free of disease refer to Table 3.4-1.

Comments of zRMS:	The applicant submitted 105 efficacy reports (for winter and spring wheat, winter and spring barley, winter triticale) where phytotoxicity of the product was also carried out at the proposed maximum use rate of 4,0 l/ha (in Maritime, North-East and ES EPPO zones). What is more in the Maritime EPPO zone in 8 trials on winter wheat and in the NE zone in 3 trials, phytotoxicity was assessed after the second application of the product with a minimum of 14 days between applications. No phytotoxicity symptoms were observed in the efficacy trials. Additionally the phytotoxicity was tested in 2 trials free of disease in the Maritime EPPO zone on: TRZAW, var. Oregrain, BBCH 53 – 57 and on TTLWI, var. Bre-hat, BBCH 39. No symptoms of phytotoxicity were observed in disease-free trials.

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.
Results are available from 2 safety trials (where disease infection was below 5%). In these trials, BAS 768 00 F was compared to Proline. Summary is presented in Table 3.4-3 below, individual results in Appendix 10 of BAD (BASF DocID 2023/2000942).

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

EPPO zone	Crop		Untreated	BAS 768 00 F 4.0 l/ha	Standard
Maritime	wheat	**dt**	83.0	85.3	83.5
		%	100.0	102.9	100.6
		min-max	-	-	-
		n	1	1	1
	triticale	**dt**	70.4	76.9	77.5

		%	100.0	109.3	110.1
		min-max	-	-	-
		n	1	1	1

Good yield responses were seen after fungicidal application, with BAS 768 00 F increasing yield up to 9% in free of disease trials (no or low disease values <5%). Standard offered an increase in yield at similar level. Based on the results it is concluded that no adverse effects on yield were seen from applications of BAS 768 00 F to cereals.

Comments of zRMS:	The effect of BAS 768 00 F on yield of winter wheat and triticale was also assessed in 2 trials free of diseases. Trials were conducted in PL (NE EPPO zone). It can be concluded that BAS 768 00 F showed no negative impact on yield (at dose rates 4,0 l/ha) of winter wheat and triticale.

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

The effect of BAS 768 00 F on cereal quality was assessed by measuring hectoliter weight of harvested grain and thousand grain weight (TGW) in free of diseases trials. 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.

Thousand grain weight

Results are available from 2 trials (where disease infection was below 5%). In these trials, BAS 768 00 F was compared to Proline. Summary is presented in Table 3.4-4 below, individual results in Appendix 10 of BAD (BASF DocID 2023/2000942).

Table 3.4-4: Thousand grain weight in trials free of disease (g and % relative to untreated) – summary table

EPPO zone	Crop		Untreated	BAS 768 00 F 4.0 l/ha	Standard
Maritime	wheat	g	38.2	38.7	38.4
		%	100.0	101.2	100.3
		min-max	-	-	-
		n	1	1	1
	triticale	g	30.4	31.8	35.6
		%	100.0	104.6	117.1
		min-max	-	-	-
		n	1	1	1

BAS 768 00 F recorded thousand grain weight of 101%-105% relative to the untreated in diseases free trials. Therefore, it is concluded that BAS 768 00 F has no adverse effects on thousand grain weight in cereals.

Hectoliter weight

Results are available from 2 trials (where disease infection was below 5%). In these trials, BAS 768 00 F was compared to Proline. Summary is presented in Table 3.4-5 below, individual results in Appendix 10 of BAD (BASF DocID 2023/2000942).

Table 3.4-5: Hectoliter weight in trials free of disease (kg and % relative to untreated) – summary table

EPPO zone	Crop		Untreated	BAS 768 00 F 4.0 l/ha	Standard
South-East	wheat	kg	78.3	79.0	78.6
		%	100.0	100.9	100.4
		min-max	-	-	-
		n	1	1	1
	triticale	kg	72.7	72.9	74.1
		%	100.0	100.2	101.9
		min-max	-	-	-
		n	1	1	1

BAS 768 00 F recorded hectoliter weight of 100%-101% relative to the untreated in diseases free trials. Therefore, it is concluded that BAS 768 00 F has no adverse effects on hectolitre weight in cereals.

Comments of zRMS:	The effect of BAS 768 00 F on winter wheat and triticale was assessed by measuring hectoliter weight of harvested grain and thousand grain weight (TGW) in two free of diseases trials. BAS 768 00 F has no adverse effects on thousand grain weight and hectolitre weight in winter wheat and triticale. There were no negative effects on yield and quality parameters after the application of BAS 768 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)

Bread-making – Wheat

Three trials have been processed with bread-making. Trial list is presented in Table 3.4-6.
Details of these studies are available in Document **BASF DocID 2022/2060989**. The summary is presented below.

Table 3.4-6: Trials used for bread-making process

Uses or Crops (Number of trials)	Year	Trial n°	Test report	testing facilities / Organisation	Sites	Guidelines	Coleor Number	Trial Status	Comments
Winter wheat (3)	2021	F815/21-A-FR-FR1-172	DEV-F-2021-FR-815-A-01.0-FR-FR1-172	BASF Agro	49	CEB N°218 - 2012	OR20200903576	GEP	
		F815/21-A-FR-FR2-226	DEV-F-2021-FR-815-A-01.0-FR-FR2-226	BASF Agro	62	CEB N°218 - 2012	OR20200903576	GEP	
		F815/21-A-FR-FRE-E12	DEV-F-2021-FR-815-A-01.0-FR-FRE-E12	BASF Agro	80	CEB N°218 - 2012	OR20200903576	GEP	

The impact of BAS 768 00 F on wheat processing procedure was performed in 3 French trials in 2021. These 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.

BAS 768 00 F was applied at 4 L/ha in comparison with JOAO 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 GALYS laboratory.

After the measures of the protein content and the germination rate, the laboratory GALYS performed the usual tests: Hagberg, Zeleny, Chopin alveograph then bread-making.

● Description of the studies performed during the processing procedure

<u>Hagberg's falling time index:</u>
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 GALYS.
- 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 3.4-7 and Table 3.4-8.
In terms of yield, BAS 768 00 F at 4 L/ha achieved a gain of 3,3 dT/ha in comparison with the untreated control, and an equivalent yield compared to JOAO.
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 768 00 F nor the reference.

Table 3.4-7: Yield – bread-making trials

			UTC		BAS 76800 F (4 l/ha)		Joao (0,8 l/ha)		ANOVA		
Trials	**Disease**	**Cultivar**	**Value**	**N&K**	**Value**	**N&K**	**Value**	**N&K**	**Proba**	**CV**	**Root MSE**
Yield (dT/ha)											
F815/21-A-FR-FR1-172	(s)+(yr)	OREGRAIN	83,0	a	85,3	a	83,5	a	94,8	0,76	0,07
F815/21-A-FR-FR2-226	s	KWS EXTASE	100,5	b	107,1	ab	108,0	a	96,0	0,01	0,00
F815/21-A-FR-FRE-E12	s	RGT LIBRAVO	114,1	a	115,2	a	116,3	a	50,1	1,63	1,87
Mean value (3 trials)			**99,2**	**b**	**102,5**	**a**	**102,6**	**a**	**82,8**	**0,01**	**0,00**

Table 3.4-8: Hectoliter weight, protein content, thousand grains weight, moisture content and germination rate – bread-making trials

			UTC		BAS 76800 F (4 l/ha)		Joao (0,8 l/ha)		ANOVA		
Trials	**Disease**	**Cultivar**	**Value**	**N&K**	**Value**	**N&K**	**Value**	**N&K**	**Proba**	**CV**	**Root MSE**
Hectolitre weight (Kg/hL)											
F815/21-A-FR-FR1-172	(s)+(yr)	OREGRAIN	78,3	b	79,0	a	78,6	ab	96,4	0,90	0,01
F815/21-A-FR-FR2-226	s	KWS EXTASE	74,6	a	75,0	a	74,5	a	40,9	2,93	0,03
F815/21-A-FR-FRE-E12	s	RGT LIBRAVO	74,5	a	75,1	a	74,6	a	70,1	0,25	0,02
Mean value (3 trials)			**75,8**	**b**	**76,4**	**a**	**75,9**	**b**	**100,0**	**2,08**	**0,02**
Protein content (%)											
F815/21-A-FR-FR1-172	(s)+(yr)	OREGRAIN	11,5	a	11,4	a	11,5	a	85,0	1,02	0,12
F815/21-A-FR-FR2-226	s	KWS EXTASE	11,7	a	11,4	a	11,5	a	9,2	3,71	0,43
F815/21-A-FR-FRE-E12	s	RGT LIBRAVO	12,1	a	11,9	a	11,9	a	79,3	- 0,50	0,01
Mean value (3 trials)			**11,8**	**a**	**11,6**	**a**	**11,6**	**a**	**93,3**	**1,94**	**0,22**
Thousand grains weight (g)											
F815/21-A-FR-FR1-172	(s)+(yr)	OREGRAIN	38,2	a	38,7	a	38,4	a	33,9	0,88	0,05
F815/21-A-FR-FRE-E12	s	RGT LIBRAVO	45,6	a	46,1	a	46,6	a	45,7	1,61	0,11
Mean value (3 trials)			**41,9**	**a**	**42,4**	**a**	**42,5**	**a**	**64,0**	**0,74**	**0,04**
Moisure content (%)											
F815/21-A-FR-FR1-172	(s)+(yr)	OREGRAIN	11,7	a	11,8	a	11,8	a	15,1	0,34	0,01
F815/21-A-FR-FR2-226	s	KWS EXTASE	15,2	a	15,5	a	15,4	a	23,1	0,74	0,01
F815/21-A-FR-FRE-E12	s	RGT LIBRAVO	14,9	a	14,9	a	14,9	a	90,2	0,18	0,00
Mean value (3 trials)			**13,9**	**a**	**14,1**	**b**	**14,0**	**b**	**82,0**	**0,27**	**0,00**
Germination rate (%)											
F815/21-A-FR-FR1-172	(s)+(yr)	OREGRAIN	98,0		99,5		100,0				
F815/21-A-FR-FR2-226	s	KWS EXTASE	97,5		99,0		98,5				
F815/21-A-FR-FRE-E12	s	RGT LIBRAVO	100,0		100,0		99,0				
Mean value (3 trials)			**98,5**	**a**	**99,5**	**a**	**99,2**	**a**	**63,0**	**0,20**	**0,00**

● Results of the processing procedure studies

The bread making results are presented in Table 3.4-9.

Results show that BAS 768 00 F does not lead to significant modifications of ZELENY index, Hagberg’s falling time index or the Chopin alveograph. BAS 768 00 F at the dose rate of 4 L/ha does not show any significant difference in comparison with the references on the processing procedure for bread-making.

To conclude, all the studies and analysis confirm that BAS 768 00 F has no negative effect on wheat quality and processing procedures

Table 3.4-9: Bread-making results

Trial n°		Climatic zone	Disease complex	Cultivar	Untreated Value	BAS 768 00 F 4 l/ha Value	JOAO 0,8 l/ha Value	Difference BAS 768 00 F / JOAO	Acceptable difference
Hagberg falling time (s)									
F815/21-A-FR-FR1-172		Ma	(s)+(yr)	OREGRAIN	385,0	385,3	385,0		
F815/21-A-FR-FR2-226		Ma	s	KWS EXTASE	307,3	278,0	308,3		
F815/21-A-FR-FRE-E12		Ma	s	RGT LIBRAVO	362,0	356,7	356,0		
Mean value (6 trials)					351,4	340,0	349,8	-2,9	<10%
Sedimentation value (mm) - Zélény									
F815/21-A-FR-FR1-172		Ma	(s)+(yr)	OREGRAIN	36	35	35		
F815/21-A-FR-FR2-226		Ma	s	KWS EXTASE	38	35	36		
F815/21-A-FR-FRE-E12		Ma	s	RGT LIBRAVO	37	35	35		
Mean value (6 trials)					37,0	35,0	35,3	-1,0	<10%
Chopin alveogram									
F815/21-A-FR-FR1-172	G	Ma	(s)+(yr)	OREGRAIN	25	26	23		
F815/21-A-FR-FR2-226	G	Ma	s	KWS EXTASE	21	20	20		
F815/21-A-FR-FRE-E12	G	Ma	s	RGT LIBRAVO	21	22	22		
Mean value (6 trials)					22,0	22,4	21,5	4,2	<10%
F815/21-A-FR-FR1-172	P	Ma	(s)+(yr)	OREGRAIN	46	48	49		
F815/21-A-FR-FR2-226	P	Ma	s	KWS EXTASE	63	74	72		
F815/21-A-FR-FRE-E12	P	Ma	s	RGT LIBRAVO	69	78	71		
Mean value (6 trials)					59,3	66,7	64,0	4,0	<15%
F815/21-A-FR-FR1-172	P/L	Ma	(s)+(yr)	OREGRAIN	0,37	0,36	0,46		
F815/21-A-FR-FR2-226	P/L	Ma	s	KWS EXTASE	0,73	0,93	0,92		
F815/21-A-FR-FRE-E12	P/L	Ma	s	RGT LIBRAVO	0,81	0,82	0,74		
Mean value (6 trials)					0,6	0,7	0,7	-0,5	
F815/21-A-FR-FR1-172	W	Ma	(s)+(yr)	OREGRAIN	156	170	151		
F815/21-A-FR-FR2-226	W	Ma	s	KWS EXTASE	183	205	198		
F815/21-A-FR-FRE-E12	W	Ma	s	RGT LIBRAVO	211	258	235		
Mean value (6 trials)					183,3	211,0	194,7	7,7	<20%
Bread making									
Bread index									
F815/21-A-FR-FR1-172		Ma	(s)+(yr)	OREGRAIN	54	54	53		
F815/21-A-FR-FR2-226		Ma	s	KWS EXTASE	74	72	73		
F815/21-A-FR-FRE-E12		Ma	s	RGT LIBRAVO	47	45	45		
Mean value (6 trials)					58,3	57,0	57,0	0,0	<10 points
Bread index making									
F815/21-A-FR-FR1-172		Ma	(s)+(yr)	OREGRAIN	251	251	250		
F815/21-A-FR-FR2-226		Ma	s	KWS EXTASE	260	258	259		
F815/21-A-FR-FRE-E12		Ma	s	RGT LIBRAVO	233	231	231		
Mean value (6 trials)					248,0	246,7	246,7	0,0	<15 points
Dough index									
F815/21-A-FR-FR1-172		Ma	(s)+(yr)	OREGRAIN	97	97	97		
F815/21-A-FR-FR2-226		Ma	s	KWS EXTASE	86	86	86		
F815/21-A-FR-FRE-E12		Ma	s	RGT LIBRAVO	86	86	86		
Mean value (6 trials)					89,7	89,7	89,7	0,0	<5 points

Brewing study – Barley

The full study "**Study of unintentional effects of BAS 768 00 F product applied on winter and spring barley, harvest 2021, on malt and beer quality and process**" can be found under BASF DocID 2022/2032437.

Grains samples were taken from 2 trials on spring barley and 2 trials on winter barley. All trials were conducted in 2021. These trials received one applications of fungicide - full rate of BAS 768 00 F (4.0 l/ha) and other tested fungicides including reference product BAS 9314 1 F (Proline/Joao). The application timing followed the GAP table. 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 I'institut Français de la Brasserie et de la Malterie (IFBM, the French Institute of Brewing and Malting) with regard to brewing barley characteristics (specifications).
Detailed results of analysis realized by IFBM on barley, malting and brewing are presented in study report (DocID 2022/2032437) and summarized in tables below.

The conclusion from the study is that all results are similar between winter barley samples treated with reference product BAS 9314 1 F (Proline/Joao) and BAS 768 00 F.
Beta-glucans level is lower in the spring barley samples treated with BAS 768 00 F than in samples treated with reference product, but it is a positive effect. All other results are similar between the reference and BAS 768 00 F treated samples.
Accordingly, no restrictions need apply for the use of BAS 768 00 F for barley grown for brewing. Detailed results are presented below.

	BARLEY									
>Significance reference										
> No significance reference										
= Reference	■	●	■	●	■	●	■		■	●
< No significance reference								●		
< Significance reference										
■ : Winter barley ● :Spring barley	**Protein content**		**Germination index**		**Kernel size**		**DON**		**Ergosterol**	

	PHYSICO-CHEMICAL & FUNCTIONAL ANALYSES OF MALT															
>Significance reference				●												
> No significance reference		●				●								●		
= Reference	■		■		■		■	●	■	●	■	●	■		■	●
< No significance reference																
< Significance reference																
■ : Winter barley ● :Spring barley	**Fine grind extract**		**β-glucans**		**Viscosity**		**Friability**		**Calcofluor (modification)**		**Filtration rate**		**Attenuation limit**		**Apparent gravity (8th day)**	

BREWERY												
> Significance reference												
> No significance reference												
= Reference	■	●	■	●	■	●		●	■		■	●
< No significance reference							■			●		
< Significance reference												
■ : Winter barley ● : Spring barley	**Maïsche filtration**		**Free amino nitrogen**		**Time to ferment 5°Plato**		**Apparent attenuation**		**Head retention**		**Sensory analyses**	

= Reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between – ½ and + ½ of the significance difference.

< No significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between – 1 and - ½ of the significance difference.

> No significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is between + ½ and + 1 of the significance difference.

< Significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is lower than the significance difference.

> Significance reference: the difference between the mean of « treated samples » and the mean of « reference samples » of 2 spots is upper than the significance difference.

Comments of zRMS:	The impact of BAS 768 00 F on transformation processes was tested for winter wheat in three French trials in 2021 for bread – making and for spring barley (two French trials) and winter barley (two French trials), in 2021 for malting and brewing. The tested product was applied at the dose rate 4,0 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: hectolitre weight, TGW, moisture content, protein content, germination rate, Harberg factor, Zeleny factor, Chopin alveograph, dough index, bread index, bread -making index. It might be concluded that BAS 768 00 F at the dose rate of 4,0 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 and winter barley: The impact of BAS 768 00 F on transformation processes was tested for barley in the study “Malting and brewing trails Evaluation of different barley varieties for brewing purposes”. The tested product was applied once at the dose rate 4,0 l/ha and compared to two reference product. For malting and brewing of spring barley the following analyses were performed: Malt analyses Wort analyses Beer analyses

	Sensory beer analyses During the malt analyses only a β – glucans lover level was identified in trial with spring barley, what is a positive phenomenon for the malting processes. During malting process, barley germinates and produces hydrolytic enzymes that destructure the endosperm, making the grains soft and friable. On the other hand, a high content of β – glucans in barley grains causes improper grain modification during the malting process, because β-glucans inhibit enzymes to enter the cell walls of the endosperm. It might be concluded that BAS 768 00 F at the dose rate of 4,0 L/ha treatment did not have any direct effect on malting or beer quality.

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

According to EPPO PP1/135 (4) a special study on propagation is not necessary for submission of BAS 768 00 F because after the treatments in the efficacy trials 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 768 00 F” which is stored under BASF Doc ID 2022/2037349. Studies were conducted to establish the germination capacity of grain treated once or twice with BAS 768 00 F. A summary of results is presented below.

Five winter wheat trials located in various European countries were treated with 4.0 L/ha BAS 768 00 F at crop growth stage BBCH 30-59. Then samples were collected and tested for germination capacity.
Two winter wheat trials located in Poland were double treated with 4.0 L/ha BAS 768 00 F at crop growth stage BBCH 30-32 and 41-46. Then samples were collected and tested for germination capacity.
No significant difference in germination of the harvested seeds was determined between the BAS 768 00 F treated and the untreated plots in all of the wheat trials.

Five winter barley trials located in various European countries were treated with 4.0 L/ha BAS 768 00 F at crop growth stage BBCH 39-51. Then samples were collected and tested for germination capacity.
No significant difference in germination of the harvested seeds was determined between the BAS 768 00 F treated and the untreated plots in all of the barley trials.

Summary and conclusion

Results of study indicate that previous foliar treatment with BAS 768 00 F does not have any impact on germination of harvested cereals. For more information, please refer to original study report (BASF Doc ID 2022/2037349).

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 5 glasshouse trials for winter wheat and 5 glasshouse trials for winter barley from different countries (DE, NL, PL, FR). The studies for seedling germination were conducted according to ISTA -method (chapter 5, The Germination Test, 2006). 5 samples of wheat and 5 samples of barley were treated with 4,0 l/ha of BAS 768 00 F. Two winter wheat trials (located in PL) were double treated with 4,0 l/ha of BAS 768 00 F. The following varieties of wheat treated at growth stage BBCH 30 -59 were tested: Bataja, Torp, Akteur, Oregrain, Libravo. The germination of winter wheat double treated at growth stage BBCH 30-32 and 41-46 was tested for the following varieties: Emil, Fidelius. The germination of barley treated at growth stage BBCH 39 -51was tested for the following varieties: Planet, Irina, Valerie, Adalina, Esterel. It might be concluded that previous foliar treatment with BAS 768 00 F at the single and double dose rate of 4,0 L/ha did not show any significant differences in the germination capacity of treated grain, compared to untreated. It might be concluded that BAS 788 00 F at single and double dose rate of 4,0 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)

The influence of substrate contamination with BAS 768 00 F on the germination and growth of different crops has been tested in pot trials in the greenhouse. The full study is available under the BASF DocID 2021/2017632.

Guidelines Covered;
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.docx

Table 3.5-1: Plant species tested in pot trial

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

Zea mays	Maize	var. Ronaldinio

Before cultivation of the crops, BAS 768 00 F was incorporated into the substrate. According to the PEC soil calculation (Annex 1 of BASF DocID 2021/2017632), a dose rate of 8.0 l/ha BAS 768 00 F (= 5000 g active ingredient/ha Mefentrifluconazole + Sulfur) was applied. This is the 2-fold targeted registration rate. All crops were sown five weeks after substrate application.

The trials were carried out in a greenhouse at a temperature between 18 – 22 °C, about 70% relative humidity and 16 h daylight. The crops were irrigated by hand as required.

The randomization was done for each crop. Treated and untreated pots of each crop were placed side by side in the greenhouse to have comparable growing conditions.

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.

PEC_{soil} of Mefentrifluconazole and Sulfur after yearly, multi-year application of BAS 768 00 F to cereals and to sugar beets (GAP-C, GAP-SB scenario, respectively) and maximum concentration after application in the succeeding crop experiment at twice the application rate (SOP 2).

Table 3.5-2: PEC soil calculated for mefentrifluconazole and sulfur

Substance	**GAP scenario**			**SOP 2 scenario**
	$PEC_{soil,plateau}$ [mg/kg] (20 cm tillage)	**$PEC_{soil,max}$ [mg/kg]**	**$PEC_{soil,accu}$ [mg/kg]**	**$PEC_{soil,act}$ [mg/kg]**
Mefentrifluconazole	0.058	0.080	**0.138**	**0.154**
Sulfur	-**	**1.920**	-**	**3.692**

** Only exposure from yearly application considered [Ref. 6]
Bold: relevant for the comparison between GAP scenario and the SOP-2 scenario

Details on the calculations are provided in the appendix of BASF DocID 2021/2017632.

Results showed that none of the tested crops showed crop injury when grown in substrate treated with BAS 768 00 F. Moreover, none of the tested crops grown in substrate treated with BAS 768 00 F exhibited a negative influence on germination rate in relation to the untreated substrate. No negative effect on plant weight or plant height was observed.

It can be therefore concluded that there are no indications for expecting a risk of damage to following crops due to application of BAS 768 00 F. Thus, no restriction in the choice of succeeding crops, even in the event of crop failure, after the application of BAS 768 00 F is required.

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

PP 1/256(1) suggests that data can usually be taken from the non-target plant testing. Therefore, reference is made to Part B Section 09 (KCP 10.6). The corresponding report is available under DocID 2021/2014237.

Executive Summary
In a vegetative vigour test, six species of dicotyledonous plants (carrot, lettuce, oilseed rape, cabbage, soybean, tomato) and four species of monocotyledonous plants (onion, ryegrass, wheat, corn) were exposed to BAS 768 00 F to evaluate potential for adverse effects. BAS 768 00 F was applied post-emergence at growth stage BBCH 12 – 14 at 4.0 L/ha. Per plant species one control group (tap water only) was tested. After application, the plants were cultivated for 21 days under greenhouse conditions. The test conditions, application at early growth stage and greenhouse conditions, represent worst-case compared to realistic field conditions. Assessments for visual phytotoxicity plant development (BBCH) and plant survival were done 7, 14 and 21 days after treatment (DAT); single plant length and plant dry weight were determined at study termination 21 DAT.

After post-emergence application it can be concluded that BAS 768 00 F applied at BBCH 12-14 with a rate of 4.0 L/ha did not cause effects to plant phytotoxicity, plant survival, plant length and plant biomass for all tested plant species.
Post-emergence application of BAS 768 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 > 4.0 L/ha BAS 768 00 F for all tested plant species (the highest rate tested). The NOER for plant survival, plant length and plant biomass is equal or higher than the tested rate of 4.0 L/ha BAS 768 00 F. Lower dose rates were not tested.

These data represent worst-case test conditions. In practice, the exposure of adjacent crops from applications to cereals is at around 3% of the field rate. Combining this low exposure level with an ER50 above 4.0 L/ha BAS 768 00 F provides sufficient margins for the conclusion that no adverse effects on adjacent crops are expected from the envisioned uses of BAS 768 00 F. Therefore, the data presented within this Annex Point justifies the recommendation of no restrictions on adjacent crops after the application of BAS 768 00 F.

Comments of zRMS:	The impact of the product BAS 768 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 4,0 L/ha BAS 768 00 F was incorporated into substrate (5000 g active substances/ha Mefentrifluconazole, Sulfur). The following crops were tested: Sugar beet, Oilseed rape, Carrot, Sunflower, Winter barley, Potato, Pea, Winter wheat, Broad bean, Maize. No injury of the tested crops was observed grown in grown in substrate treated with BAS 768 00 F. Moreover, there were no negative effects on germination, plant weight, and plant height of crops grown in substrate treated with BAS 768 00 F. It might be concluded that BAS 768 00 F at the double dose rate of 4,0 L/ha has no risk of damage to above mentioned crops.

Table 3.5-3: Effect of BAS 768 00 F on plant survival (% to untreated control) - 21 DAT

Plant species	Rate BAS 768 00 F [L/ha]	Number of living plants per replicate			Plant survival 21 DAT [%]
		7 DAT	14 DAT	21 DAT	
Carrot	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Lettuce	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Oilseed rape	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Cabbage	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Soybean	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Tomato	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Onion	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Ryegrass	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Wheat	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100
Corn	0.0	6.0	6.0	6.0	100
	4.0	6.0	6.0	6.0	100

Treatment not significantly different to control

Table 3.5-4: Effect of BAS 768 00 F on plant length and biomass (% to untreated control) - 21 DAT

Plant species	Plant length Rate - BAS 768 00 F [L/ha]		Biomass (dry) Rate - BAS 768 00 F [L/ha]	
	0.0	4.0	0.0	4.0
Carrot	100.0	97.3	100.0	94.9
Lettuce	100.0	101.9	100.0	106.5
Oilseed rape	100.0	97.5	100.0	92.5
Cabbage	100.0	99.9	100.0	98.7
Soybean	100.0	102.8	100.0	101.0
Tomato	100.0	98.8	100.0	98.9
Onion	100.0	103.5	100.0	97.6
Ryegrass	100.0	97.8	100.0	98.5
Wheat	100.0	99.1	100.0	100.0
Corn	100.0	101.0	100.0	99.3

Treatment not significantly different to control

Table 3.5-5: No observed effects rates (NOER) (L/ha) for plant survival, phytotoxicity, plant length and biomass reduction 21 days after application of BAS 768 00 F at BBCH stage 12-14

Effect rate [L TI/ha]	Carrot	Lettuce	Oilseed rape	Cabbage	Soybean	Tomato	Onion	Ryegrass	Wheat	Corn
	Survival									
NOER	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0
ER_{50}	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0
	Visual phytotoxicity (estimated from visual assessment data)									
NOER	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0
	Plant length									
NOER	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0
ER_{50}	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0
	Plant dry weight (shoots above ground)									
NOER	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0	≥ 4.0
ER_{50}	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0	> 4.0

TI: Test Item BAS 768 00 F

Comments of zRMS:	The impact of the product BAS 768 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 vigour test. BAS 768 00 F was applied at dose rate 4,0 L/ha, post-emergence, at growth stage BBCH 12 – 14 of the plants which were cultivated under greenhouse conditions for 21 days. Plant survival, phytotoxicity, plant length, plant dry weight were assessed as negative symptoms for all tested plants. Based on plant survival, phytotoxicity, plant dry weight and plant length, ER50 amounted > 4,0 l/ha of BAS 768 00 F/ha for all tested plant. NOER values was > 4,0 l/ha BAS 768 00 F. Basing on phytotoxicity symptoms for all tested plant species, it might be concluded that BAS 768 00 F at the dose rate 4,0 L/ha caused no negative effects. It can be concluded that no restrictions are required on adjacent crops when BAS 768 00 F is applied.

3.5.3 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 summarized in Part B, Section 9 (Ecotoxicology).

Summary and conclusion

As a conclusion of all studies conducted, BAS 768 00 F does not have any negative impact on the cultivation of the tested adjacent and succeeding crops.

This indicates that the product BAS 768 00 F presents an extremely small risk of damage to any adjacent and succeeding crop.
It may therefore be concluded that there are no grounds for expecting a risk of damage to adjacent and succeeding crops due to application of BAS 768 00 F.
There is no necessity to recommend any restrictions concerning adjacent and succeeding crops, resulting from application of BAS 768 00 F.

3.6 Other/special studies

Tank cleaning

The attachment "Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing" - BAS 768 00 F" (BASF DocID 2021/2034436) provides results that flushing with water will satisfactorily remove residues of the product without the need of a specific tank cleaner.

Physical and chemical compatibility

The physical and chemical compatibility of BAS 768 00 F together with other plant protection products described in this report were tested according to ASTM method E 1518-05. Static and dynamic tests of the mixtures were done. The mixtures were prepared with rates recommended for tank mixtures. A list with tested mixtures of plant protection products is presented in Table 3.6-1 below.

The physical properties of the tested aqueous mixture showed that BAS 768 00 F is physically compatible with 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 768 00 F is apparently chemically compatible with the tank mix partners described in table below.

The full report on physical and chemical compatibility of BAS 768 00 F can be found with the reference DocID 2022/2060754.

Table 3.6-1: Products tested in mixture with BAS 768 00 F.

Mixture number	BAS number	Trade name	Formulation	Content active ingredient	Comment
1	BAS 9164 1 F	Amistar	SC	250 g/l azoxystrobin	Compatible using agitator, shear test done, foaming occurs, consider using anti-foam agent
2	BAS 9314 7 F	Soratel	EC	250 g/l prothioconazole	Compatible using agitator, shear test done, foaming occurs, consider using anti-foam agent
3	BAS 751 00 F	Balaya	EC	100 g/l mefentrifluconazole 100 g/l pyraclostrobin	Compatible using agitator, shear test done, foaming occurs, consider using anti-foam agent
4	BAS 703 07 F	Priaxor EC	EC	75 g/l fluxapyroxad 150 g/l pyraclostrobin	Compatible using agitator, shear test done, foaming possible
5	BAS 752 03 F	Revytrex	EC	66.7 g/l fluxapyroxad 66.7 g/l mefentrifluconazole	Compatible using agitator, shear test done

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 768 00 F. “Double rinse Procedure” without any cleaning agent were tested. For the evaluation, the application was calculated with a concentration of 4,0 l/ha of the product, diluted in 100 L water/ ha. The results showed that after a two-stage cleaning (each step with 5 % water in relation to the total tank capacity) the amount of active substances carried over into a following application will be amounted 16,3 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 768 00 F makes the contamination in the immediately following application negligible. **Physical and chemical compatibility** The physical and chemical compatibility of BAS 768 00 F with 5 other mixtures of plant protection products was conducted and reported according to the ASTM method E 1518-05. A list with the 5 tested plant protection products/mixtures is presented in Table 3.6 1of dRR. Based on the static test (where the following parameters homogeneity were examined: foaming, pH – value (once), oiling, 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 768 00 F is chemically compatible with mentioned tank mix partners in the table.

RegPest model analysis

The majority of claimed uses, especially very important pathogens like *Zymoseptoria* in wheat, are supported by many more trials than EPPO requirements. However, efficacy against *Puccinia triticina* in wheat is not demonstrated by satisfying number of trials. Therefore, results of trials conducted in other EPPO zones were 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. Summary of these analysis is presented in Table 3.6-2 below. Detailed reports are available in separate document (BASF DocID 2022/2062260).

Table 3.6-2: Summary of reports on comparison of regions.

Zone where trial was conducted (x) and similarity to region in other zone(s) (% value)			Trial ID	Crop	Pathogen	Report on comparison of regions
N-E	**Mar**	**S-E**				
82%, 82%	86%, 87%	X	DEV-F-2022-HU-C02-A-01.0-HU-HU1-001 DEV-F-2022-HU-C02-A-01.0-HU-HU1-002	TRZAW	PUCCST	Del-Dunantul (Magyarorszag) and Sachsen-Anhalt (Deutschland) Del-Dunantul (Magyarorszag) and Wielkopolskie (Polska)
75%, 75% 82%, 81%	X		DEV-F-2021-DE-C29-A-05.0-DE-D02-C29	TRZAW	PUCCST	Köln (Deutschland) and Wielkopolskie (Polska) Köln (Deutschland) and Opolskie (Polska)
X	75%, 75% 82%, 81%		DEV-F-2021-PL-C44-A-01.0-PL-PLA-027 DEV-F-2022-PL-C59-A-02.0-PL-PLA-025	HORVX	PYRNTE PUCCHD	Köln (Deutschland) and Wielkopolskie (Polska) Köln (Deutschland) and Opolskie (Polska)
X	81%, 81% 88%, 87%		DEV-F-2021-PL-C43-A-01.0-PL-PLE-D03 DEV-F-2021-PL-C44-A-01.0-PL-PLE-D04	HORVX	PYRNTE RHYNSE PUCCHD	Kujawsko-Pomorskie (Polska) and Köln (Deutschland) Kujawsko-Pomorskie (Polska) and Mecklenburg-Vorpommern (Deutschland)
X	77%, 77% 80%, 79%		DEV-F-2021-PL-C43-A-01.0-PL-PLD-001	HORVX	PYRNTE	Slaskie (Polska) and Köln (Deutschland) Slaskie (Polska) and Mecklenburg-Vorpommern (Deutschland)

The minimum level of similarity between regions where trials are conducted and regions for which are used as supportive (region with high cereals production in Poland) is always above 75%. 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.
Results of comparison clearly indicate that trials from Hungary were conducted in agroclimatic conditions similar to conditions in the North-East EPPO zone and majority of the Maritime EPPO zone. Therefore, results of these trials can be used as supportive in countries in these two zones. Trial from Germany was conducted in agroclimatic conditions similar to those prevailing in Poland. Therefore, German trials can be used to support efficacy in Poland. The rule also works the other way around and Polish trials can be used to support efficacy in most of the Maritime zone countries.

3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Con.	Institute/ Organisation	Address	GEP DocID
CZ	Vyzkumny ustav RV	Drnovska 507 16106 Praha, Czech Republic	2017/1143414
DE	BASF SE	Agrarzentrum Limburgerhof Spreyerer Strasse 2 67117 Limburgerhof	2018/1238674 2020/2095366
	Hetterich Fieldwork GbR	Bambergerstraße Schwarzach-Düllstadt 97359	2019/2041586
	Lfi Bayern	Lange Point 10 Freising-Weihenstephan D-85354	2019/2043922
DK	AARHUS UNIVER-SITY	Department of Agroecology DK-4200 Slagelse	2020/2104176
	BASF A/S	KALVEBOD BRYGGE 45 2. S. 1560 COPENHAGEN V	2020/2079424
	VKST Field Trials	Fulbyvej 15, DK-4180 Soro	2020/2082988
FR	BASF Agro SAS	21 chemin des la sauvegarde 69134 Ecully	2019/1054949 2022/2000304
HU	BASF Hungária Kft.	Központi major. 6710 Szeged-Szentmihály	2022/2028777
IE	Teagasc	OakPark, Carlow, R93 XE12, Ireland	2020/2099299
	Crop Plot Trials	Ballinaparson, Buck Leary, T45 DX 96 Cork, Ireland	2021/2034662
PL	BASF Polska Sp. z o.o.	Al. Jerozolimskie 142 B 02-305 Warszawa	2011/1269204 2021/2012841
	IOR PIB Poznań	ul. Władysława Węgorka 20 60-318 Poznań	2011/1269209
	IPP-NRI Sosnicowice	ul. Gliwicka 29 44-153 Sośnicowice	2010/1226834
	SGS Polska Sp. z o.o.	Bema 83 01-233 Warsaw	2016/1350127
	Staphyt Sp. z o.o	ul. Ziębicka 2 60-164 Poznań	2011/1269203
LT	Institute of Agriculture	Instituto ave 1 Akademija, LT-58344	2020/2105312
	Sia Agrolab Baltic	Taikos g.4-3 Mazeikiai, LT-89166	2017/1014490
LV	LPPRC, Ltd.	Struktoru iela 14a Riga LV-1039	2016/1350437
	BASF SIA	Lambertu iela 33 B Marupe LV-2167	2020/2079667
UK	BASF Plc	WINDMILL AVENUE WOOLPIT Suffolk GL7 5PU	2018/1015310
	Scotland’s Rural Col-lege	West Mains Road Edinburgh EH9 3JG	2023/2002642

Appendix 1 Lists of data considered in support of the evaluation

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.	2023	Biological Assessment Dossier - BAS 768 00 F - Central Zone - zRMS: Poland 2023/2000942 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	BASF
KCP 6/1	Kryszczuk, A.	2023	Biological Assessment Dossier - BAS 768 00 F - Central Zone - zRMS: Poland - Update 2023/2033010 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	BASF
KCP 6.1/1	Kryszczuk A. and Er-ven T.	2022	Justification of the co-formulated mixture BAS 768 00 F for cereals. 2022/2060988 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 6.1/2	Anonymous	2012	Biological Assessment Dossier -Sulfur 80% WG - Central /Southern Zone - zRMS: Slovenia/France 2012/1218514 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T1/ SEPTTR/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2020-DE-C08-A-04.0-DE-D09-007 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T1/ SEPTTR/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2020-DE-C08-A-04.0-DE-D17-017 yes Unpublished	No	BASF
6.1	Anonymous	2020	VAD: T1 SOLUTION BENCHMARKING AFTER CTL LOSS / SEPTTR / WHEAT BASF Trial ID: DEV-F-2020-DE-C50-A-04.0-DE-D11-C50 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
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T1/ SEPTTR/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2020-EX-C08-V-04.0-DE-VTF-328 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION DE PRODUITS A BASE DE SOUFRE/T1-SEPTO OIDIUM/ BLE BASF Trial ID: DEV-F-2020-FR-C08-A-01.0-FR-FR2-220 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION DE PRODUITS A BASE DE SOUFRE/T1-SEPTO OIDIUM/ BLE BASF Trial ID: DEV-F-2020-FR-C08-A-01.0-FR-FRE-E10 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T1/ SEPTTR/ ERYSGT/ WHEAT BASF Trial ID: DEV-F-2020-PL-C08-A-02.1-PL-PL1-021 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T1/ SEPTTR/ ERYSGT/ WHEAT BASF Trial ID: DEV-F-2020-PL-C08-A-02.1-PL-PL8-019 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T1/ SEPTTR/ ERYSGT/ WHEAT BASF Trial ID: DEV-F-2020-PL-C08-A-02.1-PL-PLC-061 yes Unpublished	No	BASF
6.1	Anonymous	2020	EFFICACY OF DIFFERENT PRODUCTS / P. MILDEW (GLASSHOUSE) BASF Trial ID: DEV-F-2020-PL-CG2-A-02.0-PL-PLB-B19 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C03-A-05.0-DE-IHE-B09 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C05-A-05.0-DE-IHE-B10 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
6.1	Anonymous	2021	REG BAS 754 F MARITIME/ NORTH-EAST/ PYRNTR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C25-A-05.0-DE-D04-026 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 754 F MARITIME/ NORTH-EAST/ PYRNTR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C25-A-05.0-DE-D17-019 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 754 F F MARITIME/ NORTH-EAST/ PSDCHE/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C27-A-05.0-DE-D12-C27 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C29-A-05.0-DE-D02-C29 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C29-A-05.0-DE-D11-29A yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-DE-C29-A-05.0-DE-D11-29B yes Unpublished	No	BASF
6.1	Anonymous	2021	BAS 51615F AGAINST LEAFDISEASES / TRZAW BASF Trial ID: DEV-F-2021-DK-850-A-01.0-DK-DK1-220 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ SEPTTR/ WHEAT 21330-1 BASF Trial ID: DEV-F-2021-DK-C03-A-03.1-DK-DK0-001 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-DK-C05-A-03.1-DK-DK0-V01 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
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-DK-C29-A-03.1-DK-DK0-V01 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-EX-C29-V-04.0-DE-VTF-410 yes Unpublished	No	BASF
6.1	Anonymous	2021	VAD: T1 SOLUTION BENCHMARKING/ ERYSGR, PSDCHE, SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-EX-C50-V-04.0-DE-VTF-324 yes Unpublished	No	BASF
6.1	Anonymous	2021	VAD: T1 SOLUTION BENCHMARKING/ ERYSGR, PSDCHE, SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-EX-C50-V-04.0-DE-VTF-417 yes Unpublished	No	BASF
6.1	Anonymous	2021	BAS 754 F & BAS 768 F RAINFASTNESS / SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-EX-CBQ-V-04.0-DE-VTF-428 yes Unpublished	No	BASF
6.1	Anonymous	2021	BAS 754 F & BAS 768 F RAINFASTNESS / SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-EX-CBR-V-04.0-DE-VTF-427 yes Unpublished	No	BASF
6.1	Anonymous	2021	GAMME BASF / QUALITÉ / BLE BASF Trial ID: DEV-F-2021-FR-815-A-01.0-FR-FR2-226 yes Unpublished	No	BASF
6.1	Anonymous	2021	HOMOLO. DE BAS 768 F / DOUBLE APPLICATION / BLE / SEPTORIOSE BASF Trial ID: DEV-F-2021-FR-C05-A-01.0-FR-FRD-D14 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 754 F F MARITIME/ NORTH-EAST/ PSDCHE/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-LT-C27-A-03.1-LT-LT0-001 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
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-LV-C03-A-03.1-LV-AR2-730 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-LV-C03-A-03.1-LV-LV0-M06 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-LV-C05-A-03.1-LV-LV0-M07 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 754 F MARITIME/ NORTH-EAST/ PYRNTR/ WHEAT BASF Trial ID: DEV-F-2021-LV-C25-A-03.1-LV-LV0-M08 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-LV-C29-A-03.1-LV-LV0-A09 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C03-A-03.0-PL-PL8-025 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C05-A-03.0-PL-PL8-026 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C05-A-03.0-PL-PLA-016 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C05-A-03.0-PL-PLB-B07 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
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C29-A-03.0-PL-PL8-027 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C29-A-03.0-PL-PLA-017 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C29-A-03.0-PL-PLC-097 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ ERYSGR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C29-A-03.0-PL-PLK-004 yes Unpublished	No	BASF
6.1	Anonymous	2021	VAD: T1 SOLUTION BENCHMARKING/ ERYSGR, PSDCHE, SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-PL-C50-A-04.0-PL-PL8-034 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F MARITIME/ NORTH-EAST/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-UK-C03-A-01.0-UK-UK3-F10 yes Unpublished	No	BASF
6.1	Anonymous	2021	EVALUATION BAS 832 F NEW/ SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-UK-C04-B-02.0-IE-IE0-T02 yes Unpublished	No	BASF
6.1	Anonymous	2021	VAD: T1 SOLUTION BENCHMARKING/ ERYSGR, PSDCHE, SEPTTR/ WHEAT BASF Trial ID: DEV-F-2021-UK-C50-A-03.0-UK-UK3-F12 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ TRZAW/ SEPTTR/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-DE-C04-A-04.0-DE-D04-C04 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
6.1	Anonymous	2022	VARIOUS PRODUCTS / T2 DISEASES / SPELT BASF Trial ID: DEV-F-2022-DE-C10-A-04.0-DE-D12-PER yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ TRZAW/ ERYSGR/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-DE-C21-A-04.0-DE-D02-C21 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ TRZAW/ ERYSGR/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-DE-C21-A-04.0-DE-D11-C21 yes Unpublished	No	BASF
6.1	Anonymous	2022	VAD / PACK BAS 768F/ T1-T2/ BLE BASF Trial ID: DEV-F-2022-FR-C53-A-01.0-FR-FRE-E10 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 76500F DIFFERENT TANK-MIXES / T2 DISEASES / WHEAT BASF Trial ID: DEV-F-2022-HU-C02-A-01.0-HU-HU1-001 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 76500F DIFFERENT TANK-MIXES / T2 DISEASES / WHEAT BASF Trial ID: DEV-F-2022-HU-C02-A-01.0-HU-HU1-002 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ TRZAW/ SEPTTR/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-PL-C04-A-02.0-PL-PL8-025 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ TRZAW/ ERYSGR/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-PL-C21-A-02.0-PL-PL8-026 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ TRZAW/ SEPTTR/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-UK-C04-A-02.0-UK-UK3-M15 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
6.1	Anonymous	2022	VAD: BAS 768 F PACK OPTIONS / T1-T2 / WHEAT BASF Trial ID: DEV-F-2022-UK-C53-A-03.0-UK-UK3-Z12 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F PACK OPTIONS / T1-T2 / WHEAT BASF Trial ID: MKD-F-2022-DE-002-A-02.0-DE-D08-002 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F PACK OPTIONS / T1-T2 / WHEAT BASF Trial ID: MKD-F-2022-DE-002-A-02.0-DE-D09-224 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T2/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2020-DE-C42-A-04.0-DE-D04-023 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T2/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2020-DE-C42-A-04.0-DE-D07-028 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T2/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2020-DE-C42-A-04.0-DE-D09-009 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVALUATION OF SULFUR CONCEPTS FOR T2/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2020-EX-C42-V-04.0-DE-VTF-322 yes Unpublished	No	BASF
6.1	Anonymous	2020	EVAL. DE PRODUITS À BASE DE SOUFRE /ORGE/ RAMULARIOSE BASF Trial ID: DEV-F-2020-FR-C42-A-01.0-FR-FRZ-Z61 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F & BAS 754 F MARITIME/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2021-AT-C45-A-03.0-AT-AT1-011 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
6.1	Anonymous	2021	REG BAS 754 F & 765 F MARITIME/ SOUTH-EAST/ ERYSGH/ BARLEY BASF Trial ID: DEV-F-2021-AT-C48-A-03.0-AT-AT1-010 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 754 F & 765 F MARITIME/ SOUTH-EAST/ ERYSGH/ BARLEY BASF Trial ID: DEV-F-2021-CZ-C48-A-03.0-CZ-CZ1-AHN yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F & BAS 754 F MARITIME/RAMUCC/ BARLEY BASF Trial ID: DEV-F-2021-DE-C45-A-05.0-DE-D07-023 yes Unpublished	No	BASF
6.1	Anonymous	2021	CONTROL OF RAMULARIA COLLO-CYGNI IN BARLEY BASF Trial ID: DEV-F-2021-DK-386-A-01.0-DE-DE0-004 yes Unpublished	No	BASF
6.1	Anonymous	2021	CONTROL OF RAMULARIA COLLO-CYGNI IN BARLEY BASF Trial ID: DEV-F-2021-DK-386-A-01.0-DK-DK1-001 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F & BAS 754 F MARITIME/ RAMUCC/ BARLEY 21381-1 BASF Trial ID: DEV-F-2021-DK-C45-A-03.1-DK-DK0-002 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F & BAS 754 F MARITIME/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2021-EX-C45-V-04.0-DE-VTF-315 yes Unpublished	No	BASF
6.1	Anonymous	2021	HOMOLO DE BAS 768 F ET BAS 754 F/ORGE/ RAMULARIOSE BASF Trial ID: DEV-F-2021-FR-C45-A-01.0-FR-FR4-485 yes Unpublished	No	BASF
6.1	Anonymous	2021	HOMOLO DE BAS 768 F ET BAS 754 F/ORGE/ RAMULARIOSE BASF Trial ID: DEV-F-2021-FR-C45-A-01.0-FR-FR6-659 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
6.1	Anonymous	2021	HOMOLO DE BAS 768 F ET BAS 754 F/ORGE/ RAMULARIOSE BASF Trial ID: DEV-F-2021-FR-C45-A-01.0-FR-FRF-F05 yes Unpublished	No	BASF
6.1	Anonymous	2021	EVALUATION BAS 752 F / RAMUCC/ BARLEY BASF Trial ID:DEV-F-2021-PL-C43-A-01.0-PL-PLD-001 yes Unpublished	No	BASF
6.1	Anonymous	2021	EVALUATION BAS 752 F / RAMUCC/ BARLEY BASF Trial ID: DEV-F-2021-PL-C43-A-01.0-PL-PLE-D03 yes Unpublished	No	BASF
6.1	Anonymous	2021	EVALUATION BAS 752 F / RHYNSE/ BARLEY BASF Trial ID: DEV-F-2021-PL-C44-A-01.0-PL-PLA-027 yes Unpublished	No	BASF
6.1	Anonymous	2021	EVALUATION BAS 752 F / RHYNSE/ BARLEY BASF Trial ID: DEV-F-2021-PL-C44-A-01.0-PL-PLE-D04 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F & BAS 754 F MARITIME/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2021-UK-C45-A-01.0-IE-IE0-Y02 yes Unpublished	No	BASF
6.1	Anonymous	2021	REG BAS 768 F & BAS 754 F MARITIME/ RAMUCC/ BARLEY BASF Trial ID: DEV-F-2021-UK-C45-A-01.0-UK-UK3-L16 yes Unpublished	No	BASF
6.1	Anonymous	2021	CONTROL OF RAMULARIA COLLO-CYGNI IN BARLEY BASF Trial ID: DEV-F-2021-DK-386-A-01.0-SX-SX0-003 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ HORVW/ RAMUCC/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-DE-C41-A-04.0-DE-D09-206 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
6.1	Anonymous	2022	BAS 833 F/ HORVW/ RHYNSE/ MARITIME BASF Trial ID: DEV-F-2022-DE-C44-A-04.0-DE-D09-207 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 833 F/ HORVW/ RHYNSE/ MARITIME BASF Trial ID: DEV-F-2022-DE-C44-A-04.0-DE-D17-020 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 833 F/ HORVW/ PUCCHD/ MARITIME BASF Trial ID: DEV-F-2022-DE-C46-A-04.0-DE-D04-C46 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F/ HORVW/ RAMUCC/ RATIO JUSTIFICATION BASF Trial ID: DEV-F-2022-EX-C41-V-04.0-DE-VTF-340 yes Unpublished	No	BASF
6.1	Anonymous	2022	HOMOLO. DE BAS 833 F & BAS 754 F / ORGE / RHYNCOSPORIOSE BASF Trial ID: DEV-F-2022-FR-C44-A-01.0-FR-FR4-488 yes Unpublished	No	BASF
6.1	Anonymous	2022	VAD /ETUDE PACK BAS 768 F /ORGE/ MALADIES FOLIAIRES BASF Trial ID: DEV-F-2022-FR-C59-A-01.0-FR-FRE-E13 yes Unpublished	No	BASF
6.1	Anonymous	2022	VAD: BAS 768 F PACK OPTIONS / FOLIAR DISEASES / BARLEY BASF Trial ID: DEV-F-2022-PL-C59-A-02.0-PL-PLA-025 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 833 F/ HORVW/ RHYNSE/ MARITIME BASF Trial ID: DEV-F-2022-UK-C44-A-02.0-IE-IE0-Y02 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 833 F/ HORVW/ PUCCHD/ MARITIME BASF Trial ID: DEV-F-2022-UK-C46-A-02.0-UK-UK3-K18 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
6.1	Anonymous	2022	BAS 768 F PACK OPTIONS / FOLIAR DISEASES / BARLEY BASF Trial ID: MKD-F-2022-DE-021-A-02.0-DE-D07-024 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 768 F PACK OPTIONS / FOLIAR DISEASES / BARLEY BASF Trial ID: MKD-F-2022-DE-021-A-02.0-DE-D09-213 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 754 F, 765 F & 768 F / TRITICALE BASF Trial ID: DEV-F-2021-DE-CT1-A-05.0-DE-D04-028 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F & BAS 754 F / TRITICALE BASF Trial ID: DEV-F-2021-DE-CT2-A-05.0-DE-D09-112 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F & BAS 754 F / TRITICALE BASF Trial ID: DEV-F-2021-DE-CT2-A-05.0-DE-D17-020 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 754 F, 765 F & 768 F / TRITICALE BASF Trial ID: DEV-F-2021-DK-CT1-A-03.1-DK-DK0-V01 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 754 F, 765 F & 768 F / TRITICALE BASF Trial ID: DEV-F-2021-DK-CT1-A-03.1-DK-DK1-210 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 754 F, 765 F & 768 F / TRITICALE BASF Trial ID: DEV-F-2021-LT-CT1-A-03.1-LT-LT0-002 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F / TRITICALE BASF Trial ID: DEV-F-2021-PL-CT2-A-03.0-PL-PL8-028 yes Unpublished	No	BASF

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6.1	Anonymous	2021	REGISTRATION BAS 768 F / TRITICALE BASF Trial ID: DEV-F-2021-PL-CT2-A-03.0-PL-PLB-B09 yes Unpublished	No	BASF
6.1	Anonymous	2021	REGISTRATION BAS 768 F / TRITICALE BASF Trial ID: DEV-F-2021-PL-CT2-A-03.0-PL-PLD-001 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 833 F/ TTLWI/ SEPTTR/ PUCCST/ REGISTRATION BASF Trial ID: DEV-F-2022-DE-CT1-A-04.0-DE-D04-024 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 833 F/ TTLWI/ SEPTTR/ PUCCST/ REGISTRATION BASF Trial ID: DEV-F-2022-DK-CT1-B-03.0-DK-DK0-V01 yes Unpublished	No	BASF
6.1	Anonymous	2022	HOMOLO. BAS 833F BAS 754F BAS 768F/ TRITICALE / EFFICACITE BASF Trial ID: DEV-F-2022-FR-CT1-A-01.0-FR-FRE-E15 yes Unpublished	No	BASF
6.1	Anonymous	2022	BAS 833 F/ TTLWI/ SEPTTR/ PUCCST/ REGISTRATION BASF Trial ID: DEV-F-2022-LT-CT1-A-03.0-LT-LT0-001 yes Unpublished	No	BASF
KCP 6.2/1	Wiraszka D.	2010	GEP Certificate - Institute of Plant Protection - National Research Institute in Poznan - Sosnicowice Branch - Pesticide Efficacy Testing Department, Poland 2010/1226834 Instytut Ochrony Roslin - Panstwowy Instytut Badawczy, Sosnicowice, Poland no Unpublished	No	BASF
KCP 6.2/2	Klos T.	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

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KCP 6.2/3	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 6.2/4	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	Cudere R.	2016	GEP Certificate - LPPRC, Ltd. 2016/1350437 LPPRC, Ltd., Struktoru iela 14a, Riga LV-1039 no Unpublished	No	BASF
KCP 6.2/6	Łączyński T.	2016	GEP Certificate - SGS Polska Sp. z o.o. 2016/1350127 SGS Polska Sp. z o.o., Bema 83 01-233 Warsaw no Unpublished	No	BASF
KCP 6.2/7	Fedotovas S.	2017	GEP Certificate - UAB Agrolab Baltic 2017/1014490 UAB Agrolab Baltic, Taikos g.4-3, Mazeikiai, LT-89166 no Unpublished	No	BASF
KCP 6.2/8	Minar P.	2017	GEP Certificate - Vyzkumny ustav RV 2017/1143414 Vyzkumny ustav RV, Drnovska 507, 16106 Praha, Czech Republic no Unpublished	No	BASF
KCP 6.2/9	Anonymous	2018	GEP Certificate - BASF plc, United Kingdom 2018/1015310 BASF plc, Cheadle Cheshire SK8 6QG, United Kingdom no Unpublished	No	BASF

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KCP 6.2/10	Anonymous	2018	GEP Certificate - Scotland's Rural College (SRUC) 2023/2002642 West Mains Road, Edinburgh, EH9 3JG no Unpublished	No	BASF
KCP 6.2/11	Reineck W.	2018	GEP Certificate - BASF SE Agrarzentrum Limburgerhof, Germany 2018/1238674 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.2/12	Cotillon A.C.	2019	GEP Certificate - BASF Agro SAS Ecully France 2019/1054949 BASF Agro SAS, Ecully, France no Unpublished	No	BASF
KCP 6.2/13	Maier J.	2019	GEP Certificate - Hetterich Fieldwork GbR 2019/2041586 Hetterich Fieldwork GbR, Bambergerstraße, Schwarzach-Düllstadt 97359 no Unpublished	No	BASF
KCP 6.2/14	Maier J.	2019	GEP Certificate - Hetterich Fieldwork GbR 2019/2043922 Institute for Plant Protection of the Bavarian State Research Center for Agriculture, Lange Point 10, Freising-Weihenstephan D-85354 no Unpublished	No	BASF
KCP 6.2/15	Anonymous	2020	GEP Certificate - Teagasc 2020/2099299 Teagasc, OakPark, Carlow, R93 XE12, Ireland no Unpublished	No	BASF
KCP 6.2/16	Brodsgaard H.	2020	GEP Certificate - AARHUS UNIVERSITY 2020/2104176 AARHUS UNIVERSITY, Dep. of Agroecology, Flakkebjerg DK-4200 Slagelse no Unpublished	No	BASF

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KCP 6.2/17	Brodsgaard H.	2020	GEP Certificate - BASF A/S 2020/2079424 BASF A/S, KALVEBOD BRYGGE 45 2., DK-1560 COPENHAGEN V no Unpublished	No	BASF
KCP 6.2/18	Brodsgaard H.	2020	GEP Certificate - VKST Field Trials 2020/2082988 VKST Field Trials, Fulbyvej 15, DK-4180 Soro no Unpublished	No	BASF
KCP 6.2/19	Cudere R.	2020	GEP Certificate - BASF SIA 2020/2079667 BASF SIA, Lambertu iela 33 B, Marupe LV-2167 no Unpublished	No	BASF
KCP 6.2/20	Fedotovas S.	2020	GEP Certificate - Institute of Agriculture 2020/2105312 Institute of Agriculture, Instituto ave 1, Akademija, LT-58344 no Unpublished	No	BASF
KCP 6.2/21	Reineck W.	2020	GEP Certificate - BASF SE 2020/2095366 BASF SE, Agrarzentrum Limburgerhof, Spreyerer Strasse 2, 67117 Limburgerhof no Unpublished	No	BASF
KCP 6.2/22	Anonymous	2021	GEP Certificate - Crop Plot Trials 2021/2034662 Crop Plot Trials, Ballinaparson, Buck Leary, T45 DX 96 Cork, Ireland no Unpublished	No	BASF
KCP 6.2/23	Chodkowski A.	2021	GEP Certificate - BASF Polska Sp. z.o.o., Warsaw, Poland 2021/2012841 BASF Polska Sp z o.o., Warsaw, Aleje Jerozolimskie 142 B, Poland yes Unpublished	No	BASF

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KCP 6.2/24	Girel-Zajdenweber A.	2022	GEP Certificate - BASF France SAS, Division Agro 2022/2000304 ASF France SAS, 21 chemin des la sauvegarde, 69134 Ecully yes Unpublished	No	BASF
KCP 6.2/25	Vincze E.	2022	GEP Certificate - BASF Hungária Kft. 2022/2028777 BASF Hungária Kft., Központi major., Szeged-Szentmihály 6710, Hungary yes Unpublished	No	BASF
KCP 6.2/26	Koza et al.	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 yes Unpublished	No	BASF
KCP 6.2/27	Anonymous	2022	BAS 768 00 F - summary report on comparison of regions 2022/2062260 BASF Polska Sp. z o.o., Warszawa, Poland no Unpublished	No	BASF
KCP 6.2/28	Anonymous	2022	BAS 768 00 F - single trial results 2022/2062259 <none>, <none>, <none> yes Unpublished	No	BASF
KCP 6.2/29	Anonymous	2022	BAS 768 00 F preliminary section- single trial results 2022/2062261 <none>, <none>, <none> yes Unpublished	No	BASF
KCP 6.2/30	Caudron, C.	2023	BAS 768 00 F Single trial report no disease 2023/2032202 <none> yes Unpublished	No	BASF

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KCP 6.3/1	Stammler G.	2022	BAS 768 00 F Resistance risk analysis 2022/2060986 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.4.5/1	Ben Issa R.	2022	Bread-making trials - BAS 768_Single trial reports 2022/2060989 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.4.5/2	Gless A.E.	2022	Study of unintentional effects of BAS 76800 F product applied on winter and spring barley, harvest 2021, on malt and beer quality and process. 2022/2032437 I.F.B.M., 7 ruedu Bois de la Champelle, 54500 Vandoeuvre-les-Nancy, France no Unpublished	No	BASF
KCP 6.4.6/1	Schuster A. and West-phalen A.	2022	Germination trials with harvested grains from wheat and barley treated with BAS 768 00 F 2022/2037349 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.5.1/1	Brahm L. and Fries H.J.	2021	Cultivation of different crops in substrate treated with BAS 768 00 F (succeeding crop study) 2021/2017632 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.5.2/1	Maleck A. and Dommes A.B.	2021	Effect of BAS 768 00 F on vegetative vigour of several species of terrestrial plants under greenhouse condi-tions 2021/2014237 Agro-check Dr. Teresiak & Erdmann GbR, Dorfstr. 15, 16833 Lentzke, Germany yes Unpublished	No	BASF
KCP 6.6/1	Schlotterbeck U.	2021	BAS 768 00 F: Effectiveness of procedures for cleaning application equipment and protective clothing 2021/2034436 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

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KCP 6.6/2	Popp C. and Kreucher R.	2022	Physical and Chemical Compatibility in Aqueous Tank Mixtures of BAS 768 00 F 2022/2060754 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

There are no already evaluated studies submitted with this Section