

REGISTRATION REPORT
Part B
Section 3
Efficacy Data and Information
Concise summary

Product code: BAS 736 00 F

Product name(s): **Miralon**

Chemical active substance(s):

Fluxapyroxad, 50 g/L

Azoxystrobin, 75 g/L

Central Zone
Zonal Rapporteur Member State: Poland

CORE ASSESSMENT
(new authorization)

Applicant: BASF
Submission date: 12/2021
Evaluation date: September 2022
MS Finalisation date: January 2023

Version history

When	What
12/2021	Initial dRR - BASF DocID 2020/2101111
09/2022	Version evaluated by zRMS
01/2023	Version revised to take into account comments of cMSs and the applicant

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

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

This is the version of dRR from December 2021, submitted by applicant in the framework of Article 33 of Regulation (EC) 1107/2009. The original text provided by applicant has been retained for transparency. The applicant's text is commented by zRMS and the comments and conclusions are placed in commenting boxes shaded in grey at the end of each chapter. Amendments in the text are highlighted in yellow.

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

Abstract

This evaluation concerns the registration of Miralon (product code: BAS 736 00 F), containing two active substances: fluxapyroxad (50 g/L) and azoxystrobin (75 g/L) for cereal diseases control in field uses in EU Central zone. The zRMS is Poland and cMS are Germany, Austria, Belgium, the Netherlands, Republic of Ireland, Czech Republic (Maritime zone) Hungary, Slovenia, Slovakia and Romania (S-E zone).

ZRMS confirms that the trials presented in this dossier were carried out by contractor companies and Official Research Institutes, in accordance with the principles of Good Experimental Practice (GEP) and with relevant EPPO guidelines or CEB methods. The assessment was made in accordance with the Uniform Principles.

Preliminary tests the applicant presented the data on the efficacy of single use of azoxystrobin (Amistar) and fluxapyroxad (Imtrex) in wheat and barley and compared the efficacy of single use with the mixtures of those active substances, at different ratios and also with the ratio included in BAS 736 00 F. The results showed a good to excellent control of diseases in wheat and barley. The efficacy of BAS 736 00 F at label rate, was higher or comparable to the efficacy of commercial reference products.

Minimum Effective Dose of BAS 736 00 F for cereals diseases control was determine on the base of 194 efficacy trials (86 in wheat, 67 in barley, 21 in rye and 20 in triticale), conducted across the Europe. The fungicide was tested with the target and reduced dose rates. It was concluded that BAS 736 00 F (fluxapyroxad – 50 g/L + Azoxystrobin – 150 g/L) at the targeted rate of 2.0 L/ha provided the optimum and most consistent control of the key diseases of tested cereal crops and should be considered as Minimum effective dose rate in cereals. For some countries the lower rate of BAS 736 00 F can be recommended, also.

Efficacy

The efficacy of BAS 736 00 F was tested in 106 trials in wheat, 77 trials in barley; 21 in rye and 20 trials in triticale. The efficacy trials were carried out with diseases and without disease infection. In the trials 69 varieties were tested in winter wheat, 2 in spring wheat, 38 in winter barley, 18 in spring barley; 13 in winter rye, 16 in winter triticale and 2 in oat. The data show a sufficient level of infestation by diseases to evaluate the efficacy of BAS 736 00 F in cereal crops. The infestation in untreated plots in all crops was above 5%, so presented data may be recognized as valid.

The results showed a good control of diseases (in some cases medium) on wheat, barley, rye, triticale and oat by BAS 736 00 F applied at the rate of 2.0 L/ha, under a wide range of conditions. The efficacy of tested product was higher than of the reference products. ZRMS considers that the data provided support the following uses:

- in wheat: powdery mildew (*Erysiphe graminis* (*Blumeria graminis* f.sp. *tritici*)), septoria leaf blotch (*Zymoseptoria tritici*), brown rust (*Puccinia triticina*), yellow rust (*Puccinia striiformis*) and tan spot (*Pyrenophora tritici-repentis*);
- in barley: powdery mildew (*Blumeria graminis* f.sp. *hordei*), net blotch (*Pyrenophora teres*), leaf scald (*Rhynchosporium secalis*), ramularia leaf spot (*Ramularia collo-cygni*) and leaf rust (*Puccinia hordei*).
- in rye: leaf scald (*Rhynchosporium secalis*) and leaf rust (*Puccinia recondita*).

- in triticale: powdery mildew (*Blumeria graminis*), septoria leaf (*Zymoseptoria tritici*) and rusts (*Puccinia recondita* and *Puccinia striiformis*).
- in oat: powdery mildew (*Blumeria graminis* f.sp. *avenae*) and rust (*Puccinia coronata*) – the number of data with oat is not sufficient, so, to support the registration of BAS 736 00 F for control, cMS can extrapolate the data from another crops or authorize this fungicide as minor use.

For most diseases, the applicant provided the required number of trials, while for some pathogens the number of data was insufficient or were not submitted at all, i.e. in wheat for *Puccinia striiformis* and *Pyrenophora tritici-repentis* in South-East zone, for *Erysiphe graminis* (*Blumeria graminis*) in North-East and South-East zones; in barley for *Puccinia hordei* in South-East zone, for *Rhynchosporium secalis* and *Ramularia collo-cygni* in North-East and South-East zones and for *Blumeria graminis* in North-East zone; in rye for *Puccinia recondita* and *Rhynchosporium secalis* in South-East zone; in triticale for *Septoria* species and *Puccinia recondita* in South-East zone for *Puccinia striiformis* and *Blumeria graminis* in North-East and South-East zones and in oats for *Puccinia coronata* and *Blumeria graminis* in all zones.

For pathogens with insufficient number of the trials in zone, the missing data may be extrapolate from another zone to fillfull the registration requirements or extrapolate from another crops - the efficacy data can be extrapolated from wheat to triticale and rye, according to EPPO extrapolation table 14/20152. The decision on possiblde registration and extrapolation should be taken by cMS.

The yield from efficacy trials with diseases. In the trials the parameters such as: the yield, the thousand grain weight and the hectolitre weight were determined. The results were collected from the efficacy trials in the presence of diseases. The yield was determined in 105 efficacy trials in wheat, 75 trials in barley, 21 trials in rye, 20 trials in triticale and 3 trials in oat. The thousand grain weight was determined in 81 trials in wheat, 60 trials in barley, 19 trials in rye, 18 trials in triticale and 3 trials in oat. The hectolitre weight was determined in 95 trials in wheat, 69 trials in barley, 19 trials in rye, 19 trials in triticale and 3 in oat. The yield and quality data were collected from the trials sprayed with BAS 736 00 F at the target rate of 2.0 L/ha and the reduced dose rate of 1.2 L/ha, at the growth stages of cereals between BBCH 31 and 72, in water volume ranged between 100-300 L/ha.

BAS 736 00 F did not affect negatively on cereals yields and their quality (the thousand grain weight and hectolitre weight) under a wide range of environmental conditions. The tested parameters of wheat, barley and rye, treated with BAS 736 00 F, in the vast majority were higher or on the same level than that of reference product while in triticale and oat in some cases were slightly reduced or at the same level.

Risk of possible occurrence of the development of resistance. The applicant provided a detailed description of both active substances included in BAS 736 00 F, their mode of action, discussed the risk of resistance, presented known cases of resistance to individual active substances used as a single products and a management strategy. The modified risk and the resistance management strategy proposed by the applicant seems to be sufficient to manage the risk to an acceptable level. This strategy is in line with recommendations of the HRAC and there is no need of any additional specific measures to avoid resistance. The full recommendations for minimize the risk of resistance development on fluxapyroxad and azoxystrobin, should be included in the label of tested product.

Phytotoxicity to host crop. The selectivity of BAS 736 00 F (Miralon) was assessed in all efficacy trials with or without diseases: in total of 113 trials in wheat, 82 in barley, 21 in rye, 21 in triticale and 6 in oat. The level of infestation by pathogens was considered as acceptable to validate the trials. The results of the trials both with and without diseases did not show any phytotoxicity of tested fungicide to all tested cereal crops. It should be concluded that BAS 736 00 F at the target dose rate, in accordance with GAP table, can be considered as highly selective to wheat, barley, rye, triticale and oats.

The yield from the trials without disease. The applicant submitted the yield data from disease free trials (including the trials with very low infection below the minimum infection threshold) carried out in wheat (Maritime EPPO zone - 6 trials, N-E zone - 1 trial), in barley (Maritime zone - 4 trials, N-E zone - 1 trial) in triticale (N-E zone - 1 trial) and in oats (Maritime zone - 3 trials in UK). BAS 736 00 F at the proposed label rate of 2.0 L/ha has no negative effect on the yield of wheat, barley and triticale. The yield of wheat and barley was higher than both from untreated plots and treated by standard product, while in triticale was comparable to untreated and to the standard.

Effect on the quality of plants or plant products. In the trials with no or very low symptoms of diseases

the thousand grain weight and hectolitre weight in harvested wheat, barley, triticale and oat grains were determined. The results of the trials with tested crops, treated with BAS 736 00 F at the rate of 2 L/ha demonstrate no negative impact on the thousand grains weight and the hectolitre weight in comparison to the untreated. The data were similar or higher to those obtained from the reference product.

Effects on transformation processes. The impact of BAS 736 00 F applied at the rate of 2.0 L/ha on bread making and brewing study was performed. The studies and analysis confirm that BAS 736 00 F has no negative effect on wheat quality and processing procedures and no negative impact on brewing.

Impact on treated plants or plant products to be used for propagation. In 6 trials with winter wheat and 5 trials with winter barley carried out in a greenhouse chamber, the grains germination capacity was tested. The germination of seeds (normal, abnormal and not germinated) collected from the trials with wheat and barley, treated twice by BAS 736 00 F at the rate of 2.0 L/ha, was at the same level or even higher than from untreated. The results confirm that tested product did not affect the seed germination.

Impact on succeeding crops. The germination and growth of different crops, grown in substrate treated with BAS 736 00 F has been evaluated in pot trials in the glasshouse, in order to simulate the replanting of various crops following a field failure of a crop treated with BAS 736 00 F. In the studies the crop species such as: sugar beet, oilseed rape, carrot, sunflower, winter barley, pea, potato, winter wheat, broad bean and maize were sown five weeks after substrate application. BAS 736 00 F was incorporated with the substrate at the rate of twice higher than on the label. The phytotoxicity, the germination rate and the plant height in cm (for monocots) and plant weight (fresh matter) in g/plant for all crops were measured at GS 12. BAS 736 00 F did not have any negative impact on the crops tested for replanting crops. The parameters of crops grown in substrate treated with BAS 736 00 F were not lower than of the untreated substrate.

Impact on other plants including adjacent crops. In a vegetative vigor test six species of dicotyledonous plants (carrot, lettuce, oilseed rape, cabbage, soya bean, tomato) and four species of monocotyledonous plants (onion, ryegrass, wheat, corn) were exposed to BAS 736 00 F to evaluate potential for adverse effects. The data did not show a negative effect of BAS 736 00 F on tested crops.

The proposed label claim: the application of BAS 736 00 F (Miralon) at the rate of 2.0 L/ha (fluxapyroxad – 100 g/ha + azoxystrobin – 150 g/ha) (in some countries lower rates) for diseases control in wheat, barley, triticale, rye and oat. This fungicide should be recommended as foliar application at maximum of two treatments, at the growth stages between BBCH 30 and 69, with water volume from 100 to 300 L/ha. In some countries the dose rate of tested fungicide may be reduced.

ZRMS not recommend the BAS 736 00 F registration for diseases control in oat, in Poland.

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
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Re- marks : e.g. g saf- ener/sy nergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval be- tween applications (days)	kg or L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	DE, AT, BE, NL, IE, PL	wheat TRZAW, TRZAS TRZDU, TRZSP	F	Zymoseptoria tritici – SEPTTR Puccinia triticina – PUCCRT Puccinia striiformis – PUCST Pyrenophora tritici-repentis – PYRNTR Blumeria graminis – ERYSGR	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
2	DE, AT, BE, NL, IE	barley HORVW HORVS	F	Pyrenophora teres – PYRNTE R. secalis – RHYNSE R. collo-cygni – RAMUCC Puccinia hordei – PUCCHD Blumeria graminis - ERYSGR	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150b) 0.200 / 0.300	100 - 300	35	
3	DE, AT, BE, NL, IE, PL	rye SECCW SECCS SECCE	F	R. secalis – RHYNSE Puccinia recondita – PUCCRE	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
4	DE, AT, BE, NL, IE, PL	triticale TTLWI TTLISO	F	Septoria spp. – SEPTSP Puccinia recondita – PUCCRE Puccinia striiformis – PUCST Blumeria graminis – ERYSGR	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
5	DE, AT, BE, NL, IE	oat AVESA	F	Blumeria graminis – ERYSGR Puccinia coronata – PUCCCA	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Re- marks : e.g. g saf- ener/sy nergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval be- tween applications (days)	kg or L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
6	PL	barley HORVW HORVS	F	Pyrenophora teres – PYRNTE R. secalis – RHYNSE Puccinia hordei – PUCCHD R. collo-cygni – RAMUCC	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 2.00 b) 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
7	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP	F	Zymoseptoria tritici – SEPTTR Puccinia triticina – PUCCRT Puccinia striiformis – PUCST Pyrenophora tritici-repentis – PYRNTR	Spraying (SP)	30 - 69	a) 1 b) 1		a) 1.20 - 2.00 b) 1.20 - 2.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35	
8	CZ	barley HORVW HORVS	F	Pyrenophora teres – PYRNTE R. collo-cygni – RAMUCC	Spraying (SP)	30 - 69	a) 1 b) 1		a) 1.20 - 2.00 b) 1.20 - 2.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35	
9	CZ	rye SECCW SECCS SECCE	F	R. secalis – RHYNSE Puccinia recondita – PUCCRE	Spraying (SP)	30 - 69	a) 1 b) 1		a) 1.20 - 2.00 b) 1.20 - 2.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35	
10	CZ	triticale TTLWI TTLSO	F	Septoria spp. – SEPTSP Puccinia recondita – PUCCRE Puccinia striiformis – PUCST	Spraying (SP)	30 - 69	a) 1 b) 1		a) 1.20 - 2.00 b) 1.20 - 2.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35	
11	CZ	oat AVESA	F	Puccinia coronata – PUCCCA	Spraying (SP)	30 - 69	a) 1 b) 1		a) 1.20 - 2.00 b) 1.20 - 2.00	a) 0.100 / 0.150 b) 0.100 / 0.150	100 - 300	35	

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No. ^(e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Re- marks : e.g. g saf- ener/sy nergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval be- tween applications (days)	kg or L prod- uct / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
12	HU, SI, SK, RO	wheat TRZAW, TRZAS TRZDU, TRZSP	F	Zymoseptoria tritici – SEPTTR Puccinia triticina – PUCCRT Puccinia striiformis – PUC CST	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 1.00 - 2.00 b) 1.00 - 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
13	HU, SI, SK, RO	barley HORVW HORVS	F	Pyrenophora teres – PYRNTE R. collo-cygni – RAMUCC	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 1.00 - 2.00 b) 1.00 - 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
14	HU, SI, SK, RO	rye SECCW SECCS SECCE	F	R. secalis – RHYNSE Puccinia recondita – PUCCRE	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 1.00 - 2.00 b) 1.00 - 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
15	HU, SI, SK, RO	triticale TTLWI TTL SO	F	Septoria spp. – SEPTSP Puccinia recondita – PUCCRE Puccinia striiformis – PUC CST	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 1.00 - 2.00 b) 1.00 - 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	
16	HU, SI, SK, RO	oat AVESA	F	Puccinia coronata – PUCCCA	Spraying (SP)	30 - 69	a) 2 b) 2	21	a) 1.00 - 2.00 b) 1.00 - 4.00	a) 0.100 / 0.150 b) 0.200 / 0.300	100 - 300	35	

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

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

Column 15: zRMS conclusion.

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

3.2 Efficacy data (KCP 6)

Introduction

The biological assessment dossier summarizes the biological activity of the plant protection product BAS 736 00 F containing the active substances fluxapyroxad (50 g/L) and azoxystrobin (75 g/L). BAS 736 00 F as a combination of fluxapyroxad and azoxystrobin is a powerful fungicide product for the control of cereal diseases.

The core Biological Assessment Dossier contains all information necessary for the efficacy evaluation of BAS 736 00 F in the following countries in the Central zone: Austria, Belgium, the Czech Republic, Germany, Hungary, Ireland, the Netherlands, Poland, Romania, Slovenia and Slovakia. The zonal rapporteur member state is Poland. A separate submission will be done in the United Kingdom.

Description of active substances

BAS 736 00 F is a foliar fungicide (plant protection product) containing two active substances: fluxapyroxad (50 g/L) and azoxystrobin (75 g/L).

Mode of action

Fluxapyroxad is a member of the fungicide group succinate dehydrogenase inhibitors (SDHI) and its mode of action at the molecular level is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain (FRAC Code 7). Like other complexes of the respiratory chain, this enzyme is a component of the inner mitochondrial membrane.

It consists of four nucleus encoded sub-units (SDH A, B, C, D). Two of these polypeptides (SDH C, D) anchor the complex in the membrane whilst the others project into the mitochondrial matrix where they catalyse the oxidation of succinate to fumarate as part of the tricarboxylic acid (TCA) cycle). The electrons so released are channelled into the electron transport chain via the co-substrate ubiquinol.

The lipophilic, hydrophilic and water-soluble properties of fluxapyroxad lead to a balanced systemic distribution within the crop. Applied to the leaf surface, the compound quickly forms a depot within the wax layer from where it is constantly released and acropetally translocated. This behaviour also helps to protect leaf areas not directly covered by the applied spray.

Although classified as a cellular respiration inhibitor, a class mainly known for their preventative properties, fluxapyroxad shows in addition excellent curative and long-lasting efficacy.

Fluxapyroxad is effective on a large number of pathogens belonging to the following main groups: ascomycetes, basidiomycetes, deuteromycetes and zygomycetes. In cereals, fluxapyroxad is particularly active on *Septoria*, rusts, net blotch, *Rhynchosporium*, *Ramularia*, powdery mildew and eyespot.

Azoxystrobin

Azoxystrobin is a systemic, broad-spectrum fungicide belonging to the class of methoxyacrylates, which are derived from the naturally occurring strobilurins. It demonstrates a very broad spectrum of activity and is active against fungal pathogens from all four taxonomic groups, the Oomycetes, Ascomycetes, Deuteromycetes and Basidiomycetes. Azoxystrobin shows a good systemic distribution within the plant (acropetal).

The mode of action is the inhibition of mitochondrial respiration (inhibition of Complex III: cytochrome bc1 (ubiquinol oxidase) at the Qo site (cyt b gene), FRAC Code 11). Azoxystrobin acts immediately on the target mode of action and there is no time delay for efficacy.

Azoxystrobin binds to the protein cytochrome b, which plays a vital role in converting chemical energy from food into a form that the fungus cells can use. By preventing cytochrome b from working correctly, the fungi run out of energy and die. This protein target is universal across fungi, so azoxystrobin can be used against all classes of fungal pathogens, including those fungi associated with odours, staining and general bio-deterioration which are principally of the division Ascomycetes, for example *Cladosporium* spp. and *Alternaria* spp.

Azoxystrobin: According to the classification of FRAC, azoxystrobin belongs to the Mode of Action Group C (respiration) and to the subgroup C3 (inhibition of complex III) with the target site cytochrome bc1 at QoI site and the FRAC code 11 with the group name QoI fungicides (Quinone outside inhibitors). The mode of action of QoI fungicides is the inhibition of mitochondrial respiration resulting from a blockage of the electron transport from ubiquinone to cytochrome c by means of a binding to the ubiquinone oxidation centre (Qo) of the cytochrome bc1 complex (complex III). This leads to a reduction of energy-rich ATP that is available to support a range of essential processes in the fungal cell.

Table 3.2-1: Details of the active substances

Active substance	Fluxapyroxad	Azoxystrobin
Concentration	50 g/L	75 g/L
Group	succinate dehydrogenase inhibitors (SDHI)	quinone outside inhibitors (QoI)
Subgroup	pyrazole-4-carboxamides	methoxy-acrylates
Mode of action	C2: inhibition of complex II of mitochondrial respiration	C3: inhibition of complex III: cytochrome bc1(ubiquinol oxidase) at Qo site (cyt b gene)
FRAC code	7	11

Description of the plant protection product

BAS 736 00 F is a new fungicide developed by BASF for the control of the major diseases in cereals. It is formulated as an emulsion concentrate (EC) containing 50 g/L of fluxapyroxad and 75 g/L of azoxystrobin for use in cereals.

BAS 736 00 F is intended for treatment with 2 L of product per ha in wheat, barley, rye, triticale and oats. The maximum number of applications is 2 applications per season for all countries except the Czech Republic where only 1 application is allowed. The applications should be made between GS 30-69.

Table 3.2-2: Simplified table of currently registered uses and requested uses for BAS 736 00 F

Uses		Member State			Requested rate(s) (maximum)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)	MA EPPO Zone	NE EPPO Zone	SE EPPO Zone		
Wheat	<i>Zymoseptoria tritici</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Puccinia striiformis</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Puccinia triticina</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Blumeria graminis</i>	AT, BE, CZ, DE, NL, IE	PL	-	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha
	<i>Pyrenophora tritici-repentis</i>	AT, BE, CZ, DE, NL, IE	PL	-	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha
Barley	<i>Pyrenophora teres</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Rhynchosporium secalis</i>	AT, BE, CZ, DE, NL, IE	PL	-	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha
	<i>Ramularia collo-cygni</i>	AT, BE, CZ, DE, NL, IE	-	-	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha
	<i>Puccinia hordei</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Blumeria graminis</i>	AT, BE, CZ, DE, NL	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
Rye	<i>Rhynchosporium secalis</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Puccinia recondita</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
Triticale	<i>Zymoseptoria sp.</i>	AT, BE, CZ,	PL	HU, RO,	2 L/ha	For CZ: Dose rate range of

Uses		Member State			Requested rate(s) (maximum)	Comments / Other relevant details on GAPs
Crop(s)	Target(s)	MA EPPO Zone	NE EPPO Zone	SE EPPO Zone		
		DE, NL, IE		SK, SI		1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Puccinia recondita</i>	AT, BE, CZ, DE, NL, IE	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Puccinia striiformis</i>	AT, BE, CZ, DE, NL	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Blumeria graminis</i>	AT, BE, CZ, DE, NL	PL	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
Oats	<i>Puccinia coronata</i>	AT, BE, CZ, DE, NL, IE	-	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha
	<i>Blumeria graminis</i>	AT, BE, CZ, DE, NL, IE	-	HU, RO, SK, SI	2 L/ha	For CZ: Dose rate range of 1.2-2 L/ha For HU, RO, SK, SI: Dose rate range of 1-2 L/ha

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.

EPP0 code	Scientific name	English name
ERYSGR	<i>Blumeria graminis</i>	powdery mildew of cereals
ERYSGT	<i>Blumeria graminis f. sp. tritici</i>	powdery mildew of wheat
PUCCCA	<i>Puccinia coronata var. avenae</i>	crown rust of oats
PUCCCO	<i>Puccinia coronata</i>	crown rust of grasses
PUCCHD	<i>Puccinia hordei</i>	brown rust of barley
PUCCRE	<i>Puccinia recondita</i>	brown rust of cereals
PUCCRT	<i>Puccinia triticina</i>	brown rust of wheat
PUCCSI	<i>Puccinia striiformis f. sp. tritici</i>	yellow rust of wheat
PUC CST	<i>Puccinia striiformis</i>	yellow rust
PYRNTE	<i>Pyrenophora teres</i>	net blotch of barley
PYRNTR	<i>Pyrenophora tritici repentis</i>	tan spot of wheat, tan spot of cereals
RAMUCC	<i>Ramularia collo-cygni</i>	ramularia leaf spot of barley
RHYNSE	<i>Rhynchosporium secalis</i>	<i>Rhynchosporium</i> leaf scald of barley, rye and triticale/ leaf blotch of cereals
SEPTTR	<i>Zymoseptoria tritici</i>	<i>Septoria</i> leaf blotch/ <i>Septoria</i> leaf spot of wheat/ speckled leaf blotch of wheat
SEPTSP	<i>Septoria</i> species	<i>Septoria</i> species

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

Crop	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		major	minor
Wheat (winter wheat, spring wheat, durum wheat, spelt wheat)	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	-	<i>Zymoseptoria tritici</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	-
			<i>Puccinia striiformis</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	-
			<i>Puccinia triticina</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	-
			<i>Blumeria graminis</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	-
			<i>Pyrenophora tritici-repentis</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK	UK
Barley (winter barley, spring barley)	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	-	<i>Pyrenophora teres</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	
			<i>Ramularia collo - cygni</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, UK	SK
			<i>Rhynchosporium secalis</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	
			<i>Puccinia hordei</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	
			<i>Blumeria graminis</i>	AT, BE, CZ, DE, HU, IE, NL, PL, RO, SI, SK, UK	
Rye	AT, BE, CZ, AT, DE, PL, HU, SK (winter)	NL, IE, RO, SI, SK (spring), UK	<i>Puccinia recondita</i>	AT, BE, CZ, DE, PL, HU, RO, SI, SK (winter)	NL, IE, RO, SK, UK
			<i>Rhynchosporium secalis</i>	AT, BE, CZ, DE, PL, HU, RO, SI, SK (winter)	NL, IE, RO, SK, UK
Triticale	AT, BE, CZ, DE,	IE, NL, RO, UK	<i>Zymoseptoria tritici</i>	AT, BE, CZ, DE, HU, NL, PL, RO, SI,	IE, RO, SK, UK

Crop	Crop status		Pests or group of pests controlled	Pest status	
	Major	minor		major	minor
	HU, NL, PL, SI, SK		<i>Puccinia recondita</i>	AT, BE, CZ, DE, HU, NL, PL, RO, SI	IE, SK, RO, UK,
			<i>Zymoseptoria tritici</i>	AT, BE, CZ, DE, HU, NL, PL, RO, SI,	IE, RO, SK, UK
			<i>Blumeria graminis</i>	AT, BE, CZ, DE, HU, NL, PL, RO, SI	IE, RO, SK, UK
Oats	BE, CZ, DE, PL, RO, SK	AT, DE, HU, IE, NL, SI, UK	<i>Blumeria graminis</i>	BE, CZ, PL, RO, SI	AT, DE, IE, HU, NL, SK, UK
			<i>Puccinia coronata</i>	BE, CZ, PL, PL, RO, SK, SI, PL	AT, DE, IE, HU, NL, SK, UK

Comments of zRMS	<p>ZRMS confirm that the active substances and their mode of actions and the tested plant protection product BAS 736 00 F (Miralon) were clearly and widely described.</p> <p>The ZMRS recognized the status of crops and pests (major / minor) for intended uses as presented by the applicant in the table above. If crop status or pest status in the individual countries are different than in the table zRMS asks cMS about such information.</p>
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Compliance with the Uniform Principles

All trials were conducted in compliance with relevant EPPO guidelines or CEB methods (French trials) as listed in relevant overview table with trial methodology: Table 3.2-14.

The field trials presented in this BAD were performed by BASF or officially recognized testing organizations. All trials followed GEP principles and all testing organizations had the appropriate GEP certificate – see chapter 3.7.

Comments of zRMS	<p>ZRMS confirms that the trials presented in this dossier were carried out by contractor companies and Official Research Institutes, in accordance with the principles of Good Experimental Practice (GEP) and with relevant EPPO guidelines or CEB methods.</p> <p>The assessment was made in accordance with the Uniform Principles.</p>
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Information on trials submitted (3.1 Efficacy data)

A total of 227 efficacy trials with disease and 16 efficacy trials without disease have been included in this BAD to justify the minimum effective dose, as well as to demonstrate the efficacy and selectivity of BAS 736 00 F when used on wheat, barley, rye, triticale and oats. Trials were conducted between years 2019 and 2020 in countries belonging to the different EPPO climatic zones, namely Maritime, North East and South East zones.

Overview of submitted trials per crop and application timing is provided in the tables below.

Table 3.2-5: Presentation of trials, Wheat, Efficacy trials with disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Wheat	BG	MED+E	-	-	5	2019-2020	GEP
	CZ	MED+E	6	-	-	2019-2020	GEP
	DK	MED+E	7	-	-	2019-2020	GEP
	FI	MED+E	-	2	-	2019-2020	GEP
	FR	MED+E	8	-	-	2019-2020	GEP
		E	7	-	-	2019-2020	GEP
	DE	MED+E	14	-	-	2019-2020	GEP
		E	6	-	-	2020	GEP
	HU	MED+E	-	-	2	2019-2020	GEP
	IE	MED+E	3	-	-	2019-2020	GEP
		E	1	-	-	2020	GEP
	LV	MED+E	-	2	-	2019	GEP
	LT	MED+E	-	1	-	2019	GEP
	NL	MED+E	3	-	-	2020	GEP
	PL	MED+E	-	19	-	2019-2020	GEP
		E	-	2	-	2019-2020	GEP
	RO	MED+E	-	-	7	2019-2020	GEP
		E	-	-	1	2020	GEP
	SK	MED+E	-	-	1	2020	GEP
	UK	MED+E	8	-	-	2019-2020	GEP
		E	1	-	-	2020	GEP
TOTAL 1			64	26	16	-	-
TOTAL 2			106			-	-

* MED = minimum effective dose, E = efficacy trial

** Official: carried out by a national official organisation

Table 3.2-6: Presentation of trials, Wheat, Efficacy trials without disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Wheat	FR	Y+Q	3	-	-	2019-2020	GEP
	DE	Y+Q	2	-	-	2019	GEP
	PL	Y+Q	1	-	-	2020	GEP
	UK	Y	1	-	-	2020	GEP
TOTAL 1			7	0	0	-	-
TOTAL 2			7			-	-

* Y = trial with yield assessment, Q = trial with quality assessment, P = trial with assessment of impact on propagation

** Official: carried out by a national official organisation

Table 3.2-7: Presentation of trials, Barley, Efficacy trials with disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Barley	BG	MED+E	-	-	2	2019	GEP
	CZ	MED+E	1	-	-	2020	GEP
	DK	MED+E	2	-	-	2019	GEP
		E	1	-	-	2019	GEP
		MED+E	2	-	-	2020	GEP
	FI	MED+E	-	2	-	2019-2020	GEP
	FR	MED+E	12	-	-	2019-2020	GEP
		E	2	-	-	2020	GEP
	DE	MED+E	15	-	-	2019-2020	GEP
		E	3	-	-	2020	GEP
	HU	MED+E	-	-	2	2019-2020	GEP
	IE	MED+E	3	-	-	2019-2020	GEP
	LV	MED+E	-	2	-	2020	GEP
	LT	MED+E	-	2 3	-	2019-2020	GEP
	PL	MED+E	-	10	-	2019-2020	GEP
		E	-	3	-	2020	GEP
	RO	MED+E	-	-	3	2019-2020	GEP
		E	-	-	2	2020	GEP
	SK	MED+E	-	-	3	2019-2020	GEP
	UK	MED+E	4	-	-	2019-2020	GEP
TOTAL 1			45	20	12	-	-
TOTAL 2			77			-	-

* MED = minimum effective dose, E = efficacy trial
** Official: carried out by a national official organisation

Table 3.2-8: Presentation of trials, Barley, Efficacy trials without disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Barley	UK	Y+Q	4	-	-	2019-2020	GEP
	LT	Y+Q	-	1	-	2019	GEP
TOTAL 1			4	1	-	-	-
TOTAL 2			5			-	-

* Y = trial with yield assessment, Q = trial with quality assessment, P = trial with assessment of impact on propagation
** Official: carried out by a national official organisation

Table 3.2-9: Presentation of trials, Rye, Efficacy trials with disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Rye	DK	MED+E	1	-	-	2020	GEP
	FR	MED+E	2	-	-	2019-2020	GEP
	DE	MED+E	7	-	-	2019-2020	GEP
	LV	MED+E	-	2	-	2019-2020	GEP
	PL	MED+E	-	8	-	2019-2020	GEP
	SE	MED+E	1	-	-	2019	GEP
TOTAL 1			11	10	0	-	-
TOTAL 2			21			-	-

* MED = minimum effective dose, E = efficacy trial

** Official: carried out by a national official organisation

Table 3.2-10: Presentation of trials, Triticale, Efficacy trials with disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Triticale	DK	MED+E	2	-	-	2019-2020	GEP
	FR	MED+E	2	-	-	2019-2020	GEP
	DE	MED+E	8	-	-	2019-2020	GEP
	LT	MED+E	-	1	-	2019	GEP
	PL	MED+E	-	7	-	2019-2020	GEP
TOTAL 1			12	8	0	-	-
TOTAL 2			20			-	-

* MED = minimum effective dose, E = efficacy trial

** Official: carried out by a national official organisation

Table 3.2-11: Presentation of trials, Triticale, Efficacy trials without disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Triticale	PL	Y+Q	-	1	-	2019	GEP
TOTAL 1			0	1	0	-	-
TOTAL 2			1			-	-

* Y = trial with yield assessment, Q = trial with quality assessment, P = trial with assessment of impact on propagation

** Official: carried out by a national official organisation

Table 3.2-12: Presentation of trials, Oats, Efficacy trials with disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Oats	UK	E	3	-	-	2019	GEP
TOTAL 1			3	0	0	-	-
TOTAL 2			3			-	-

* MED = minimum effective dose, E = efficacy trial

** Official: carried out by a national official organisation

Table 3.2-13: Presentation of trials, Oats, Efficacy trials without disease

Crop	Country	Type of trial*	Number of trials per zone			Years	GEP, non-GEP, official**
			Maritime	North East	South East		
Oats	UK	Y+Q	3	-	-	2019	GEP
TOTAL 1			3	0	0	-	-
TOTAL 2			3			-	-

* Y = trial with yield assessment, Q = trial with quality assessment, P = trial with assessment of impact on propagation

** Official: carried out by a national official organisation

Table 3.2-14: Details on trial methodology

Details on trial methodology			
Guidelines	General	EPPO PP 1/135 (4): Phytotoxicity assessment EPPO PP 1/152 (4): Design and analysis of efficacy evaluation trials EPPO PP 1/181 (4): Conduct and reporting of efficacy evaluation trials including good experimental practice EPPO PP 1/223 (2): Introduction to the efficacy evaluation of plant protection products EPPO PP 1/239 (2): Introduction to the efficacy evaluation of plant protection products	
	Specific	EPPO PP 1/26 (4) Foliar diseases of cereals CEB n°218 Method for the study of unintended effects of plant protection products on soft wheat quality and transformed products from wheat	
Experimental design	Plot design	Randomised blocks (RB)	
	Plot size	Efficacy trials with disease 10-45 m ²	
	Number of replications	3-4 (3 replications conducted in 6 French trials in wheat according to CEB n°218 – baking study; trials excluded from efficacy summary)	
Crop	Trials per crop	efficacy trials with disease efficacy trials without disease Wheat winter 104 7 Wheat spring 2 0 Barley winter 57 4 Barley spring 20 1 Rye 21 0 Triticale 20 1 Oats 3 3	
	Varieties per crop	<u>Wheat winter (69):</u> AKTEUR, ALEKSANDER, ANNIE, APACHE, ARIESAN, ARKADIA, BARREL, BENCHMARK, BENNINGTON, BERGAMO, BERMUDE, BISCAY, BOREGAR, CLARE, CLEVELAND, CORDIALE, COSTELLO, CRUSOE, CUBUS, DESAMO, DINOSOR, EDVINS, EINSTEIN, ETANA, EUFORIA, EVINA, FRUCTIDOR, GLOSA, GRAHAM, GRAPELI, HEREFORD, HORATIO, HYFI, HYWIN, INGENIO, JANTARKA, JB ASANO, JULIUS, KINETIC, KWS EXTASE, KWS LILI, KWS LOFT, KWS OZON, KWS TALENT, LG IMPOSANTO, LUKULLUS /EU, LUMOS, MATRIX, MURGAVETS, MV TALLÉR, PORTHUS, PRINCEPS, PS KVALITAS, REFLECTION, RGT DEPOT, RIBAND /EU, RITMO, SADOVO, SAILOR, SISKIN, SKAGEN, SOFRU, SUBSTANCE, TALENT, TERROIR, TOBAK, UNIK, VICTO/EU, ZYTA, <u>Wheat spring (2):</u> AMARETTO, WANAMO	

Details on trial methodology			
		<p><u>Barley winter (38):</u> ANTONELLA, AZRAH, BAZANT, CALIFORNIA, DANILO, ETINCEL, FINITA, FLAGON, GLORIA, ISOCHEL, JALON, JUP, KETOS, KWS JOY, KWS ORWELL, KWS TENOR, LOMERIT, MALTESSE, MARGAUX, MARRIS OTTER, MEMENTO, METAXA, NOVETA, OBZOR, PASTORAL, PIXEL, QUADRIGA, SALAMANDRE, SANDRA, SAPHIRA, SU ELLEN, SURGE, SU VIRENI, SY VENTURE, TOWER, VESLETS, ZANZIBAR</p> <p><u>Barley spring (18):</u> BLANÍK, DANTE, GANGWAY, GRACE, CHAPEAU, KWS IRINA, LAURIKKA, MALZ, PASSADENA, PENGUIN, PROPINO, QUENCH, RGT PLANET, RINGO, SEBASTIAN, TEKSAS, TOCADA, VOITTO</p> <p><u>Rye winter (13):</u> COSSANI, DANKOWSKIE DIAM, DANKOWSKIE ZLOT, DOLARO, KAUPOL, KWS BINNTTO, KWS BONO, MEPHISTO, SU FORSETTI, SU MEPHISTO, SU NASRI, SU PERFORMER, VINETTO</p> <p><u>Triticale winter (16):</u> AGENDUS, CAPPRICIA, FREDRO, GRENADO, KWS AVEO, KWS FIDO, LOMBARDO, MELOMAN, NEOGEN, RGT OMEAC, ROTONDO, SECURO, SU AGENDUS, TANTRIS, TRISMART, TULUS</p> <p><u>Oats winter (2):</u> FUSION, MASCANI</p>	
	Sowing period	<p>Wheat winter SEP 12th – DEC 05th Wheat spring APR 30th – MAY 07th Barley winter AUG 05th – DEC 06th Barley spring MAR 22nd – MAY 17th Rye SEP 05th – OCT 30th Triticale SEP 18th – OCT 25th Oats SEP 28th – OCT 17th</p>	
Application	Crop stage (BBCH) at application	<p>wheat BBCH 31-69 (72 – see the comment below the table) barley BBCH 28-69 rye BBCH 33-59 triticale BBCH 31-59 oats BBCH 30-59</p>	
	Number of applications	1-2	
	Spray volumes	<p>wheat 100-300 L/ha barley 100-300 L/ha rye 150-300 L/ha triticale 200-300 L/ha oats 200 L/ha</p>	
Assessment	Assessment types	<p>Disease severity (in %) Phytotoxicity (in %) Yield (in dt/ha) Thousand grain weight (in g/1000grains) Hectolitre weight in (kg/100L)</p>	<p>P%INF/ZCOUNT in % PHYTOX ERTRNE TAUKOG HEKLIT</p>

Trial layout

The trials were set up in the randomized block design with generally 4 replications.

As an exception, altogether 6 French trials in wheat were conducted with 3 replications. The trials were primarily set up to study unintentional effects on baking properties and followed the relevant CEB guideline N°218-2012 (method for the study of unintended effects of plant protection products on soft wheat quality and transformed products from wheat). Out of the 6 trials, 4 the trials provided valuable efficacy data on *Zymoseptoria tritici*. The trials are still considered relevant for efficacy evaluation and have been included in the respective chapter (3.2.3.1.2), however they have not been included in the summary. Other two trials with 3 repetitions are trials without disease that are presented with phytotoxicity assessments and effects on yield in chapters 3.4.3 and 3.4.4.

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.

Varieties

Disease sensitive varieties were chosen for the testing.

Most of the trials were conducted on winter cultivars and the reason is that winter cereals are much more popular as well as winter cultivars being more susceptible to foliar diseases. In the case of spring cultivars, the susceptibility is obviously lower due to the later initialization of the disease. Several trials were conducted on spring varieties of wheat and barley. In the efficacy tables (summary tables) however, the distinction between the winter and the spring cultivars has been done only for wheat and barley in the North-East zone to provide satisfying information for Poland where especially spring barley is of an importance.

Applications

Applications were carried out according to the GAP. They targeted a range of timings covering BBCH 30 - 69 to represent usual farmer practice as well as target disease at onset. In the majority of trials, one application was conducted. Depending on the disease development, the farmer has the option of the second treatment to control a later appearance of the disease. To cover such situations, two applications were tested in several trials. In the trials, the second application followed according to the disease development.

There were 2 exceptions when the application was conducted behind BBCH 69. In one Romanian trial in wheat the BBCH at application ranged up to 72. In this trial, the crop was very inhomogeneous, where some plants were more mature than the others. The growth stage in the field ranged from 47 to 72 while the average growth stage was BBCH 51. Therefore, this trial is still considered reliable for the evaluation of the disease efficacy. The other case was a German trial with 2 applications where the second application was done at BBCH 72. In this case, the application at later growth stage was driven by late appearance of the disease. In practice, the farmer should not apply behind BBCH 69 from other than efficacy reasons. For the purpose of efficacy evaluation however the trial is still considered useful and valid.

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 nozzle types used were representative of the range occurring in commercial practice. For more details see the corresponding Site details report in Appendix 4 or the Dossier Trial Data Reports.

The trials were designed to target disease at the onset of the attack, thus allowing the targeting of ideally one pathogen written in the protocol. However, a trial is often infected by more than one disease. Therefore, the treatments may not appropriately target the infection of other diseases as the spray time might be too late or too early to act preventatively.

In the practical world the window of application might be narrow whilst 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. For adequate disease control, the target must be hit no later than half-way through the latent period, while the physical symptoms are not yet visible. In trials presented in this dossier, some of the lower efficacy figures might be explained by applications being too late while the disease had already passed half of the latent period. This can be confirmed by the unsatisfactory performance of the standard.

The growth stages at the application time determine the protected leaves in the crop. Treatments at BBCH 31-33 target protection of leaf 3, while the application at BBCH 39 onwards targets protection of the flag leaf. Those application timings depend on disease development and may offer protectant control on more leaf layers. The early application may suppress disease in the canopy and therefore the symptoms on the flag leaf could be diminished. Also, in some cases while the disease infection might come late, the early application can offer protection of all top three leaves. This is in response to fungicidal treatment which is dependable on the disease progress.

BAS 736 00 F under normal conditions, provides long lasting efficacy at least comparable to the standard even with a high disease pressure. This advantage is confirmed in the vast majority of field trials. However, in the situation of uncommon disease patterns as well as unusual disease pressure, the activity of BAS 736 00F as well as the standard(s) were reduced. These trials are described in respective chapters.

The specificities of field trials allow products to be assessed in a wide range of practical situations. However, these trials are strongly dependent on weather conditions, disease development in the season and potential interruption from human error. All these factors can influence or interfere with the result of the trial.

Assessments

The assessments were carried out in accordance with EPPO standard PP1/26 (4) – ‘Foliar Diseases of Cereals’. The disease levels were usually assessed at application and at various intervals after application as a visual percentage cover of infection on a particular plant part. Where multiple diseases were present, each disease was assessed individually.

Diseases were assessed according to the percentage of infestation. This infestation was expressed as the **intensity of attack** (=severity). The intensity of attack was obtained as a visual estimation of the percentage coverage of each plant part area (leaves) and is marked as P%INF in the protocols. In several trials (usually on *Puccinia recondita* in France), another assessment – ZCOUNT- was applied. ZCOUNT means counting the living individuals after treatment. Based on this the efficacy in % is calculated with the ABBOTT formula. Both variables P%INF and ZCOUNT in % are considered comparable and are therefore summarized together in data tables.

In general, the assessments were done based on the **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 compared to other countries but is still relevant. The term ‘leaf’ is used, as it is an assessment of disease levels typically on 2 or 3 leaves having disease present. The levels of infection are expressed as the mean of the percentage of disease present on the assessed leaves. Trials where this assessment method is used present usually lower efficacy scores due to assessing leaves not targeted during application (ex. T2 spray at BBCH 39, assessed leaves: 1, 2 and 3). Therefore, no overestimation has to be expected in case of “leaf” assessments.

Crop selectivity was assessed visually at various intervals after application as the percentage relative to untreated plots. It was measured on a scale of phytotoxicity (%), 0 to 100.

Most of the trials were harvested. Grain yield from a known harvested area was adjusted to a fixed moisture level (according to the national standard) and expressed as decitonnes per hectare (dt/ha). Relative yield (% untreated) was calculated. Other yield parameters such as thousand grain weight and hectolitre weight were measured.

Statistical analysis

The observed or calculated variables of yield and quality were subjected to an analysis of variance (ANOVA). When the result of the analysis was significant, a multiple comparison of treatments was performed by **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 ($P < 0.05$).

Trial Numbering/References

Full trial reference numbers are used in the data tables and the tables of site and application details. Taking one of the wheat trials as an example:

DEV-F-2019-PL-C03-A-02.0-PL-PL8-027

“DEV” indicates that this is a development trial as distinct from other trial types

“F” indicates that this is a fungicide treatment trial

“2019” indicates the year in which the trial was conducted (in case of an autumn sown crop it is the harvest year)

“C03” is the trial protocol number (subsequent information detailing the version)

“PL” is the country code, in this case for Poland

“PL8” is a specific local region in the country

“027” is a unique identifier for this trial taking into consideration the preceding information.

Data evaluation and layout

In each section of the BAD, the data are ordered by the target crop, in the efficacy chapter each crop is further separated by individual diseases.

Product efficacy figures are derived from the top three leaves. This leaf layer selection, particularly in wheat, was chosen because the top three leaves have the greatest contribution to yield. The other factor limiting the relevance of lower leaf layer assessment is the relatively late assessment timing. The earliest applications were done around BBCH 30 while the considered assessments in many cases were done often around BBCH 75. At such a late growth stage, the assessment done on lower leaves may not be relevant anymore, as at that time the lower leaves are already dried out even in the absence of the disease. However, in case of 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 still used in few cases providing that assessment was done not later than BBCH 59.

Only trials and assessments with sufficient infestation level in the untreated plot are considered for evaluation. The **mean threshold** considered in this dossier is usually **5%** of intensity of attack for diseases of the cereal crops unless stated differently.

In the majority of cases, the focus of this dossier was to target **the late assessment done ideally about 35-40 days after the last treatment (DALT)**. In some exception, the considered assessment was done earlier, for example in case when later on the disease 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.

In each efficacy table, percentage control in relation to the untreated plot is presented. For each trial results table, a data summary is provided with the number of trials presented, the average, minimum and maximum values. The results are sorted by EPPO zones.

For treated plots, a relative percentage of efficacy has been calculated using the Abbott formula. All values have been rounded to one decimal place.

$$\text{Abbott formula: } ABB = \frac{C - T}{C} \times 100$$

C = infection degree in the untreated object

T = infection degree in the treated object

The yield and quality data are presented separately for efficacy trials with and without disease (no or <5% infection level in untreated control).

In the summary tables, the results are separated by climatic EPPO zones according to PP 1/241 (2).

Extrapolations

BAS 736 00 F was tested with numerous trials across three different climatic EPPO zones within Europe on 5 most important cereal crops: wheat, barley, rye, triticale and oats. During the testing, a huge data set demonstrating the efficacy on various more or less frequent cereal diseases has been collected. On some crucial pathogens like *Zymoseptoria tritici* and *Puccinia recondita* in wheat, a robust data set is available from each concerned climatic zoned. On the other hand, on some other pathogens the minimum number of 6 trials, as recommended by the EPPO guideline PP1/226, cannot be always provided per each zone. Due to the large field of activity of the product and the fact that the weather conditions do not always support the development of the registration trial it is hardly possible to obtain full data set according to the EPPO recommendation for all uses in all crops and zones. However, there is a common interest to provide wide-range product information to the end user. Labels without a complete direction for use can result in the application of unnecessary tank-mixes (the addition of one or more groups of fungicide) or in the non-essential increase of the dose rate. The applicant therefore refers to several facts that should be considered in support of the registration in such cases.

One of them is the fact that both active ingredients of the product, azoxystrobin and fluxapyroxad, are already well-known and the products based on one or the other active substance as a solo active ingredient are registered for efficacy on the most pathogens claimed in the GAP for BAS 736 00 F. An overview of the existing registrations is given in the BAD. There is an assumption that when two solo active ingredient products have confirmed efficacy on a certain pathogen in a certain crop, a product consisting of these two active substances will provide such efficacy as well. The available trials confirm this hypothesis.

The other fact is that in most cases it is observed that the overall efficacy of the product in Europe is similar between the climatic zones. The observable differences are more related to pathogen pressures than to climatic conditions. The product efficacy across all diseases is on a comparable level across zones, assuring the idea of trial extrapolations between the zones.

Last but not least it is proposed that the efficacy data are extrapolated between the crops in support of the registration. It is proposed that the evaluation of the data should consider supporting results which come from different crops but against the same pathogen (for example *Zymoseptoria tritici* in wheat and in triticale where a robust data set is available on wheat). To support this extrapolation an additional data collation is provided at the end of efficacy chapter 3.2. In this table the data is grouped primarily by pathogen and then by the crop.

Table 3.2-15: Presentation of reference standards used in efficacy trials

Crop	Reference standard	Countries where the product is registered	Authorization number	Trade name(s)	Active substance(s)	Formulation Type	Conc. of a.s.	Registered application rate in countries	Application rate in trials (per treatment)
Wheat Barley Rye Triticale Oats	BAS 9314 1 F	Austria	3771/0	Proline	prothioconazole	EC	250 g/L	0.8 L/ha	0.8 L/ha
		Belgium	9805P/B	Proline				0.8 L/ha	
		Bulgaria	n/a	Paradise/ Praktis/ Power				0.8 L/ha	
		Czech Republic	4523-1	Proline 250 EC				0.8 L/ha	
		Denmark	18-473/72200	Proline 250 EC				0.4-0.8 L/ha	
		Finland	2788	Proline 250 EC				0.2-0.8 L/ha	
		France	2060116	Joao				0.8 L/ha	
		Germany	025287-00	Proline				0.8 L/ha	
		Hungary	2220	Proline				0.6-0.8 L/ha	
		Ireland	3786	Proline				0.8 L/ha	
		Latvia	637	Proline				0.6-0.8 L/ha	
		Lithuania	AS2-6F(2018)	Proline				0.8 L/ha	
		Netherlands	W3-12725	Proline				0.8 L/ha	
		Poland	R-222/2019	Praktis				0.8 L/ha	
		Romania	457PC	Proline 250 EC				0.8 L/ha	
		Slovakia	06-02-0768	Proline				0.6-0.8 L/ha	
	BAS 9314 4 F	United Kingdom	14790	Proline 275			275 g/L	0.72 L/ha	0.72 L/ha
	BAS 9578 0 F	Austria	3829/0, 3829/1	Elatus Era	prothioconazole + benzindiflupyr	EC	150 g/L + 75 g/L	1.0 L/ha	1.0 L/ha
		Czech Republic	5311-0					1.0 L/ha	
		Finland	3334					0.5-1.0 L/ha	
		France	2160959					1.0 L/ha	
		Germany	008406-00					1.0 L/ha	
		Hungary	1878					0.5-1.0 L/ha	
		Ireland	5379					1.0 L/ha	
		Latvia	552					0.75-1.0 L/ha	
		Lithuania	AS2-55F(2017)					0.75-1.0 L/ha	
		Netherlands	15483					1.0 L/ha	
		Poland	R-229/2017					1.0 L/ha	
		Romania	342PC					0.5-1.0 L/ha	
		Slovakia	17-00108-AU					0.75-1.0 L/ha	
		Slovenia	U34330-48/19/3					1.0 L/ha	
		United Kingdom	17889					1.0 L/ha	

EC = emulsifiable concentrate

Comments of zRMS:	<p>Information on trials submitted</p> <p>The applicant presented an overall information about the efficacy trials in each cereal crop (type of the trials, the numbers of trials per zone, the year of conducting trials, details on trial methodology). The trials were carried out with disease and without disease, except rye (only trials with disease). For some pathogens, except <i>Zymoseptoria tritici</i> and <i>Puccinia recondita</i> in wheat, the possibility of data extrapolation in the case of failure to meet the minimum number of 6 studies for each zone, in accordance with EPPO PP1/226 guideline, was given also. The extrapolation can be made between the zones or between the crops. The presented informations are authoritative and meets the requirements for assessment.</p>
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3.2.1 Preliminary tests (KCP 6.1)

Ratio and Co-formulation justification (KCP 6.1)

Rationale for the co-formulation BAS 736 00 F

BAS 736 00 F consists of fluxapyroxad and azoxystrobin.

Fluxapyroxad belongs to the carboxamide class of chemicals and acts as a succinate dehydrogenase inhibitor (“SDHI” FRAC group 7) with known efficacy against several cereal diseases in particular *Zymoseptoria tritici*, *Puccinia spp.* in wheat as well as *Pyrenophora teres* and *Rhynchosporium secalis* in barley. Fluxapyroxad became widely available in Europe since 2013 and it is sold either solo (Imtrex, Imbrex) or in mixes with other mode of action (like triazoles or QoI).

Azoxystrobin is a strobilurin fungicide acting as a Quinone outside inhibitor (“QoI”, FRAC group 11) with known efficacy in particular *Zymoseptoria tritici*, *Puccinia spp.* in wheat as well as *Pyrenophora teres*, *Rhynchosporium secalis* and *Puccinia hordei* in barley. Azoxystrobin has been first approved in Europe in 1996 and since then is widely available to protect also cereal crops from fungal diseases. Since 2002 the efficacy of strobilurins against *Zymoseptoria tritici* has been declined due to a widespread G143A resistance, especially in western European countries. In more eastern countries still rather sensitive populations can be found, In barley *Pyrenophora teres* developed resistance towards Azoxystrobin (F129L) especially in western European countries. In the eastern countries mostly sensitive population can be found. For further details please see chapter 3.3 Information on the occurrence or possible occurrence of the development of 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 the BAD in part 3.2.0.4 Overview on existing uses of the active ingredient (KCP 6).

Currently in Europe a few products with QoI and SDHI as a mixture are available in the market. Table 3.2-16 presents approved products. Hence the product concept is well established across Europe.

Table 3.2-16: Cereal products containing QoI and SDHI

Country	Trade name	Registration number	A.i. combination	Formul.	Concentration	Company
Czech Rep., Latvia, Lithuania, Latvia, Lithuania	Cayunis	5727-0, 743, AS2-10F(2021), 743, AS2-10F(2021)	Bixafen, spiroxamine, trifloxystrobin	EC	75+150+100 G/L	BAYER
Netherlands	Signum	W19-12630	Boscalid, pyraclostrobin	WG	26.7+6.7 %	BASF
Czech Rep., Slovenia, Finland, Italy, Sweden, Hungary, Poland, Romania, Slovakia, Estonia, Latvia, Lithuania, Croatia, Austria, Belgium, France, Germany, Greece, Ireland, Netherlands, Spain, United Kingdom (UK)	Mizona, PRI-AXOR, PRI-AXOR EC (IMPERIS ULTRA), Syrex,	5672-0, U34330-85/18/8, 3444, 17003, 5345, 6300/2834-1/2020, R-46/2016, 273PC, 16-02-1746, 569, 514, AS2-89F(2019), UP/I-320-20/14-01/435, 3623/0, 10616P/B, 2161101, 008180-00, 60950, 5264, 15711, ES-00458, 17371	Fluxapyroxad, Pyraclostrobin	EC	75+150 G/L	BASF

Justification of BAS 736 00 F

BAS 736 00 F concept was tested in robust data set of efficacy trials conducted in Europe in years 2019-2021.

Efficacy trials were conducted along EPPO guidelines PP 1/26(4) and PP1/28(3).

The efficacy data is split into two chapters – efficacy of the solo active ingredients (azoxystrobin and fluxapyroxad) and efficacy of single and combined active ingredients of BAS 736 00 F in different ratios. Overview of the tested products as well as the reference standards can be found in Table 3.2-17 and Table 3.2-18.

Table 3.2-17: Tested items and standards used in efficacy trials with solo active ingredients of BAS 736 00 F

	Active ingredient	g a i /ha	Formulation	Commercial name	BAS code
Tested items	Fluxapyroxad	93.75 or 100	EC	Imtrex	BAS 70009 F
	Fluxapyroxad	100	EC	-	BAS 70000 F
	Azoxystrobin	150	SC	Amistar	BAS 91641 F
Standards	mefentrifluconazole	100	EC	Myresa 1 l/ha	BAS 750 01 F
	benzofindiflupyr	75	EC	Elatus Plus 0.75 l/ha	BAS 95660 F
	prothioconazole	200	EC	Proline 0.8 l/ha	BAS 931 41 F
	prothioconazole	200	EC	Proline 275 0.72 l/ha*	BAS 931 44 F*
	pyraclostrobin	150	EC	Comet at 0.75 l/ha	BAS 500 06 F
	pyraclostrobin	150	SC	formulation not registered**	BAS 500 22 F
	fluxapyroxad + pyraclostrobin	112.5 + 225	EC	Priaxor 1.5 l/ha	BAS 703 07 F
	mefentrifluconazole + pyraclostrobin	150 + 150	EC	Rylox 1.5 l/ha	BAS 751 00 F

* in UK trials only

**used in 2 trials

Table 3.2-18: Tested items and standards used in efficacy trials testing various ratios of BAS 736 00 F

	Active ingredient	g a i /ha	Formulation	Commercial name	BAS code
Tested items	Fluxapyroxad	100	EC	Imtrex	BAS 70009 F
	Azoxystrobin	150	SC	Amistar	BAS 91641 F
	Fluxapyroxad + Azoxystrobin	100 + 90	EC + SC	-	BAS 70009 F + BAS 91641 F
	Fluxapyroxad + Azoxystrobin	60 + 150	EC + SC	-	BAS 70009 F + BAS 91641 F
	Fluxapyroxad + Azoxystrobin (as BAS 736 00 F)	100 + 150	EC	-	BAS 736 00 F
Standards	prothioconazole	200	EC	Proline – 0.8 l/ha	BAS 931 41 F
	prothioconazole	200	EC	Proline 275 – 0.72 l/ha	BAS 931 44 F

* in UK trials only

All trials were set up fully randomized and with four replicates. The disease was assessed visually by estimating the percentage of leaf area infected by the disease. This is then expressed as severity of attack (P% INF). The assessments were conducted at different times after the application. One assessment per trial was chosen for evaluation. It was usually an assessment between 20-52 days after the treatment. If more leaf layers were assessed on one assessment, an average of the upper three leaves (flag leaf, leaf 2 and leaf 3) was calculated.

Justification of BAS 736 00 Efficacy of the single active ingredients at rates as used in BAS 736 00 F

Efficacy of 150g/ha azoxystrobin

For BAS 736 00 F, the rate of azoxystrobin has been preliminary set at 150 g/ha. This is 60% of the approved individual dose rate of 250 g/ha azoxystrobin. Hence the aim of the tests was to confirm the efficacy of azoxystrobin at 150 g/ha in comparison to the standard.

The efficacy trials were conducted across different EPPO zones within years 2019-2021. The results are summarized in Table 3.2-19.

Table 3.2-19: Efficacy of azoxystrobin solo on major diseases of wheat and barley, infection and intensity in %; summary

Disease	EPPO zone	No of trials	DALT		Untreated infection	Azoxystrobin 150 g/ha efficacy	Standard efficacy
Septoria leaf blotch of wheat (<i>Zymoseptoria tritici</i>)	All zones	14	20 - 43	Average min-max	16 5 - 41	59 39 - 100	77 52 - 100
	Mar	7	20 - 43	Average min-max	23 13 - 41	52 39 - 70	74 56 - 86
	N-E	1		Average min-max	8	100	100
	S-E	6	21 - 42	Average min-max	9 5 - 13	61 44 - 100	75 52 - 100
Brown rust of wheat (<i>Puccinia triticina</i>)	All zones	8	29 - 43	Average min-max	32 6 - 85	82 63 - 100	86 58 - 100
	Mar	4	33 - 43	Average min-max	57 8 - 85	79 63 - 93	90 75 - 100
	N-E	1	29	Average min-max	6	100	100
	S-E	3	32 - 42	Average min-max	8 7 - 10	81 70 - 87	76 58 - 93
Yellow rust of wheat (<i>Puccinia striiformis</i>)	All zones	9	21 - 42	Average min-max	47 7 - 98	74 25 - 96	81 54 - 97
	Mar	8	21 - 42	Average min-max	41 7 - 98	72 25 - 96	80 54 - 97
	S-E	1	40	Average min-max	96	88	93
Net blotch of barley (<i>Pyrenophora teres</i>)	All zones	13	27 - 45	Average min-max	27 5 - 90	58 28 - 85	80 58 - 93
	Mar	6	29 - 45	Average min-max	50 6 - 90	59 35 - 80	79 58 - 90
	N-E	3	31 - 37	Average min-max	6 6 - 7	56 41 - 64	78 73 - 82
	S-E	4	27 - 35	Average min-max	7 5 - 9	59 28 - 85	83 63 - 93
Rust of barley (<i>Puccinia hordei</i>)	All zones	8	26 - 43	Average min-max	15 5 - 49	80 56 - 94	91 80 - 100
	Mar	3	26 - 43	Average min-max	29 18 - 49	81 76 - 85	89 80 - 99

Disease	EPPO zone	No of trials	DALT		Untreated infection	Azoxystrobin 150 g/ha efficacy	Standard efficacy
	N-E	2	32 - 37	Average min-max	9 8 - 10	83 76 - 90	97 94 - 100
	S-E	3	32 - 33	Average min-max	6 5 - 8	77 56 - 94	90 85 - 92
Leaf scald of barley (<i>Rhynchosporium secalis</i>)	All zones	2	36 - 41	Average min-max	14 12 - 16	56 45 - 67	75 66 - 84
	Mar	2	36 - 41	Average min-max	14 12 - 16	56 45 - 67	75 66 - 84
Powdery mildew of barley (<i>Blumeria graminis hordei</i>)	All zones	4	26 - 33	Average min-max	16 14 - 21	73 66 - 84	81 75 - 89
	S-E	4	26 - 33	Average min-max	16 14 - 21	73 66 - 84	81 75 - 89

In summary, azoxystrobin at 150 gai/ha offered a very good efficacy on *Puccinia triticina* approaching the standard at the full dose rate. Good efficacy was also observed on *Puccinia striiformis*, *Puccinia hordei* and *Blumeria graminis hordei*. In case of *Zymoseptoria tritici*, *Pyrenophora teres* and *Rhynchosporium secalis* the efficacy dropped slightly below 60% but still provided useful reduction of disease.

In all diseases, the efficacy of 150 gai/ha azoxystrobin was inferior to the performance of the standard at full registered dose rate.

Efficacy of 150g/ha fluxapyroxad

At the intended target rate of 2 L/ha for BAS 736 00 F, the applied rate for fluxapyroxad is 100 g/ha. This is 80% of the approved individual dose rate of 125 g/ha fluxapyroxad.

The efficacy of 100 g/ha fluxapyroxad compared to the standard was tested across different EPPO zones within years 2019-2021. The results are summarized in Table 3.2-20.

Table 3.2-20: Efficacy of 100 g/ha fluxapyroxad solo on major diseases of wheat and barley, infection and intensity in %; summary

Disease	EPPO zone	No of trials	DALT		Un-treated infection	Fluxapyroxad 93.75 100 g/ha efficacy	Standard efficacy
Septoria leaf blotch of wheat (<i>Zymoseptoria tritici</i>)	All zones	11	21 - 42	Average min-max	15 5 - 41	85 68 - 100	75 52 - 100
	Mar	4	33 - 40	Average min-max	27 13 - 41	79 68 - 95	69 56 - 86
	N-E	1	29	Average min-max	8	100	100
	S-E	6	21 - 42	Average min-max	9 5 - 13	87 76 - 100	75 52 - 100
Brown rust of wheat (<i>Puccinia triticina</i>)	All zones	5	29 - 42	Average min-max	19 6 - 64	96 92 - 100	83 58 - 100
	Mar	1	33	Average min-max	64	94	89
	N-E	1	29	Average min-max	6	100	100
	S-E	3	32 - 42	Average min-max	8 7 - 10	96 92 - 100	76 58 - 93
Yellow rust of wheat (<i>Puccinia striiformis</i>)	All zones	7	27 - 42	Average min-max	57 7 - 98	78 47 - 97	80 54 - 97
	Mar	6	27 - 42	Average min-max	51 7 - 98	75 47 - 96	78 54 - 97
	S-E	1	40	Average min-max	96	97	93
Net blotch of barley (<i>Pyrenophora teres</i>)	All zones	14	27 - 52	Average min-max	19 5 - 90	72 45 - 88	77 58 - 93
	Mar	7	35 - 52	Average min-max	31 5 - 90	72 45 - 83	73 58 - 85
	N-E	3	31 - 37	Average min-max	6 6 - 7	61 45 - 82	78 73 - 82
	S-E	4	27 - 35	Average min-max	7 5 - 9	82 73 - 88	83 63 - 93
Rust of barley (<i>Puccinia hordei</i>)	All zones	10	26 - 52	Average min-max	16 5 - 49	89 79 - 100	89 73 - 100
	Mar	5	26 - 52	Average min-max	25 11 - 49	89 84 - 96	86 73 - 100

Disease	EPPO zone	No of trials	DALT		Un-treated infection	Fluxapyroxad 93.75 100 g/ha efficacy	Standard efficacy
	N-E	2	32 - 37	Average min-max	9 8 - 10	88 87 - 90	97 94 - 100
	S-E	3	32 - 33	Average min-max	6 5 - 8	90 79 - 100	90 85 - 92
Leaf scald of barley (<i>Rhynchosporium secalis</i>)	All zones	2	36 - 48	Average min-max	11 6 - 16	80 60 - 100	71 57 - 84
	Mar	2	36 - 48	Average min-max	11 6 - 16	80 60 - 100	71 57 - 84
Ramularia leaf spot of barley (<i>Ramularia collo-cygni</i>)	All zones	13	32 - 52	Average min-max	49 5 - 88	65 37 - 82	73 51 - 90
	Mar	13	26 - 47	Average min-max	49 5 - 88	65 37 - 82	73 51 - 90
Powdery mildew of barley (<i>Blumeria graminis hordei</i>)	All zones	4	26 - 33	Average min-max	16 14 - 21	77 73 - 82	81 75 - 89
	S-E	4	26 - 33	Average min-max	16 14 - 21	77 73 - 82	81 75 - 89

In summary, fluxapyroxad at 100 gai/ha offered good to excellent efficacy on all major cereal diseases tested. On *Puccinia triticina*, an excellent efficacy superior to the standard was reached. Good to very good efficacy, superior or on the level of the standard, was observed on *Zymoseptoria tritici*, *Puccinia striiformis*, *Pyrenophora teres*, *Puccinia hordei*, *Rhynchosporium secalis* and *Blumeria graminis hordei*. Against *Ramularia collo-cygni*, only medium efficacy was seen on average 65% were achieved but can be still considered as a useful efficacy.

Both actives show good to excellent control of rust diseases in cereal crops and *Rhynchosporium secalis*. Depending on the resistance situation the performance of Azoxystrobin- against *Zymoseptoria tritici* and *Pyrenophora teres* may be compromised and can be seen only as an add on effect. Nevertheless, with Fluxapyroxad excellent efficacy was seen in the trials. To improve the efficacy and gain a more consistent performance against rust while maintaining a broad-spectrum disease control, both actives were combined in one product. Different ratios of both actives were tested to find the optimal one. Results will be presented in the next chapter.

Efficacy of the single and combined active ingredients of BAS 736 00 F

In 2020, wheat and barley trials were conducted to compare the efficacy of the solo actives in direct comparison to their suboptimal mixtures and the finally chosen ratio of BAS 736 00 F. To complete the picture, Proline was included at full dose rate as registration standard in all trials.

Results are summarized in Table 3.2-21.

An increased efficacy of the mixtures in comparison to the single actives was visible on most diseases.

On *Zymoseptoria tritici*, all three treatments with 100 g/ha fluxapyroxad achieved comparable efficacy clearly superior to the standard. Nevertheless, the performance of BAS 736 00 F was slightly more consistent than the other options. It is emphasized that more significant difference between the ratios could be expected in situations of high to very high infection level in untreated. Such situation is visible in the German trial with 41% infection in the untreated control. In this trial a dose response is very clear and BAS 736 00 F is clearly superior to the alternative ratios.

On *Puccinia triticina*, the combination of both actives clearly increased the efficacy. Out of the three available trials 2 showed excellent efficacy of 100 % for all mixtures, therefore in summary only limited differentiation between the different ratios is visible.

Against *Puccinia striiformis* as well, the mixtures performed significantly better to the solos. When comparing the different ratios, a superior performance of BAS 736 00 F was visible. The superiority of BAS 736 00 F was especially confirmed in trials with more than 30% of intensity of attack where the best efficacy was achieved with BAS 736 00 F in all trials. The average performance of BAS 736 00 F was clearly superior to the standard.

On *Pyrenophora teres*, very good add on effect of all mixtures was observed. The two alternative mixtures provided efficacy on the level of the standard while BAS 736 00 F was clearly superior to all other treatments.

Concerning *Puccinia hordei*, also here the efficacy increased with the mixing of actives and BAS 736 00 F showed to be the best option out of them.

Only 1 result was available for *Rhynchosporium secalis*. All treatments containing 100 g/ha fluxapyroxad reached excellent efficacy and were superior to the standard.

On *Blumeria graminis hordei*, just one result was obtained either. BAS 736 00 F was clearly the best option and comparable to the standard.

Table 3.2-21: Efficacy of azoxystrobin, fluxapyroxad and their mixes on major diseases of wheat and barley, infection and intensity in %; summary

Disease	EPP O zone	No of trials	DALT		UTC infecti on	Azoxystro bin 150 g/ha efficacy in %	Fluxapyrox ad 100 g/ha efficacy in %	Fluxapyrox ad + Azoxystrob in 100 + 90 g/ha efficacy in %	Fluxapyrox ad + Azoxystrob in 60 + 150 g/ha efficacy in %	Fluxapyrox ad + Azoxystrob in 100 + 150 g/ha efficacy in %	Stand ard
Septoria leaf blotch of wheat (<i>Zymoseptoria tritici</i>)	All zone s	6	29 - 40	Averag e min- max	21 8 - 41	61 45 - 100	84 68 - 100	86 67 - 100	79 65 - 100	86 72 - 100	76 56 - 100
	Mar	4	33 - 40	Averag e min- max	27 13 - 41	52 45 - 58	79 68 - 95	81 67 - 97	73 65 - 76	81 72 - 96	69 56 - 86
	N-E	1	29	Averag e min- max	8	100	100	100	100	100	100
	S-E	1	32	Averag e min- max	9	63	88	90	84	91	82
Brown rust of wheat (<i>Puccinia tritica</i>)	All zone s	3	23 - 32	Averag e min- max	7 6 - 8	73 50 - 100	80 40 - 100	92 76 - 100	91 73 - 100	92 76 - 100	91 80 - 100
	Mar	1	23	Averag e min- max	7	50	40	76	73	76	80
	N-E	1	29	Averag e min- max	6	100	100	100	100	100	100
	S-E	1	32	Averag e min- max	8	70	100	100	100	100	93
Yellow rust of wheat (<i>Puccinia striiformis</i>)	All zone s	5	27 - 40	Averag e min- max	43 7 - 98	66 25 - 96	72 47 - 96	82 61 - 97	84 64 - 96	86 66 - 97	74 54 - 93
	Mar	5	27 - 40	Averag e min- max	43 7 - 98	66 25 - 96	72 47 - 96	82 61 - 97	84 64 - 96	86 66 - 97	74 54 - 93
Net blotch of barley (<i>Pyrenophora teres</i>)	All zone s	8	31 - 42	Averag e min- max	18 6 - 90	59 35 - 80	68 45 - 83	77 59 - 91	76 51 - 88	84 67 - 93	79 58 - 89
	Mar	3	35 - 42	Averag e min- max	37 6 - 90	59 35 - 80	68 45 - 80	69 59 - 86	73 51 - 85	78 67 - 88	75 58 - 85
	N-E	3	31 - 37	Averag e min- max	6 6 - 7	56 41 - 64	61 45 - 82	76 68 - 84	73 64 - 82	84 82 - 86	78 73 - 82
	S-E	2	32 - 35	Averag e min- max	9 8 - 9	62 57 - 66	78 73 - 83	91 91 - 91	87 86 - 88	92 92 - 93	87 86 - 89
Rust of barley (<i>Puccinia hordei</i>)	All zone s	5	26 - 43	Averag e min- max	18 5 - 49	77 56 - 90	88 79 - 97	93 83 - 100	90 82 - 99	95 80 - 100	93 85 - 100
	Mar	2	26 - 43	Averag e min- max	33 18 - 49	81 76 - 85	92 87 - 97	98 96 - 99	96 93 - 99	98 96 - 100	93 87 - 99
	N-E	2	32 - 37	Averag e min- max	9 8 - 10	83 76 - 90	88 87 - 90	92 83 - 100	87 85 - 90	100 100 - 100	97 94 - 100

Disease	EPP O zone	No of trials	DALT		UTC infecti on	Azoxystro bin 150 g/ha efficacy in %	Fluxapyrox ad 100 g/ha efficacy in %	Fluxapyrox ad + Azoxystrob in 100 + 90 g/ha efficacy in %	Fluxapyrox ad + Azoxystrob in 60 + 150 g/ha efficacy in %	Fluxapyrox ad + Azoxystrob in 100 + 150 g/ha efficacy in %	Standa rd
	S-E	1	32	Averag e min- max	5	56	79	87	82	80	85
Leaf scald of barley (<i>Rhynchospori um secalis</i>)	All zone s	1	36	Averag e min- max	16	45	100	96	94	100	84
	Mar	1	36	Averag e min- max	16	45	100	96	94	100	84
Powdery mildew of barley (<i>Blumeria graminis hordei</i>)	All zone s	1	32	Averag e min- max	15	84	81	79	83	87	89
	S-E	1	32	Averag e min- max	15	84	81	79	83	87	89

Summary and conclusions on the preliminary trials

The efficacy of the different active ingredients was tested at the dose rates as used in BAS 736 00 F in comparison to a standard. Azoxystrobin offered at 150 g/ha a very good efficacy on rust diseases in wheat and barley and for *Rhynchosporium secalis*. Depending on the resistance situation the performance of Azoxystrobin against *Zymoseptoria tritici* and *Pyrenophora teres* may be compromised. Fluxapyroxad at 100 g/ha showed a good to excellent efficacy on all major cereal diseases. To increase the performance for rust diseases and maintain a broad-spectrum efficacy against major diseases in wheat and barley both actives are combined in BAS 736 00 F.

The data show increased performance of any mixture (Azoxystrobin + Fluxapyroxad) in comparison to the single active ingredients. Additionally, the alternative ratios tested did show either a lower performance or a reduced consistency compared to BAS 736 00 F at 2.0 L/ha.

It can be concluded that BAS 736 00 F at the ratio of 100 g Fluxapyroxad and 150 g Azoxystrobin provides a consistent and reliable control of major diseases in cereal crops.

Comments of zRMS	<p>Preliminary tests</p> <p>The active substances fluxapyroxad and azoxystrobin included in BAS 736 00 F (Miralon) fungicide are approved in some countries as a single product or in mixes with other mode of action products, for some pathogens control in cereals. The fungicidal activity of separately used substances is well-known but the ratio of both substances in the mixture was determined in the trials submitted by applicant.</p> <p>To justify the mixture of both active substances included in BAS 736 00 F the applicant presented data on the efficacy of single use of azoxystrobin (fungicide Amistar) and fluxapyroxad (fungicide Imtrex) in wheat and barley and compared the efficacy of single use with the mixtures of those active substances, at different ratios and also with the ratio included in BAS 736 00 F, which was tested for the registration. The results showed a good to excellent control of diseases in wheat and barley. ZRMS agree with applicant conclusion that “BAS 736 00 F at the ratio of 100 g Fluxapyroxad and 150 g Azoxystrobin provides a consistent and reliable control of major diseases in cereal crops”.</p>
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3.2.2 Minimum effective dose tests (KCP 6.2)

Between the years 2019-2020 the minimum effective dose tests for BAS 736 00 F were conducted in ~~193~~ 194 field trials across the Europe. All trials were performed in accordance with the EPPO standard PP 1/225 '*Minimum effective dose*'.

BAS 736 00 F was tested at 2 rates: 2.0 L/ha and the reduced dose rate. In the Maritime and the North-East zone 1.2 L/ha (60% of the target maximum dose rate) was tested as the reduced dose rate. In the South-east zone (Hungary, Slovakia, Slovenia and Romania) a dose rate range of 1.0-2.0 L/ha is requested in the GAP. The background for the need of the dose rate range in the countries of the South east zone is explained in the separate chapter "Dose rate range justification". As only minimum difference in performance can be expected between the dose rates of 1.0 and 1.2 L/ha, no sense was seen in testing both rates alongside in the South east zone. Therefore, the dose rate of 1.0 L/ha is considered to be the reduced dose rate for the purpose of the minimum effective dose rate justification in the South east zone. In the summary tables, both reduced dose rates have been merged in one column "reduced dose rate" where in the Maritime and the North east zones it represents always 1.2 L/ha and in the South east zone it represents 1.0 L/ha.

The same assessments are presented in the Minimum effective dose tests chapter as in the Efficacy tests chapter. Trials which were from any reason excluded from the summarization in the Efficacy tests were not included for minimum dose justification.

***Zymoseptoria tritici*, Wheat**

Altogether 59 field trials were carried out in order to determine the minimum effective dose for the control of *Zymoseptoria tritici* on wheat. Trials were conducted in years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, Denmark, France, Germany, Ireland and the United Kingdom), the North East climatic zone (Latvia, Lithuania and Poland) and the South East climatic zone (Bulgaria, Romania and Slovakia). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-72. The very late application at BBCH 72 occurred just in one Romanian trial can be explained by a very inhomogeneous crop, where some plants were more mature. The average growth stage at application was BBCH 51. The trial is therefore considered valid for the evaluation.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 45-82 and 12-50 DALT on the upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-22.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 53 out of 59 trials. In average of all trials across all climatic zones, the full dose rate resulted in +7.9 percentage points above the reduced dose rate and was more consistent in performance (unlike with the reduced dose rate the efficacy of the full dose rate did not drop below 50%).

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Zymoseptoria tritici* in wheat under a wide range of environmental conditions.

Table 3.2-22: Minimum Effective Dose, Wheat (TRZAW), SEPTTR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F				Standard	
				infect	Reduced dose rate		Target dose rate		infect	efficacy
					infect	efficacy	infect	efficacy		
Maritime	all	n = 29	mean (min-max)	36.8 (5.3-100)	8.4 (0-37.6)	77.4 (46.4-100)	5.9 (0-24.4)	83.9 (50-100)	12.9 (0-70.6)	68.6 (29.2-100)
	UTC<35%	n = 21	mean (min-max)	19.3 (5.3-32.5)	4.5 (0-16.1)	76.5 (46.4-100)	3.3 (0-11.3)	82.9 (50-100)	5.8 (0-17.5)	70.1 (42.4-100)
	UTC≥35%	n = 8	mean (min-max)	82.7 (36.9-100)	18.5 (4.8-37.6)	79.6 (62-95.3)	12.8 (3.2-24.4)	86.3 (75.4-94.2)	31.4 (3.8-70.6)	64.9 (29.2-96.3)
North east		n = 17	mean (min-max)	15.9 (7.9-28.9)	4.1 (0-11.5)	76.6 (51-100)	3.0 (0-9.3)	83.2 (61.5-100)	4.3 (0-13)	74.8 (45-100)
South east		n = 13	mean (min-max)	14.9 (7.5-25.1)	3.8 (1.3-9.4)	77.6 (62.3-88.3)	1.8 (0-5.1)	90.3 (76.5-100)	2.6 (0-6.9)	83.7 (51.9-100)
Total ALL		n = 59	mean (min-max)	26.0 (5.3-100)	6.1 (0-37.6)	77.2 (46.4-100)	4.2 (0-24.4)	85.1 (50-100)	8.2 (0-70.6)	73.7 (29.2-100)

Puccinia striiformis, Wheat

Altogether 28 field trials were carried out in order to determine the minimum effective dose for the control of *Puccinia striiformis* on wheat. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (France, Germany, the Netherlands and the United Kingdom), the North East climatic zone (Finland and Poland) and the South East climatic zone (Hungary). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-65.

The same assessments are presented in this chapter as in the main efficacy chapter. Assessments ranging within BBCH 39-85 and 11-49 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-23.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 19 out of 28 trials. In average of all trials across all climatic zones, the full dose rate resulted in +4.4 percentage points above the reduced dose rate and was considerably more consistent in performance. In the trials with the higher infection level in the untreated (35-100%), the efficacy of the full dose rate did not drop below 60% in single trials while with the reduced dose rate also efficacy below 50% was observed in few cases.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Puccinia striiformis* in wheat under a wide range of environmental conditions.

Table 3.2-23: Minimum Effective Dose, Wheat, PUCCSI, intensity of attack (infect and efficacy in %), leaf; summary

EPPO Zone climatic				Untreated	BAS 736 00 F				Standard	
				infect	Reduced dose rate infect efficacy		Target dose rate infect efficacy		infect	efficacy
Maritime	all	n = 19	mean (min-max)	38.8 (7.1-97.8)	8.3 (0-53)	82.0 (45.7-100)	6.1 (0-36.5)	87.0 (60.6-100)	9.2 (0-55.8)	79.2 (42.7-100)
	UTC<35%	n = 10	mean (min-max)	21.0 (7.1-34.4)	3.3 (0-10)	87.5 (66-100)	1.6 (0-5.3)	93.8 (85.2-100)	4.0 (0-10.8)	81.9 (42.7-100)
	UTC≥35%	n = 9	mean (min-max)	54.1 (33.8-97.8)	12.5 (0.3-53)	76.8 (45.7-99.4)	9.8 (0.3-36.5)	81.2 (60.6-99.4)	13.9 (1-55.8)	75.8 (43-96.2)
North east		n = 7	mean (min-max)	7.8 (5.4-13)	0.3 (0-1.3)	96.3 (83.7-100)	0.1 (0-0.5)	98.4 (93.4-100)	0.3 (0-1.5)	96.5 (88.5-100)
South east		n = 2	mean (min-max)	88.3 (81-95.5)	12.9 (11.1-14.8)	85.1 (81.9-88.3)	6.8 (4.4-9.3)	92.0 (88.6-95.4)	12.1 (7.1-17)	85.8 (79.1-92.5)
Total ALL		n = 28	mean (min-max)	34.6 (5.4-97.8)	6.6 (0-53)	85.8 (45.7-100)	4.7 (0-36.5)	90.2 (60.6-100)	7.2 (0-55.8)	84.0 (42.7-100)

***Puccinia triticina*, Wheat**

Altogether 32 field trials were carried out in order to determine the minimum effective dose for the control of *Puccinia triticina* on wheat. Trials were conducted in years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, France, Germany and the United Kingdom), the North East climatic zone (Poland) and the South East climatic zone (Bulgaria, Romania and Slovakia). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-72. The very late application (BBCH 72) in one Romanian trial be explained by a very inhomogeneous crop, where some plants were more mature. The average growth stage at application was BBCH 51.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 69-83 and 12-49 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-24.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 23 out of 32 trials. In average of all trials across all climatic zones, the full dose rate resulted in +5.1 percentage points above the reduced dose rate and was considerably more consistent in performance which did not drop below 75%.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Puccinia triticina* in wheat under a wide range of environmental conditions.

Table 3.2-24: Minimum Effective Dose, Wheat, PuccRT, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F				Standard	
				infect	Reduced dose rate		Target dose rate		infect	efficacy
					infect	efficacy	infect	efficacy		
Maritime	all	n = 15	mean (min-max)	32.2 (5.8-100)	3.3 (0-10.8)	87.4 (57.4-100)	2.1 (0-6.5)	92.9 (75-100)	13.6 (0-65)	65.3 (25-100)
	UTC<35%	n = 11	mean (min-max)	18.2 (5.8-34.4)	2.6 (0-10.8)	85.9 (57.4-100)	1.4 (0-5.4)	92.6 (75-100)	5.3 (0-12.6)	70.2 (25-100)
	UTC≥35%	n = 4	mean (min-max)	70.9 (48.8-100)	5.3 (0.9-9.6)	91.7 (80.4-98.6)	4.1 (0.1-6.5)	93.6 (87.2-99.8)	36.5 (16.9-65)	51.8 (35-73.2)
North east		n = 8	mean (min-max)	12.3 (6-34.5)	1.8 (0-8.4)	89.0 (57.9-100)	1.1 (0-5.6)	92.8 (76.7-100)	2.3 (0-11)	86.3 (66.2-100)
South east		n = 9	mean (min-max)	9.0 (5-26)	1.1 (0.1-5.3)	91.7 (88.1-97.7)	0.5 (0-3.3)	97.2 (88.6-100)	1.4 (0-4.1)	85.3 (58.1-100)
Total ALL		n = 32	mean (min-max)	20.7 (5-100)	2.3 (0-10.8)	89.0 (57.4-100)	1.4 (0-6.5)	94.1 (75-100)	7.4 (0-65)	76.2 (25-100)

***Pyrenophora tritici-repentis*, Wheat**

Altogether 17 field trials were carried out in order to determine the minimum effective dose for the control of *Pyrenophora tritici-repentis* on wheat. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, Denmark and Germany), the North East climatic zone (Finland, Latvia and Poland) and the South East climatic zone (Bulgaria). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-69.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 59-85 and 21-50 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-25.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 13 out of 17 trials. In average of all trials across all climatic zones, the full dose rate resulted in +5.4 percentage points above the reduced dose rate and was more consistent in performance which did not drop below 58%.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Pyrenophora tritici-repentis* in wheat under a wide range of environmental conditions.

Table 3.2-25: Minimum Effective Dose, Wheat, PYRNTR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate			
				infect	efficacy	infect	efficacy	infect	efficacy
Maritime	n = 8	mean	25.4	9.2	68.1	7.6	75.3	8.1	70.6
		(min-max)	(6.4-50)	(0-24.6)	(48.5-100)	(0-20)	(58.7-100)	(0-20.3)	(55-100)
North east	n = 8	mean	16.3	4.0	78.6	3.4	82.4	4.5	74.4
		(min-max)	(7.3-25.3)	(0-8.8)	(53.5-100)	(0-7.5)	(60.3-100)	(0-10.3)	(53.5-100)
South east	n = 1	mean	5.0	0.5	90.0	0.3	95.0	0.5	90.0
Total ALL	n = 17	mean	19.9	6.2	74.4	5.2	79.8	6.0	73.5
		(min-max)	(5-50)	(0-24.6)	(48.5-100)	(0-20)	(58.7-100)	(0-20.3)	(53.5-100)

***Blumeria graminis*, Wheat**

Altogether 9 field trials were carried out in order to determine the minimum effective dose for the control of *Blumeria graminis* on wheat. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (the Czech Republic and Germany) and the North East climatic zone (Lithuania and Poland). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 37-72.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 59-80 and 10-43 DAT on upper 3 leaf layers with min 4.3% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-26 (summary).

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 5 out of 7 trials. In average of all trials across all climatic zones, the full dose rate resulted in +9.4 percentage points above the reduced dose rate and was more consistent in performance (unlike with the reduced dose rate the efficacy of the full dose rate did not drop below 60%).

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Blumeria graminis* in wheat under a wide range of environmental conditions.

Table 3.2-26: Minimum Effective Dose, Wheat, ERYSGR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target: 2.0 L/ha		infect	efficacy
				infect	efficacy	infect	efficacy		
Maritime	n = 5	mean	8.9	2.5	73.6	2.2	78.8	1.9	76.3
		(min-max)	(4.3-18.1)	(1-7.3)	(58.8-90.5)	(0.8-6.8)	(61.3-90.5)	(1-4)	(52.9-88.1)
North east	n = 4	mean	9.4	3.2	64.8	1.7	79.6	1.6	84.3
		(min-max)	(5-18.7)	(1.5-5.3)	(44.5-77.9)	(0.3-2.7)	(62.7-96.2)	(0-3.3)	(55-100)
Total ALL	n = 9	mean	9.1	2.8	69.7	2.0	79.1	1.7	79.8
		(min-max)	(4.3-18.7)	(1-7.3)	(44.5-90.5)	(0.3-6.8)	(61.3-96.2)	(0-4)	(52.9-100)

***Pyrenophora teres*, Barley**

Altogether 37 field trials were carried out in order to determine the minimum effective dose for the control of *Pyrenophora teres* on barley. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, Denmark, France, Germany and the United Kingdom), the North East climatic zone (Finland, Latvia, Lithuania and Poland) and the South East climatic zone (Bulgaria, Hungary, Romania and Slovakia). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-62.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 59-87 and 20-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-27.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 37 out of 38 trials. In average of all trials across all climatic zones, the full dose rate resulted in +9.7 percentage points above the reduced dose rate and was considerably more consistent in performance which did not drop below 63%.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Pyrenophora teres* in barley under a wide range of environmental conditions.

Table 3.2-27: Minimum Effective Dose, Barley, PYRNTE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate		infect	efficacy
	n	mean (min-max)		infect	efficacy	infect	efficacy		
Maritime	n = 17	mean (min-max)	26.0 (5-75.9)	6.5 (1-37.6)	75.4 (18.7-96.4)	4.5 (0.3-31.2)	85.0 (63.6-97.7)	5.9 (0-20.4)	76.7 (30.6-100)
North east	n = 12	mean (min-max)	27.3 (6.1-78.1)	7.0 (0.3-26.1)	76.0 (56.5-97.8)	4.4 (0.1-17.4)	84.6 (66.3-99.1)	6.4 (0.1-20.3)	76.3 (47.8-98.4)
South east	n = 9	mean (min-max)	21.4 (5-87.9)	6.4 (0.8-30.1)	75.2 (66.1-84.9)	3.4 (0.5-17.5)	86.5 (80.3-94.7)	8.1 (0.3-48.8)	75.1 (44.9-93.5)
Total ALL	n = 38	mean (min-max)	25.3 (5-87.9)	6.6 (0.3-37.6)	75.5 (18.7-97.8)	4.2 (0.1-31.2)	85.2 (63.6-99.1)	6.6 (0-48.8)	76.2 (30.6-100)

***Puccinia hordei*, Barley**

Altogether 18 field trials were carried out in order to determine the minimum effective dose for the control of *Puccinia hordei* on barley. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (Denmark, France, Germany and the United Kingdom), the North East climatic zone (Poland) and the South East climatic zone (Hungary and Romania). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-62.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 59-83 and 18-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-28.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 15 out of 18 trials. In average of all trials across all climatic zones, the full dose rate resulted in +3.6 percentage points above the reduced dose rate and was considerably more consistent in performance which did not drop below 61%.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Puccinia hordei* in barley under a wide range of environmental conditions.

Table 3.2-28: Minimum Effective Dose, Barley, PUCCHD, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate			
				infect	efficacy	infect	efficacy	infect	efficacy
Maritime	n = 10	mean	24.7	4.0	87.7	2.8	91.0	5.9	82.0
		(min-max)	(8.8-54)	(0-23.8)	(43.5-100)	(0-16.3)	(61.3-100)	(0-21.8)	(48.2-100)
North east	n = 6	mean	19.8	2.7	87.5	1.8	91.7	3.3	84.2
		(min-max)	(8.5-38)	(0.8-10.3)	(62.3-97.4)	(0.3-7.6)	(71.9-98.7)	(0.9-11.6)	(58.3-96.4)
South east	n = 2	mean	6.6	0.5	93.0	0.3	95.9	0.6	91.8
		(min-max)	(5.8-7.5)	(0.4-0.5)	(92.6-93.3)	(0.3-0.3)	(94.8-97)	(0.5-0.6)	(91.8-91.8)
Total ALL	n = 18	mean	21.1	3.2	88.2	2.2	91.8	4.4	83.8
		(min-max)	(5.8-54)	(0-23.8)	(43.5-100)	(0-16.3)	(61.3-100)	(0-21.8)	(48.2-100)

***Rhynchosporium secalis*, Barley**

Altogether 16 field trials were carried out in order to determine the minimum effective dose for the control of *Rhynchosporium secalis* on barley. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (France, Germany and the United Kingdom), the North East climatic zone (Latvia, Poland) and the South East climatic zone (Romania). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-62.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 59-83 and 19-45 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-29.

Higher performance of the full dose rate in comparison to the reduced dose rate was observed in 14 out of 16 trials. In average of all trials across all climatic zones, the full dose rate resulted in +8.1 percentage points above the reduced dose rate and was considerably more consistent in performance which did not drop below 57%.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Rhynchosporium secalis* in barley under a wide range of environmental conditions.

Table 3.2-29: Minimum Effective Dose, Barley, RHYNSE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate			
				infect	efficacy	infect	efficacy	infect	efficacy
Maritime	n = 11	mean	43.9	8.1	75.9	5.1	85.8	7.7	80.2
		(min-max)	(7.5-94)	(0.4-28.3)	(42.7-98.3)	(0.4-15.2)	(57.3-98.6)	(0.4-26.2)	(51.7-99.2)
North east	n = 4	mean	6.5	0.7	88.3	0.5	91.6	0.7	88.4
		(min-max)	(5.8-7.3)	(0-1.5)	(75-100)	(0.4-0.8)	(87-94.8)	(0.5-1)	(83.3-93.1)
South east	n = 1	mean	5.4	1.0	80.7	0.6	88.6	1.1	80.0
		(min-max)	(5.4-5.4)	(1-1)	(80.7-80.7)	(0.6-0.6)	(88.6-88.6)	(1.1-1.1)	(80-80)
Total ALL	n = 16	mean	32.2	5.8	79.3	3.7	87.4	5.5	82.2
		(min-max)	(5.4-94)	(0-28.3)	(42.7-100)	(0.4-15.2)	(57.3-98.6)	(0.4-26.2)	(51.7-99.2)

***Ramularia collo-cygni*, Barley**

Altogether 19 field trials were carried out in order to determine the minimum effective dose for the control of *Ramularia collo-cygni* on barley. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (Denmark, France, Germany and the United Kingdom) and the North East climatic zone (Latvia). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 31-69.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 69-85 and 9-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-30.

Higher performance of the full dose rate in comparison to the reduced dose rate was observed in 16 out of 19 trials. In average of all trials across all climatic zones, the full dose rate resulted in +11.7 percentage points above the reduced dose rate and was considerably more consistent in performance which did not drop below 48%.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Ramularia collo-cygni* in barley under a wide range of environmental conditions.

Table 3.2-30: Minimum Effective Dose, Barley, RAMUCC, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate		infect	efficacy
				infect	efficacy	infect	efficacy		
Maritime	n = 18	mean	34.3	12.0	62.6	8.1	75.1	7.8	75.8
		(min-max)	(5-98.6)	(1-47.1)	(0-90.5)	(0.8-33.8)	(48.9-93.6)	(0-29.9)	(25.8-100)
North east	n = 1	mean	8.8	1.3	85.7	1.5	82.9	2.0	77.1
		(min-max)	(8.8-8.8)	(1.3-1.3)	(85.7-85.7)	(1.5-1.5)	(82.9-82.9)	(2-2)	(77.1-77.1)
Total ALL	n = 19	mean	32.9	11.4	63.8	7.8	75.5	7.5	75.9
		(min-max)	(5-98.6)	(1-47.1)	(0-90.5)	(0.8-33.8)	(48.9-93.6)	(0-29.9)	(25.8-100)

***Blumeria graminis*, Barley**

Altogether 12 field trials were carried out in order to determine the minimum effective dose for the control of *Erysiphe graminis* on barley. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany and the United Kingdom), the North East climatic zone (Latvia) and the South East climatic zone (Hungary, Romania and Slovakia). The crop was sprayed with the reduced and the target dose rates once within BBCH 37-56.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 59-83 and 22-43 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-31.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 11 out of 12 trials. In average of all trials across all climatic zones, the full dose rate resulted in +9.9 percentage points above the reduced dose rate and was considerably more consistent in performance which did not drop below 60%.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Erysiphe graminis* in barley under a wide range of environmental conditions.

Table 3.2-31: Minimum Effective Dose, Barley, ERYSGR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate			
				infect	efficacy	infect	efficacy	infect	efficacy
Maritime	n = 5	mean	11.6	4.7	62.7	2.7	78.0	2.6	82.4
		(min-max)	(5.5-19)	(0.8-14.4)	(22.2-95.2)	(0.5-7)	(60.7-91.9)	(0-9)	(56.2-100)
North east	n = 1	mean	11.6	4.4	61.8	2.5	78.5	2.9	75.3
		(min-max)	(11.6-11.6)	(4.4-4.4)	(61.8-61.8)	(2.5-2.5)	(78.5-78.5)	(2.9-2.9)	(75.3-75.3)
South east	n = 6	mean	19.6	6.4	70.8	4.4	79.2	4.8	77.7
		(min-max)	(6.7-38.1)	(1.6-18.1)	(53.3-88.3)	(0.3-13)	(67.1-97.5)	(1.5-11.8)	(69.8-89)
Total ALL	n = 12	mean	15.6	5.5	66.7	3.5	78.6	3.7	79.5
		(min-max)	(5.5-38.1)	(0.8-18.1)	(22.2-95.2)	(0.3-13)	(60.7-97.5)	(0-11.8)	(56.2-100)

***Puccinia recondita*, Rye**

Altogether 18 field trials were carried out in order to determine the minimum effective dose for the control of *Puccinia recondita* in rye. Trials were conducted in years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany, France and Sweden) and the North East climatic zone (Latvia and Poland). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 33-59.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 69-79 and 28-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-32.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 15 out of 18 trials. In average of all trials across all climatic zones, the full dose rate resulted in +5.3 percentage points above the reduced dose rate and was more consistent in performance.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Puccinia recondita* in rye under a wide range of environmental conditions.

Table 3.2-32: Minimum Effective Dose, Rye, PUCCRE, intensity of attack (infect and efficacy in %); summary

Eppo Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate			
				infect	efficacy	infect	efficacy	infect	efficacy
Maritime	n = 10	mean	15.3	2.0	91.1	1.0	95.1	2.0	88.5
		(min-max)	(5.5–50.8)	(0–11.7)	(77.7–100)	(0–4.9)	(89.1–100)	(0–7)	(61.9–100)
North east	n = 8	mean	22.3	3.3	88.2	1.5	95.0	4.2	85.1
		(min-max)	(5.8–43.8)	(0.1–9.8)	(77.7–98.5)	(0–4.5)	(89.7–100)	(0.1–13.3)	(55.6–99.1)
Total ALL	n = 18	mean	18.4	2.6	89.8	1.2	95.1	3.0	87.0
		(min-max)	(5.5–50.8)	(0–11.7)	(77.7–100)	(0–4.9)	(89.1–100)	(0–13.3)	(55.6–100)

***Rhynchosporium secalis*, Rye**

Altogether 11 field trials were carried out in order to determine the minimum effective dose for the control of *Rhynchosporium secalis* in rye. Trials were conducted in years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany and Sweden) and the North East climatic zone (Latvia and Poland). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 33-59.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 59-77 and 15-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-33.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 10 out of 11 trials. In average of all trials across all climatic zones, the full dose rate resulted in +9.6 percentage points above the reduced dose rate and was more consistent in performance.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Rhynchosporium secalis* in rye under a wide range of environmental conditions.

Table 3.2-33: Minimum Effective Dose, Rye, RHYNSE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate			
				infect	efficacy	infect	efficacy	infect	efficacy
Maritime	n = 5	mean	21.4	3.7	81.4	2.3	88.3	3.0	82.6
		(min-max)	(8.5–41.3)	(1.7–7.4)	(67.6–93.7)	(1.5–3)	(79.4–95.5)	(1.8–4)	(64.7–91.2)
North east	n = 6	mean	16.7	4.8	75.1	3.2	86.9	4.4	77.5
		(min-max)	(6–33.8)	(0.6–11)	(68.5–90.3)	(0–9.5)	(74.9–100)	(0.2–14.7)	(52.8–97.4)
Total ALL	n = 11	mean	18.9	4.3	77.9	2.8	87.5	3.8	79.8
		(min-max)	(6–41.3)	(0.6–11)	(67.6–93.7)	(0–9.5)	(74.9–100)	(0.2–14.7)	(52.8–97.4)

***Septoria* species, Triticale**

Altogether 13 field trials were carried out in order to determine the minimum effective dose for the control of *Septoria* sp. in triticale. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany) and the North East climatic zone (Poland). The crop was sprayed once or twice with the reduced and the target dose rates within BBCH 33-59.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 37-77 and 19-49 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-34.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 11 out of 13 trials. In average of all trials across all climatic zones, the full dose rate resulted in +4.4 percentage points above the reduced dose.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Septoria* sp. in triticale under a wide range of environmental conditions.

Table 3.2-34: Minimum Effective Dose, Triticale, SEPTSP, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated infect	BAS 736 00 F				Standard	
				Reduced dose rate		Target dose rate		infect	efficacy
				infect	efficacy	infect	efficacy		
Maritime	n = 6	mean	22.1	2.8	88.7	2.0	91.4	3.6	83.6
		(min-max)	(8.5–38.3)	(0.3–4.6)	(80–97.2)	(0–3.8)	(72.7–100)	(0–7.8)	(43.6–100)
North east	n = 7	mean	14.5	3.2	83.1	2.2	89.1	2.6	86.6
		(min-max)	(6–23.3)	(0–6.5)	(72–100)	(0–4.5)	(78.8–100)	(0–6.1)	(68.5–100)
Total ALL	n = 13	mean	18.0	3.0	85.7	2.1	90.1	3.1	85.2
		(min-max)	(6–38.3)	(0–6.5)	(72–100)	(0–4.5)	(72.7–100)	(0–7.8)	(43.6–100)

***Puccinia striiformis*, Triticale**

Altogether 11 field trials were carried out in order to determine the minimum effective dose for the control of *Puccinia striiformis* in triticale. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany and France) and the North East climatic zone (Poland). The crop was sprayed with the reduced and the target dose rates once or twice within BBCH 33-53.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 63-83 and 30-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-35.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 6 out of 11 trials. In average of all trials across all climatic zones, the full dose rate resulted in +2 percentage points above the reduced dose rate and was more consistent in performance.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Puccinia striiformis* in triticale under a wide range of environmental conditions.

Table 3.2-35: Minimum Effective Dose, Triticale, PUCCSI, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic		Untreated infect	BAS 736 00 F				Standard	
			Reduced dose rate		Target dose rate			
			infect	efficacy	infect	efficacy	infect	efficacy
Maritime	n = 10 mean (min-max)	40.8 (13.4–100)	3.7 (0–12.6)	92.7 (77.3–100)	2.9 (0–9.7)	94.8 (79.3–100)	3.5 (0–13.6)	91.9 (69.9–100)
North east	n = 1 mean (min-max)	36.3 (36.3–36.3)	6.3 (6.3–6.3)	82.8 (82.8–82.8)	5.8 (5.8–5.8)	84.1 (84.1–84.1)	3.5 (3.5–3.5)	90.3 (90.3–90.3)
Total ALL	n = 11 mean (min-max)	40.4 (13.4–100)	3.9 (0–12.6)	91.8 (77.3–100)	3.2 (0–9.7)	93.8 (79.3–100)	3.5 (0–13.6)	91.8 (69.9–100)

***Puccinia recondita*, Triticale**

Altogether 8 field trials were carried out in order to determine the minimum effective dose for the control of *Puccinia recondita* in triticale. Trials were conducted in the years 2019 and 2020 in the Maritime climatic zone (Denmark and Germany) and the North East climatic zone (Poland). The crop was sprayed with the reduced and the target dose rates once within BBCH 31-59.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 65-77 and 28-64 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-36.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 6 out of 8 trials. In average of all trials across all climatic zones, the full dose rate resulted in +5.8 percentage points above the reduced dose rate and was more consistent in performance.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Puccinia recondita* in triticale under a wide range of environmental conditions.

Table 3.2-36: Minimum Effective Dose, Triticale, PUCCRE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic		Untreated infect	BAS 736 00 F				Standard	
			Reduced dose rate infect	efficacy	Target dose rate infect	efficacy	infect	efficacy
Maritime	n = 4 mean (min-max)	23.7 (14.5–34.4)	5.3 (1.2–14.6)	79.2 (57.4–88.2)	3.2 (0.9–9)	86.8 (73.8–97.4)	7.8 (0.7–18.5)	64.8 (27.8–97.6)
North east	n = 4 mean (min-max)	15.5 (7.1–28.5)	2.2 (0–4.5)	89.0 (75–99.6)	1.3 (0–3)	93.1 (83.3–99.6)	2.5 (0.1–4.2)	83.6 (64.7–99.1)
Total ALL	n = 8 mean (min-max)	19.6 (7.1–34.4)	3.7 (0–14.6)	84.1 (57.4–99.6)	2.3 (0–9)	89.9 (73.8–99.6)	5.1 (0.1–18.5)	74.2 (27.8–99.1)

***Blumeria graminis*, Triticale**

Altogether 6 field trials were carried out in order to determine the minimum effective dose for the control of *Blumeria graminis* in triticale. Trials were conducted in years 2019 and 2020 in the Maritime climatic zone (Germany) and the North East climatic zone (Lithuania and Poland). The crop was sprayed with the reduced and the target dose rates once within BBCH 33-41.

The same assessments are presented in this chapter as in the main efficacy chapter. The assessments ranging within BBCH 51-75 and 20-45 DALT on upper 4 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A summary of the dose response results is provided in Table 3.2-37.

Higher performance of the full dose rate in comparison to reduced dose rate was observed in 5 out of 6 trials. In average of all trials across all climatic zones, the full dose rate resulted in +5 percentage points above the reduced dose rate and was more consistent in performance.

Conclusion

The proposed dose rate of 2 L/ha of BAS 736 00 F provided the optimum overall control and should be considered as the minimum effective dose to deliver optimum control of *Blumeria graminis* in triticale under a wide range of environmental conditions.

Table 3.2-37: Minimum Effective Dose, Triticale, ERYSGR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic		Untreated infect	BAS 736 00 F				Standard	
			Reduced dose rate infect	efficacy	Target dose rate infect	efficacy	infect	efficacy
Maritime	n = 4 mean (min-max)	9.8 (4.5–16.8)	2.0 (1–3.7)	77.3 (61.1–89.5)	1.7 (1–2.8)	80.9 (66.7–89.5)	2.4 (0.8–6.5)	79.1 (61.3–92.1)
North east	n = 2 mean (min-max)	20.9 (11.8–30)	4.0 (3.5–4.5)	75.5 (61.7–89.3)	2.4 (1.4–3.5)	83.2 (70.2–96.2)	2.4 (1.8–3)	84.7 (74.5–95)
Total ALL	n = 6 mean (min-max)	13.5 (4.5–30)	2.7 (1–4.5)	76.7 (61.1–89.5)	1.9 (1–3.5)	81.7 (66.7–96.2)	2.4 (0.8–6.5)	81.0 (61.3–95)

Summary and conclusions on the minimum effective dose

The dose response of BAS 736 00 F has been demonstrated with altogether 194 trials conducted in wheat (86 trials), barley (67 trials), rye (21 trials) and triticale (20 trials) in which the performances of the target dose rate and the reduced dose rate were compared. An overview is provided in Table 3.2-38.

The full dose rate of 2 L/ha provided clearly the best control of all disease in all crops. The strongest dose response was observed on *Zymoseptoria tritici* and *Blumeria graminis* in wheat, *Pyrenophora teres*, *Ramularia collo-cygni*, *Rhynchosporium secalis* and *Blumeria graminis* in barley, *Rhynchosporium secalis* in rye. Weaker dose response (less than +5% points) was given on *Puccinia hordei* in barley and on *Septoria* species and *Puccinia striiformis* in triticale. On *Puccinia hordei* in barley however the target dose was clearly more consistent (the efficacy did not drop below 60%). On *Septoria* species and *Puccinia striiformis* in triticale, very good results were often obtained already with the reduced dose rate of 1.2 L/ha. With the full dose rate however the average efficacy on both diseases got over 90% and outperformed the standard.

In summary, according to the presented results, BAS 736 00 F at the targeted dose rate of 2.0 L/ha provided the optimum and most consistent control of the key diseases of important cereal crops and should be considered as the minimum effective dose rate in cereals under a wide range of environmental conditions.

Nevertheless, it was observed that there were also conditions and disease pressures under which even the reduced dose rate of the product led to a satisfying performance. Therefore, the farmer should have the possibility to apply a lower dose rate. In some countries, this is only possible when a dose rate range is registered. Detailed information concerning the need for a dose rate range in certain countries is given in chapter “Dose rate range justification”.

Table 3.2-38: Minimum Effective Dose, Summary all crops; intensity of attack (infect and efficacy in %)

EPPO Zone climatic	Crop	No. of trials	*	Untreated infect	Reduced dose rate		BAS 736 00 F Target dose rate		Difference (%) eff. target rate – eff. reduced rate	Standard	
					infect	efficacy	infect	efficacy		infect	efficacy
Wheat	SEPTTR	n = 59	mean (min-max)	26.0 (5.3-100)	6.1 (0-37.6)	77.2 (46.4-100)	4.2 (0-24.4)	85.1 (50-100)	+7.9	8.2 (0-70.6)	73.7 (29.2-100)
	PUCCSI	n = 28	mean (min-max)	34.6 (5.4-97.8)	6.6 (0-53)	85.8 (45.7-100)	4.7 (0-36.5)	90.2 (60.6-100)	+4.4	7.2 (0-55.8)	84.0 (42.7-100)
	PUCCRT	n = 32	mean (min-max)	20.7 (5-100)	2.3 (0-10.8)	89.0 (57.4-100)	1.4 (0-6.5)	94.1 (75-100)	+5.1	7.4 (0-65)	76.2 (25-100)
	PYRNTR	n = 17	mean (min-max)	19.9 (5-50)	6.2 (0-24.6)	74.4 (48.5-100)	5.2 (0-20)	79.8 (58.7-100)	+5.4	6.0 (0-20.3)	73.5 (53.5-100)
	ERYSGR	n = 9	mean (min-max)	9.1 (4.3-18.7)	2.8 (1-7.3)	69.7 (44.5-90.5)	2.0 (0.3-6.8)	79.1 (61.3-96.2)	+9.4	1.7 (0-4)	79.8 (52.9-100)
Barley	PYRNTE	n = 38	mean (min-max)	25.3 (5-87.9)	6.6 (0.3-37.6)	75.5 (18.7-97.8)	4.2 (0.1-31.2)	85.2 (63.6-99.1)	+9.7	6.6 (0-48.8)	76.2 (30.6-100)
	PUCCHD	n = 18	mean (min-max)	21.1 (5.8-54)	3.2 (0-23.8)	88.2 (43.5-100)	2.2 (0-16.3)	91.8 (61.3-100)	+3.6	4.4 (0-21.8)	83.8 (48.2-100)
	RHYNSE	n = 16	mean (min-max)	32.2 (5.4-94)	5.8 (0-28.3)	79.3 (42.7-100)	3.7 (0.4-15.2)	87.4 (57.3-98.6)	+8.1	5.5 (0.4-26.2)	82.2 (51.7-99.2)
	RAMUCC	n = 19	mean (min-max)	32.9 (5-98.6)	11.4 (1-47.1)	63.8 (0-90.5)	7.8 (0.8-33.8)	75.5 (48.9-93.6)	+11.7	7.5 (0-29.9)	75.9 (25.8-100)
	ERYSGR	n = 12	mean (min-max)	15.6 (5.5-38.1)	5.5 (0.8-18.1)	66.7 (22.2-95.2)	3.5 (0.3-13)	78.6 (60.7-97.5)	+11.9	3.7 (0-11.8)	79.5 (56.2-100)
Rye	PUCCRE	n = 18	mean (min-max)	18.4 (5.5-50.8)	2.6 (0-11.7)	89.8 (77.7-100)	1.2 (0-4.9)	95.1 (89.1-100)	+5.3	3.0 (0-13.3)	87.0 (55.6-100)
	RHYNSE	n = 11	mean (min-max)	18.9 (6-41.3)	4.3 (0.6-11)	77.9 (67.6-93.7)	2.8 (0-9.5)	87.5 (74.9-100)	+9.6	3.8 (0.2-14.7)	79.8 (52.8-97.4)
Triticale	SEPTSP	n = 13	mean (min-max)	18.0 (6-38.3)	3.0 (0-6.5)	85.7 (72-100)	2.1 (0-4.5)	90.1 (72.7-100)	+4.4	3.1 (0-7.8)	85.2 (43.6-100)

EPPO Zone climatic	Crop	No. of trials	*	Untreated infect	BAS 736 00 F					Standard	
					Reduced dose rate		Target dose rate		Difference (%) eff. target rate – eff. reduced rate	infect	efficacy
					infect	efficacy	infect	efficacy			
	PUCCSI	n = 11	mean (min-max)	40.4 (13.4–100)	3.9 (0–12.6)	91.8 (77.3–100)	3.2 (0–9.7)	93.8 (79.3–100)	+2.0	3.5 (0–13.6)	91.8 (69.9–100)
	PUCCRE	n = 8	mean (min-max)	19.6 (7.1–34.4)	3.7 (0–14.6)	84.1 (57.4–99.6)	2.3 (0–9)	89.9 (73.8–99.6)	+5.8	5.1 (0.1–18.5)	74.2 (27.8–99.1)
	ERYSGR	n = 6	mean (min-max)	13.5 (4.5–30)	2.7 (1–4.5)	76.7 (61.1–89.5)	1.9 (1–3.5)	81.7 (66.7–96.2)	+5.0	2.4 (0.8–6.5)	81.0 (61.3–95)

Comments of zRMS:	Minimum Effective Dose (MED)
	<p>The Minimum Effective Dose (MED) of BAS 736 00 F (Miralon) for cereals diseases control was determine on the base of 194 efficacy trials (86 in wheat, 67 in barley, 21 in rye and 20 in triticale), conducted across the Europe. This fungicide was tested with the target and reduced dose rates. In Maritime and North-East zones it was tested at the rates of 2.0 and 1.2 L/ha and in South-East zone at 2.0 and 1.0 L/ha.</p> <p>The field trials were carried out in order to determine the MED for the control of: <i>Zymoseptoria tritici</i>, <i>Puccinia striiformis</i>, <i>Puccinia triticina</i>, <i>Pyrenophora tritici-repentis</i> and <i>Blumeria graminis</i> in wheat; <i>Pyrenophora teres</i>, <i>Puccinia hordei</i>, <i>Rhynchosporium secalis</i>, <i>Ramularia collo-cygni</i> and <i>Blumeria graminis</i> in barley; <i>Puccinia recondite</i> and <i>Rhynchosporium secalis</i> in rye; <i>Septoria species</i>, <i>Puccinia striiformis</i>, <i>Puccinia recondite</i> and <i>Blumeria graminis</i> in triticale.</p> <p>In almost all trials and in all climatic zones, the efficacy of BAS 736 00 F was higher than that of the reference products, and in remain trials on the same level.</p> <p>Conclusion. ZRMS agree with applicant that “BAS 736 00 F (fluxapyroxad – 50 g/L + Azoxystrobin – 150 g/L) at the target dose rate of 2.0 L/ha provided the optimum and most consistent control of the key diseases of important cereal crops and should be considered as the minimum effective dose rate in cereals under a wide range of environmental conditions”.</p> <p>According to EPPO guideline PP 1/225(2) “the minimum effective dose of a plant protection product is the dose that is the minimum necessary to achieve sufficient efficacy against a target pest across the broad range of situations in which the product will be applied”. In some situations “where the product is proposed for use under diverse conditions, there may be situations that warrant the use of different doses, for example, in situations with different cropping practices or crop structures or variation in the inherent sensitivity of the target pest. Thus for a specific target, it may be possible to justify a number of specific ‘minimum effective doses’ under defined conditions, which should be established using the principles in this standard”. This statemen justifies the recognition of a lower dose than 2.0 L/ha in some countries.</p>

3.2.3 Efficacy tests (KCP 6.2)

Comments of zRMS:	<p>Efficacy - Information on submitted trials</p> <p>The efficacy of BAS 736 00 F (Miralon) was tested in 106 trials in wheat (Maritime EPPO zone - 64, North-East zone – 26, South-East zone - 16), 77 trials in barley (Maritime zone - 45, N-E zone – 20, S-E zone - 12); 21 in rye (Maritime zone - 11, N-E zone – 10); and 20 trials in triticale (Maritime zone - 12, N-E zone - 8). In wheat 104 trials were carried out in winter wheat and 2 in spring wheat, while in barley 57 trials were conducted in winter barley and 20 in spring barley. The efficacy trials were carried out with disease and without diseases. In the trials 69 varieties were tested in winter wheat, 2 in spring wheat, 38 in winter barley, 18 in spring barley; 13 in winter rye, 16 in winter triticale and 2 in oat.</p> <p>All the trials were carried out by organizations officially recognized for efficacy testing of plant protection products, by the authorities of relevant countries, according to GEP, in accordance with EPPO general guidelines: PP 1/135 (4), PP 1/152 (4), PP 1/181 (4), PP 1/223 (2), PP 1/239 (2) and specific guidelines: EPPO PP 1/26 (4) and CEB n°218. No major deviation from the EPPO guidelines was observed, except of 6 trials in wheat, carried out in France, conducted in 3 replications.</p> <p>The data show a sufficient level of infestation by diseases to evaluate the efficacy of BAS 736 00 F in cereal crops. In the individual zones the following mean infection by diseases was noted: in wheat – <i>Zymoseptoria tritici</i> – 14.5-36.7%, <i>Puccinia striiformis</i> – 7.8-88.3%, <i>Puccinia triticina</i> – 8.9-33.4%, <i>Pyrenophora tritici-repentis</i> – 15.3-28.4%, <i>Erysiphe graminis</i> – 8.5-9.0%; in barley – <i>Pyrenophora teres</i> – 19.1-28.8%, <i>Puccinia hordei</i> – 6.4-26.6%, <i>Rhynchosporium secalis</i> – 6.5-41.6%, <i>Ramularia collo-cygni</i> – 8.8-39.0%, <i>Blumeria graminis</i> – 11.6-18.9%; in rye – <i>Puccinia recondita</i> – 15.3-22.3%, <i>Rhynchosporium secalis</i> – 14.5-22.1%; in triticale: <i>Septoria</i> species – 14.5-22.1%, <i>Puccinia striiformis</i> – 36.3-40.8%, <i>Puccinia recondita</i> – 15.5-23.7, <i>Blumeria graminis</i> – 9.8-20.9%; in oat – <i>Puccinia coronata</i> – 20.8%, <i>Blumeria graminis</i> – 12.5%.</p> <p>Across all trials the level of infestation by diseases on untreated plots in all cereal crops was above 5%, so presented data may be recognized as valid.</p> <p>The number of trials for the major pathogens on the major crops varies from 6 to 15, however, taking into account the high efficacy of BAS 736 00 F and the fact that in the vast majority of the trials the efficacy of tested fungicide was higher than that of the reference product (only in some cases it was lower) it can be assumed that 6 trials is sufficient for registration.</p>
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Information on trials submitted in wheat

Between 2019 and 2020, altogether 106 efficacy trials were carried out to prove the fungicidal efficacy of BAS 736 00 F in wheat. The trials were conducted in the Czech Republic, Denmark, France, Germany, Ireland, the Netherlands and the United Kingdom (Maritime zone), Finland, Latvia, Lithuania and Poland (North-East zone) and Bulgaria, Hungary, Romania and Slovakia (South-East zone). The distribution of trials by country and year and by EPPO zone is provided in Table 3.2-39 and Table 3.2-40.

Product at target dose rate of 2.0 L/ha was applied according to the GAP once or twice within the BBCH stage ranging from 31-69.

In 2 trials a later application at BBCH 72 is mentioned. The late application in one Romanian trial can be explained by a very inhomogeneous crop, where some plants were more mature. The average growth stage at application was BBCH 51. Therefore, this trial is still considered reliable for the evaluation of the disease efficacy.

The second trial with a late application is a German trial. In this trial 2 applications were done: the first application occurred within BBCH 39-52 and the second at BBCH 72. The application timing was too late to control Septoria leaf spot but still valid in regard to the late arrival of brown rust and powdery mildew. It was thus excluded from efficacy evaluation on Septoria but was used for the other two diseases. For the purpose of this dossier, the application after the BBCH range described in the GAP is considered acceptable however in the practise it should not be done later than at BBCH 69.

BAS 9314 1 F known as Proline at the dose rate of 0.8 L/ha (prothioconazole 250 g/L) was used as a reference product in the vast majority of the trials. In the trials conducted in the United Kingdom, BAS 9314 4 F at 0.72 L/ha (prothioconazole 275 g/L) was applied. In altogether 2 trials BAS 9578 0 F (Elatus Era, prothioconazole 150 g/L+ benzindiflupyr 75 g/L) at the dose rate of 1 L/ha was applied as a standard. The trials with both prothioconazole based standards have been summarized together. The trials with Elatus Era are marked with an asterisk in the detailed tables.

The vast majority of the trials (97) was conducted in the winter wheat. On spring wheat, 2 trials from the North east zone are available. In the summary tables, the means for winter and spring crop are presented separately for the North East EPPO zone to provide additional information for Poland where the spring crop is of an importance.

Table 3.2-39: Distribution of trials by location and year; Wheat

Crop	EPPO Zone	Country	Year		TOTAL
			2019	2020	per country
Wheat winter and spring	Maritime	CZ	2	4	6
		DE	7	13	20
		DK	2	5	7
		FR	5	10	15
		IE	1	3	4
		NL	0	3	3
		UK	5	4	9
	North East	FI	1	1	2
		LT	1	0	1
		LV	2	0	2
		PL	13	8	21
	South East	BG	4	1	5
		HU	1	1	2
		RO	4	4	8
		SK	0	1	1
Total					106

Table 3.2-40: Distribution of trials by EPPO zone; Wheat

Crop	EPPO Zone	TOTAL per zone
Wheat winter and spring	Maritime	64
	North East	26 (2 TRZAS)
	South East	16
TOTAL ALL		106

***Zymoseptoria tritici*, Wheat**

A total of 73 trials showed a sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Zymoseptoria tritici* in winter wheat. BAS 736 00 F at the dose rate of 2 L/ha was applied once or twice within BBCH 31-72. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, Denmark, France, Germany, Ireland and the United Kingdom), the North East climatic zone (Latvia, Lithuania and Poland) and the South East climatic zone (Bulgaria, Romania and Slovakia).

Summary of results is available in Table 3.2-41.

The assessments ranging from BBCH 45-82, 12-50 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

One German trial was not included in the calculation of the summary. For transparency the trial is presented in the detailed table, but it has been greyed out and was not included in the mean value per trial and consequently in the summary table. Neither BAS 736 00 F nor the standard showed sufficient efficacy on the disease. In this trial, the crop was attacked by several different diseases (SEPTTR, PUCCRT, ERYSGR). On *Zymoseptoria tritici*, the treatment was done too late to be able to control the disease sufficiently. The second application at BBCH 72 was applied even behind the proposed BBCH range in the GAP. The poor performance of standard confirms the challenging conditions. On the diseases which arrived later (PUCCRT, ERYSGR), however, the trial still provides useful information and is therefore considered useful for the purpose of this BAD.

Also, in 2 Irish trials, the assessments on the 3rd leaves have been greyed out and were not included in the summary. These trials were influenced by unusual dry weather conditions and the disease levels were lower than normal for this location. In both trials, the symptoms were already present on the 4th leaf at application, but the disease levels were very low in the earlier assessments. At the top leaves the disease arrived too late to be effectively controlled. It explains the lower efficacy observed.

There were 4 French trials in which only 3 replications were done. These trials are presented in the detailed table for single efficacy on *Zymoseptoria tritici* but they have not been included in the calculations of the average values in the summary tables.

A summary of 67 trials across all EPPO zones showed that the mean infestation of 26.1% in the untreated was reduced with BAS 736 00 F by 85.4%. The performance of the product was superior to the standard (74.6%).

The average efficacies obtained in the Maritime and the North East climatic zones were comparable, the best result was observed in the South East zone. The Maritime zone offered the most challenging conditions with infection range in the untreated of up to 100%. BAS 736 00 F proved its strong fungicidal activity also under these challenging situations. Separation of mean efficacy in the Maritime zone in two groups according to the level of infection in the untreated – a group with less than 35% infection and a group with infection of 35-100% – showed that even in the challenging situations of the infection pressure above 35% BAS 736 00 F kept its high efficacy. It stayed comparable to the efficacy observed in the North east zone under less challenging conditions and slightly increased its superiority to the standard.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Zymoseptoria tritici* in wheat under a wide range of agroclimatic conditions. The available data fully support registration in the Maritime, the North East and the South East zones.

Table 3.2-41: Efficacy, Wheat (TRZAW), SEPTTR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 34	mean	36.7	6.1	83.4	12.5	68.8
		(min-max)	(5.3-100)	(0-24.4)	(50-100)	(0-70.6)	(29.2-100)
	UTC<35%	n = 24	19.6	3.3	83.0	5.9	69.6
		(min-max)	(5.3-32.5)	(0-11.3)	(50-100)	(0-17.5)	(42.4-100)
	UTC≥35%	n = 10	77.2	12.5	84.6	28.1	66.8
		(min-max)	(36.9-100)	(3.2-24.4)	(73.1-94.2)	(3.8-70.6)	(29.2-96.3)
North east	n = 19	mean	15.8	2.7	84.9	4.0	77.0
		(min-max)	(7.9-28.9)	(0-9.3)	(61.5-100)	(0-13)	(45-100)
South east	n = 14	mean	14.5	1.8	90.4	2.6	83.6
		(min-max)	(7.5-25.1)	(0-5.1)	(76.5-100)	(0-6.9)	(51.9-100)
Total ALL	n = 67	mean	26.1	4.2	85.4	8.0	74.6
		(min-max)	(5.3-100)	(0-24.4)	(50-100)	(0-70.6)	(29.2-100)

Comments of zRMS	<u>Diseases control in wheat</u>
	<i>Zymoseptoria tritici</i> (67 trials – 34 in Maritime, 19 in N-E, 14 in S-E zone).
	The results showed a good control of <i>Zymoseptoria tritici</i> on wheat by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 83-90.4%), under a wide range of conditions. In all cases the efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F in the Maritime, the North-East and the South-East zones, for <i>Zymoseptoria tritici</i> control.
	For the registration of BAS 736 00 F to <i>Zymoseptoria tritici</i> control in winter wheat in Poland, the following trials can be accepted - 19 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 14 trials, Czech Republic – 4 trials) and South-East zone (Slovakia – 1 trial).
	For spring wheat applicant did not submitted any data (for extrapolation a full package of trials required for the main crop (indicator crops) and at least 2 trials for the crop to which we extrapolate), so in this case the registration of BAS 736 00 F for <i>Zymoseptoria tritici</i> control in spring wheat is not possible.

***Puccinia striiformis*, Wheat**

A total of 34 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Puccinia striiformis* in winter and spring wheat. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter or spring wheat once or twice within BBCH 31-65. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (Denmark, France, Germany, the Netherlands and the United Kingdom), the North East climatic zone (Finland and Poland) and the South East climatic zone (Hungary).

Summary of results is provided in Table 3.2-42.

The assessments ranging from BBCH 39-85, 11-49 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Puccinia striiformis* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that under relatively high mean infestation of 38.6 % in the untreated BAS 736 00 F reached efficacy of 89.5 %. The performance of the product was superior to the standard (82.1%).

The overall mean efficacy was lower in the Maritime zone compared to the other two zones. However, at the same time the Maritime zone was the zone with the largest number of trials showing strong to very strong attack (half of the trials had 35-100% infection in the untreated). BAS 736 00 F proved its strong fungicidal activity also under these challenging conditions. Separation of mean efficacy in the Maritime zone in two groups according to the infection level in the untreated – a group with less than 35% infection and a group with infection of 35-100% – showed that within the same range of infection level in the untreated (5-35%), the Maritime zone reached efficacy above 90% comparable to the South east zone. Under the high infection pressure of 35-100%, BAS 736 00 F still kept the mean efficacy of 83% and stayed superior to the standard.

In the North east zone altogether 7 trials proved very high and consistent efficacy of the product – out of them 6 trials in winter wheat and 1 trial in spring wheat. In order to further support the claim in the North east zone, 6 highly comparable German locations in winter wheat were identified via RegPest. As a result, altogether 12 trials in winter wheat and 1 trial in spring wheat support the registration in the North east zone.

In the South east zone, 2 trials showed infection by *Puccinia striiformis*. Both proved good to very good efficacy under very strong disease attack. Considering the fact that a robust data set proving very good efficacy of the product was presented from the Maritime zone and that 7 trials from the North east zone showed even an excellent control of *Puccinia striiformis*. It is therefore suggested that the full data set from the South east zone is waived. To further support this idea, the RegPest model was used to identify the trials from the North east zone that were located in regions with high comparability to the representative regions of the South east zone. Based on the RegPest analysis, 5 Polish trials were extrapolated to the South east zone. As a result, altogether 7 trials support the registration in wheat in the South east zone.

In addition, it should as well be considered in support of registrations in all zones that both active substances contained in BAS 736 00 F are registered against *Puccinia striiformis* as solo active ingredient products in Maritime, North east and South east zones. Azoxystrobin is registered across Europe under many trade names and at its maximum dose rate of 1 L/ha it delivers 250 grams of active substance per hectare (BAS 736 00 F: 150 g a.i./ha). Fluxapyroxad is widely registered under different trade names and applied at 2 L/ha it provides 125 grams of active substance per hectare (BAS 736 00 F: 100 g a.i./ha). Obviously, both solo active ingredient products at their maximum dose rates deliver higher amount of the active substance per hectare than contained in BAS 736 00 F. For azoxystrobin however a dose rate range is registered in several countries with the lower limit at 150 gai/ha in Poland and Romania, at 187.5 gai/ha in Hungary and at 200 gai/ha in Slovenia, Slovakia and the Czech Republic.

For purpose of ratio justification, the reduced dose rates of azoxystrobin (150 gai/ha) and fluxapyroxad (100 gai/ha) as combined in BAS 736 00 F were tested. It has been proven that, even with the reduced dose rates of both active ingredients, good efficacies on *Puccinia striiformis* were achieved with azoxystrobin solo (10 trials, average efficacy 72%, see Table 3.2-19) and with fluxapyroxad solo (7 trials, average efficacy 78%, see Table 3.2-20). It was further shown with 5 trials, that when both actives were combined in BAS 736 00 F, the efficacy further increased and clearly outperformed the standard. It is therefore concluded that the fact that both active substances of BAS 736 00 F are registered on *Puccinia striiformis* can be considered as supportive for registration of BAS 736 00 F.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Puccinia striiformis* in wheat under a wide range of agroclimatic conditions. The available data fully support registration in the Maritime and the North east zones. A registration in the South east zone is supported by data extrapolation from the North east zone and by reference to the existing registrations of the solo active substances.

Table 3.2-42: Efficacy, Wheat, PUCSSI, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F 2.0 L/ha		Standard	
				infect	infect	efficacy	infect	efficacy
Maritime	all	n = 25	mean	43.2	6.5	86.9	10.6	77.8
			(min-max)	(6.5-98.3)	(0-36.5)	(60.6-100)	(0-55.8)	(42.7-100)
	UTC<35%	n = 12	mean	20.1	1.8	91.7	4.1	79.2
			(min-max)	(6.5-34.4)	(0-5.3)	(73.5-100)	(0-10.8)	(42.7-100)
	UTC≥35%	n = 13	mean	60.4	10.0	83.3	15.7	76.1
			(min-max)	(33.8-98.3)	(0.3-36.5)	(60.6-99.4)	(0.5-55.8)	(43-99.3)
North east	all	n = 7	mean	7.8	0.1	98.4	0.3	96.5
			(min-max)	(5.4-13)	(0-0.5)	(93.4-100)	(0-1.5)	(88.5-100)
	TRZAW	n = 6	mean	8.0	0.1	99.3	0.3	97.1
			(min-max)	(5.4-13)	(0-0.5)	(96.2-100)	(0-1.5)	(88.5-100)
	TRZAW NE incl. extrapolated trials from MA	n = 12	mean	25.6	6.4	91.5	9.5	85.0
			(min-max)	(5.4-98.3)	(0-36.5)	(62.7-100)	(0-55.8)	(43-100)
	TRZAS	n = 1	mean	7.1	0.5	93.4	0.5	93.2
			(min-max)	(7.1-7.1)	(0.5-0.5)	(93.4-93.4)	(0.5-0.5)	(93.2-93.2)
South east		n = 2	mean	88.3	6.8	92.0	12.1	85.8
			(min-max)	(81-95.5)	(4.4-9.3)	(88.6-95.4)	(7.1-17)	(79.1-92.5)
	SE incl. extrapolated trials from NE	n = 7	mean	30.6	2.0	97.1	3.7	93.4
			(min-max)	(5.4-95.5)	(0-9.3)	(88.6-100)	(0-17)	(79.1-100)
Total ALL		n = 34	mean	38.6	5.2	89.5	8.6	82.1
			(min-max)	(5.4-98.3)	(0-36.5)	(60.6-100)	(0-55.8)	(42.7-100)

Comments of zRMS	<p><u>Diseases control in wheat</u></p> <p><i>Puccinia striiformis</i> (34 trials – 25 in Maritime, 7 in N-E, 2 in S-E zone)</p> <p>The results showed a good control of <i>Puccinia striiformis</i> on wheat by BAS 736 00 F applied at the rate 2.0 L/ha (mean control 86.9-98.4%), under a wide range of conditions. In all cases the efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F in Maritime and North-East zones for <i>Puccinia striiformis</i> control and for South-East zone the registration can be supported by extrapolation of data from the Maritime and North-East zones. The decision about extrapolation should be taken be cMS.</p> <p>For the registration of BAS 736 00 F for <i>Puccinia striiformis</i> control in winter wheat in Poland, the following trials can be accepted - 7 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 12 trials, Czech Repiblik – 3 trials).</p> <p>The applicant submitted only 1 trials on <i>Puccinia striiformis</i> control in spring wheat, but taking into account that active substances included in BAS 736 00 F (fluxapyroxad and azoxystrobin) are effective in <i>Puccinia striiformis</i> control when were used in other products, so evaluator suggests to extrapolate the data from winter wheat to spring wheat.</p>
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***Puccinia triticina*, Wheat**

A total of 36 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Puccinia triticina* in winter wheat. BAS 736 00 F at the dose rate of 2 L/ha was applied once or twice within BBCH 31-72. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, France, Germany and the United Kingdom), the North East climatic zone (Poland) and the South East climatic zone (Bulgaria, Romania and Slovakia).

Summary of results is provided in Table 3.2-43.

The assessments ranging from BBCH 69-83, 12-49 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Puccinia triticina* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 20.7 % in the untreated was reduced with BAS 736 00 F by 94.7 %. The performance of the product was clearly superior to the standard (78.1%).

The efficacies obtained in different climatic zones were comparable, with differences in efficacies between the individual climatic zones of less than 5 percentage points. The highest mean efficacy, however, was observed in the South east zone. Out of three EPPO zones, the lowest mean efficacy, but still 93.2%, was shown in the Maritime zone which at the same time offered the most challenging conditions with infection range in the untreated of up to 100%. BAS 736 00 F proved its strong fungicidal activity also under these challenging situations. Separation of mean efficacy in the Maritime zone in two groups according to the level of infection in the untreated – a group with less than 35% infection and a group with infection of 35-100% – showed that even in the challenging situations of the infection pressure above 35% BAS 736 00 F kept its high efficacy. It stayed comparable to the efficacy observed in the North east zone under less challenging conditions and significantly increased its superiority to the standard.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Puccinia triticina* in wheat under a wide range of agroclimatic conditions. The available data fully support registration in the Maritime, the North east and the South east zones.

Table 3.2-43: Efficacy, Wheat, PUCCRT, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 16	mean	33.4	2.1	93.2	13.3	66.2
		(min-max)	(5.8-100)	(0-6.5)	(75-100)	(0-65)	(25-100)
	UTC<35%	n = 11	18.2	1.4	92.6	5.3	70.2
		(min-max)	(5.8-34.4)	(0-5.4)	(75-100)	(0-12.6)	(25-100)
	UTC≥35%	n = 5	67.1	3.6	94.4	30.8	57.6
		(min-max)	(48.8-100)	(0.1-6.5)	(87.2-99.8)	(8.3-65)	(35-80.9)
North east	n = 10	mean	12.1	0.9	94.3	1.9	89.0
		(min-max)	(6-34.5)	(0-5.6)	(76.7-100)	(0-11)	(66.2-100)
South east	n = 10	mean	8.9	0.5	97.5	1.3	86.1
		(min-max)	(5-26)	(0-3.3)	(88.6-100)	(0-4.1)	(58.1-100)
Total ALL	n = 36	mean	20.7	1.3	94.7	6.8	78.1
		(min-max)	(5-100)	(0-6.5)	(75-100)	(0-65)	(25-100)

Comments of zRMS	<p><u>Diseases control in wheat</u></p> <p><i>Puccinia triticina</i> (36 trials – 16 in Maritime, 10 in N-E, 10 in S-E zone).</p> <p>The results showed a good control of <i>Puccinia triticina</i> on wheat by BAS 736 00 F applied at the rate of 2.0 L/ha (means control 93.2-97.5%), under a wide range of conditions. In all cases the efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F in the Maritime, the North-East zone and the South-East zones for <i>Puccinia triticina</i> control.</p> <p>For the registration of BAS 736 00 F for <i>Puccinia triticina</i> control in winter wheat in Poland, the following trials can be accepted - 10 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 7 trials, Czech Repiblik – 4 trials) and from South-East zone (Slovakia – 1 trial).</p> <p>For spring wheat applicant did not submitted any data (for extrapolation a full package of trials required for the main crop (indicator crops) and at least 2 trials for the crop to which we extrapolate), so in this case the registration of BAS 736 00 F for <i>Puccinia triticina</i> control in spring wheat is not possible.</p>
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***Pyrenophora tritici-repentis*, Wheat**

A total of 17 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Pyrenophora tritici-repentis* in winter and spring wheat. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter or spring wheat once or twice within BBCH 31-69. Trials were conducted in harvest years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, Denmark and Germany), the North East climatic zone (Finland, Latvia and Poland).

Summary of results is provided in Table 3.2-44.

The assessments ranging from BBCH 59-85, 21-50 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Pyrenophora tritici-repentis* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 20.1 % in the untreated was reduced with BAS 736 00 F by 89.8 %. The performance of the product was superior to the standard (73.5%).

The overall mean efficacy was lower in the Maritime zone compared to the North east zone. However, at the same time there was a higher infection level in the Maritime zone. Separation of mean efficacy in the Maritime zone in two groups according to the infection level in the untreated – a group with less than 35% infection and a group with infection of 35% and more – showed that with the same range of infection level in the untreated (5-35%), the Maritime zone reached comparable efficacy to the North east zone (80.3% versus 81.9%). Under the infection pressure of 35-100%, efficacy of BAS 736 00 F in the Maritime zone declined to 66.9%, which is still a useful control and comparable to the standard.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Pyrenophora tritici-repentis* in wheat under a wide range of agroclimatic conditions. The available results provide full data sets for registrations in the Maritime and the North east zones.

Table 3.2-44: Efficacy, Wheat, PYRNTR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F 2.0 L/ha		Standard	
				infect	infect	efficacy	infect	efficacy
Maritime		n = 8	mean (min-max)	25.4 (6.4-50)	7.6 (0-20)	75.3 (58.7-100)	8.1 (0-20.3)	70.6 (55-100)
	UTC<35%	n = 5	mean (min-max)	11.6 (6.4-21.2)	2.5 (0-7.2)	80.3 (62.5-100)	3.2 (0-9.1)	73.4 (55-100)
	UTC≥35%	n = 3	mean (min-max)	48.3 (47.5-50)	16.0 (8.9-20)	66.9 (58.7-81.9)	16.4 (12.1-20.3)	66.0 (57.4-76.1)
North east	TRZAX	n = 9	mean (min-max)	15.3 (7.3-25.3)	3.2 (0-7.5)	81.9 (60.3-100)	4.1 (0-10.3)	76.1 (53.5-100)
	TRZAW	n = 7	mean (min-max)	14.4 (7.3-25.3)	2.7 (0-7.5)	84.2 (60.3-100)	4.3 (0-10.3)	74.6 (53.5-100)
	TRZAS	n = 2	mean (min-max)	18.8 (16.6-20.9)	4.8 (2.8-6.8)	74.1 (61.4-86.9)	3.3 (1.7-5)	81.6 (71.3-91.8)
Total ALL		n = 17	mean (min-max)	20.1 (6.4-50)	5.2 (0-20)	78.8 (58.7-100)	6.0 (0-20.3)	73.5 (53.5-100)

Comments of zRMS:	Diseases control in wheat
	<i>Pyrenophora tritici-repentis</i> (17 trials – 8 in Maritime, 9 in N-E zone).
	The results showed a good to medium control of <i>Pyrenophora tritici-repentis</i> on wheat by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 66.9-84.2%), under a wide range of conditions. In all cases the efficacy was higher than of the reference product. Due to the moderate effectiveness in <i>Pyrenophora tritici-repentis</i> control the evaluator suggests to insert information into the product label that the product shows moderate effectiveness.
	The presented data fully support the registration of BAS 736 00 F in the Maritime and the North-East zones for <i>Pyrenophora tritici-repentis</i> control. The applicant did not submit any data from the South-East zone, so the registration in this zone may be supported by extrapolation of data from the Maritime and North-East zones (cMS decision).
	For the registration of BAS 736 00 F for <i>Pyrenophora tritici-repentis</i> control in winter wheat in Poland, the following trials can be accepted – 9 trials from North-East EPPO zone and also the trials from Maritime zone (Germany – 7 trials, Czech Repiblik – 2 trials).
	The applicant submitted the two trials on <i>Pyrenophora tritici-repentis</i> control in spring wheat, so the data extrapolation from winter wheat to spring wheat can be accepted, and the number of trials for this disease will be met.

***Erysiphe graminis*, Wheat**

A total of 13 12 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Blumeria graminis* in wheat. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter wheat once or twice within BBCH 33-72. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, France and Germany) and the North East climatic zone (Lithuania and Poland).

Summary of results is provided in Table 3.2-45.

The assessments ranging from BBCH 59-80, 10-43 DAT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation. In addition, 1 Czech trial and 2 German trials with infection level in the untreated control slightly below the threshold (4.3, 4.5 and 4.3%) were included in the evaluation.

In one Czech trial with a very strong infection of *Blumeria graminis* (75% in UTC) 30 days after the treatment, no control of powdery mildew was achieved by both BAS 736 00 F and the standard. The application timing of this trial was targeted on *Zymoseptoria tritici* at its onset. It can thus be concluded that the application timing was not appropriate to control *Blumeria graminis* which is confirmed by no effect of the standard. However, the infection level of SEPTTR remained very low and has not been evaluated in this BAD. On the other hand, this trial provided a good efficacy on *Pyrenophora tritici-repentis* and is therefore still considered useful for this dossier. For transparency the trial is kept also in the detailed table for *Blumeria graminis*, but it has been greyed out and was not included in the calculation of the mean values in the summary table.

A significant reduction of *Blumeria graminis* was achieved in 12 trials across both EPPO zones. The summary across all EPPO zones showed that the mean infestation of 8.7 % in the untreated was reduced with BAS 736 00 F by 80.2%. The performance of BAS 736 00 F was comparable to the standard (81.0%). The infection level and the mean efficacy obtained in the Maritime zone and the North east zone were comparable.

7 trials are available from the Maritime zone and 5 trials from the North east zone. The RegPest model was used to identify the trials from the Maritime zone that could be extrapolated to the North east zone and vice versa. Based on the RegPest analysis that proved high similarity of the compared regions, 4 trials from the North east zone (PL) were extrapolated to the Maritime zone and 3 trials from the Maritime zone (DE) were extrapolated to the North east zone. As a result, altogether relevant 11 trials support registration in the Maritime zone and 8 trials support registration in the North east zone.

Generally, there are forms of *Blumeria graminis* specific for individual crops which do not cross-infect. However, results on other cereals can give idea about pathogen reaction to the product. Therefore, it is suggested that the results of powdery mildew control on barley can be considered supportive for registration in wheat (5 trials from Maritime zone with average efficacy of 78%, 1 trial from North-East zone with average efficacy of 78.5% and 7 trials from the South east zone with average efficacy of 80.3%). It is further referred to Table 3.2-86 that summarizes the efficacy data of all concerned crops and confirms that efficacy on powdery mildew is observed across cereals (beside wheat and barley also 5 trials in triticale and 3 trials in oats are presented in this BAD).

Blumeria graminis represents a rather seldom disease and the occurrence depends on the season. It is therefore difficult to collect full data sets per EPPO zones. It should however be considered in support of registrations in both zones that both active substances contained in BAS 736 00 F are already registered against *Blumeria graminis* as solo active ingredient products. Azoxystrobin is registered across Europe under many trade names and at its maximum dose rate of 1 L/ha it delivers 250 grams of active substance per hectare (BAS 736 00 F: 150 g a.i./ha). Fluxapyroxad is widely registered under different trade names, applied at 2 L/ha it provides 125 grams of active substance per hectare (BAS 736 00 F: 100 g a.i./ha). Obviously, both solo active ingredient products deliver higher amount of the active substance per hectare than contained in BAS 736 00 F. For azoxystrobin however a dose rate range is registered in several countries with the lower limit at 150 gai/ha in Poland and Romania, at 187.5 gai/ha in Hungary and at 200 gai/ha in Slovenia, Slovakia and the Czech Republic.

For the purpose of ratio justification, the reduced dose rates of azoxystrobin (150 gai/ha) and fluxapyroxad (100 gai/ha) as combined in BAS 736 00 F were tested. No *Blumeria graminis* occurred in those trials, however, 4 trials are available in barley. It has been proven that even with the reduced dose rates of both active ingredients good efficacies of in average 73 and 77% respectively were achieved on *Blumeria graminis* (see Table 3.2-19 and Table 3.2-20). It was further shown with 1 trial, that when both actives were combined in BAS 736 00 F the efficacy further increased. It can therefore be concluded that BAS 736 00 F as a combination of both active substances should provide good efficacy on *Blumeria graminis* in wheat.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Blumeria graminis* in wheat under a wide range of agroclimatic conditions. The registration in the Maritime and the North east zones is supported by the available data together with mutual extrapolations between the zones, reference to the available trials in barley and reference to the existing registrations of the solo active substances.

Table 3.2-45: Efficacy, Wheat, ERYSGR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F 2.0 L/ha		Standard	
				infect	infect	efficacy	infect	efficacy
Maritime		n = 7	mean	8.5	1.9	79.2	1.5	79.4
			(min-max)	(4.3-18.1)	(0.8-6.8)	(61.3-90.5)	(0.4-4)	(52.9-96.6)
	MA incl. extrapolated trials from NE	n = 11	mean	8.9	1.7	81.8	1.4	83.3
			(min-max)	(4.3-18.7)	(0.3-6.8)	(61.3-96.2)	(0-4)	(52.9-100)
North east	TRZAW	n = 5	mean	9.0	1.5	81.6	1.6	83.2
			(min-max)	(5-18.7)	(0.3-2.7)	(62.7-96.2)	(0-3.3)	(55-100)
	TRZAW	n = 8	mean	9.8	2.1	79.5	1.9	79.2
	NE incl extrapolated trials from MA		(min-max)	(4.3-18.7)	(0.3-6.8)	(61.3-96.2)	(0-4)	(52.9-100)
Total ALL		n = 12	mean	8.7	1.7	80.2	1.6	81.0
			(min-max)	(4.3-18.7)	(0.3-6.8)	(61.3-96.2)	(0-4)	(52.9-100)

Comments of zRMS	Diseases control in wheat
	<i>Erysiphe graminis</i> (<i>Blumeria graminis</i>) (12 trials – 7 in Maritime, 5 in N-E zone).
	The results showed a good to medium control of <i>Erysiphe graminis</i> on wheat by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 79.2-81.6%), under a wide range of conditions. In all cases the efficacy was very close to the reference product. Due to the moderate effectiveness in <i>Erysiphe graminis</i> control the evaluator suggests to insert information into the product label that the product shows moderate effectiveness. The presented data fully support the registration of BAS 736 00 F for <i>Erysiphe graminis</i> control in the Maritime zone and for registration in North-East zone the data of at least one trial can be extrapolated from the Maritime zone. The applicant did not submit any data from South-East zone, so the registration of BAS 736 00 F for this disease control could be based on the results from the Maritime and the North-East zones (cMS decision).
	For the registration of BAS 736 00 F for <i>Erysiphe graminis</i> control in winter wheat in Poland, the following trials can be accepted - 5 trials from North-East EPPO zone and also the trials from Maritime zone (Germany – 7 trials, Czech Republik – 1 trial).
	For spring wheat applicant did not submitted any data, so in this case the registration of BAS 736 00 F for <i>Erysiphe graminis</i> control in spring wheat is not possible.

Information on trials submitted in Barley

Between 2019 and 2020, altogether 77 efficacy trials were carried out to prove the fungicidal efficacy of BAS 736 00 F in barley. The trials were conducted in the Czech Republic, Denmark, France, Germany, Ireland and the United Kingdom (Maritime zone), Finland, Latvia, Lithuania and Poland (North-East zone) and Bulgaria, Hungary, Romania and Slovakia (South-East zone). The distribution of trials by country and year and by EPPO zone is provided in Table 3.2-46 and

Table 3.2-47.

BAS 736 00 F at target dose rate of 2 L/ha was applied according to the GAP once or twice within a BBCH stage ranging from 28-69.

BAS 9314 1 F known as Proline at the dose rate of 0.8 L/ha (prothioconazole 250 g/L) was used as a reference product in all trials. In the trials conducted in the United Kingdom, BAS 9314 4 F at 0.72 L/ha (prothioconazole 275 g/L) was applied.

The vast majority of the trials (57) was conducted in the winter barley. On the spring barley, altogether 20 are available, out of them 11 trials in the North east climatic zone. In the summary tables, the means for winter and spring crop are presented separately for the North east EPPO zone to provide additional information for Poland where the spring barley is of an importance.

Table 3.2-46: Distribution of trials by location and year; Barley

Crop	EPPO Zone	Country	Year		TOTAL
			2019	2020	per country
Barley winter and spring	Maritime	CZ	0	1	1
		DE	10	8	18
		DK	3	2	5
		FR	8	6	14
		IE	1	2	3
		UK	3	1	4
	North East	FI	1	1	2
		LT	1	1	2
		LV	0	3	3
		PL	8	5	13
	South East	BG	2	0	2
		HU	1	1	2
		RO	2	3	5
		SK	2	1	3
Total					77

Table 3.2-47: Distribution of trials by EPPO zone; Barley

Crop	EPPO Zone	TOTAL per zone
Barley winter and spring	Maritime	45 (7 HORVS)
	North East	20 (11 HORVS)
	South East	12 (2 HORVS)
TOTAL ALL		77 (20 HORVS)

***Pyrenophora teres*, Barley**

A total of 46 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Pyrenophora teres* in barley. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter and spring barley once or twice within BBCH 31-62. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (the Czech Republic, Denmark, France, Germany and the United Kingdom), the North East climatic zone (Finland, Latvia, Lithuania and Poland) and the South East climatic zone (Bulgaria, Hungary, Romania and Slovakia).

Summary of results is provided in Table 3.2-48.

The assessments ranging from BBCH 59-87, 20-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Pyrenophora teres* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 24.9 % in the untreated was reduced with BAS 736 00 F by 84.8 %. The performance of the product was superior to the standard (77%).

The efficacies obtained in different climatic zones were comparable, however the best result was observed in the South east zone. The lowest mean efficacy was reached in the Maritime zone. However, in the same time the Maritime zone offered the highest infection level in the untreated out of all zones. BAS 736 00 F proved its strong fungicidal activity also under these challenging situations. The product was superior to the standard in all zones.

Conclusion

According to the trial results, it can be concluded that an application of BAS 736 00 F at 2 L/ha controls *Pyrenophora teres* in barley under a wide range of agroclimatic conditions. The available results represent a sufficient data set to support registrations in the Maritime, the North east and the South east zones.

Table 3.2-48: Efficacy, Barley, PYRNTE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F 2.0 L/ha		Standard	
				infect	infect	efficacy	infect	efficacy
Maritime	all	n = 19	mean	28.8	5.9	83.7	6.9	76.8
			(min-max)	(5-90.3)	(0.3-31.3)	(63.6-97.7)	(0-28.6)	(30.6-100)
North east	all	n = 16	mean	24.1	3.9	84.3	5.8	77.1
			(min-max)	(5.5-78.1)	(0.1-17.4)	(66.3-99.1)	(0.1-20.3)	(47.8-98.4)
	HORVW	n = 7	mean	7.2	1.1	84.8	1.4	80.2
			(min-max)	(5.5-10.5)	(0.6-1.8)	(81.8-90.6)	(0.7-2.1)	(70.3-88.9)
	HORVS	n = 9	mean	37.3	6.1	83.9	9.1	74.8
			(min-max)	(8.8-78.1)	(0.1-17.4)	(66.3-99.1)	(0.1-20.3)	(47.8-98.4)
South east	all	n = 11	mean	19.1	3.0	87.6	6.9	77.4
			(min-max)	(5-87.9)	(0.5-17.5)	(80.3-94.7)	(0.3-48.8)	(44.9-93.5)
Total ALL	all	n = 46	mean	24.9	4.5	84.8	6.5	77.0
			(min-max)	(5-90.3)	(0.1-31.3)	(63.6-99.1)	(0-48.8)	(30.6-100)

Comments of zRMS	<p><u>Diseases control in barley</u></p> <p><i>Pyrenophora teres</i> (46 trials – 19 in Maritime, 16 in N-E zone (7 in winter and 9 in spring barley), 11 trials in S-E zone).</p> <p>The results showed a good control of <i>Pyrenophora teres</i> on barley by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 83.7-87.6%) under a wide range of conditions. In all cases the efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Pyrenophora teres</i> control in the Maritime, the North-East and the South-East zones.</p> <p>For the registration of BAS 736 00 F to <i>Pyrenophora teres</i> control in winter barley in Poland, the following trials can be accepted – 7 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 7 trials) and South-East zone (Slovakia – 2 trials).</p> <p>For the registration in spring barley the following trials can be accepted – 9 trials from North-East EPPO zone and the trials from Maritime zone (Czech Republik – 1 trial) and South-East zone (Slovakia – 1 trial). The numbers of trials for <i>Pyrenophora teres</i> control in winter barley and spring barley in Poland are sufficient to registration.</p>
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***Puccinia hordei*, Barley**

A total of 23 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Puccinia hordei* in barley. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter and spring barley once or twice within BBCH 31-62. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (Denmark, France, Germany and the United Kingdom), the North East climatic zone (Poland) and the South East climatic zone (Hungary and Romania).

Summary of results is provided in Table 3.2-49.

The assessments ranging from BBCH 59-83, 18-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Puccinia hordei* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 20.4 % in the untreated was reduced with BAS 736 00 F by 92.3 %. The performance of the product was superior to the standard (85.8%).

Comparable mean efficacies were reached in all three zones while the Maritime zone offered the highest infection level in the untreated. The product was superior to the standard in all zones.

In the South east zone, 3 trials showed infection by *Puccinia hordei*. Both proved good to very good efficacy. Besides, full data sets proving very good efficacy of the product were presented from the Maritime zone and the North east zone. It is therefore suggested that the full data set from the South east zone is waived. To further support this idea, the RegPest model was used to identify the trials from the North east zone that were located in regions with high comparability to the representative regions of the South east zone. Based on the RegPest analysis, 6 Polish trials were extrapolated to the South east zone. As a result, altogether 9 trials support the registration for *Puccinia hordei* in the South east zone.

In addition, it should also be considered in support of registrations in all zones that both active substances contained in BAS 736 00 F are registered against *Puccinia hordei* as solo active ingredient products. Azoxystrobin is registered across Europe under many trade names and at its maximum dose rate of 1 L/ha it delivers 250 grams of active substance per hectare (BAS 736 00 F: 150 g a.i./ha). Fluxapyroxad is widely registered under different trade names, applied at 2 L/ha it provides 125 grams of active substance per hectare (BAS 736 00 F: 100 g a.i./ha). Obviously, both solo active ingredient products deliver higher amount of the active substance per hectare than contained in BAS 736 00 F. For azoxystrobin however a dose rate range is registered in several countries with the lower limit at 150 gai/ha in Poland and Romania, at 187.5 gai/ha in Hungary and at 200 gai/ha in Slovenia, Slovakia and the Czech Republic.

For the purpose of ratio justification, the reduced dose rates of azoxystrobin (150 gai/ha) and fluxapyroxad (100 gai/ha) as combined in BAS 736 00 F were tested. It has been proven that even with the reduced dose rates of both active ingredients good efficacies on *Puccinia hordei* were achieved. In altogether 8 trials with 150 g/ha azoxystrobin an average efficacy of 80% was reached (see Table 3.2-19) while 100 g/ha fluxapyroxad achieved with 10 trials an average efficacy of 89% (see Table 3.2-20). When combined in BAS 736 00 F, the efficacy of the product further increased and slightly outperformed the standard (proven with 5 trials). It is therefore concluded that the fact that both active substances of BAS 736 00 F are registered on *Puccinia hordei* can be considered as supportive for registration of BAS 736 00 F.

Conclusion

According to the trial results, it can be concluded that an application of BAS 736 00 F at 2 L/ha controls *Puccinia hordei* in barley under a wide range of agroclimatic conditions. The available results represent sufficient data sets to support registrations in the Maritime and the North east zones.

A registration in the South east zone is supported by data extrapolation from the North east zone and by reference to the existing registrations of the solo active substances.

Table 3.2-49: Efficacy, Barley, PUCCHD, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime		n = 12 mean (min-max)	26.2 (8.8-54)	2.5 (0-16.3)	92.2 (61.3-100)	5.4 (0-21.8)	83.8 (48.2-100)
North east	all	n = 8 mean (min-max)	17.0 (7.7-38)	1.3 (0-7.6)	93.8 (71.9-100)	2.5 (0-11.6)	87.5 (58.3-100)
	HORVW	n = 6 mean (min-max)	16.5 (7.7-38)	0.4 (0-1.1)	97.6 (94-100)	1.2 (0-3.2)	92.2 (80-100)
	HORVS	n = 2 mean (min-max)	18.6 (8.5-28.7)	4.1 (0.6-7.6)	82.2 (71.9-92.6)	6.3 (1-11.6)	73.3 (58.3-88.2)
South east		n = 3 mean (min-max)	6.4 (5.8-7.5)	0.6 (0.3-1.4)	89.3 (76.2-97)	0.7 (0.5-1)	88.9 (83.1-91.8)
	SE incl. extrapolated trials from NE	n = 9 mean (min-max)	15.4 (5.8-38)	1.3 (0-7.6)	91.5 (71.9-100)	2.3 (0-11.6)	86.8 (58.3-100)
Total ALL		n = 23 mean (min-max)	20.4 (5.8-54)	1.9 (0-16.3)	92.3 (61.3-100)	3.8 (0-21.8)	85.8 (48.2-100)

Comments of zRMS	Diseases control in barley
	<i>Puccinia hordei</i> (23 trials – 12 in Maritime, 8 in N-E and 3 in S-E zones)
	The results showed a good control of <i>Puccinia hordei</i> on barley by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 89.3-93.8%) under a wide range of conditions. In all cases the efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Puccinia hordei</i> control in the Maritime and North-East zones, while the number of trials for registration in South-East zone is not sufficient, so for the possible registration the data extrapolation from the Maritime and N-E zone is recommended. The decision should be taken by CMS.
	For the registration of BAS 736 00 F to <i>Puccinia hordei</i> control in winter barley in Poland, the following trials can be accepted – 6 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 5 trials). For the registration in spring barley the following trials can be accepted – 2 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 5 trials).
	The numbers of trials for <i>Puccinia hordei</i> control in winter barley and spring barley in Poland are sufficient to registration.

***Rhynchosporium secalis*, Barley**

A total of 16 trials showed a sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Rhynchosporium secalis* in barley. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter and spring barley once or twice within BBCH 28-55. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (France, Germany and the United Kingdom) and the North East climatic zone (Latvia, Poland).

Summary of results is provided in Table 3.2-50.

The assessments ranging from BBCH 59-83, 19-45 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Rhynchosporium secalis* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 32.8% in the untreated was reduced with BAS 736 00 F by 88.1%. The performance of the product was superior to the standard (82.5%). The product performance was comparable in the Maritime and the North east zones.

A full data set according to the EPPO guidelines is provided from the Maritime zone. Altogether 3 trials in winter barley and 1 trial in spring barley are available from the North east zone. All of them showed very good efficacy of BAS 736 00 F on *Rhynchosporium secalis*. In regard to the solid data set proving very good efficacy in the Maritime zone and comparable efficacy observed in the available trials from the North east zone it is suggested that the full data set in the North east zone can be waived. However in addition, the RegPest model was used to identify the trials from the Maritime zone that could be extrapolated to the North east zone. Based on the RegPest analysis that proved high similarity of the compared regions, 3 trials from the Maritime zone (DE) were extrapolated to the North east zone. As a result, altogether 6 trials in winter barley and 1 trial in spring barley support the registration in the North east zone.

In addition, it should also be considered in support of registrations in both zones that both active substances contained in BAS 736 00 F are registered against *Rhynchosporium secalis* as solo active ingredient products. Azoxystrobin is registered across Europe under many trade names and at its maximum dose rate of 1 L/ha it delivers 250 grams of active substance per hectare (BAS 736 00 F: 150 g a.i./ha). Fluxapyroxad is widely registered under different trade names, applied at 2 L/ha it provides 125 grams of active substance per hectare (BAS 736 00 F: 100 g a.i./ha). Obviously, both solo active ingredient products deliver higher amount of the active substance per hectare than contained in BAS 736 00 F. For azoxystrobin however a dose rate range is registered in several countries with the lower limit at 150 gai/ha in Poland and Romania, at 187.5 gai/ha in Hungary and at 200 gai/ha in Slovenia, Slovakia and the Czech Republic.

For the purpose of ratio justification, the reduced dose rates of azoxystrobin (150 gai/ha) and fluxapyroxad (100 gai/ha) as combined in BAS 736 00 F were tested. It has been proven that even with the reduced dose rates still useful reduction of *Rhynchosporium secalis* has been achieved with azoxystrobin (2 trials, average efficacy 56%, see Table 3.2-19) and good efficacy was reached with fluxapyroxad (2 trials, average efficacy 80%, see Table 3.2-20). It is therefore concluded that the fact that both active substances of BAS 736 00 F are registered on *Rhynchosporium secalis* can be considered as supportive for registration of BAS 736 00 F.

It is also referred to 6 trials from the North east zone available in rye that reached very good efficacy on comparable level as observed in barley (87.5% in average). It is therefore concluded that a comparable efficacy on *Rhynchosporium secalis* can be expected across both cereal crops and trials in rye can thus be considered in support of registration in barley.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Rhynchosporium secalis* in barley under a wide range of agroclimatic conditions. The available results represent full data set to support registration in the Maritime zone. In the North east zone, it is suggested that the available data is supported by extrapolation from the Maritime zone. It is also referred to the comparable efficacy in rye and to the existing registrations of the solo active substances.

Table 3.2-50: Efficacy, Barley, RHYNSE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F 2.0 L/ha		Standard	
				infect	infect	efficacy	infect	efficacy
Maritime		n = 12	mean (min-max)	41.6 (7.5-94)	4.7 (0-15.2)	87.0 (57.3-100)	7.3 (0.4-26.2)	80.5 (51.7-99.2)
North east	all	n = 4	mean (min-max)	6.5 (5.8-7.3)	0.5 (0.4-0.8)	91.6 (87-94.8)	0.7 (0.5-1)	88.4 (83.3-93.1)
	HORVW	n = 3	mean (min-max)	6.3 (5.8-7)	0.6 (0.5-0.8)	90.5 (87-92.9)	0.8 (0.6-1)	86.9 (83.3-91.4)
	HORVW	n = 6	mean (min-max)	18.4 (5.8-67.8)	3.6 (0.5-11.3)	80.4 (57.3-92.9)	4.9 (0.6-16)	73.7 (51.7-91.4)
	NE incl. extrapolated trials from MA							
	HORVS	n = 1	mean (min-max)	7.3 (7.3-7.3)	0.4 (0.4-0.4)	94.8 (94.8-94.8)	0.5 (0.5-0.5)	93.1 (93.1-93.1)
Total ALL		n = 16	mean (min-max)	32.8 (5.8-94)	3.6 (0-15.2)	88.1 (57.3-100)	5.6 (0.4-26.2)	82.5 (51.7-99.2)

Comments of zRMS	<u>Diseases control in barley</u>
	<i>Rhynchosporium secalis</i> (16 trials – 12 in Maritime, 4 in N-E zones)
	The results showed a good control of <i>Rhynchosporium secalis</i> on barley by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 87-91.6%) under a wide range of conditions. In all cases the efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Rhynchosporium secalis</i> control in the Maritime zone, while the number of trials for registration in North-East zone is not sufficient, so the data extrapolation from the Maritime zone is recommended. For BAS 736 00 F registration in South-East zone the data extrapolation from Maritime and North-East zones is suggested also. The decision should be taken by cMS.
	For the registration of BAS 736 00 F for <i>Rhynchosporium secalis</i> control in winter barley in Poland, the following trials can be accepted – 3 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 5 trials). For spring barley applicant did not submitted any data so in this case the registration of BAS 736 00 F for <i>Rhynchosporium secalis</i> control in spring barley in Poland is not possible.

***Ramularia collo-cygni*, Barley**

A total of 19 20 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Ramularia collo-cygni* in barley. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter and spring barley once or twice within BBCH 32-69. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (Denmark, France, Germany and the United Kingdom) and the North East climatic zone (Latvia).

Summary of results is provided in Table 3.2-51.

Usually, the last assessments around BBCH 75 (range BBCH 69-85), 19-54 DALT on the upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Ramularia collo-cygni* was achieved in all trials. The summary across both EPPO zones showed that the mean infestation of 36% in the untreated was reduced with BAS 736 00 F by 75.9%. BAS 736 00 F performed at comparable level as the standard (77.9%).

In one UK trial, the efficacy of BAS 736 00 F was slightly below 50%. In the same trial, the standard performed better but still remained below its average performance. A late arrival of *Ramularia*, where the first symptoms were assessed 43 days after the treatment could explain these lower performances.

In one Danish trial, the performance of the standard was very low, only about 25% but the trial is still considered valid (BAS 736 00 F below the average but still approaching 70%). In this case, there was a very high disease pressure in the trial. Beside *Ramularia* the crop was relatively strongly attacked also by *Pyrenophora teres* and *Puccinia hordei*. Both diseases were well controlled by both BAS 736 00 F and the standard. *Ramularia* arrived late and the standard was not able to effectively control it anymore while BAS 736 00 F still provided a reasonable efficacy.

In one Latvian trial, only the assessment on the second leaf was considered for the calculation of the mean value. The 3rd leaf was greyed out and not included in summary. This trial was targeting *Pyrenophora teres* on its onset and the timing was not optimal for *Ramularia* therefore it was not able to sufficiently control the disease on the 3rd leaf anymore. It is confirmed by the poor performance of the standard. On the 2nd leaf, however, efficacy was observed with both BAS 736 00 F and the standard.

Altogether, a robust data set of 18 trials was obtained in the Maritime zone while only in 2 trials in the North east zone *Ramularia collo-cygni* occurred. The number of trials is not sufficient for a label claim on *Ramularia collo-cygni* in the North east zone, however the trials obtained there can provide additional supportive evidence for registration in the Maritime zone and are therefore presented here. A summary of 20 trials across both EPPO zones showed that the mean infestation of 36% in the untreated was reduced with BAS 736 00 F by 75.9%. The performance of the product was on the level of the standard (77.9%).

Conclusion

According to the trial results, it can be concluded that an application of BAS 736 00 F at 2 L/ha controls *Ramularia collo-cygni* in barley under a wide range of agroclimatic conditions. The available results provide full data set for registration in the Maritime zone.

Table 3.2-51: Efficacy, Barley, RAMUCC, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F 2.0 L/ha		Standard	
				infect	infect	efficacy	infect	efficacy
Maritime	n = 18	mean		39.0	8.6	75.2	7.9	78.0
		(min-max)		(5-98.6)	(1.3-33.8)	(48.9-91.1)	(0-29.9)	(25.8-100)
North east	HORVS	n = 2	mean	8.8	1.5	82.9	2.0	77.1
			(min-max)	(8.8-8.8)	(1.5-1.5)	(82.9-82.9)	(2-2)	(77.1-77.1)
Total ALL	n = 20	mean		36.0	7.9	75.9	7.4	77.9
		(min-max)		(5-98.6)	(1.3-33.8)	(48.9-91.1)	(0-29.9)	(25.8-100)

Comments of zRMS	<p>Diseases control in barley</p> <p><i>Ramularia collo-cygni</i> (20 trials – 18 in Maritime and 2 in N-E)</p> <p>The results showed a good control of <i>Ramularia collo-cygni</i> on barley by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 75.2-82.9%) under a wide range of conditions. The efficacy of tested product in the Maritime zone was slightly lower and in the N-E zone was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Ramularia collo-cygni</i> control in the Maritime zone, while the number of trials for registration in the North East zone is not sufficient and for South-East zone applicant did not submitted any data. For these zones the data extrapolation from the Maritime zone is recommended. The decision should be taken by CMS.</p> <p>For the registration of BAS 736 00 F for <i>Ramularia collo-cygni</i> control in winter barley in Poland applicant did not submitted any data from North-East EPPO zone, but provided 9 trials from Maritime zone. According to Polish requirements the registration of BAS 736 00 F for <i>Ramularia collo-cygni</i> control in winter barley in Poland is not possible but evaluator suggests to consider such registration due to high efficacy of tested product in other experiments.</p> <p>For spring barley applicant submitted 3 trials from North-East EPPO zone, so possible is extrapolation of data from winter barley, then the number of trials will met the requirements.</p>
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***Blumeria graminis*, Barley**

A total of 13 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Blumeria graminis* in barley. BAS 736 00 F at the dose rate of 2 L/ha was applied in winter and spring barley with one treatment within BBCH 37-56. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany and the United Kingdom), the North East climatic zone (Latvia) and the South East climatic zone (Hungary, Romania and Slovakia).

Summary of results is provided in Table 3.2-52.

Usually, the last assessments around BBCH 75 (range BBCH 59-87), 22-50 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Blumeria graminis* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 15.6% in the untreated was reduced with BAS 736 00 F by 79.3%. The performance of BAS 736 00 F was comparable to the standard (80.2%). The efficacies obtained in different climatic zones were comparable.

Only 1 trial in spring barley is available from the North east zone. The RegPest model was used to identify the trials from the Maritime and South east zone that could be extrapolated to the North east zone. Based on the RegPest analysis that proved high similarity of the compared regions, 1 trial in winter barley from the Maritime zone (Germany) and 2 trials in winter or spring barley from the South east zone (Slovakia) were extrapolated to the North east zone. As a result, altogether 4 trials, from them 2 in spring barley and 2 in winter barley, support the registration in the North east zone.

Generally, there are forms of *Blumeria graminis* specific for individual crops which do not cross-infect. However, results on other cereals can give an idea about pathogen reaction to the product. Therefore, it is suggested that the results of powdery mildew control on wheat can be considered supportive for registration in barley (7 trials from Maritime zone with average efficacy 79.2%, 5 trials from North-East zone with average efficacy 81.6%). It is further referred to Table 3.2-86 that summarizes the efficacy data of all concerned crops and confirms that efficacy on powdery mildew is observed across cereals (beside wheat and barley also 5 trials in triticale and 3 trials in oats are presented in this BAD).

Blumeria graminis represents a rather seldom disease and the occurrence depends on the season. It is therefore difficult to collect full data sets per EPPO zones. It should however be considered in support of registrations in the Maritime and the North east zones that both active substances contained in BAS 736 00 F are registered against *Blumeria graminis* as solo active ingredient products. Azoxystrobin is registered

across Europe under many trade names and at its maximum dose rate of 1 L/ha it delivers 250 grams of active substance per hectare (BAS 736 00 F: 150 g a.i./ha). Also, fluxapyroxad solo is widely registered under different trade names. Applied at 2 L/ha it provides 125 grams of active substance per hectare (BAS 736 00 F: 100 g a.i./ha). Obviously, both solo active ingredient products deliver higher amount of the active substance per hectare than contained in BAS 736 00 F. For azoxystrobin however a dose rate range is registered in several countries with the lower limit at 150 gai/ha in Poland and Romania, at 187.5 gai/ha in Hungary and at 200 gai/ha in Slovenia, Slovakia and the Czech Republic.

For the purpose of ratio justification, the reduced dose rates of azoxystrobin (150 gai/ha) and fluxapyroxad (100 gai/ha) as combined in BAS 736 00 F were tested. It has been proven with altogether 4 trials that even with the reduced dose rates of both active ingredients good efficacies of in average 73 and 77% respectively were achieved on *Blumeria graminis hordei* (see Table 3.2-19 and Table 3.2-20). When combined in BAS 736 00 F, the efficacy of the product further increased and reached the level of the standard. It is therefore concluded that the fact that both active substances of BAS 736 00 F are registered on *Blumeria graminis* can be considered as supportive for registration of BAS 736 00 F.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Blumeria graminis* in barley under a wide range of agroclimatic conditions. The registration in the Maritime, the North east and the South east zones is supported by the available data together with extrapolations between the zones, reference to the available trials in wheat and reference to the existing registrations of the solo active substances.

Table 3.2-52: Efficacy, Barley, ERYSGR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic				Untreated	BAS 736 00 F 2.0 L/ha		Standard	
				infect	infect	efficacy	infect	efficacy
Maritime		n = 5	mean (min-max)	11.6 (5.5-19)	2.7 (0.5-7)	78.0 (60.7-91.9)	2.6 (0-9)	82.4 (56.2-100)
North east	HORVS	n = 1	mean (min-max)	11.6 (11.6-11.6)	2.5 (2.5-2.5)	78.5 (78.5-78.5)	2.9 (2.9-2.9)	75.3 (75.3-75.3)
	HORVS	n = 2	mean (min-max)	13.5 (11.6-15.3)	2.8 (2.5-3.1)	80.4 (78.5-82.4)	3.1 (2.9-3.4)	77.5 (75.3-79.8)
	NE incl. extrapolated trials from SE							
	HORVW	n = 2	mean (min-max)	14.5 (13.2-15.8)	2.9 (1.8-4)	78.0 (67.1-88.9)	0.8 (0-1.5)	94.5 (89-100)
South east	all (HORVW+HORVS)	n = 7	mean (min-max)	18.9 (6.7-38.1)	4.0 (0.3-13)	80.3 (67.1-97.5)	4.3 (1.5-11.8)	79.4 (69.8-89.4)
Total ALL	all	n = 13	mean (min-max)	15.6 (5.5-38.1)	3.4 (0.3-13)	79.3 (60.7-97.5)	3.6 (0-11.8)	80.2 (56.2-100)

Comments of zRMS	<p><u>Diseases control in barley</u></p> <p><i>Blumeria graminis</i> (13 trials – 5 in Maritime, 1 in N-E and 7 in S-E zones)</p> <p>The results showed a good control of <i>Blumeria graminis</i> on barley by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 78-80.3%) under a wide range of conditions. The efficacy of tested product in the Maritime zone was slightly lower and in N-E zone was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Blumeria graminis</i> control in South-East zone and the number of data in Maritime zone can be considered as sufficient, due to a very good efficacy. The number of trials for registration in the North-East zone is not sufficient and the data extrapolation from the Maritime and South-East zones is recommended. The decision should be taken by cMS. The efficacy of BAS 736 00 F in winter barley was slightly higher than in spring barley.</p> <p>For the registration of BAS 736 00 F for <i>Blumeria graminis</i> control in winter barley in Poland applicant did not submitted any data from North-East EPPO zone, but provided 1 trial from Maritime zone (Germany) and 1 trial from South-East zone (Slovakia). According to Polish requirements the registration of BAS 736 00 F for <i>Blumeria graminis</i> control in winter barley in Poland is not possible.</p> <p>For spring barley applicant submitted only 1 trial from North-East zone and 1 trial from South-East zone (Slovakia). The number of trials is too low and the registration of tested product in Poland for <i>Blumeria graminis</i> control in spring barley in not possible.</p>
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Information on trials submitted in Rye

Between 2019 and 2020, altogether 21 efficacy trials were carried out to prove the fungicidal efficacy of BAS 736 00 F in rye. The trials were conducted in Denmark, Germany, France and Sweden (Maritime zone) and Latvia and Poland (North-East zone). The distribution of trials by country and year and by EPPO zone is provided in Table 3.2-53 and Table 3.2-54.

BAS 736 00 F at the target dose rate of 2 L/ha was applied according to the GAP once or twice within the BBCH stage ranging from 33-59.

BAS 9314 1 F known as Proline at the dose rate of 0.8 L/ha (prothioconazole 250 g/L) was used as a reference product in all trials. In the trials conducted in the United Kingdom, BAS 9314 4 F at 0.72 L/ha (prothioconazole 275 g/L) was applied.

No trials in rye were conducted in the South east zone. In some countries of the South east zone (Romania, Slovenia), rye is considered to be a minor crop, in others the fungicidal treatment in rye is understood as minor use (Slovakia). In some countries, the major/minor status of the crop depends on a variable factor as the growing area.

In support of registration in the South east zone, it is referred to the available trials in rye obtained in the Maritime and the North east zones, as the most favourable conditions for the disease development are usually found in the Maritime or the North east zone. Comparable performance of BAS 736 00 F was observed in both zones. It is thus assumed that no overestimation occurs when extrapolation of the efficacy data from these zones to the South east zone is used. Furthermore, it is referred to results collected on the same species in wheat (brown rust) and barley (RHYNSE) which show stable efficacies across the crops. Last but not least it is proposed to consider the fact that both active ingredients of BAS 736 00 F are registered on the same diseases as solo active ingredients in many European countries.

It is proposed that the final decision on acceptability of extrapolation to the South east zone is done by the concerned member states.

Table 3.2-53: Distribution of trials by location and year; Rye

Crop	EPPO Zone	Country	Year		TOTAL
			2019	2020	per country
Rye	Maritime	DE	3	4	7
		FR	1	1	2
		DK	0	1	1
		SE	1	0	1
	North East	LV	1	1	2
		PL	4	4	8
Total					21

Table 3.2-54: Distribution of trials by EPPO zone; Rye

Crop	EPPO Zone	TOTAL per zone
Rye	Maritime	11
	North East	10
TOTAL ALL		21

***Puccinia recondita*, Rye**

A total of 18 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Puccinia recondita* in rye. BAS 736 00 F at the dose rate of 2 L/ha was applied once or twice within BBCH 33-59. Trials were conducted in the harvest years 2019 and 2020 in the Maritime climatic zone (Germany, France and Sweden) and the North East climatic zone (Poland).

Summary of results is provided in Table 3.2-55.

The assessments ranging from BBCH 69-79, 28-54 DALT on the upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Puccinia recondita* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 18.4 % in the untreated was reduced with BAS 736 00 F by 95.1%. The performance of the product was superior to the standard (87%).

No trials in rye are available from the South east EPPO zone. It is however referred to 10 trials in winter wheat that clearly demonstrate a very high (97.5%) and stable efficacy on brown rust in the South east zone (see Table 3.2-43). Furthermore, high, stable and comparable efficacy (between the zones) on brown rust was observed in the Maritime and the North east zones in rye and also in all three zones in wheat. There is no indication that lower performance should be expected in the South east zone in rye and the results obtained on *Puccinia recondita* in the Maritime and the North east zones in rye can thus be considered in support of the registration in the South east zone.

An overview of efficacy on brown rust in all concerned crops is provided in Table 3.2-86. It demonstrates that BAS 736 00 F provided high and stable efficacy in all tested crops.

The registration can be further supported by the fact that both active substances contained in BAS 736 00 F are registered against *Puccinia recondita* in rye as solo active ingredient products.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Puccinia recondita* in rye under a wide range of agroclimatic conditions.

The available data fully support the registration in the Maritime and the North east zones. For the registration in the South east zone an extrapolation between the zones and, within the same pathogen, between the crops is proposed. Registration in all zones is supported by the reference to the existing registrations of the solo active substances.

Table 3.2-55: Efficacy, Rye, PUCCRE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 10	mean (min-max)	15.3 (5.5–50.8)	1.0 (0–4.9)	95.1 (89.1–100)	2.0 (0–7)	88.5 (61.9–100)
North east	n = 8	mean (min-max)	22.3 (5.8–43.8)	1.5 (0–4.5)	95.0 (89.7–100)	4.2 (0.1–13.3)	85.1 (55.6–99.1)
Total ALL	n = 18	mean (min-max)	18.4 (5.5–50.8)	1.2 (0–4.9)	95.1 (89.1–100)	3.0 (0–13.3)	87.0 (55.6–100)

Comments of zRMS	<p>Diseases control in rye</p> <p><i>Puccinia recondita</i> (18 trials – 10 in Maritime, 8 in N-E zones)</p> <p>The results showed a good control of <i>Puccinia recondita</i> on rye by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 95-95.1%) under a wide range of conditions. In all cases the average efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Puccinia recondita</i> control in the Maritime and North-East zones. The applicant did not submit any data from the South-East zone, so the data extrapolation from the Maritime zone and North-East zones is recommended for registration. The decision should be taken by CMS.</p> <p>For the registration of BAS 736 00 F for <i>Puccinia recondita</i> control in winter rye in Poland, the following trials can be accepted – 8 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 7 trials). The numbers of trials for <i>Puccinia recondita</i> control in winter rye in Poland is sufficient to registration.</p>
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***Rhynchosporium secalis*, Rye**

A total of 11 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Rhynchosporium secalis* in rye. BAS 736 00 F at the dose rate of 2 L/ha was applied once or twice within BBCH 33-59. Trials were conducted in harvest years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany and Sweden) and the North East climatic zone (Latvia and Poland).

Summary of results is provided in Table 3.2-56.

The assessments ranging from BBCH 59-77, 15-54 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Rhynchosporium secalis* was achieved in all trials. The summary across both EPPO zones showed that the mean infestation of 18.9 % in the untreated was reduced with BAS 736 00 F by 87.5%. The performance of the product was superior to the standard (79.8%).

In support of registrations for *Rhynchosporium secalis* in rye it is referred to the available 16 trials in barley. 12 trials from the Maritime zone and 4 trials from the North east zone obtained in barley gave an average efficacy of 87.8%. It is comparable to the efficacy observed in rye (87.5%). It is suggested that the trials in barley are considered in support of registration in rye (see Table 3.2-50 or an overview in Table 3.2-86).

No trials in rye are available from the South east EPPO zone. However, it should be considered that high, stable and comparable efficacy (between the zones) on *Rhynchosporium secalis* was observed in the Maritime and the North east zones in both rye and barley. An extrapolation from the Maritime and the North east zones in rye and barley is thus proposed for the registration in the South east EPPO zone.

In addition, it should be considered that both active substances contained in BAS 736 00 F are registered against *Rhynchosporium secalis* as solo active ingredient products in several countries.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Rhynchosporium secalis* in rye under a wide range of agroclimatic conditions.

The available data in the Maritime and the North east zones are supported by extrapolation from barley. In the South east zone both an extrapolation between the zones and, within the same pathogen, also between the crops is proposed. Registration in all zones is supported by the reference to the existing registrations of the solo active substances.

Table 3.2-56: Efficacy, Rye, RHYNSE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 5	mean (min-max)	21.4 (8.5–41.3)	2.3 (1.5–3)	88.3 (79.4–95.5)	3.0 (1.8–4)	82.6 (64.7–91.2)
North east	n = 6	mean (min-max)	16.7 (6–33.8)	3.2 (0–9.5)	86.9 (74.9–100)	4.4 (0.2–14.7)	77.5 (52.8–97.4)
Total ALL	n = 11	mean (min-max)	18.9 (6–41.3)	2.8 (0–9.5)	87.5 (74.9–100)	3.8 (0.2–14.7)	79.8 (52.8–97.4)

Comments of zRMS	<u>Diseases control in rye</u>
	<p><i>Rhynchosporium secalis</i> (11 trials – 5 in Maritime, 6 in N-E zones)</p> <p>The results showed a good control of <i>Rhynchosporium secalis</i> on rye by BAS 736 00 F applied at the rate of 2,0 L/ha (mean control 86.9-88.3%) under a wide range of conditions. In all cases the average efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Rhynchosporium secalis</i> control in the North-East zone. For registration in Maritime zone the data of one trial should be extrapolated from N-E zone, although 5 trials presented in dossier could be considered sufficient due to the good efficacy of BAS 736 00 F and better control of <i>Rhynchosporium secalis</i>, in comparison to the reference product. The applicant did not submit any data from S-E zone, so the possible registration should be based on the data from other zones but it is under decision of cMS.</p> <p>For the registration of BAS 736 00 F for <i>Rhynchosporium secalis</i> control in winter rye in Poland, the following trials can be accepted – 6 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 3 trials). The numbers of trials for <i>Rhynchosporium secalis</i> control in winter rye in Poland is sufficient to registration.</p>

Information on trials submitted in Triticale

Between 2019 and 2020, altogether 20 efficacy trials were carried out to prove the fungicidal efficacy of BAS 736 00 F in triticale. The trials were conducted in Denmark, Germany, France and Sweden (Maritime zone) and Latvia and Poland (North-East zone). The distribution of trials by country and year and by EPPO zone is provided in Table 3.2-57 and Table 3.2-58.

BAS 736 00 F at target dose rate of 2 L/ha was applied according to the GAP once or twice within the BBCH stage ranging from 31-59.

BAS 9314 1 F known as Proline at the dose rate of 0.8 L/ha (prothioconazole 250 g/L) was used as a reference product in all trials. In the trials conducted in the United Kingdom, BAS 9314 4 F at 0.72 L/ha (prothioconazole 275 g/L) was applied.

No trials in triticale were conducted in the South east zone. In some countries of the South east zone (Romania), triticale is considered to be a minor crop, in others the fungicidal treatment in triticale is understood as minor use (Slovakia). In some countries, the major/minor status of the crop depends on a variable factor as the growing area.

In support of registration in the South east zone, it is referred to the available trials in triticale obtained in the Maritime and the North east zones. As the most favourable conditions for the disease development are usually found in the Maritime or the North east zone, it is assumed that no overestimation occurs when extrapolating the efficacy data from these zones to the South east zone. Furthermore, it is referred to results collected on the same species in wheat or rye which show stable efficacies across the crops. Last but not least it is proposed to consider the fact that both active ingredients of BAS 736 00 F are registered on the same diseases as solo active ingredients in many European countries.

It is proposed that the final decision on acceptability of extrapolation to the South east zone is done by the concerned member states.

Table 3.2-57: Distribution of trials by location and year; Triticale

Crop	EPPO Zone	Country	Year		TOTAL
			2019	2020	per country
Triticale	Maritime	DE	4	4	8
		FR	1	1	2
		DK	1	1	2
	North East	LT	1	0	1
		PL	3	4	7
Total					20

Table 3.2-58: Distribution of trials by EPPO zone; Triticale

Crop	EPPO Zone	TOTAL per zone
Triticale	Maritime	12
	North East	8
TOTAL ALL		20

***Septoria* species, Triticale**

A total of 13 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Septoria* sp. in triticale. BAS 736 00 F at the dose rate of 2 L/ha was applied once or twice within BBCH 33-59. Trials were conducted in harvest years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany) and the North East climatic zone (Poland).

Summary of results is provided in Table 3.2-59.

The assessments ranging from BBCH 37-77, 19-49 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Septoria* sp. was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 18 % in the untreated was reduced with BAS 736 00 F by 90.1%. The performance of the product was superior to the standard (85.2%).

In support of registrations in all three zones it is referred to the available robust data set of 66 trials in wheat (see Table 3.2-41). Across all zones a high efficacy was confirmed in wheat.

No trials in triticale are available from the South east EPPO zone. It is referred to the available trials in the Maritime and the North east zones from which data can be extrapolated. Furthermore, in support of registration in all three zones, it is referred to 16 trials available on the same pathogen in barley (see an overview in Table 3.2-86). In all available trials across the crops, BAS 736 00 F provided high and comparable efficacy over wide range of situations.

It should be further considered that both active substances contained in BAS 736 00 F are registered against *Septoria* sp. as solo active ingredient products in several countries.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Septoria* sp. in triticale under a wide range of agroclimatic conditions.

The available data in the Maritime and the North east zones are supported by extrapolation from wheat. In the South east zone both an extrapolation between the zones and, within the same pathogen, also between the crops (wheat) is proposed. Registration in all zones is supported by the reference to the existing registrations of the solo active substances.

Table 3.2-59: Efficacy, Triticale SEPTSP, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 6	mean	22.1	2.0	91.4	3.6	83.6
		(min-max)	(8.5–38.3)	(0–3.8)	(72.7–100)	(0–7.8)	(43.6–100)
North east	n = 7	mean	14.5	2.2	89.1	2.6	86.6
		(min-max)	(6–23.3)	(0–4.5)	(78.8–100)	(0–6.1)	(68.5–100)
Total ALL	n = 13	mean	18.0	2.1	90.1	3.1	85.2
		(min-max)	(6–38.3)	(0–4.5)	(72.7–100)	(0–7.8)	(43.6–100)

Comments of zRMS	<p>Diseases control in triticale</p> <p><i>Septoria</i> species (13 trials – 6 in Maritime, 7 in N-E zones)</p> <p>The results showed a good control of <i>Septoria</i> species on triticale by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 89.1-91.4%) under a wide range of conditions. In all cases the average efficacy was higher than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Septoria</i> species control in Maritime and North-East zones. The applicant did not submit any data from South-East zone, so the possible registration should be based on the data from other zones but it is the decision of CMS.</p> <p>For the registration of BAS 736 00 F for <i>Septoria</i> species control in triticale in Poland, the following trials can be accepted – 7 trials from North-East EPPO zone and the trials from Maritime zone (Germany – 5 trials). The numbers of trials for <i>Septoria</i> species control in triticale in Poland is sufficient to registration.</p>
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***Puccinia striiformis*, Triticale**

A total of 11 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Puccinia striiformis* in triticale. BAS 736 00 F at the dose rate of 2 L/ha was applied once or twice within BBCH 33-53. Trials were conducted in harvest years 2019 and 2020 in the Maritime climatic zone (Denmark, Germany and France) and the North East climatic zone (Poland).

Summary of results is provided in Table 3.2-60.

The assessments ranging from BBCH 59-83, 30-47 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Puccinia striiformis* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 40.4 % in the untreated was reduced with BAS 736 00 F by 93.8%. The performance of the product was comparable to the standard (91.8%).

In support of registrations in the North east zone it is referred to the available data set of 7 trials on the same pathogen in wheat with an excellent average efficacy of 98.4% from which the data can be extrapolated (see Table 3.2-42 or Table 3.2-86). Across all zones a high efficacy was confirmed in wheat. It is further referred to the stable and consistent efficacy observed in trials in triticale in the Maritime zone.

No trials in triticale are available from the South east EPPO zone. It is referred to the available trials in the Maritime and the North east zones with stable and consistent efficacy (even under very high disease pressure) from which data can be extrapolated.

It should be further considered that both active substances contained in BAS 736 00 F are registered against *Puccinia striiformis* as solo active ingredient products in several countries.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Puccinia striiformis* in triticale under a wide range of agroclimatic conditions.

The available data fully support registration in the Maritime zone. The registration in the North east and the South east zones is supported by extrapolation from the very good data set in the Maritime zone. In the North east zone, it is in addition referred to the existing data in wheat. Registration in all zones is supported by the reference to the existing registrations of the solo active substances.

Table 3.2-60: Efficacy, Triticale PuccSI, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 10	mean (min-max)	40.8 (13.4–100)	2.9 (0–9.7)	94.8 (79.3–100)	3.5 (0–13.6)	91.9 (69.9–100)
North east	n = 1	mean (min-max)	36.3 (36.3–36.3)	5.8 (5.8–5.8)	84.1 (84.1–84.1)	3.5 (3.5–3.5)	90.3 (90.3–90.3)
Total ALL	n = 11	mean (min-max)	40.4 (13.4–100)	3.2 (0–9.7)	93.8 (79.3–100)	3.5 (0–13.6)	91.8 (69.9–100)

Comments of zRMS	Diseases control in triticales
	<p><i>Puccinia striiformis</i> (11 trials – 10 in Maritime, 1 in N-E zones)</p> <p>The results showed a good control of <i>Puccinia striiformis</i> on triticales by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 84.1-94.8%) under a wide range of conditions. The efficacy of tested product in the Maritime zone was higher and in the North-East zone slightly lower than of the reference product. The presented data fully support the registration of BAS 736 00 F for <i>Puccinia striiformis</i> control in the Maritime zone. The applicant submit only 1 trial from North-East zone and did not submit any data from South-East zone, so for the possible registration in North-East zone the data of 5 trials and for South-East zone all required data should be extrapolated from Maritime zone. In both zones the CMS have to decide on the suggested extrapolation.</p> <p>For the registration of BAS 736 00 F for <i>Puccinia striiformis</i> control in triticales in Poland, applicant submitted 1 trial from North-East zone (PL) and 7 trials from Maritime zone (Germany). The number of trials for <i>Puccinia striiformis</i> control in triticales in Poland is sufficient to registration.</p>

***Puccinia recondita*, Triticale**

A total of 8 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Puccinia recondita* in triticales. BAS 736 00 F at the dose rate of 2 L/ha was applied with one treatment within BBCH 31-59. Trials were conducted in harvest years 2019 and 2020 in the Maritime climatic zone (Denmark and German) and the North East climatic zone (Poland).

Summary of results is provided in Table 3.2-61.

The assessments ranging from BBCH 65-77, 28-64 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Puccinia recondita* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 19.6 % in the untreated was reduced with BAS 736 00 F by 89.9%. The performance of the product was superior to the standard (74.2%).

In support of registrations in all three zones it is referred to available 35 trials on the same pathogen in wheat from which the data can be extrapolated (see Table 3.2-43 or Table 3.2-86). Across all zones a high efficacy over 90% in wide range of situations was confirmed in wheat.

In case of the South east zone where no trials are available, an extrapolation from the Maritime and the North east zones is proposed.

It should be further considered in support of registration that both active substances contained in BAS 736 00 F are registered against *Puccinia recondita* as solo active ingredient products in several countries.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Puccinia recondita* in triticale under a wide range of agroclimatic conditions.

The available data in the Maritime and the North east zones are supported by extrapolation from wheat. In the South east zone both an extrapolation between the zones and, within the same pathogen, also between the crops is proposed. Registration in all zones is supported by the reference to the existing registrations of the solo active substances.

Table 3.2-61: Efficacy, Triticale PUCCRE, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 4	mean (min-max)	23.7 (14.5–34.4)	3.2 (0.9–9)	86.8 (73.8–97.4)	7.8 (0.7–18.5)	64.8 (27.8–97.6)
North east	n = 4	mean (min-max)	15.5 (7.1–28.5)	1.3 (0–3)	93.1 (83.3–99.6)	2.5 (0.1–4.2)	83.6 (64.7–99.1)
Total ALL	n = 8	mean (min-max)	19.6 (7.1–34.4)	2.3 (0–9)	89.9 (73.8–99.6)	5.1 (0.1–18.5)	74.2 (27.8–99.1)

Comments of zRMS:	<u>Diseases control in triticale</u>
	<p><i>Puccinia recondita</i> (8 trials – 4 in Maritime, 4 in N-E zones)</p> <p>The results showed a good control of <i>Puccinia recondita</i> on triticale by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 86.8-93.1%) under a wide range of conditions. In all zones the average efficacy was higher than of the reference product. The presented data not fully support the registration of BAS 736 00 F for <i>Puccinia recondita</i> control in Maritime and the North East zones, so to fulfill the registration requirements, the extrapolation of data from wheat or extrapolation between the Maritime zone and North East zones can be use. In both zones the cMS have to decide on the suggested extrapolation. The applicant did not submit any data from South-East zone, so the possible registration should be based on the data from Maritime and N-E zones but it has to be decided by the cMS.</p> <p>For the registration of BAS 736 00 F for <i>Puccinia recondita</i> control in triticale in Poland, applicant submitted 4 trial from North-East zone (PL) and 3 trials from Maritime zone (Germany). The number of trials for <i>Puccinia recondita</i> control in triticale in Poland is sufficient to registration.</p>

Blumeria graminis, Triticale

A total of 6 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Blumeria graminis* in triticale. BAS 736 00 F at the dose rate of 2 L/ha was applied with one treatment within BBCH 33-41. Trials were conducted in harvest years 2019 and 2020 in the Maritime climatic zone (Germany) and the North East climatic zone (Lithuania and Poland).

Summary of results is provided in Table 3.2-62.

The assessments ranging from BBCH 51-75, 20-45 DALT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation. In 2 German trials that were assessed earlier (within BBCH 51-59) also the 4th and 5th leaf layer respectively was included in evaluation as it was still found

relevant for the evaluation at that time. In one of the two German trials the infection level in the untreated control was slightly below the threshold (4.5%) but as there was differentiation between the treatments it is considered valid for evaluation.

A significant reduction of *Blumeria graminis* was achieved in all trials across all EPPO zones. The summary across all EPPO zones showed that the mean infestation of 13.5 % in the untreated was reduced with BAS 736 00 F by 81.7%. The performance of the product was comparable to the standard (81%).

Reduced data sets on triticale are available from the Maritime and the North east zones and no trials are available from the South east zone. However, the available results of 12 trials on winter wheat (7 trials Maritime zone, 5 trials North east zone) clearly demonstrate control of powdery mildew (see Table 3.2-45 or Table 3.2-86). These data can be extrapolated from winter wheat to triticale. Across the Maritime and the North east zones, a mean efficacy of 80.2% was observed in wheat. Additionally, for Maritime and North-East EPPO zones very similar results of *Blumeria graminis* control with BAS 736 00 F were obtained on both wheat and triticale. Therefore, it is concluded that the data on wheat are sufficient to claim control of powdery mildew on triticale.

As already explained in wheat chapter, results obtained in barley may also be considered as additional supportive evidence of product efficacy in cereals. Therefore, it is suggested that the results of powdery mildew control on barley can be considered as further supportive evidence for registration in triticale (5 trials from Maritime zone with average efficacy of 78%, 1 trial from North-East zone with average efficacy of 78.5% and 7 trials from the South east zone with average efficacy of 80.3%). It is further referred to Table 3.2-86 that summarizes the efficacy data of all concerned crop and confirms that efficacy on powdery mildew is observed across cereals.

It should be further considered in support of registration that both active substances contained in BAS 736 00 F are registered against *Blumeria graminis* in triticale as solo active ingredient products in several countries.

Conclusion

According to the trial results, it can be concluded that application of BAS 736 00 F at 2 L/ha controls *Blumeria graminis* in triticale under a wide range of agroclimatic conditions.

Table 3.2-62: Efficacy, Triticale, ERYSGR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			infect	infect	efficacy	infect	efficacy
Maritime	n = 4	mean	9.8	1.7	80.9	2.4	79.1
		(min-max)	(4.5–16.8)	(1–2.8)	(66.7–89.5)	(0.8–6.5)	(61.3–92.1)
North east	n = 2	mean	20.9	2.4	83.2	2.4	84.7
		(min-max)	(11.8–30)	(1.4–3.5)	(70.2–96.2)	(1.8–3)	(74.5–95)
Total ALL	n = 6	mean	13.5	1.9	81.7	2.4	81.0
		(min-max)	(4.5–30)	(1–3.5)	(66.7–96.2)	(0.8–6.5)	(61.3–95)

Comments of zRMS:	<p>Diseases control in triticale</p> <p><i>Blumeria graminis</i> (6 trials – 4 in Maritime, 2 in N-E zones)</p> <p>The results showed a good control of <i>Blumeria graminis</i> on triticale by BAS 736 00 F, applied at the rate of 2.0 L/ha (mean control 80.9-83.2%) under a wide range of conditions. In all cases the efficacy was very close to the reference product. The presented data not fully support the registration of BAS 736 00 F for <i>Blumeria graminis</i> control in the Maritime and North East zones, so to fulfill the registration requirements, the extrapolation of data from wheat and extrapolation between the zones (Maritime and North East) should be used. The applicant did not submit any data from South-East zone, so the possible registration should be based on the data from other zones but it has to be decided by the CMS.</p> <p>For the registration of BAS 736 00 F to <i>Blumeria graminis</i> control in triticale in Poland, applicant submitted 2 trial from North-East zone (PL) and 3 trials from Maritime zone (Germany). The number of trials for <i>Blumeria graminis</i> control in triticale in Poland not fully meet the Polish requirements, so the missing data should be extrapolated from winter wheat.</p>
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Information on trials submitted in Oats

In 2019, altogether 3 efficacy trials were carried out to prove the fungicidal efficacy of BAS 736 00 F in oats. All trials were conducted in the United Kingdom (Maritime zone).

BAS 736 00 F at target dose rate of 2 L/ha was applied according to the GAP once within the BBCH stage ranging from 30-59.

BAS 9314 4 F known as Proline at the dose rate of 0.72 L/ha (prothioconazole 275 g/L) was used as a reference product in all trials.

Only few trials are available in oats, none in the North east and the South east zones, following a lower economic importance of the crop in Europe. In many countries, oats are considered as a minor crop or the uses may be understood as minor. Both active substances contained in BAS 736 00 F, azoxystrobin and fluxapyroxad are registered against *Puccinia coronata* or *Erysiphe graminis* as solo active ingredient products in many European countries. It is therefore proposed that the final decision on registration is done by the concerned member states.

Puccinia coronata, Oats

A total of 2 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Puccinia coronata* in oats. BAS 736 00 F at the dose rate of 2 L/ha was applied in one treatment within BBCH 30-59. Trials were conducted in harvest year 2019 in the United Kingdom (the Maritime climatic zone).

Summary of results is available in Table 3.2-63.

The last assessments around BBCH 75 (range BBCH 75-83), 35-64 DAT on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Puccinia coronata* in oats was achieved in both trials. The overall summary showed that the mean infestation of 20.8 % in the untreated was reduced with BAS 736 00 F by 80 %. The performance of the product was comparable to the standard (78.9%).

Conclusion

According to the available trial results against *Puccinia coronata*, a robust data set available on efficacy of the products on other *Puccinia* species in other cereal crops and the existing registrations of solo active ingredient products on *Puccinia coronata* across Europe, and the fact that in some concerned members states oats is considered to be a minor crop it is proposed that the registration on *Puccinia coronata* is decided on the member state level.

Table 3.2-63: Efficacy, Oats, PuccCO, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic		Untreated infect	BAS 736 00 F 2.0 L/ha		Standard	
			infect	efficacy	infect	efficacy
Maritime	n = 2 mean (min-max)	20.8 (17.3–24.4)	3.9 (2–5.9)	80.0 (67.6–92.3)	4.3 (3–5.6)	78.9 (69.3–88.4)

Comments of zRMS:	Diseases control in oat
	<i>Puccinia coronata</i> (2 trials in Maritime zone - UK)
	The trials were carried out in UK, and considering that the UK left the EU on January 31, 2020 and the studies has been started earlier, the results from this country should be considered in assessment.
	The results showed a good control of <i>Puccinia coronata</i> on oat by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 80%). The average efficacy of tested product was slightly higher than of the reference product.
	The number of presented data is not sufficient for registration of BAS 736 00 F for <i>Puccinia coronata</i> control in the Maritime zone, so, to support the registration cMS can extrapolate the data from another crops or authorize this fungicide as minor use. The applicant did not submit any data from the North East and South-East zones, so the possible registration in these zones should be based on the data from Maritime zone and missing data should be refill by extrapolation from another crops or cMS may authorize this fungicide as minor use.
	The registration of BAS 736 00 F for <i>Puccinia coronata</i> control in oats in Poland is not possible. Applicant did not submit any data from North-East zone or neighboring countries of Poland.

***Blumeria graminis*, Oats**

A total of 3 trials showed sufficient level of infestation to evaluate the efficacy of BAS 736 00 F against *Erysiphe graminis* in oats. BAS 736 00 F at the dose rate of 2 L/ha was applied in one treatment within BBCH 30-59. Trials were conducted in harvest year 2019 in the United Kingdom (the Maritime climatic zone).

Summary of results is available in Table 3.2-63.

The last assessments around BBCH 75 (range BBCH 65-73) on upper 3 leaf layers with min 5% infection threshold in untreated were chosen for evaluation.

A significant reduction of *Erysiphe graminis* in oats was achieved in all trials. The overall summary showed that the mean infestation of 12.5 % in the untreated was reduced with BAS 736 00 F by 65.8 %. The performance of the product was inferior to the standard (89.3%).

Conclusion

According to the available trial results against *Erysiphe graminis*, the data set available on efficacy of the products on *Blumeria graminis* in other cereal crops and the existing registrations of solo active ingredient products on *Erysiphe graminis* across Europe, and the fact that in some concerned members states oats is considered to be a minor crop it is proposed that the registration on *Erysiphe graminis* is decided on the member state level.

Table 3.2-64: Efficacy, Oats, ERYSGR, intensity of attack (infect and efficacy in %); summary

EPPO Zone climatic		Untreated	BAS 736 00 F 2.0 L/ha		Standard	
		infect	infect	efficacy	infect	efficacy
Maritime	n = 3 mean (min-max)	12.5 (7.5–19.8)	5.2 (1.3–10.9)	65.8 (51.8–83.3)	1.5 (0–3.1)	89.3 (80–100)

Comments of zRMS:	Diseases control in oat
	<i>Blumeria graminis</i> (3 trials in Maritime zone - UK)
	The trials were carried out in UK, and considering that the UK left the EU on January 31, 2020 and the studies has been started earlier, the results from this country should be considered in assessment.
	The results showed a good control of <i>Blumeria graminis</i> on oat by BAS 736 00 F applied at the rate of 2.0 L/ha (mean control 65.5%). The efficacy of tested product was lower than of the reference product.
	The number of presented data is not sufficient for registration of BAS 736 00 F for <i>Blumeria graminis</i> control in the Maritime zone, so, to support the registration cMS can extrapolate the data from another crops or authorize this fungicide as minor use. The applicant did not submit any data from the North East and South-East zones, so the possible registration in these zones should be based on the data from Maritime zone and missing data should be refill by extrapolation from another crops or cMS may authorize this fungicide as minor use.
	The registration of BAS 736 00 F for <i>Blumeria graminis</i> control in oats in Poland is not possible. Applicant did not submit any data from North-East zone or nieghbering countries of Poland.

Dose rate range justification

In certain countries within the EU28, among them Hungary, Romania, Slovakia and Slovenia, regulations do not allow the farmer to apply lower dose rates than the registered ones, even in cases where the use of a

lower dose rate might be justified. In other countries the label gives the farmer guidance on the dose rates to be used and thus the explicit dose rate on the label is seen as a benefit (the Czech Republic).

A dose rate range is therefore requested for these countries 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.

The requested dose rate ranges are 1.2-2.0 L/ha for the Czech Republic and 1.0–2.0 L/ha for the concerned member states from the South east EPPO zone: Hungary, Romania, Slovakia and Slovenia.

Across results, it was demonstrated that mentioned lower dose rates of BAS 736 00 F can be effective under certain agricultural conditions. Number of trials carried out on different cereal crops and presented in the Minimum Effective Dose chapter support this. Therefore, it is referred to the results presented in the Minimum Effective Dose chapter and only a summary of results is presented in this chapter.

In addition, a dose rate of 0.6 L/ha was tested in some trials in wheat and barley in the South east zone in order to confirm 1.0 L/ha as the lower limit of the dose rate range in the South east zone. The data are presented in the following subchapters.

In rye and triticale, no results are available from the South east zone, thus an extrapolation from the Maritime and North east zones is proposed. The dose rates of 1.2 and 2.0 L/ha were presented in the Maritime and North east zones in Minimum Effective Dose chapter. However, there are several trials available in the Maritime and North east zones in which additionally also 1.0 L/ha was tested. These trials are presented for rye and triticale in this chapter. The dose rate of 0.6 L/ha was not tested in rye and triticale.

Based on the fact that the above mentioned countries need a dose rate range and that the efficacy of the lower dose rate has been demonstrated with data, it is proposed to allow a dose rate range of 1.2-2.0 L/ha L/ha for the Czech Republic and 1.0–2.0 L/ha for Hungary, Romania, Slovakia and Slovenia.

Dose rate range justification, Wheat

Efficacy data from altogether 86 trials following application of BAS 736 00 F at reduced dose rate of 1.2 L/ha (in the Maritime and the North east zones) or 1.0 L/ha (in the South east zone) in comparison to the full dose rate of 2.0 L/ha were presented in wheat in the Minimum Effective Dose chapter.

The benefit of the full dose rate of 2.0 L/ha was obvious: it provided clearly superior and more consistent control of all target diseases in each EPPO zone. On the other hand, it was observed that in some cases already the reduced dose rate achieved reasonable efficacy on the level of the standard.

In Table 3.2-65 a summary of the Maritime zone data is presented. BAS 736 00 F at the reduced dose rate outperformed the standard even with the reduced dose rate on *Zymoseptoria tritici* and *Puccinia triticina*. On *Puccinia striiformis* and *Pyrenophora tritici-repentis*, the reduced dose rate performed on the similar level to the standard. On *Blumeria graminis*, the reduced dose rate was inferior to the standard but still achieved a reasonable average efficacy of 73.6%.

In the South east zone, a dose rate 0.6 L/ha was tested in some trials in order to confirm the 1.0 L/ha as the lower limit of the dose rate range. An orthogonal comparison of all tested dose rates is provided in Table 3.2-66. While the full dose rate clearly outperformed the standard in all diseases - *Zymoseptoria tritici*, *Puccinia triticina*, *Puccinia striiformis* and *Pyrenophora tritici-repentis* – the reduced dose rate of 1.0 L/ha was still superior to the standard on *Puccinia triticina* and performed on the similar level in case of *Puccinia striiformis* and *Pyrenophora tritici-repentis*. On *Zymoseptoria tritici*, the reduced dose rate was inferior to the standard but still provided reasonable average efficacy of 77%.

Conclusion

The proposed dose rate ranges of 1.0 - 2.0 L/ha of BAS 736 00 F for Hungary, Romania, Slovakia, Slovenia and 1.2 - 2.0 L/ha of BAS 736 00 F for the Czech Republic are considered justified.

Disease				Untreated	BAS 736 00 F				Standard	
					1.2 L/ha		2.0 L/ha			
				infect	infect	efficacy	infect	efficacy	infect	efficacy
SEPTTR	ALL	n = 29	mean (min-max)	36.8 (5.3-100)	8.4 (0-37.6)	77.4 (46.4-100)	5.9 (0-24.4)	83.9 (50-100)	12.9 (0-70.6)	68.6 (29.2-100)
	UTC<35%	n = 21	mean (min-max)	19.3 (5.3-32.5)	4.5 (0-16.1)	76.5 (46.4-100)	3.3 (0-11.3)	82.9 (50-100)	5.8 (0-17.5)	70.1 (42.4-100)
	UTC≥35%	n = 8	mean (min-max)	82.7 (36.9-100)	18.5 (4.8-37.6)	79.6 (62-95.3)	12.8 (3.2-24.4)	86.3 (75.4-94.2)	31.4 (3.8-70.6)	64.9 (29.2-96.3)
PUCCSI	ALL	n = 19	mean (min-max)	38.8 (7.1-97.8)	8.3 (0-53)	82.0 (45.7-100)	6.1 (0-36.5)	87.0 (60.6-100)	9.2 (0-55.8)	79.2 (42.7-100)
	UTC<35%	n = 10	mean (min-max)	21.0 (7.1-34.4)	3.3 (0-10)	87.5 (66-100)	1.6 (0-5.3)	93.8 (85.2-100)	4.0 (0-10.8)	81.9 (42.7-100)
	UTC≥35%	n = 9	mean (min-max)	54.1 (33.8-97.8)	12.5 (0.3-53)	76.8 (45.7-99.4)	9.8 (0.3-36.5)	81.2 (60.6-99.4)	13.9 (1-55.8)	75.8 (43-96.2)
PUCCRT	ALL	n = 15	mean (min-max)	32.2 (5.8-100)	3.3 (0-10.8)	87.4 (57.4-100)	2.1 (0-6.5)	92.9 (75-100)	13.6 (0-65)	65.3 (25-100)
	UTC<35%	n = 11	mean (min-max)	18.2 (5.8-34.4)	2.6 (0-10.8)	85.9 (57.4-100)	1.4 (0-5.4)	92.6 (75-100)	5.3 (0-12.6)	70.2 (25-100)
	UTC≥35%	n = 4	mean (min-max)	70.9 (48.8-100)	5.3 (0.9-9.6)	91.7 (80.4-98.6)	4.1 (0.1-6.5)	93.6 (87.2-99.8)	36.5 (16.9-65)	51.8 (35-73.2)
PYRNTR		n = 8	mean (min-max)	25.4 (6.4-50)	9.2 (0-24.6)	68.1 (48.5-100)	7.6 (0-20)	75.3 (58.7-100)	8.1 (0-20.3)	70.6 (55-100)
ERYSGR		n = 5	mean (min-max)	8.9 (4.3-18.1)	2.5 (1-7.3)	73.6 (58.8-90.5)	2.2 (0.8-6.8)	78.8 (61.3-90.5)	1.9 (1-4)	76.3 (52.9-88.1)

Disease			Untreated	BAS 736 00 F						Standard	
				0.6 L/ha		1.0 L/ha		2.0 L/ha			
			infect	infect	efficacy	infect	efficacy	infect	efficacy	infect	efficacy
SEPTTR	n = 13	mean (min-max)	14.9 (7.5-25.1)	5.9 (2.1-14.5)	62.7 (37.6-82.9)	3.8 (1.3-9.4)	77.6 (62.3-88.3)	1.8 (0-5.1)	90.3 (76.5-100)	2.6 (0-6.9)	83.7 (51.9-100)
PUCCSI	n = 2	mean (min-max)	88.3 (81-95.5)	20.5 (20.3-20.8)	76.7 (75.2-78.3)	12.9 (11.1-14.8)	85.1 (81.9-88.3)	6.8 (4.4-9.3)	92.0 (88.6-95.4)	12.1 (7.1-17)	85.8 (79.1-92.5)
PUCCRT	n = 9	mean (min-max)	9.0 (5-26)	2.0 (0.3-7.8)	81.7 (60-95.5)	1.1 (0.1-5.3)	91.7 (88.1-97.7)	0.5 (0-3.3)	97.2 (88.6-100)	1.4 (0-4.1)	85.3 (58.1-100)
PYRNTR	n = 1	mean	5.0	2.0	60.0	0.5	90.0	0.3	95.0	0.5	90.0

Dose rate range justification, Barley

Efficacy data from altogether 66 trials following application of BAS 736 00 F at reduced dose rate of 1.2 L/ha (in the Maritime and the North east zones) or 1.0 L/ha (in the South east zone) in comparison to the full dose rate of 2.0 L/ha were presented in barley in the Minimum Effective Dose chapter.

The benefit of the full dose rate of 2.0 L/ha was obvious: it provided clearly superior and more consistent control of all target diseases in each EPPO zone. On the other hand, it was observed that in some cases already the reduced dose rate achieved reasonable efficacy on the level of the standard.

In Table 3.2-67 a summary of the Maritime zone data is presented. BAS 736 00 F at the reduced dose rate of 1.2 L/ha outperformed the standard even with the reduced dose rate on *Puccinia hordei* and provided average efficacy comparable to the standard on *Pyrenophora teres* and *Rhynchosporium secalis*. On *Ramularia collo-cygni* and *Erysiphe graminis*, the full dose rate was needed to reach the efficacy level of the standard, however, the reduced dose rate still provided an average efficacy above 60% and achieved efficacy of 90.5% and 95.2% respectively in single cases.

In the South east zone, a dose rate 0.6 L/ha was tested in some trials in order to confirm the 1.0 L/ha as the lower limit of the dose rate range. An orthogonal comparison of all tested dose rates is provided in Table 3.2-68. While the full dose rate outperformed the standard on *Pyrenophora teres*, *Puccinia hordei*, *Rhynchosporium secalis* and was comparable to it on *Erysiphe graminis*, the reduced dose rate of 1.0 L/ha performed similar to the standard on *Pyrenophora teres*, *Puccinia hordei* and *Rhynchosporium secalis*. On *Erysiphe graminis*, the reduced dose rate of 1.0 L/ha was inferior to the standard but still provided reasonable average efficacy of 70.8%.

Conclusion

The proposed dose rate ranges of 1.0 - 2.0 L/ha of BAS 736 00 F for Hungary, Romania, Slovakia, Slovenia and 1.2 - 2.0 L/ha of BAS 736 00 F for the Czech Republic are considered justified.

Table 3.2-67: Dose rate range in MA zone, Barley, different diseases, intensity of attack (infect and efficacy in %); summary

Disease	Untreated	BAS 736 00 F				Standard	
		1.2 L/ha		2.0 L/ha			
		infect	efficacy	infect	efficacy	infect	efficacy
PYRNTE n = 17 mean	26.0	6.5	75.4	4.5	85.0	5.9	76.7
(min-max)	(5-75.9)	(1-37.6)	(18.7-96.4)	(0.3-31.2)	(63.6-97.7)	(0-20.4)	(30.6-100)
PUCCHD n = 10 mean	24.7	4.0	87.7	2.8	91.0	5.9	82.0
(min-max)	(8.8-54)	(0-23.8)	(43.5-100)	(0-16.3)	(61.3-100)	(0-21.8)	(48.2-100)
RHYNSE n = 11 mean	47.3	8.4	76.5	5.3	85.6	7.9	79.9
(min-max)	(7.5-94)	(0.4-28.3)	(42.7-98.3)	(0.4-15.2)	(57.3-98.6)	(0.7-26.2)	(51.7-96)
RAMUCC n = 18 mean	34.3	12.0	62.6	8.1	75.1	7.8	75.8
(min-max)	(5-98.6)	(1-47.1)	(0-90.5)	(0.8-33.8)	(48.9-93.6)	(0-29.9)	(25.8-100)
ERYSGR n = 5 mean	11.6	4.7	62.7	2.7	78.0	2.6	82.4
(min-max)	(5.5-19)	(0.8-14.4)	(22.2-95.2)	(0.5-7)	(60.7-91.9)	(0-9)	(56.2-100)

Table 3.2-68: Dose rate range in SE zone, Barley, different diseases, intensity of attack (infect and efficacy in %); summary

Disease			Untreated	BAS 736 00 F						Standard	
				0.6 L/ha		1.0 L/ha		2.0 L/ha			
			infect	infect	efficacy	infect	efficacy	infect	efficacy	infect	efficacy
PYRNTE	n = 9	mean	21.4	8.1	68.9	6.4	75.2	3.4	86.5	8.1	75.1
		(min-max)	(5-87.9)	(1.1-40)	(54.8-78.4)	(0.8-30.1)	(66.1-84.9)	(0.5-17.5)	(80.3-94.7)	(0.3-48.8)	(44.9-93.5)
PUCCHD	n = 2	mean	6.6	0.8	87.2	0.5	93.0	0.3	95.9	0.6	91.8
		(min-max)	(5.8-7.5)	(0.6-1)	(82.7-91.8)	(0.4-0.5)	(92.6-93.3)	(0.3-0.3)	(94.8-97)	(0.5-0.6)	(91.8-91.8)
RHYNSE	n = 1	mean	5.4	2.0	63.6	1.0	80.7	0.6	88.6	1.1	80.0
		(min-max)	(5.4-5.4)	(2-2)	(63.6-63.6)	(1-1)	(80.7-80.7)	(0.6-0.6)	(88.6-88.6)	(1.1-1.1)	(80-80)
ERYSGR	n = 6	mean	19.6	8.1	62.3	6.4	70.8	4.4	79.2	4.8	77.7
		(min-max)	(6.7-38.1)	(2.4-22.8)	(41.8-79.6)	(1.6-18.1)	(53.3-88.3)	(0.3-13)	(67.1-97.5)	(1.5-11.8)	(69.8-89)

Dose rate range justification, Rye

Efficacy data from altogether 21 trials following application of BAS 736 00 F at reduced dose rate of 1.2 L/ha (in the Maritime and the North east zones) in comparison to the full dose rate of 2.0 L/ha were presented in rye in the Minimum Effective Dose chapter.

The benefit of the full dose rate of 2.0 L/ha was obvious: it provided clearly superior and more consistent control of all target diseases in each EPPO zone. On the other hand, it was observed that in some cases already the reduced dose rate achieved reasonable efficacy on the level of the standard.

In the South east zone, no trials in rye were conducted. Nevertheless, a dose rate of 1.0 L/ha was tested in some trials in the Maritime and the North east zones. An extrapolation to the South east zone is proposed.

An orthogonal comparison of all tested dose rates is provided in Table 3.2-69. While the full dose rate clearly outperformed the standard on both *Puccinia recondita* and *Rhynchosporium secalis*, the reduced dose rate of 1.2 L/ha was still comparable to the standard or even better to it. With the reduced dose rate of 1.0 L/ha the average efficacy dropped below the level of standard but still stayed on a reasonable level of about 70-78% in average and the performance was still relatively stable and did not drop below 50%.

Conclusion

The proposed dose rate ranges of 1.0 - 2.0 L/ha of BAS 736 00 F for Hungary, Romania, Slovakia, Slovenia and 1.2 - 2.0 L/ha of BAS 736 00 F for the Czech Republic are considered justified.

Table 3.2-69: Dose rate range, Rye, different diseases, intensity of attack (infect and efficacy in %); summary

Disease				Untreated	BAS 736 00 F						Standard	
					1.0 L/ha		1.2 L/ha		2.0 L/ha			
				infect	infect	efficacy	infect	efficacy	infect	efficacy	infect	efficacy
PUCCRE	Maritime	n = 4	mean	23.8	5.8	77.9	4.1	86.5	1.9	92.4	3.9	81.5
			(min-max)	(5.8–50.8)	(0.4–12.2)	(55.2–92.4)	(0.6–11.7)	(77.7–96)	(0.3–4.9)	(89.1–98.7)	(1.1–7.1)	(62.1–94.2)
	ALL	n = 4	mean	20.5	6.1	69.7	4.0	79.2	2.0	90.0	3.0	78.5
			(min-max)	(7.1–41.3)	(1.3–10.8)	(53.5–89.7)	(1.8–7.4)	(71.3–86.4)	(0.9–3)	(86.7–95.5)	(1.8–4)	(54.8–91.2)
	Maritime	n = 3	mean	24.9	7.1	75.1	4.7	81.8	2.4	90.2	3.1	86.4
			(min-max)	(11.1–41.3)	(1.3–10.8)	(60–89.7)	(1.8–7.4)	(77.8–86.4)	(1.5–3)	(86.7–95.5)	(1.8–4)	(82.2–91.2)
	North east	n = 1	mean	7.1	3.2	53.5	2.0	71.3	0.9	89.4	3.0	54.8
			(min-max)	(7.1–7.1)	(3.2–3.2)	(53.5–53.5)	(2–2)	(71.3–71.3)	(0.9–0.9)	(89.4–89.4)	(3–3)	(54.8–54.8)

Dose rate range justification, Triticale

Efficacy data from altogether 20 trials following application of BAS 736 00 F at reduced dose rate of 1.2 L/ha (in the Maritime and the North east zones) in comparison to the full dose rate of 2.0 L/ha were presented in rye in the Minimum Effective Dose chapter.

The benefit of the full dose rate of 2.0 L/ha was obvious: it provided clearly superior and more consistent control of all target diseases in each EPPO zone. On the other hand, it was observed that in some cases already the reduced dose rate achieved reasonable efficacy on the level of the standard.

In the South east zone, no trials in rye were conducted. Nevertheless, a dose rate of 1.0 L/ha was tested in some trials in the Maritime and the North east zones. An extrapolation to the South east zone is proposed.

An orthogonal comparison of all tested dose rates is provided in Table 3.2-70. While the full dose rate outperformed the standard on all diseases - *Septoria* species, *Puccinia striiformis*, *Puccinia recondita* and *Erysiphe graminis* – both reduced dose rate (1.0 L/ha and 1.2 L/ha) still performed in average per disease similar (SEPTSP, PUCCSI, ERYSGR) or even better than the standard (PUCCRE).

Conclusion

The proposed dose rate ranges of 1.0 - 2.0 L/ha of BAS 736 00 F for Hungary, Romania, Slovakia, Slovenia and 1.2 - 2.0 L/ha of BAS 736 00 F for the Czech Republic are considered justified.

Table 3.2-70: Dose rate range, Triticale, different diseases, intensity of attack (infect and efficacy in %); summary

Disease			Untreated	BAS 736 00 F						Standard	
				1.0 L/ha		1.2 L/ha		2.0 L/ha		infect	efficacy
			infect	infect	efficacy	infect	efficacy	infect	efficacy		
SEPTSP Maritime	n = 4	mean	20.4	3.7	83.1	2.8	87.9	2.3	89.5	3.8	80.0
		(min-max)	(8.5–38.3)	(0.3–6)	(56.4–97.1)	(0.3–4.5)	(80–97.1)	(0–3.8)	(72.7–100)	(0–7.8)	(43.6–100)
PUCCSI Maritime	n = 4	mean	36.7	6.2	87.8	3.8	91.5	2.5	95.4	4.7	87.6
		(min-max)	(14.8–90)	(0.2–21.5)	(75.4–99.2)	(0.2–12.6)	(84.9–99.2)	(0–9.2)	(89.7–100)	(0.1–13.6)	(69.9–99.5)
PUCCRE Maritime	n = 3	mean	26.5	6.9	75.3	6.7	76.2	3.9	86.4	9.9	57.1
		(min-max)	(14.5–34.4)	(1–16.1)	(53.1–96.1)	(2.5–14.6)	(57.4–88.1)	(0.9–9)	(73.8–97.4)	(0.7–18.5)	(27.8–97.6)
ERYSGR all	n = 3	mean	21.6	4.4	79.5	4.0	81.3	2.6	87.5	4.0	79.4
		(min-max)	(16.8–30)	(3.8–5.1)	(70.2–88.6)	(3.5–4.8)	(75.6–89.3)	(1.4–3.5)	(81.2–96.2)	(1.8–6.5)	(61.3–95)
Maritime	n = 2	mean	17.4	4.7	74.9	4.2	77.4	3.2	83.2	5.1	71.5
		(min-max)	(16.8–18)	(4.3–5.1)	(70.2–79.5)	(3.7–4.8)	(75.6–79.1)	(2.8–3.5)	(81.2–85.2)	(3.6–6.5)	(61.3–81.7)
North east	n = 1	mean	30.0	3.8	88.6	3.5	89.3	1.4	96.2	1.8	95.0
		(min-max)	(30–30)	(3.8–3.8)	(88.6–88.6)	(3.5–3.5)	(89.3–89.3)	(1.4–1.4)	(96.2–96.2)	(1.8–1.8)	(95–95)

Comments of zRMS	<u>Efficacy</u>
	<p>The data presented in this report support the registration of BAS 736 00 F (Miralon) for following diseases control in cereal crops:</p> <ul style="list-style-type: none"> – in wheat: powdery mildew (<i>Blumeria graminis</i> f.sp. <i>tritici</i>), Septoria leaf blotch (<i>Zymoseptoria tritici</i>), brown rust (<i>Puccinia triticina</i>), yellow rust (<i>Puccinia striiformis</i>) and tan spot (<i>Pyrenophora tritici-repentis</i>); – in barley: powdery mildew (<i>Blumeria graminis</i> f.sp. <i>hordei</i>), net blotch (<i>Pyrenophora teres</i>), leaf scald (<i>Rhynchosporium secalis</i>), Ramularia leaf spot (<i>Ramularia collo-cygni</i>) and leaf rust (<i>Puccinia hordei</i>). – in rye: leaf scald (<i>Rhynchosporium secalis</i>) and leaf rust (<i>Puccinia recondita</i>). – in triticale: powdery mildew (<i>Blumeria graminis</i>), Septoria leaf <i>Zymoseptoria tritici</i>) and rusts (<i>Puccinia recondita</i> and <i>Puccinia striiformis</i>). – in oat: powdery mildew (<i>Blumeria graminis</i> f.sp. <i>avenae</i>) and rust (<i>Puccinia coronata</i>) – the number of data with oat is not sufficient, so, to support the registration of BAS 736

	<p>00 F for control, cMS can extrapolate the data from another crops or authorize this fungicide as minor use.</p> <p>For some countries (DE, AT, BE, NL, IE, PL) applicant recommends the use of BAS 736 00 F at the rate of 2.0 L/ha in each treatment, while for Hungary, Romania, Slovakia and Slovenia proposes the dose rates of 1.0–2.0 L/ha and for the Czech Republic 1.2–2.0 L/ha. ZRMS agrees with applicant that the proposed dose rates of BAS 736 00 F for those countries are acceptable. The regulations in these countries do not allow the farmer to apply lower dose rates than the registered ones, even in cases where the use of a lower dose rate might be justified. A dose rate range is therefore requested for these countries to allow farmers to use the product as a part of an Integrated Pest Management approach and adapt the rate to the needs and conditions. Crop variety, crop vigour, disease pressure and the prevailing climatic conditions are all potential factors that could affect the application rate.</p> <p>In the trials BAS 736 00 F was used at the growth stages between BBCH 30 and 69. The amount of water volume used for spraying ranged between 100-300 L/ha. The minimum intervals between both applications terms of tested product was 21 days. Given the high selectivity of tested fungicide for diseases control in cereal crops ZRMS suggests to keep the recommendations as presented in GAP table, although the CMS should define the application time of BAS 736 00 F for intended uses for his own countries.</p> <p>The number of efficacy trials to support the registration of BAS 736 00 F for the most diseases control in cereal crops in Central registration zone, as well as in Poland, is sufficient. The presented data indicate that efficacy of BAS 736 00 F is on the same level or higher than from the reference products. The ZRMS accept the extrapolation of data from other countries, even from another zone, for BAS 736 00 F registration in individual countries, due to the high effectiveness of this fungicide, which in the vast majority is higher than the reference products.</p> <p>ZRMS suggests that the registration of BAS 736 00 F for diseases control in cereal crops for which the number of submitted data is insufficient and cMS do not agree to extrapolate the data from another zone or the number of available data is too low, can be made as minor use, in accordance with art. 51 of Regulation (EC) No. 1107/2009. According to applicant's information all cereal crops in which BAS 736 00 F is intended to be use are a major crops, except rye in NL, IE, RO, SI, SK (spring), triticale in IE, NL, RO, UK and oat in AT, DE, HU, IE, NL and SI. The diseases under experiments have a major status in wheat (all) and barley (except SK) and remain pathogens have a major or minor status, as shown in the table 3.2-4. Too low number of available trials mainly refers to oat.</p> <p>Taking into account a high efficacy and a good selectivity of BAS 736 00 F (Miralon) to tested cereal crops, the time of possible infection by pathogens, the risk of developing resistance by pathogens and also recommendations of the solo use of both active substances (fluxapyroxad and azoxystrobin), ZRMS agree with applicant and suggests the registration of BAS 736 00 F in cereal crops and the use of this product according to GAP. The justification of BAS 736 00 F registration by the fact that the individual active substances are approved for the use as separate fungicides in many countries, is not fully acceptable, but may be helpful in interpreting the test results.</p> <p>The proposed label claim: the application of BAS 736 00 F (Miralon) at the rate of 2.0 L/ha (fluxapyroxad – 100 g/ha + azoxystrobin – 150 g/ha) for diseases control in wheat, barley, triticale, rye and oat. The authorization in oats should be included as minor use. The fungicide should be recommended as foliar application at a maximum of two treatments, at the growth stages between BBCH 30 and BBCH 69, with water volume from 100 to 300 L/ha.</p> <p>ZRMS not recommend the BAS 736 00 F registration for diseases control in oat in Poland.</p>
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Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

A summary of the yield data from efficacy trials with disease is presented in this chapter.

In some trials, the assessments of the thousand grain weight or the hectolitre weight were done on a bulk sample. In such cases, the statistics could not be calculated.

In some trials, the data on thousand grain weight and the hectolitre weight were obtained from a bulk sample. In such cases, no statistical evaluation was possible in the trial and it is marked as “---” in the respective column of the table.

Yield, Wheat, Efficacy trials with disease

Altogether 105 from 106 efficacy trials on wheat, carried out between 2019 and 2020, have been harvested to confirm the yield response of BAS 736 00 F in the presence of diseases. The presented data cover range of trials with one or two applications conducted within BBCH 31-72. The BBCH 72, which slightly exceeds the GAP, appears in 2 trials. Both are considered relevant for the BAD as already explained in respective efficacy chapter.

Data is provided for both the target dose rate of 2 L/ha and the reduced dose rate which is represented by 1.2 L/ha in the Maritime and North east zones and 1.0 L/ha in the South east zone.

Yield in dt/ha is presented by 105 results. Summary can be found in Table 3.2-71.

81 trial results are available for thousand grains weight, see summary in Table 3.2-72.

Altogether 95 trials provided information on hectolitre weight. For results see summary in Table 3.2-73. Through results presented across all EPPO zones, BAS 736 00 F shows that the yield in dt/ha has improved in comparison to the untreated with both the reduced dose rate (14.6% yield increase) and the full dose rate (17.4% yield increase), without any significant negative impact on quality parameters such as thousand grains weight and hectolitre weight.

Table 3.2-71: Yield in presence of disease (in dt/ha and % of UTC), Wheat; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.0/1.2 L/ha*		BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 63	mean	82.3	-	-	98.4	124.6	94.7	119.6
		(min-max)	(19-126.1)	-	-	(29.4-133.1)	(100.5-315.6)	(28.5-132)	(69.8-282.4)
	n = 49	mean	81.5	94.3	119.7	97.0	122.7	93.0	117.6
		(min-max)	(19-124.5)	(26.4-131.4)	(102.1-259.4)	(29.4-133.1)	(100.5-315.6)	(28.5-132)	(69.8-282.4)
North east	n = 26	mean	72.3	-	-	78.1	108.5	76.3	106.0
		(min-max)	(49.1-110.7)	-	-	(52-116.2)	(102-121.8)	(51.6-112.6)	(98.7-122.8)
	TRZAW n = 22	mean	72.7	77.5	107.0	78.6	108.7	76.9	106.2
		(min-max)	(50.1-106.4)	(53.2-108.8)	(100.4-118.7)	(55.8-109)	(102-121.8)	(53.4-108.3)	(98.7-122.8)
	TRZAS n = 2	mean	51.6	54.3	105.1	54.9	106.4	54.1	104.7
		(min-max)	(49.1-54.2)	(50.5-58.1)	(102.9-107.2)	(52-57.8)	(106-106.8)	(51.6-56.5)	(104.4-105.1)
South east	n = 16	mean	57.9	-	-	66.0	114.0	64.4	110.9
		(min-max)	(17-83.6)	-	-	(18.6-99.2)	(107.2-121.5)	(17.4-97.2)	(102.5-123)
	n = 15	mean	57.6	64.0	110.4	65.9	114.3	64.4	111.3
		(min-max)	(17-83.6)	(18-101)	(101.4-120.9)	(18.6-99.2)	(107.2-121.5)	(17.4-97.2)	(102.5-123)
Total ALL	n = 105	mean	76.1	-	-	88.4	119.0	85.5	114.9
		(min-max)	(17-126.1)	-	-	(18.6-133.1)	(100.5-315.6)	(17.4-132)	(69.8-282.4)
	n = 88	mean	74.5	84.0	114.6	86.2	117.4	83.2	113.4
		(min-max)	(17-124.5)	(18-131.4)	(100.4-259.4)	(18.6-133.1)	(100.5-315.6)	(17.4-132)	(69.8-282.4)

Table 3.2-72: Thousand grain weight in presence of disease (in g and % of UTC), Wheat; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.0/1.2 L/ha*		BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC	g	%UTC
Maritime	n = 40	mean	37.8	-	-	40.9	108.9	40.0	106.2
		(min-max)	(22.5-59.2)	-	-	(21.7-59.3)	(96.5-137.8)	(19.6-62.1)	(87.1-132.6)
	n = 32	mean	37.4	40.3	108.4	40.6	109.0	39.6	106.0
		(min-max)	(22.5-59.2)	(23.5-59.8)	(98.3-125.5)	(21.7-59.3)	(96.5-137.8)	(19.6-62.1)	(87.1-121.1)
North east	n = 26	mean	38.5	-	-	39.9	103.8	39.6	103.0
		(min-max)	(25-47.2)	-	-	(26.6-50.3)	(97.7-110.7)	(26.8-48.4)	(96.4-111.7)
	TRZAW n = 22	mean	38.8	40.3	104.0	40.2	103.9	39.8	102.9
		(min-max)	(25-47.2)	(26.5-50.1)	(95.9-111.6)	(26.6-50.3)	(98-110.7)	(26.8-48.4)	(96.4-111.7)
	TRZAS n = 2	mean	33.9	35.2	103.8	35.4	104.3	34.3	101.0
		(min-max)	(30.5-37.3)	(31.8-38.5)	(103.2-104.4)	(31.8-39)	(104.2-104.5)	(30.7-37.8)	(100.7-101.4)
South east	n = 15	mean	42.6	-	-	74.7	104.8	44.2	103.7
		(min-max)	(35.5-49.4)	-	-	(35.4-115.2)	(96.5-115.2)	(35.8-52.3)	(95-113.3)
Total ALL	n = 81	mean	38.9	-	-	41.3	106.5	40.7	104.7
		(min-max)	(22.5-59.2)	-	-	(21.7-59.3)	(96.5-137.8)	(19.6-62.1)	(87.1-132.6)
	n = 71	mean	38.9	40.9	105.8	41.2	106.4	40.5	104.4
		(min-max)	(22.5-59.2)	(23.5-59.8)	(95.3-125.5)	(21.7-59.3)	(96.5-137.8)	(19.6-62.1)	(87.1-121.1)

Table 3.2-73: Hectolitre weight in presence of disease (in kg and % of UTC), Wheat; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.0/1.2 L/ha*		BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC	g	%UTC
Maritime	n = 53	mean	74.1	-	-	76.0	102.7	75.7	102.2
		(min-max)	(53.1-82.8)	-	-	(51.8-85.1)	(97.6-119.1)	(51.1-89.1)	(91.8-122.4)
	n = 41	mean	73.5	75.3	102.7	75.3	102.6	74.9	101.9
		(min-max)	(53.1-82.8)	(54.6-85.1)	(99.2-118.4)	(51.8-84.9)	(97.6-119.1)	(51.1-86.3)	(91.8-111.5)
North east	n = 26	mean	73.9	-	-	75.0	101.6	74.8	101.4
		(min-max)	(63.5-79.7)	-	-	(64.6-80.9)	(99-109)	(64.9-80.2)	(99-105.8)
	TRZAW n = 22	mean	73.8	74.7	101.2	75.0	101.7	74.8	101.5
		(min-max)	(63.5-79.7)	(64.3-79.6)	(99-108.8)	(64.6-80.9)	(99-109)	(64.9-80.2)	(99-105.8)
	TRZAS n = 2	mean	75.6	76.5	101.2	76.5	101.2	76.3	100.8
		(min-max)	(74.7-76.6)	(76.1-76.9)	(100.5-101.8)	(76.1-77)	(100.5-101.9)	(75.3-77.3)	(100.7-100.9)
South east	n = 16	mean	75.5	-	-	77.4	102.5	77.0	102.1
		(min-max)	(65-81.6)	-	-	(68.5-87.3)	(99.5-110.8)	(68.7-82.7)	(100-110.1)
	n = 15	mean	75.3	76.9	102.2	77.2	102.6	76.9	102.2
		(min-max)	(65-81.6)	(68.9-85.8)	(99.6-109.3)	(68.5-87.3)	(99.5-110.8)	(68.7-82.7)	(100-110.1)
Total ALL	n = 95	mean	74.3	-	-	76.0	102.4	75.7	101.9
		(min-max)	(53.1-82.8)	-	-	(51.8-87.3)	(97.6-119.1)	(51.1-89.1)	(91.8-122.4)
	n = 80	mean	74.0	75.5	102.2	75.6	102.3	75.3	101.8
		(min-max)	(53.1-82.8)	(54.6-85.8)	(99-118.4)	(51.8-87.3)	(97.6-119.1)	(51.1-86.3)	(91.8-111.5)

Yield, Barley, Efficacy trials with disease

Altogether 75 from 77 efficacy trials on barley, carried out between 2019 and 2020, have been harvested to confirm the yield response of BAS 736 00 F in the presence of diseases. The presented data cover the range of trials with one or two applications conducted within BBCH 28-69.

Data is provided for both the target dose rate of 2 L/ha and the reduced dose rate which is represented by 1.2 L/ha in the Maritime and North east zones and 1.0 L/ha in the South east zone.

Yield in dt/ha is presented by 75 results. Summary can be found in Table 3.2-71.

61 trial results are available for thousand grains weight, see summary in Table 3.2-72.

Altogether 69 trials provided information on hectolitre weight. For results see summary in Table 3.2-73.

Through results presented across all EPPO zones, BAS 736 00 F shows that the yield in dt/ha has improved in comparison to the untreated with both the reduced dose rate and the full dose rate without any significant negative impact on quality parameters such as thousand grains weight and hectolitre weight.

In one UK trial there was 10% reduction of yield in dt/ha compared to the untreated. It is explained by huge variation in the trial. this trial suffering from large swathes of lodged crop. The technician observed patches and areas of barley that were totally flat due to inclement weather that had no correlation to the treatments. However, the reduction still was not statistically significant.

Table 3.2-74: Yield in presence of disease (in dt/ha and % of UTC), Barley; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.0/1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 44	mean	78.0	-	-	89.4	115.3	89.1	114.6
		(min-max)	(32-124.7)	-	-	(37-135.3)	(90.2-142.2)	(37.1-132.9)	(98.1-136.5)
	n = 38	mean	78.0	87.0	112.3	88.3	114.1	87.9	113.2
		(min-max)	(32-124.7)	(36.9-131.6)	(90.4-135.6)	(37-135.3)	(90.2-142.2)	(37.1-132.9)	(98.1-136.5)
North east	n = 19	mean	58.4	-	-	66.4	114.7	65.3	112.6
		(min-max)	(15.3-89.5)	-	-	(17.1-98.4)	(97.3-149.5)	(18-101.4)	(98.8-145.6)
	TRZAW n = 6	mean	65.9	74.0	113.9	75.7	116.1	74.1	112.9
		(min-max)	(45.4-89.5)	(52.9-98.8)	(97.2-126.5)	(52.2-98.4)	(101.8-127.4)	(49.9-101.4)	(100.7-122.1)
	TRZAS n = 10	mean	53.5	59.5	112.5	59.7	113.2	59.8	113.4
		(min-max)	(15.3-69.1)	(17.6-71.3)	(101.3-134.5)	(17.1-69.2)	(97.3-149.5)	(18-71.8)	(98.8-145.6)
South east	n = 12	mean	44.0	-	-	53.2	124.0	51.7	120.1
		(min-max)	(24.5-60.5)	-	-	(29.4-71.4)	(108-195.4)	(27-68.6)	(104.4-169.7)
	n = 10	mean	45.4	53.3	121.1	55.3	125.1	53.3	119.7
		(min-max)	(24.5-60.5)	(32.8-67.7)	(106.2-181.9)	(29.4-71.4)	(108.6-195.4)	(27-68.6)	(104.4-169.7)
Total ALL	n = 75	mean	67.6	-	-	77.8	116.5	77.1	114.9
		(min-max)	(15.3-124.7)	-	-	(17.1-135.3)	(90.2-195.4)	(18-132.9)	(98.1-169.7)
	n = 64	mean	67.9	76.2	113.9	77.5	115.9	76.8	114.2
		(min-max)	(15.3-124.7)	(17.6-131.6)	(90.4-181.9)	(17.1-135.3)	(90.2-195.4)	(18-132.9)	(98.1-169.7)

Table 3.2-75: Thousand grain weight in presence of disease (in G and % of UTC), Barley; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.0/1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC	g	%UTC
Maritime	n = 33	mean	41.4	-	-	44.7	108.7	44.4	107.8
		(min-max)	(29.5-53.7)	-	-	(32.1-56.8)	(99.2-132.2)	(32.4-56.2)	(98.1-132.3)
	n = 30	mean	40.9	43.6	107.1	44.2	108.9	43.9	107.9
		(min-max)	(29.5-53.7)	(33.2-59.4)	(98.9-123.6)	(32.1-56.8)	(99.2-132.2)	(32.4-56.2)	(98.1-132.3)
North east	n = 15	mean	39.5	-	-	41.3	105.0	40.8	103.7
		(min-max)	(28.2-55.4)	-	-	(29.6-56.9)	(98.6-111.9)	(29.5-55.5)	(96.4-109.7)
	TRZAW n = 5	mean	40.0	41.1	103.2	41.9	105.2	40.9	103.0
		(min-max)	(28.2-55.4)	(28.5-54.5)	(98.5-105.7)	(29.6-56.9)	(102.7-108.3)	(29.5-53.4)	(96.4-105.5)
	TRZAS n = 7	mean	42.1	43.5	103.1	43.1	102.4	43.5	103.1
		(min-max)	(34.6-53.8)	(35.1-57)	(98.8-108.3)	(36.1-54.8)	(98.6-108.3)	(35.8-55.5)	(99.4-109.7)
South east	n = 12	mean	43.1	-	-	45.2	106.1	45.1	105.5
		(min-max)	(31.5-52.8)	-	-	(36.8-53.3)	(96.4-135.2)	(36.2-53.6)	(99-128.9)
	n = 10	mean	44.0	46.6	106.9	46.4	106.9	46.1	105.9
		(min-max)	(31.5-52.8)	(37.4-53.8)	(100.9-127.9)	(36.8-53.3)	(96.4-135.2)	(36.2-53.6)	(99-128.9)
Total ALL	n = 60	mean	41.3	-	-	44.0	107.2	43.7	106.3
		(min-max)	(28.2-55.4)	-	-	(29.6-56.9)	(96.4-135.2)	(29.5-56.2)	(96.4-132.3)
	n = 52	mean	41.5	43.9	106.2	44.3	107.3	44.0	106.4
		(min-max)	(28.2-55.4)	(28.5-59.4)	(98.5-127.9)	(29.6-56.9)	(96.4-135.2)	(29.5-56.2)	(96.4-132.3)

Table 3.2-76: Hectolitre weight in presence of disease (in kg and % of UTC), Barley; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.0/1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC	kg	%UTC
Maritime	n = 38	mean	61.4	-	-	63.4	103.2	62.9	102.2
		(min-max)	(0.1-71.6)	-	-	(0.1-72.8)	(97.3-111.1)	(0.1-73.2)	(84.4-108.3)
	n = 34	mean	61.3	63.1	102.9	63.4	103.4	62.9	102.6
		(min-max)	(0.1-71.6)	(0.1-72.5)	(98.2-110.2)	(0.1-72.8)	(97.3-111.1)	(0.1-73.2)	(84.4-108.3)
North east	n = 19	mean	60.8	63.1	102.8	62.2	102.4	62.3	102.7
		(min-max)	(50.5-70.3)	(53-71.8)	(100.5-110.9)	(53.4-71.8)	(98.5-106)	(53.5-71.7)	(100.7-110.5)
	TRZAW n = 6	mean	60.1	62.4	104.1	62.3	103.9	62.5	104.4
		(min-max)	(50.5-70.2)	(53-71.6)	(101.6-110.9)	(53.4-71.8)	(102.4-106)	(54.2-71.7)	(101.9-110.5)
	TRZAS n = 10	mean	62.3	63.5	102.0	63.1	101.4	63.5	102.0
		(min-max)	(51.5-70.3)	(53.1-71.8)	(100.5-104.2)	(54.4-70.6)	(98.5-105.6)	(53.5-71.7)	(100.9-103.9)
South east	n = 12	mean	61.5	-	-	62.9	102.2	62.7	101.9
		(min-max)	(54.3-69.7)	-	-	(56.8-72.3)	(99.2-107.5)	(56.9-71.9)	(99.5-104.9)
	n = 10	mean	62.4	63.9	102.6	63.7	102.2	63.4	101.6
		(min-max)	(54.9-69.7)	(57.8-72.1)	(98.6-109.6)	(56.8-72.3)	(99.2-107.5)	(56.9-71.9)	(99.5-103.9)
Total ALL	n = 69	mean	61.3	-	-	63.0	102.7	62.7	102.3
		(min-max)	(0.1-71.6)	-	-	(0.1-72.8)	(97.3-111.1)	(0.1-73.2)	(84.4-110.5)
	n = 58	mean	61.5	63.2	102.8	63.3	102.9	63.1	102.5
		(min-max)	(0.1-71.6)	(0.1-72.5)	(98.2-110.9)	(0.1-72.8)	(97.3-111.1)	(0.1-73.2)	(84.4-110.5)

Yield, Rye, Efficacy trials with disease

All 21 efficacy trials on rye, carried out between 2019 and 2020, have been harvested to confirm the yield response of BAS 736 00 F in the presence of diseases. The presented data cover the range of trials with one or two applications conducted within BBCH 33-59.

Data is provided for both the target dose rate of 2 L/ha and the reduced dose rate of 1.2 L/ha.

Yield in dt/ha is presented by 21 results. Summary can be found in Table 3.2-77.

19 trial results are available for thousand grains weight, see summary in Table 3.2-78.

Altogether 19 trials provided information on hectolitre weight. For results see summary in Table 3.2-79.

Through results presented across the Maritime and the North east zones, BAS 736 00 F shows that the yield in dt/ha has improved in comparison to the untreated with both the reduced dose rate (14.7% yield increase) and the full dose rate (16.8% yield increase), without any significant impact on quality parameters such as thousand grains weight and hectolitre weight.

Table 3.2-77: Yield in presence of disease (in dt/ha and % of UTC), Rye; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 11	mean	88.0	95.9	108.9	98.2	111.6	96.7	110.0
		(min-max)	(56.5-108.7)	(62.7-116.9)	(102.1-111.9)	(64.5-117.1)	(101.8-118.8)	(64.7-115.4)	(102.9-114.9)
North east	n = 10	mean	72.0	85.3	120.9	86.7	122.4	83.3	118.4
		(min-max)	(52.4-94.5)	(65.3-106.9)	(106.2-138.6)	(67.3-109.6)	(105-144.5)	(61.3-107.3)	(103.6-142.1)
Total ALL	n = 21	mean	80.4	90.9	114.7	92.7	116.8	90.3	114.0
		(min-max)	(52.4-108.7)	(62.7-116.9)	(102.1-138.6)	(64.5-117.1)	(101.8-144.5)	(61.3-115.4)	(102.9-142.1)

Table 3.2-78: Thousand grain weight in presence of disease (in g and % of UTC), Rye; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC	g	%UTC
Maritime	n = 9	mean	29.3	30.0	102.4	30.5	104.0	29.8	101.6
		(min-max)	(18.8-35.5)	(18.7-36.6)	(88.4-110.6)	(19.8-37.3)	(89.9-108.9)	(18.3-37.1)	(87.4-108.7)
North east	n = 10	mean	31.0	32.0	104.0	32.0	104.2	31.4	102.6
		(min-max)	(23.1-41.5)	(23.4-39.9)	(95-112.7)	(25.3-40.8)	(93.9-112)	(22.6-41.3)	(88.9-114.7)
Total ALL	n = 19	mean	30.2	31.1	103.2	31.3	104.1	30.7	102.1
		(min-max)	(18.8-41.5)	(18.7-39.9)	(88.4-112.7)	(19.8-40.8)	(89.9-112)	(18.3-41.3)	(87.4-114.7)

Table 3.2-79: Hectolitre weight in presence of disease (in kg and % of UTC), Rye; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC	kg	%UTC
Maritime	n = 10	mean	75.5	76.1	100.7	76.1	100.7	76.2	100.9
		(min-max)	(71.3-79)	(70.2-81.1)	(98.5-103.5)	(70.7-80)	(98.6-104.5)	(70.3-80.9)	(98.6-103.2)
North east	n = 9	mean	72.6	73.2	100.9	73.3	101.1	72.9	100.5
		(min-max)	(65.9-79.6)	(65.9-79)	(98.9-103.9)	(66.6-79.9)	(99.4-103.8)	(64.6-79.4)	(98-103.6)
Total ALL	n = 19	mean	74.1	74.7	100.8	74.8	100.9	74.7	100.7
		(min-max)	(65.9-79.6)	(65.9-81.1)	(98.5-103.9)	(66.6-80)	(98.6-104.5)	(64.6-80.9)	(98-103.6)

Yield, Triticale, Efficacy trials with disease

All 20 efficacy trials on triticale, carried out between 2019 and 2020, have been harvested to confirm the yield response of BAS 736 00 F in the presence of diseases. The presented data cover the range of trials with one or two applications conducted within BBCH 28-69.

Data is provided for both the target dose rate of 2 L/ha and the reduced dose rate of 1.2 L/ha.

Yield in dt/ha is presented by 20 results. Summary can be found in Table 3.2-80.

Altogether 18 trial results are available for thousand grains weight, see summary in Table 3.2-81.

Altogether 19 trials provided information on hectolitre weight. For results see summary in Table 3.2-82.

Through results presented across the Maritime and the North east zones, BAS 736 00 F shows that the yield in dt/ha has improved in comparison to the untreated with both the reduced dose rate (28.5% yield increase) and the full dose rate (30.5% yield increase). Also, an increase of the thousand grain weight was observed after BAS 736 00 F in both dose rates. Data showed no significant impact on hectolitre weight.

Table 3.2-80: Yield in presence of disease (in dt/ha and % of UTC), Triticale; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 12	mean	72.4	95.0	139.2	97.1	141.6	97.5	144.0
		(min-max)	(41.6-102.6)	(67.8-114.2)	(104.4-270.5)	(71.6-114.5)	(109.6-256.9)	(81.9-118)	(107.9-279.3)
North east	n = 8	mean	73.5	81.9	112.5	82.7	113.8	80.5	110.0
		(min-max)	(48.6-99)	(59-104.8)	(103.7-126.4)	(62.8-105.5)	(105-129.2)	(52.8-104.6)	(101.3-123.5)
Total ALL	n = 20	mean	72.9	89.8	128.5	91.3	130.5	90.7	130.4
		(min-max)	(41.6-102.6)	(59-114.2)	(103.7-270.5)	(62.8-114.5)	(105-256.9)	(52.8-118)	(101.3-279.3)

Table 3.2-81: Thousand grain weight in presence of disease (in g and % of UTC), Triticale; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC	g	%UTC
Maritime	n = 10	mean	36.3	41.3	116.4	42.0	118.5	41.5	117.4
		(min-max)	(24.7-46.5)	(32.8-48.8)	(101.1-146.6)	(33.2-49.9)	(99.9-153)	(32.1-48.7)	(95.7-162.8)
North east	n = 8	mean	35.8	37.1	103.8	37.1	104.1	38.0	106.2
		(min-max)	(24.9-44.7)	(24.9-45.6)	(100-108.4)	(25.6-45.3)	(98.8-111.4)	(25.7-46.6)	(100.7-120.1)
Total ALL	n = 18	mean	36.1	39.4	110.8	39.8	112.6	39.9	112.4
		(min-max)	(24.7-46.5)	(24.9-48.8)	(100-146.6)	(25.6-49.9)	(98.8-153)	(25.7-48.7)	(95.7-162.8)

Table 3.2-82: Hectolitre weight in presence of disease (in kg and % of UTC), Triticale; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 1.2 L/ha		BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC	kg	%UTC
Maritime	n = 11	mean	68.2	72.1	106.1	72.3	106.3	72.0	105.8
		(min-max)	(61.3-74.4)	(69.2-80.5)	(100.3-131.2)	(68.7-79.5)	(100.7-129.7)	(65.4-81.2)	(99-132.4)
North east	n = 8	mean	66.3	67.6	102.0	67.5	101.8	67.3	101.5
		(min-max)	(61.1-74.2)	(60.6-75)	(99.1-106.2)	(59.8-75)	(97.9-106.2)	(60.2-75)	(98.5-106.1)
Total ALL	n = 19	mean	67.4	70.2	104.4	70.3	104.4	70.0	104.0
		(min-max)	(61.1-74.4)	(60.6-80.5)	(99.1-131.2)	(59.8-79.5)	(97.9-129.7)	(60.2-81.2)	(98.5-132.4)

Yield, Oats, Efficacy trials with disease

All 3 efficacy trials on oats, carried out in the harvest year 2019, have been harvested to confirm the yield response of BAS 736 00 F in the presence of diseases. The yield data represent trials with one application conducted within BBCH 30-59.

Data is provided for the target dose rate of 2 L/ha on:

- yield in dt/ha: see summary in Table 3.2-83.

thousand grains weight: see summary in

- Table 3.2-84.

hectolitre weight: see summary in

- Table 3.2-85.

Through results presented from 3 efficacy trials with disease, no significant effect of BAS 736 00 F at the maximum dose rate on the yield in dt/ha, the thousand grains weight and the hectolitre weight in comparison to the untreated has been confirmed.

Table 3.2-83: Yield in presence of disease (in dt/ha and % of UTC), Oats; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 3	mean (min-max)	65.3 (62.5-67.6)	71.9 (64.9-85.3)	109.8 (99.4-126.2)	73.6 (63.8-83.9)	112.6 (96.8-124.1)

Table 3.2-84: Thousand grain weight in presence of disease (in g and % of UTC), Oats; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC
Maritime	n = 3	mean (min-max)	32.6 (22.3-38.7)	33.6 (22.6-39.3)	102.9 (101.2-105.9)	34.0 (23.1-39.8)	104.4 (101-108.6)

Table 3.2-85: Hectolitre weight in presence of disease (in kg and % of UTC), Oats; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC
Maritime	n = 3	mean (min-max)	52.3 (50.8-55)	53.1 (51.4-56.3)	101.5 (100.9-102.4)	52.9 (51.4-55.6)	101.2 (100.9-101.7)

Comments of zRMS:	<u>The yield from efficacy trials with diseases</u>
	In the trials the parameters such as: the yield, the thousand grain weight and the hectolitre weight was determined. The results were collected from the efficacy trials in the presence of diseases. In wheat the yield was determined in 105 efficacy trials (63 in Maritime, 26 in N-E and 16 in S-E zones), the thousand grain weight in 81 trials (40 in Maritime, 26 in N-E and 15 in S-E zones) and hectolitre weight in 95 trials (53 in Maritime, 26 in N-E and 16 in S-E zones). In barley the yield was determined in 75 efficacy trials (44 in Maritime, 19 in N-E and 12 in S-E zones), the thousand grain weight in 60 trials (33 in Maritime, 15 in N-E and 12 in S-E zones) and hectolitre weight in 69 trials (38 in Maritime, 19 in N-E and 12 in S-E zones). In rye the yield was determined in 21 efficacy trials (11 in Maritime and 10 in N-E zones), the thousand grain weight in 19 trials (9 in Maritime and 10 in N-E zones) and hectolitre weight in 19 trials (10 in Maritime and 9 in N-E zones).

	<p>In triticale the yield was determined in 20 efficacy trials (12 in Maritime and 8 in N-E zones), the thousand grain weight in 18 trials (10 in Maritime and 8 in N-E zones) and hectolitre weight in 19 trials (11 in Maritime and 8 in N-E zones). In oat the yield, the thousand grain weight and hectolitre weight were evaluated in Maritime zone only, in 3 trials for each parameter. The trials were conducted in accordance to general and specific EPPO guidelines (see table 3.2-14).</p> <p>The yield and quality data were collected from the trials sprayed with BAS 736 00 F at the target rate of 2.0 L/ha and the reduced dose rate of 1.2 L/ha, at the growth stages of cereals between BBCH 31 and 72, in water volume ranged between 100-300 L/ha.</p> <p>BAS 736 00 F did not affect negatively on cereal yield and their quality (the thousand grain weight and hectolitre weight) under a wide range of environmental conditions. The yield, the thousand grain weight and the hectolitre weight of wheat, barley and rye treated with BAS 736 00 F at the rate of 2.0 L/ha and at lower rates of 1-1.2 L/ha in the vast majority were higher or on the same level than that of the reference products, while in triticale and oat in some cases were slightly reduced or at the same level.</p> <p>The ZRMS confirms that the positive results of the yield and yield parameters (the thousand grain weight and the hectolitre weight) obtained in the trials across all EPPO zones show that the registration of BAS 736 00 F in cereals is fully justified.</p> <p>ZRMS agree with applicant that the positive impact of BAS 736 00 F (Miralon) on the yield and yield parameters (the thousand grain weight and the hectolitre weight) in cereals across all EPPO zones fully confirms its intended registration for diseases control in cereals in the Central registration zone. Tested fungicide is safe to the cereal crops.</p>
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Summary and conclusion on 3.2

The result presented from altogether 225 efficacy trials in wheat, barley, rye, triticale and oats confirm the claim that BAS 736 00 F is a highly effective fungicide offering a great opportunity for the control of important foliar pathogens. The active substances with well-known fungicidal activities as solo active ingredient products contribute to an efficacy against the most important cereal pathogens. Performance of BAS 736 00 F against most key diseases matched that of the standard(s), though as a rule it exceeded it. An overall summary in Table 3.2-86 recapitulates the results organized in a different order than in the efficacy chapter. They are ordered first by pathogen and then within the pathogen by the target crop. The aim is to visualize the fact 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 736 00 F and confirmed no negative or slightly positive impact of the product on the parameters such as thousand grain weight and hectolitre weight in wheat, barley, rye, triticale and oats.

The submitted data together with the argumentation provided support the claim for registration of BAS 736 00 F as required in the GAP.

Table 3.2-86: Efficacy summary (full rate of BAS 736 00 F)

Disease	Crop	EPPO Zone climatic	No. of trials		Untreated	BAS 736 00 F 2.0 L/ha		Standard	
					infect	infect	efficacy	infect	efficacy
SEPTTR/SEPTSP	Wheat	Total ALL	n = 67	mean (min-max)	26.1 (5.3-100)	4.2 (0-24.4)	85.4 (50-100)	8.0 (0-70.6)	74.6 (29.2-100)
		Maritime	n = 34	mean (min-max)	36.7 (5.3-100)	6.1 (0-24.4)	83.4 (50-100)	12.5 (0-70.6)	68.8 (29.2-100)
		North east	n = 19	mean (min-max)	15.8 (7.9-28.9)	2.7 (0-9.3)	84.9 (61.5-100)	4.0 (0-13)	77.0 (45-100)
		South east	n = 14	mean (min-max)	14.5 (7.5-25.1)	1.8 (0-5.1)	90.4 (76.5-100)	2.6 (0-6.9)	83.6 (51.9-100)
	Triticale	ALL zones	n = 13	mean (min-max)	18.0 (6-38.3)	2.1 (0-4.5)	90.1 (72.7-100)	3.1 (0-7.8)	85.2 (43.6-100)
		Maritime	n = 6	mean (min-max)	22.1 (8.5-38.3)	2.0 (0-3.8)	91.4 (72.7-100)	3.6 (0-7.8)	83.6 (43.6-100)
		North east	n = 7	mean (min-max)	14.5 (6-23.3)	2.2 (0-4.5)	89.1 (78.8-100)	2.6 (0-6.1)	86.6 (68.5-100)
	Total				n = 80				
PUCCST	Wheat	ALL zones	n = 34	mean (min-max)	38.6 (5.4-98.3)	5.2 (0-36.5)	89.5 (60.6-100)	8.6 (0-55.8)	82.1 (42.7-100)
		Maritime	n = 25	mean (min-max)	43.2 (6.5-98.3)	6.5 (0-36.5)	86.9 (60.6-100)	10.6 (0-55.8)	77.8 (42.7-100)
		North east	n = 7	mean (min-max)	7.8 (5.4-13)	0.1 (0-0.5)	98.4 (93.4-100)	0.3 (0-1.5)	96.5 (88.5-100)
		South east	n = 2	mean (min-max)	88.3 (81-95.5)	6.8 (4.4-9.3)	92.0 (88.6-95.4)	12.1 (7.1-17)	85.8 (79.1-92.5)
	Triticale	ALL zones	n = 11	mean (min-max)	40.4 (13.4-100)	3.2 (0-9.7)	93.8 (79.3-100)	3.5 (0-13.6)	91.8 (69.9-100)
		Maritime	n = 10	mean (min-max)	40.8 (13.4-100)	2.9 (0-9.7)	94.8 (79.3-100)	3.5 (0-13.6)	91.9 (69.9-100)
		North east	n = 1	mean (min-max)	36.3 (36.3-36.3)	5.8 (5.8-5.8)	84.1 (84.1-84.1)	3.5 (3.5-3.5)	90.3 (90.3-90.3)
	Total				n = 45				

Disease	Crop	EPPO Zone climatic	No. of trials		Untreated	BAS 736 00 F 2.0 L/ha		Standard	
					infect	infect	efficacy	infect	efficacy
PUCCRE/PUCCHD	Wheat	ALL zones	n = 36	mean (min-max)	20.7 (5-100)	1.3 (0-6.5)	94.7 (75-100)	6.8 (0-65)	78.1 (25-100)
		Maritime	n = 16	mean (min-max)	33.4 (5.8-100)	2.1 (0-6.5)	93.2 (75-100)	13.3 (0-65)	66.2 (25-100)
		North east	n = 10	mean (min-max)	12.1 (6-34.5)	0.9 (0-5.6)	94.3 (76.7-100)	1.9 (0-11)	89.0 (66.2-100)
		South east	n = 10	mean (min-max)	8.9 (5-26)	0.5 (0-3.3)	97.5 (88.6-100)	1.3 (0-4.1)	86.1 (58.1-100)
	Barley	ALL zones	n = 23	mean (min-max)	20.4 (5.8-54)	1.9 (0-16.3)	92.3 (61.3-100)	3.8 (0-21.8)	85.8 (48.2-100)
		Maritime	n = 12	mean (min-max)	26.2 (8.8-54)	2.5 (0-16.3)	92.2 (61.3-100)	5.4 (0-21.8)	83.8 (48.2-100)
		North east	n = 8	mean (min-max)	17.0 (7.7-38)	1.3 (0-7.6)	93.8 (71.9-100)	2.5 (0-11.6)	87.5 (58.3-100)
		South east	n = 3	mean (min-max)	6.4 (5.8-7.5)	0.6 (0.3-1.4)	89.3 (76.2-97)	0.7 (0.5-1)	88.9 (83.1-91.8)
	Rye	ALL zones	n = 18	mean (min-max)	18.4 (5.5-50.8)	1.2 (0-4.9)	95.1 (89.1-100)	3.0 (0-13.3)	87.0 (55.6-100)
		Maritime	n = 10	mean (min-max)	15.3 (5.5-50.8)	1.0 (0-4.9)	95.1 (89.1-100)	2.0 (0-7)	88.5 (61.9-100)
		North east	n = 8	mean (min-max)	22.3 (5.8-43.8)	1.5 (0-4.5)	95.0 (89.7-100)	4.2 (0.1-13.3)	85.1 (55.6-99.1)
	Triticale	ALL zones	n = 8	mean (min-max)	19.6 (7.1-34.4)	2.3 (0-9)	89.9 (73.8-99.6)	5.1 (0.1-18.5)	74.2 (27.8-99.1)
		Maritime	n = 4	mean (min-max)	23.7 (14.5-34.4)	3.2 (0.9-9)	86.8 (73.8-97.4)	7.8 (0.7-18.5)	64.8 (27.8-97.6)
		North east	n = 4	mean (min-max)	15.5 (7.1-28.5)	1.3 (0-3)	93.1 (83.3-99.6)	2.5 (0.1-4.2)	83.6 (64.7-99.1)
	Total				n = 85				
PUCCCO	Oats	ALL zones	n = 2	mean (min-max)	20.8 (17.3-24.4)	3.9 (2-5.9)	80.0 (67.6-92.3)	4.3 (3-5.6)	78.9 (69.3-88.4)
		Maritime	n = 2	mean (min-max)	20.8 (17.3-24.4)	3.9 (2-5.9)	80.0 (67.6-92.3)	4.3 (3-5.6)	78.9 (69.3-88.4)
PYRNTR	Wheat	ALL zones	n = 17	mean (min-max)	20.1 (6.4-50)	5.2 (0-20)	78.8 (58.7-100)	6.0 (0-20.3)	73.5 (53.5-100)
		Maritime	n = 8	mean (min-max)	25.4 (6.4-50)	7.6 (0-20)	75.3 (58.7-100)	8.1 (0-20.3)	70.6 (55-100)
		North east	n = 9	mean (min-max)	15.3 (7.3-25.3)	3.2 (0-7.5)	81.9 (60.3-100)	4.1 (0-10.3)	76.1 (53.5-100)
PYRNTE	Barley	Total ALL	n = 46	mean (min-max)	24.9 (5-90.3)	4.5 (0.1-31.3)	84.8 (63.6-99.1)	6.5 (0-48.8)	77.0 (30.6-100)
		Maritime	n = 19	mean (min-max)	28.8 (5-90.3)	5.9 (0.3-31.3)	83.7 (63.6-97.7)	6.9 (0-28.6)	76.8 (30.6-100)
		North east	n = 16	mean (min-max)	24.1 (5.5-78.1)	3.9 (0.1-17.4)	84.3 (66.3-99.1)	5.8 (0.1-20.3)	77.1 (47.8-98.4)
		South east	n = 11	mean (min-max)	19.1 (5-87.9)	3.0 (0.5-17.5)	87.6 (80.3-94.7)	6.9 (0.3-48.8)	77.4 (44.9-93.5)

Disease	Crop	EPPO Zone climatic	No. of trials		Untreated	BAS 736 00 F 2.0 L/ha		Standard	
					infect	infect	efficacy	infect	efficacy
ERYSGR	Wheat	ALL zones	n = 12	mean (min-max)	8.7 (4.3-18.7)	1.7 (0.3-6.8)	80.2 (61.3-96.2)	1.6 (0-4)	81.0 (52.9-100)
		Maritime	n = 7	mean (min-max)	8.5 (4.3-18.1)	1.9 (0.8-6.8)	79.2 (61.3-90.5)	1.5 (0.4-4)	79.4 (52.9-96.6)
		North east	n = 5	mean (min-max)	9.0 (5-18.7)	1.5 (0.3-2.7)	81.6 (62.7-96.2)	1.6 (0-3.3)	83.2 (55-100)
	Barley	ALL zones	n = 13	mean (min-max)	15.6 (5.5-38.1)	3.4 (0.3-13)	79.3 (60.7-97.5)	3.6 (0-11.8)	80.2 (56.2-100)
		Maritime	n = 5	mean (min-max)	11.6 (5.5-19)	2.7 (0.5-7)	78.0 (60.7-91.9)	2.6 (0-9)	82.4 (56.2-100)
		North east	n = 1	mean (min-max)	11.6 (11.6-11.6)	2.5 (2.5-2.5)	78.5 (78.5-78.5)	2.9 (2.9-2.9)	75.3 (75.3-75.3)
		South east	n = 7	mean (min-max)	18.9 (6.7-38.1)	4.0 (0.3-13)	80.3 (67.1-97.5)	4.3 (1.5-11.8)	79.4 (69.8-89.4)
	Triticale	ALL zones	n = 6	mean (min-max)	13.5 (4.5-30)	1.9 (1-3.5)	81.7 (66.7-96.2)	2.4 (0.8-6.5)	81.0 (61.3-95)
		Maritime	n = 4	mean (min-max)	9.8 (4.5-16.8)	1.7 (1-2.8)	80.9 (66.7-89.5)	2.4 (0.8-6.5)	79.1 (61.3-92.1)
		North east	n = 2	mean (min-max)	20.9 (11.8-30)	2.4 (1.4-3.5)	83.2 (70.2-96.2)	2.4 (1.8-3)	84.7 (74.5-95)
	Oats	ALL zones	n = 3	mean (min-max)	12.5 (7.5-19.8)	5.2 (1.3-10.9)	65.8 (51.8-83.3)	1.5 (0-3.1)	89.3 (80-100)
		Maritime	n = 3	mean (min-max)	12.5 (7.5-19.8)	5.2 (1.3-10.9)	65.8 (51.8-83.3)	1.5 (0-3.1)	89.3 (80-100)
	Total		n = 33						
RHYNSE	Barley	ALL zones	n = 16	mean (min-max)	32.8 (5.8-94)	3.6 (0-15.2)	88.1 (57.3-100)	5.6 (0.4-26.2)	82.5 (51.7-99.2)
		Maritime	n = 12	mean (min-max)	41.6 (7.5-94)	4.7 (0-15.2)	87.0 (57.3-100)	7.3 (0.4-26.2)	80.5 (51.7-99.2)
		North east	n = 4	mean (min-max)	6.5 (5.8-7.3)	0.5 (0.4-0.8)	91.6 (87-94.8)	0.7 (0.5-1)	88.4 (83.3-93.1)
	Rye	ALL zones	n = 11	mean (min-max)	18.9 (6-41.3)	2.8 (0-9.5)	87.5 (74.9-100)	3.8 (0.2-14.7)	79.8 (52.8-97.4)
		Maritime	n = 5	mean (min-max)	21.4 (8.5-41.3)	2.3 (1.5-3)	88.3 (79.4-95.5)	3.0 (1.8-4)	82.6 (64.7-91.2)
		North east	n = 6	mean (min-max)	16.7 (6-33.8)	3.2 (0-9.5)	86.9 (74.9-100)	4.4 (0.2-14.7)	77.5 (52.8-97.4)
	Total		n = 27						
RAMUCC	Barley	Total ALL	n = 20	mean (min-max)	36.0 (5-98.6)	7.9 (1.3-33.8)	75.9 (48.9-91.1)	7.4 (0-29.9)	77.9 (25.8-100)
		Maritime	n = 18	mean (min-max)	39.0 (5-98.6)	8.6 (1.3-33.8)	75.2 (48.9-91.1)	7.9 (0-29.9)	78.0 (25.8-100)
		North east	n = 2	mean (min-max)	8.8 (8.8-8.8)	1.5 (1.5-1.5)	82.9 (82.9-82.9)	2.0 (2-2)	77.1 (77.1-77.1)

Comments of zRMS	Conclusion
	The submitted data fully support the registration of BAS 736 00 F (Miralon) at the rate of 2.0 L/ha (fluxapyroxad – 100 g/ha + azoxystrobin – 150 g/ha) and a lower rates in some countries, for diseases control in wheat, barley, triticale, rye and oat. The authorization in oats should be included as minor use. BAS 736 00 F should be recommended as foliar application at a maximum of two treatments, at the growth stages BBCH 30-69, with water volume from 100 to 300 L/ha.

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

BAS 736 00 F (50 g fluxapyroxad + 75 g azoxystrobin per litre EC formulation) is intended for control of the following diseases.

In wheat it is intended for control of powdery mildew (*Blumeria graminis* f.sp. *tritici*), Septoria leaf blotch (*Zymoseptoria tritici*), brown rust (*Puccinia triticina*), yellow rust (*Puccinia striiformis*) and tan spot (*Pyrenophora tritici-repentis*).

In barley it is intended for control of powdery mildew (*Blumeria graminis* f.sp. *hordei*), net blotch (*Pyrenophora teres*), leaf scald (*Rhynchosporium secalis*), Ramularia leaf spot (*Ramularia collo-cygni*) and leaf rust (*Puccinia hordei*).

In rye it is intended for control of leaf scald (*Rhynchosporium secalis*) and leaf rust (*Puccinia recondita*).

In triticale it is intended for control of powdery mildew (*Blumeria graminis*), Septoria leaf and glume blotch (*Zymoseptoria tritici* and *Parastagonospora nodorum*) and rusts (*Puccinia recondita* and *Puccinia striiformis*).

In oat it is intended for control of powdery mildew (*Blumeria graminis* f.sp. *avenae*) and rust (*Puccinia coronata*).

In accordance with the EPPO guideline PP 1/213(4), a Resistance Risk Analysis has been conducted. A summary of the study is provided in this chapter.

Mode of action

Fluxapyroxad is a member of the fungicide group succinate dehydrogenase inhibitors (SDHI, mode of action class C2) and the mode of action of fluxapyroxad at the molecular level is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain (Kulka and von Schmeling 1995). Like other complexes of the respiratory chain, this enzyme is a component of the inner mitochondrial membrane. It consists of four nucleus-encoded subunits (SDH A, B, C, D). Two of these polypeptides (SDH C, D) anchor the complex in the membrane, whilst the others project into the mitochondrial matrix where they catalyse the oxidation of succinate to fumarate as part of the tricarboxylic acid (TCA) cycle. The electrons so released are channelled into the electron transport chain via the co-substrate ubiquinol. Complex II occupies a key function in fungal metabolism. It does not only deliver high-energy electrons for energy production, it also forms an essential junction where components of the TCA cycle can be diverted to become the building blocks for amino acids and lipids. Through its inhibition of complex II, fluxapyroxad disrupts fungal growth by preventing energy production and by eliminating the availability of the chemical building blocks for the synthesis of other essential cellular components.

Azoxystrobin: According to the classification of FRAC, azoxystrobin belongs to the Mode of Action Group C (respiration) and to the subgroup C3 (inhibition of complex III) with the target site cytochrome bc1 at QoI site and the FRAC code 11 with the group name QoI fungicides (Quinone outside inhibitors). The mode of action of QoI fungicides is the inhibition of mitochondrial respiration resulting from a blockage of the electron transport from ubihydroquinone to cytochrome c by means of a binding to the ubihydroquinone oxidation centre (Qo) of the cytochrome bc1 complex (complex III). This leads to a reduction of energy-rich ATP that is available to support a range of essential processes in the fungal cell.

Mechanism of resistance

Fluxapyroxad belongs to the succinate dehydrogenase inhibitors (SDHI). The target enzyme is succinate dehydrogenase (SDH), which is a functional part of the tricarboxylic cycle and of the mitochondrial electron transport chain (Matsson and Hederstedt 2001, Keon et al. 1991). SDH consists of four subunits (A-D). Information about the putative mechanism of resistance to the SDHI carboxin has been reported for some plant pathogenic fungi (Keon et al. 1991, Ben-Yephet et al. 1975, Gunatilleke et al. 1976, Skinner et al. 1998, Stammler et al. 2007a,b, Stammler 2008, FRAC 2021) and it has been found that some specific mutations, which lead to amino acid substitutions in conserved regions in the B- (Keon et al. 1991, Skinner et al. 1998, Li et al. 2006, Stammler et al. 2007a, b, Stammler 2008), C- (Ito et al. 2004, Stammler 2008) or D-subunit (Matsson et al. 1998, Glättli et al. 2009), result in reduced sensitivity. Amino acid exchanges found in the SDH subunits of SDHI resistant mutants and their possible impact on SDH structure and SDHI binding are described and reviewed in more detail by Stammler et al. (2015).

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

It is interesting to note that some fungal species do not show this mutation even after more than 20 years of intensive control by QoI fungicides, e.g. different rust species (*Puccinia* spp.), *Pyrenophora teres*, *Monilinia laxa*, *Monilinia fruticola*, *Guignardia bidwellii* and *Alternaria solani*. For these species this is connected with the presence of an intron (encoding a maturase, BASF internal studies) starting within or directly after the codon 143 (Grasso et al. 2006, Miessner and Stammler 2010, Miessner et al. 2011, Stammler et al. 2006). It is assumed that a mutation from a glycine- to an alanine-codon would lead to an incorrect splicing and consequently to a non-functional cytochrome b (Grasso et al. 2006).

A mutation at codon 129, which leads to the substitution of phenylalanine by leucine (F129L) is described for some of these “intron” species (e.g. *Pyrenophora teres*, and *Alternaria solani*, Stammler et al. 2006, Pasche et al. 2005). The mutation F129L results generally in lower resistance factors (FRAC 2021, Semar et al. 2007).

Another mutation, the G137R has been rarely found in *Pyrenophora teres* and *Pyrenophora tritici-repentis* (BASF internal studies) and plays obviously only a minor role in the sensitivity response to QoI fungicides (FRAC 2021). Internal studies indicate that this mutation is connected with fitness penalties.

For the target pathogens in this resistance risk analysis an intron after the G143A is present in all *Puccinia* species and in *Pyrenophora teres* (Grasso et al. 2006, Stammler et al. 2006).

Evidence of resistance

Fluxapyroxad: Several mutations in the target protein at different positions in the three SDH subunits B, C and D were detected in field isolates of plant pathogens such as *Alternaria alternata*, *Botrytis cinerea*, *Corynespora cassiicola*, *Didymella bryoniae*, *Pyrenophora teres*, *Ramularia collo-cygni*, *Sclerotinia sclerotiorum* and in *Zymoseptoria tritici* (Skinner et al. 1998, Avenot and Michaelidis 2007, Stammer 2008, Stammer et al. 2007a, b, 2010, Ishii 2007, Glättli et al. 2009, Veloukas et al. 2011, Scalliet et al. 2012, Semar et al. 2014, Rehfus et al. 2016, 2018, 2019). Even within a single species, different mutations were found at one location (e.g. B-P225L,F,T or B-H272Y,R,L in *Botrytis cinerea*), and at different locations in different subunits (e.g. B-H277Y, C-H134R, D-H133R in *Alternaria alternata*). Some mutations are part of the binding site with explainable effects on SDHI binding (e.g. in case of B-H272-exchanges in *B. cinerea*) or outside of the binding area which excludes a direct influence on SDHI binding. The impact of the mutation on the resistance level is not correlated with its proximity to the binding site (Glättli et al. 2009) and exchanges at one position can cause different resistance factors (e.g. H272Y,R,L in *B. cinerea*). In most cases mutated SDH has a lower activity, which might confer fitness penalties of SDHI resistant isolates (Scalliet et al. 2012).

Considering the target pathogen of this Resistance Risk Analysis, SDHI resistance has been detected for *Pyrenophora teres*, *Zymoseptoria tritici* and *Ramularia collo-cygni*.

Isolates of *Pyrenophora teres* with reduced SDHI sensitivity carried mutations in the B-, C- and D-subunits (B-H277Y, C-S73P, C-G79R, C-N75S, C-H134R, C-S135R, D-D124N/E, D-H134R, D-D145G and D-E178K) (Stammer et al. 2015, Rehfus et al. 2016, 2018, 2020, FRAC 2021).

Isolates of *Zymoseptoria tritici* with reduced SDHI sensitivity had different mutations in the SDH gene (e.g. B-T268I, B-N225I/T, C-T79N, C-W80S, C-N86S, C-V166M and others), which cause low to moderate adaptation; that means that EC50 values for fluxapyroxad were found to be outside the baseline sensitivity. Single isolates with higher EC50 values were reported since 2015 in the FRAC WG meeting and also found by BASF in monitoring studies carrying the C-H152R, C-S83G or B-H267L mutation (Rehfus et al. 2018, 2020, FRAC 2021). In last years, monitoring studies also various double mutants had been detected, some with high resistance levels (FRAC 2021, BASF internal studies).

Isolates of *Ramularia collo-cygni* with reduced SDHI sensitivity had also different mutations in the SDH-genes; in the B-subunit N224T, R264P, H266L/R/Y, T267I, I268V and in the C-subunit N87S, G91R, H146R/L, R152M, H153R, G171D (Rehfus et al. 2019, 2020).

No SDHI resistance has so far been detected in *Blumeria graminis*, *Puccinia* species, *Rhynchosporium secalis* or *Parastagonospora nodorum*.

Azoxystrobin: The evidence of resistance to QoIs comes from cases of field resistance shown by different plant pathogens. The pathogens have been isolated and found to be resistant to high concentrations of QoIs indicating a disruptive (single step) resistance (FRAC 2021).

The G143A mutation in the cytochrome b gene has been detected in several plant pathogenic fungi, including the target pathogens *Blumeria graminis*, *Zymoseptoria tritici*, *Parastagonospora nodorum*, *Pyrenophora tritici-repentis* and *Ramularia collo-cygni* of this resistance risk analysis, but not in *Puccinia* species or *Pyrenophora teres*. Only single cases are known for *Rhynchosporium secalis* from the last years monitoring's (FRAC 2021).

The mutation F129L has been found in *Pyrenophora teres* and *Pyrenophora tritici-repentis* and in these two pathogens also – but rarely - the mutation G137R (BASF internal studies, FRAC 2021).

An actual list of plant pathogenic fungi where QoI resistance has been detected can be found on the FRAC webpage and in Sierotzki (2015) and Sierotzki and Stammer (2019).

Cross resistance

Fluxapyroxad: BASF internal studies showed that there is cross resistance between SDHI fungicides in different tested fungal species, which is also confirmed by modelling studies with different SDHIs (Glättli et al. 2009). The FRAC SDHI Working Group states on the webpage: “The SDHI fungicides (benodanil, benzovindiflupyr, bixafen, boscalid, carboxin, fenfuram, fluindapyr, fluopyram, flutolanil, fluxapyroxad, furametpyr, inpyrfluxam, isofetamid, isoflucypram, isopyrazam, mepronil, oxycarboxin, penflufen, penthiopyrad, pydiflumetofen, sedaxane, thifluzamide) are in the same cross-resistance group” (FRAC 2021).

There is no cross resistance between SDHIs and fungicides with other modes of action.

Azoxystrobin: Studies to date have shown that there is cross resistance between QoI fungicides (FRAC 2021), in particular when the mutation G143A in the cytochrome b gene is the cause of resistance.

There is no indication of cross resistance with azoxystrobin and fungicides from outside the QoI group (FRAC 2021, Sierotzki and Stammler 2019).

Baseline sensitivity / Monitoring data

In the following chapter, BASF baseline sensitivity data and the most recent BASF monitoring data are provided, followed by the latest statements of FRAC available on the FRAC website. Sensitivities to SDHIs and/or fluxapyroxad are described in subchapter A, followed by sensitivities to QoIs and/or azoxystrobin in subchapter B.

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

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

In this chapter the term EC50 is used when they were evaluated with in vitro test systems (e.g. microtiter tests) and the term ED50 is used when the data are based on in vivo test systems (e.g. detached leaf tests).

A. Fluxapyroxad

Baseline studies (BASF)

The sensitivities of European populations of *Zymoseptoria tritici*, *Pyrenophora teres*, *Rhynchosporium secalis* and *Puccinia triticina* to fluxapyroxad have been established before market introduction and can therefore be seen as the baseline sensitivity. Since adaptation have been detected in various plant pathogenic fungi, including the target pathogens *Zymoseptoria tritici* and *Pyrenophora teres* of this Resistance Risk Analysis, we focus here on newest monitoring data.

A1. *Zymoseptoria tritici*

Monitoring data

First description of SDHI adapted isolates was in 2012 (FRAC 2021, Rehfus et al. 2018). In the following years more SDHI adapted isolates were identified in BASF random monitoring studies performed by the company Epilogic, Freising, Germany. An increase of SDHI adaptation was identified from 2017 to 2018, but in the following seasons (2019 and 2020) SDHI resistance did not significantly increase over Europe (Figure 1). Genetic analysis was undertaken in BASF. Most of the SDHI adapted strains contained mutations which cause low to moderate levels of adaptation (mainly C-N86S and C-T79N). The mutation causing higher resistance levels, the C-H152R was detected at lower frequencies. Table 1 describes the frequencies of mutations in resistant isolates identified in the 2020 monitoring. From the isolates with acquired resistance (n=258 out of 830), most isolates had mutations which confer a low to moderate resistance, isolates with higher resistance levels (n=36) are 14% in this group and 4% of all isolates monitored.

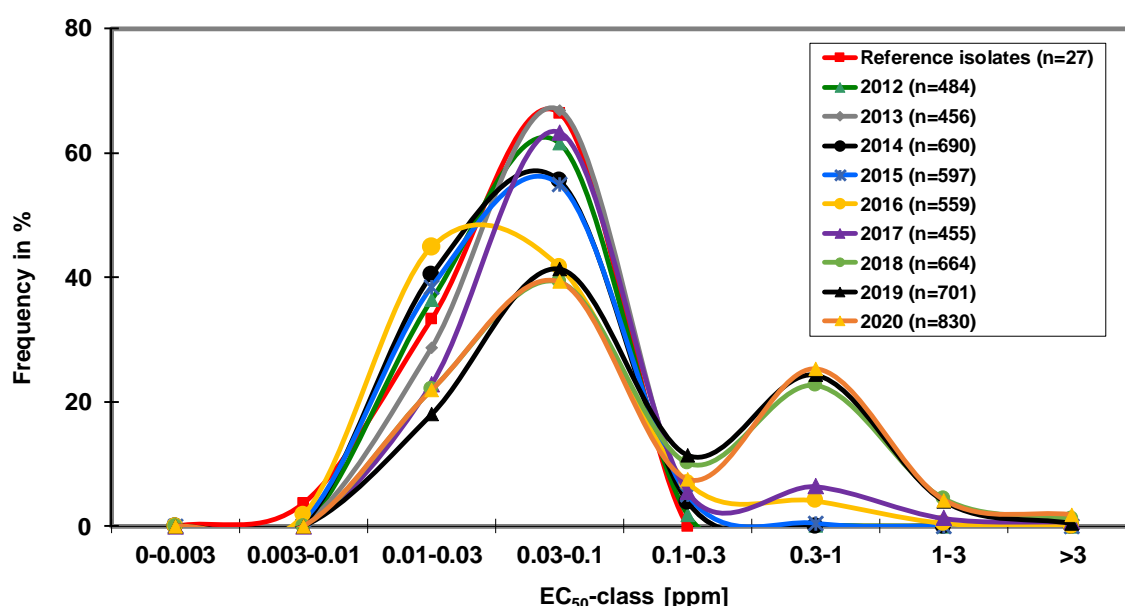


Figure 1: Frequency distribution of EC50 values for *Zymoseptoria tritici* and fluxapyroxad from 2012 to 2020. All isolates with EC50 > 0.3 ppm are seen as isolates with acquired SDHI resistance. Frequency of SDHI adaptation increased from 2017 to 2018 but is stable since then.

Table 3.3-1: Frequency of mutations in the SDH-genes within the group of isolates with an EC₅₀ >0.3 ppm (Fluxapyroxad). 2020 BASF monitoring, sensitivity tests done by Epilogic, molecular genetic analysis in BASF.

Mutation	Frequency (%) within all isolates with EC₅₀ > 0.3 ppm
B-N225T/I	2.3
B-T268I	1.6
B-H267L	0.4
C-T79N	22.5
B-H269V	0.4
C-W80S/L	1.6
C-N86S	50.4
C-N86A	0.4
C-N86H	0.4
C-H152R	9.7
C-S83G	0.4
B-N225T+C-N86S	1.9
B-269V+C-H152R	0.4
B-H267L+C-N86S	0.8
B-H269V+C-T79N	0.4
No mutation	6.6

FRAC statement

FRAC summary of the 2020 status of SDHI resistance in *Zymoseptoria tritici* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Wheat – Septoria leaf blotch (*Zymoseptoria tritici* syn. *Septoria tritici* syn. *Mycosphaerella graminicola*)
(Bayer, Syngenta, BASF, Isagro/ FMC, Sumitomo, Adama)

Disease pressure in **2020** was low to moderate with very dry conditions in some countries. Field performance of SDHI-fungicides when applied according to manufacturers' recommendations against Septoria was good.

All isolates from Bulgaria, Croatia, Czech Republic, Denmark, Hungary, Norway, Slovakia, Spain, Turkey, Romania, Russia and Ukraine were sensitive.

As in **2019**, the majority of isolates in **2020** was sensitive in Europe with the exception of Ireland and the United Kingdom. C-T79N and C-N86S were the most frequent mutations with low resistance factor in the last years.

For information on mutations detected in the *sdh*, please refer to the following [link](#).
For information on mutations detected in the *sdh*, please refer to the following [link](#).

Depending on the SDHI, the sensitivity impact of the different mutations detected so far in *Z. tritici*, can be different.

C-H152R and the following double mutations C-N86S+B-N225T and C-N86S+C-L85P were shown to impact the sensitivity of *Z. tritici* to SDHIs most. Evidence for fitness penalties associated with the mutation C-H152R were observed in research studies by FRAC member companies.

As in previous years, isolates bearing the mutation C-H152R continued to be detected at overall low frequencies in 2020 in Ireland and the United Kingdom. In Switzerland, France, Italy, the Netherlands and Germany, this mutation was detected at low frequencies in single locations only.

Low frequencies of reduced sensitivity (depending on the testing system: mutations or adapted phenotypes) were found in the following countries: Austria, Switzerland, Sweden, France, Italy, Lithuania, Latvia, Poland, Belgium.

Low frequencies were found in Germany with a more widespread distribution.

Moderate frequencies were detected in Ireland, the United Kingdom and the Netherlands.

Outside of Europe, an overall sensitive situation was found in New Zealand in monitoring programs from **2016** to **2019** with the exception of a single population in a single trial location.

A.2. *Puccinia triticina* (syn. *Puccinia recondita*) and *Puccinia* spp.

Puccinia triticina

Monitoring data

European monitoring studies are running since 2012 with the company Epilagic. Isolates were collected over Europe by air trap sampling and analysed by detached leaf tests by the company Epilagic (Figure 2). No resistant isolates have been detected so far. Last data are from 2020, which showed that all isolates are still sensitive as in previous years monitorings. Only for 1 isolate the ED50 value was slightly enhanced, but this has been seen as a natural variability (resistance factor = 3 and no SDH mutations detected).

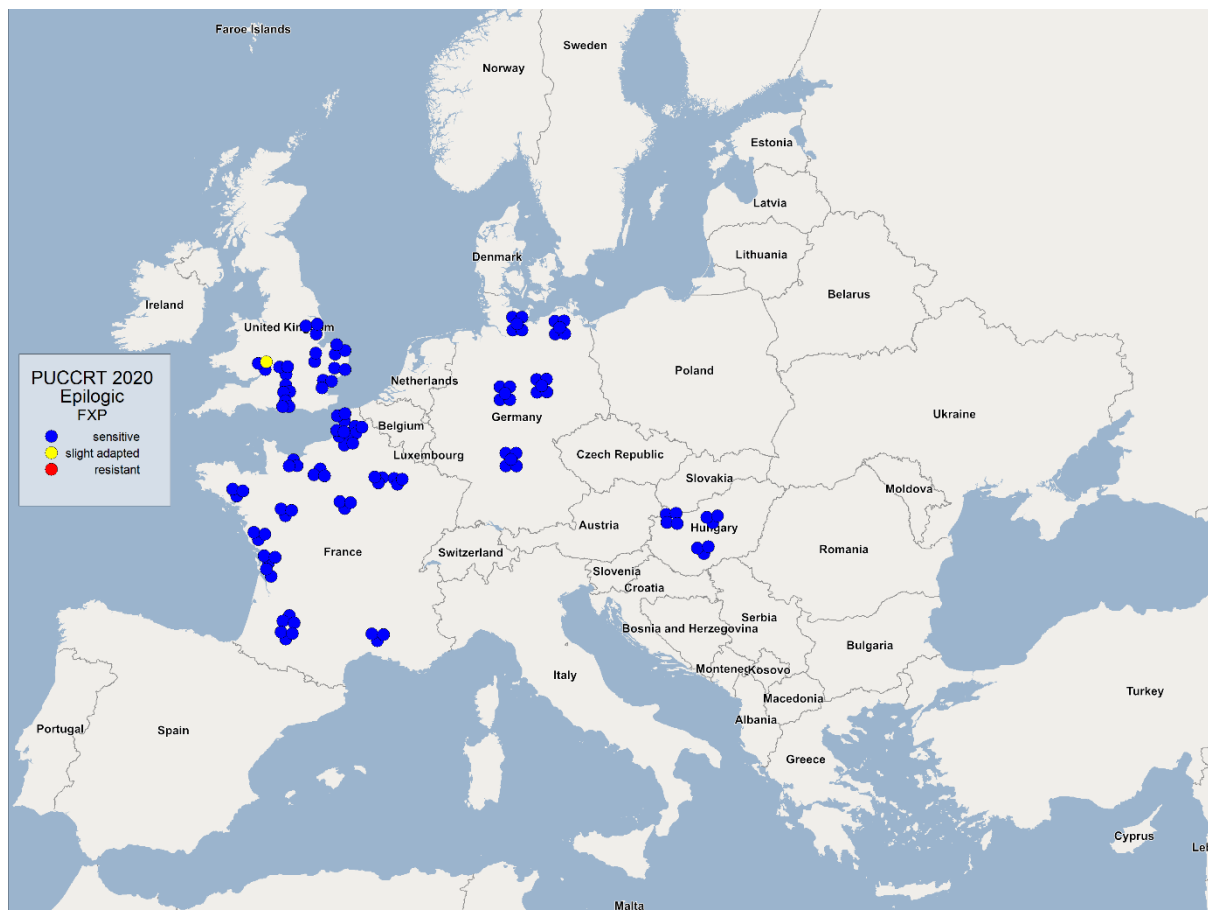


Figure 2: Results of the random monitoring of *Puccinia triticina* to fluxapyroxad (2020 monitoring). Each dot (n=110) represents an isolate made from samples collected in different European countries. All strains were sensitive in a detached leaf test (indicated by blue colour), one (yellow dot) was with slightly higher ED50 value (0.32 versus 0.095, the mean value of all others) and this is seen to be in the natural variability.

FRAC statement

FRAC summary of the 2020 status of SDHI resistance in *Puccinia* spp. based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Wheat – Brown rust (*Puccinia triticina* syn. *Puccinia recondita*) (Syngenta, Bayer, Sumitomo)

Extensive monitoring programs were carried out since 2005.

In **2020**, samples originating from France, Poland, Denmark, Germany, Hungary and the United Kingdom showed full sensitivity.

Historic background:

Samples from the following countries were tested in **2018**: Belgium, Denmark, France, Germany, Hungary, Sweden and the United Kingdom. All tested isolates were sensitive, within the baseline.

One single isolate, showing a low resistance factor (~5) has been identified in Pas de Calais, France and was genetically characterized without any detection of a mutation in *sdh* subunits B, C and D.

In **2019**, samples were analysed from Belgium, Czech Republic, France, Germany, Italy, Poland, Slovakia and the United Kingdom and showed full sensitivity.

Puccinia hordei

Monitoring data

There are no regular monitoring studies running for *Puccinia hordei* in BASF. However, FRAC describes a fully sensitive situation so far.

FRAC statement

FRAC summary of the status of SDHI resistance in *Puccinia hordei* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Barley – Rust (*Puccinia hordei*) (Sumitomo, Syngenta)

2020 samples from Denmark, France, Germany, Italy, Poland, Romania, Spain, United Kingdom showed full sensitivity. Monitoring is ongoing.

Puccinia striiformis

Monitoring data

There are no regular monitoring studies running for *Puccinia striiformis* in BASF. However, FRAC describes a fully sensitive situation so far.

FRAC statement

FRAC summary of the status of SDHI resistance in *Puccinia striiformis* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Wheat – Yellow rust (*Puccinia striiformis*) (Bayer, Sumitomo, Syngenta)

2020 Samples originating from Belgium, Denmark, Germany, France, Italy, Poland, Portugal, Spain and the United Kingdom showed full sensitivity.
In **2019**, samples from Belgium, Denmark, Germany, Latvia, Sweden and the United Kingdom were tested and showed full sensitivity, within the baseline.

A.3. *Pyrenophora teres*

Monitoring data

Pyrenophora teres: Random monitoring in 2012 showed for the first time two isolates outside the baseline sensitivity. These were found in Germany and had slightly increased EC₅₀ values. Isolates carried the H277Y mutation in the SDH-B subunit. Monitoring for 2013 showed an increase of SDHI resistance compared with 2012. Different mutations in the genes of the SDH subunits have been detected in less sensitive isolates. These are mainly C-G79R and to a lower frequency C-S135R, C-N75S, B-H277Y, C-H134R and others. In 2014-2020 monitoring showed SDHI adapted isolates mainly in France, Belgium, Netherlands and Germany. Results of the 2020 monitoring studies are shown in Figure 3.

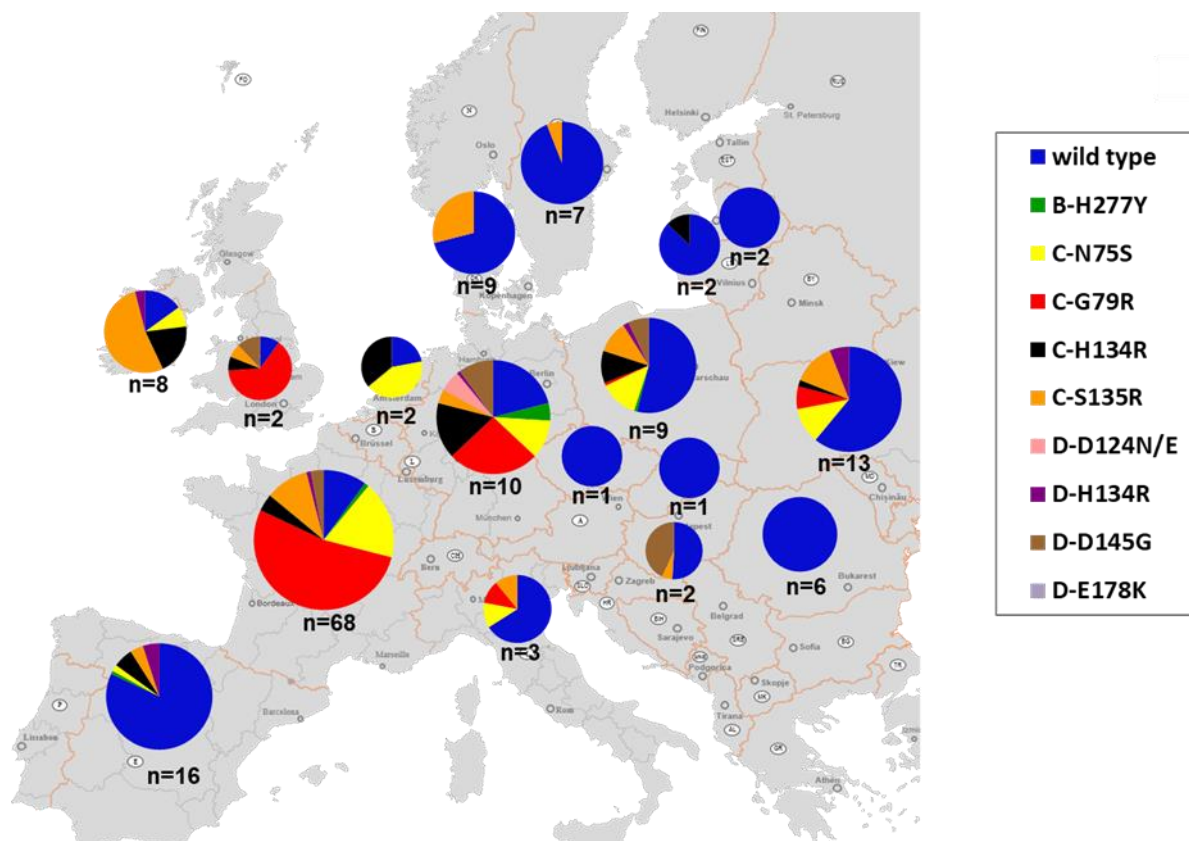


Figure 3: Results of the quantitative genetic monitoring of *Pyrenophora teres* to mutations in the SDH genes (2020). In total 162 samples were analysed. Legend shows the colour of the mutation. Number of samples represented in a pie chart is provided in each pie chart.

FRAC statement

FRAC summary of the status of SDHI resistance in *Pyrenophora teres* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Barley – Net blotch (*Pyrenophora teres*)
(Adama, BASF, Bayer, Sumitomo, Syngenta)

Disease pressure in **2020** was low to moderate.

In **2020**, the frequency of mutations was similar to the previous season.

No mutations or reduced sensitivity were detected in Bulgaria, Romania, Russia and Slovakia.

The frequency of mutations or reduced sensitivity was low in Czech Republic, Denmark, Hungary, Italy, Latvia, Lithuania, Spain, Sweden, Switzerland and Ukraine.

Moderate to high frequencies were observed in Austria, Belgium, France, Germany, Ireland, Poland, the Netherlands and the United Kingdom. Among the mutations with moderately decreased sensitivity, C-G79R, C-H134R and C-S135R are the most frequently detected mutations.

A4. *Rhynchosporium secalis* (syn. *Rhynchosporium commune*)

Monitoring data

In 2020, sensitivity monitoring was carried out in BASF for fluxapyroxad and *Rhynchosporium secalis*. Sensitivity of isolates from samples from European barley growing regions was in the baseline range (Figure 4).

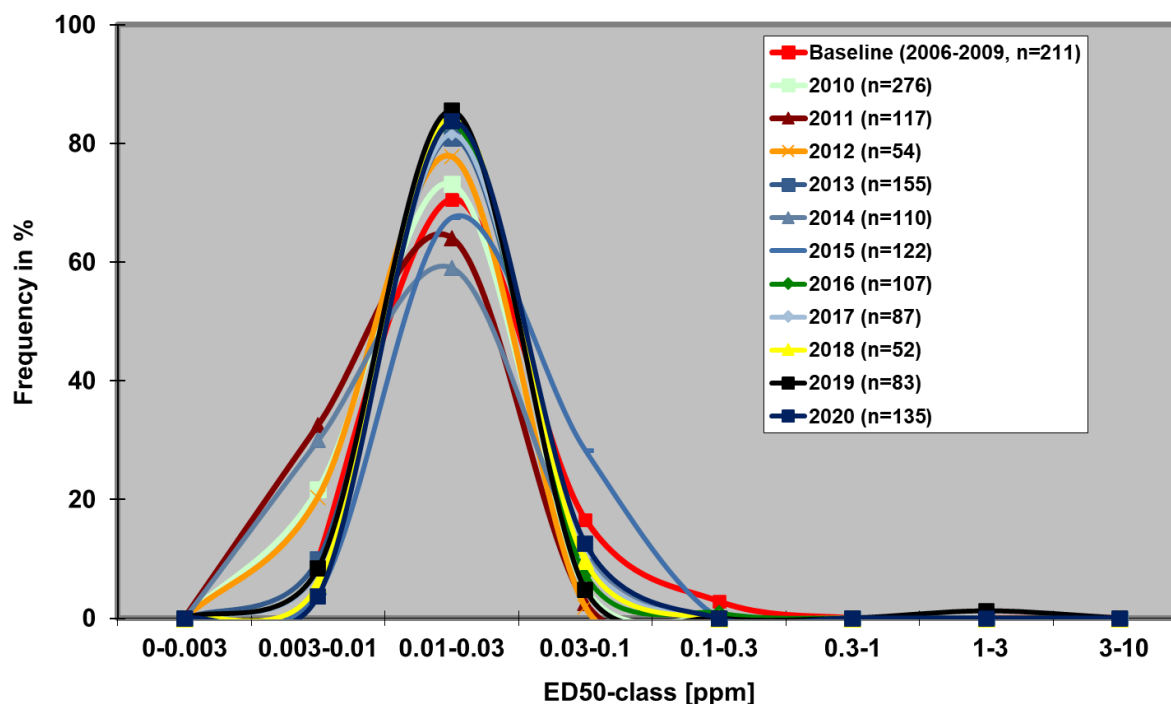


Figure 4: Results of the random monitoring of *Rhynchosporium secalis* to fluxapyroxad (2010-2020 monitoring). Samples were taken from different European barley growing regions and isolates were made from them and tested in microtiter plates for fluxapyroxad sensitivity. EC50 values were calculated and assigned to classes, which were made according to the fluxapyroxad concentrations used in the sensitivity test.

FRAC statement

FRAC summary of the status of SDHI resistance in *Rhynchosporium secalis* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Barley – Scald (*Rhynchosporium commune* syn. *Rhynchosporium secalis*)
(BASF, Sumitomo, Syngenta)

2020 samples originating from France, Germany, Hungary, Ireland, Italy, Latvia, the Netherlands, Poland, Slovakia, Spain, Ukraine, the United Kingdom showed full sensitivity.

A5. *Blumeria graminis*

Blumeria graminis f.sp. tritici

Monitoring data

In 2020, sensitivity monitoring was carried out in BASF for fluxapyroxad and *Blumeria graminis f.sp. tritici*. All isolates from different European regions were sensitive (Figure 5). Sensitivity studies were performed by Epilagic.

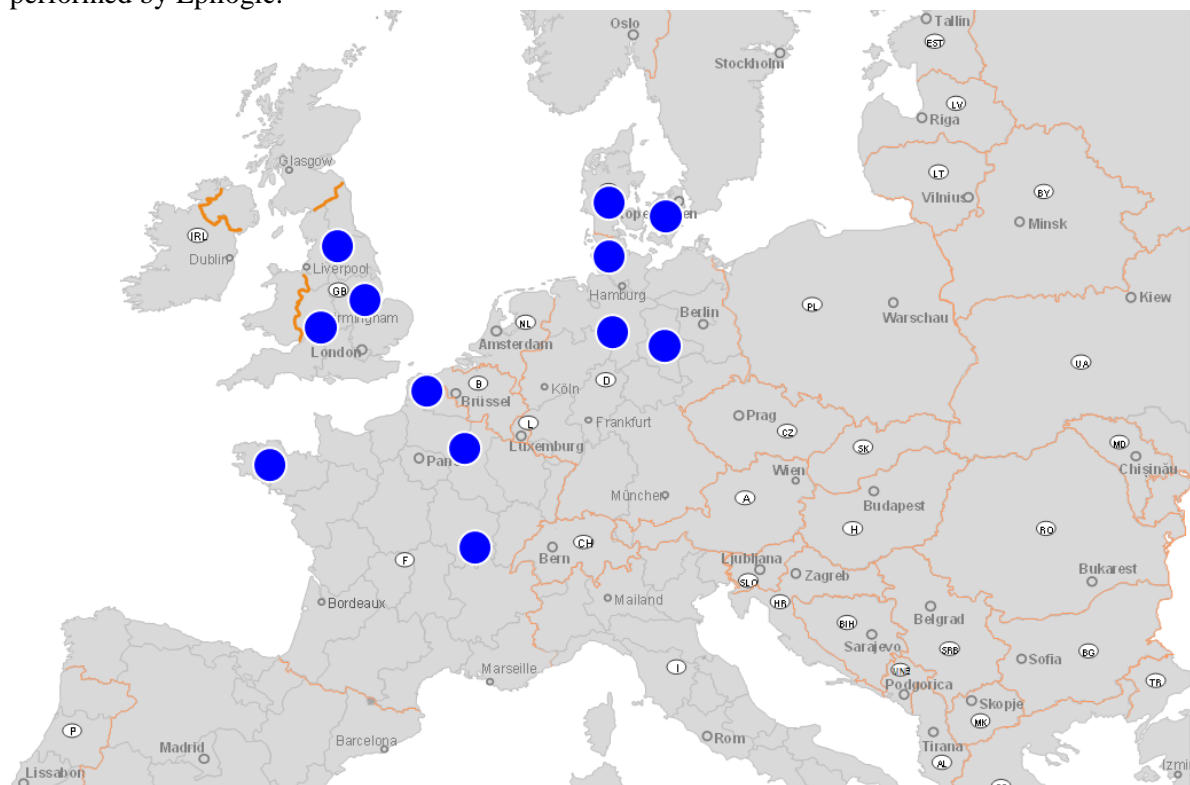


Figure 5: Results of the random monitoring of *Blumeria graminis f.sp. tritici* to fluxapyroxad (2020 monitoring). Blue dots mean that all isolates from this region were sensitive. Sampling was organised and monitoring was done by Epilagic. Monitoring method was a detached leaf assay using discriminatory doses for identification of sensitivity loss. In total 102 isolates were analysed from 12 regions.

FRAC statement

FRAC summary of the status of SDHI resistance in *Blumeria graminis f.sp. tritici* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Wheat – Powdery mildew (*Blumeria graminis*) (BASF)

In 2020, samples from Denmark, France, Germany and the United Kingdom showed full sensitivity.

Blumeria graminis f.sp. hordei

Monitoring data

There are no regular monitoring studies running for this forma speciale of this species in BASF.

FRAC statement

FRAC summary of the status of SDHI resistance in *Blumeria graminis f.sp. hordei* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Barley – Powdery mildew (*Blumeria graminis*)

No monitoring results are available from **2020**.

2019 monitoring programs included samples from Czech Republic, France, Germany and the United Kingdom and showed full sensitivity.

Blumeria graminis in triticales and oat

There are no regular monitoring studies running for these forma speciales of this species in BASF. No data are available by FRAC and a literature research in the data base “Web of Knowledge” from July 2020 was done without any findings on sensitivity data of this species to SDHI. No data of SDHI resistance or field failure due to resistance issues have been reported so far.

A6. *Parastagonospora nodorum* (syn. *Leptosphaeria nodorum*, *Phaeosphaeria nodorum* or *Septoria nodorum*)

There are no regular monitoring studies running for this species in BASF.

FRAC statement

FRAC summary of the status of SDHI resistance in *Parastagonospora nodorum* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Wheat – Glume blotch (*Phaeosphaeria nodorum* syn. *Stagonospora nodorum*)
(Syngenta)

Single isolates from **2019** and **2020** originating from the Czech Republic and Sweden were analysed and showed full sensitivity.

A7. *Pyrenophora tritici-repentis*

There are no regular monitoring studies running for this species in BASF.

FRAC statement

FRAC summary of the status of SDHI resistance in *Pyrenophora tritici-repentis* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Wheat – Tan spot (*Pyrenophora tritici-repentis*)
(Sumitomo, Syngenta)

In **2020**, samples from Czech Republic, Germany, Hungary, Poland, Romania, Sweden showed full sensitivity.

2019 samples from Finland, Latvia and the United Kingdom showed full sensitivity.

A8. *Ramularia collo-cygni*

Monitoring data

In 2020 BASF monitoring, isolates with increased EC50 values were detected (Figure 6). Sensitivity monitoring was done by Agrotest Fyto, Kromeriz, Czech Republic using a Petridish assay. The results indicate a heterogenous situation in Europe. Genetic analysis was made in BASF with isolates from 2016 (Figure 7). A genetic analysis of the SDHI resistant isolates from the 2020 season is currently ongoing.

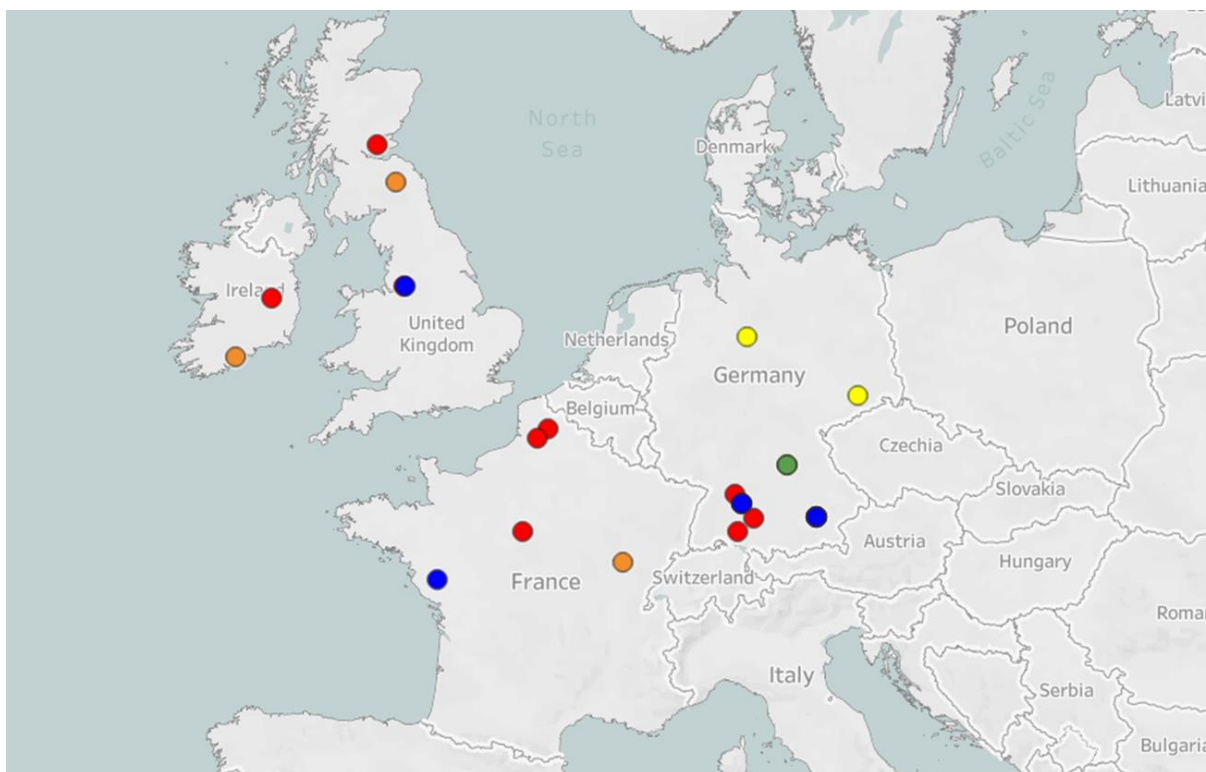


Figure 6: Results of the random monitoring of *Ramularia collo-cygni* to fluxapyroxad (2020). Blue dots mean that all isolates from this location were sensitive, green dots that 2-10% were outside baseline sensitivity, yellow 10-30%, orange 30-75% and red >75%.

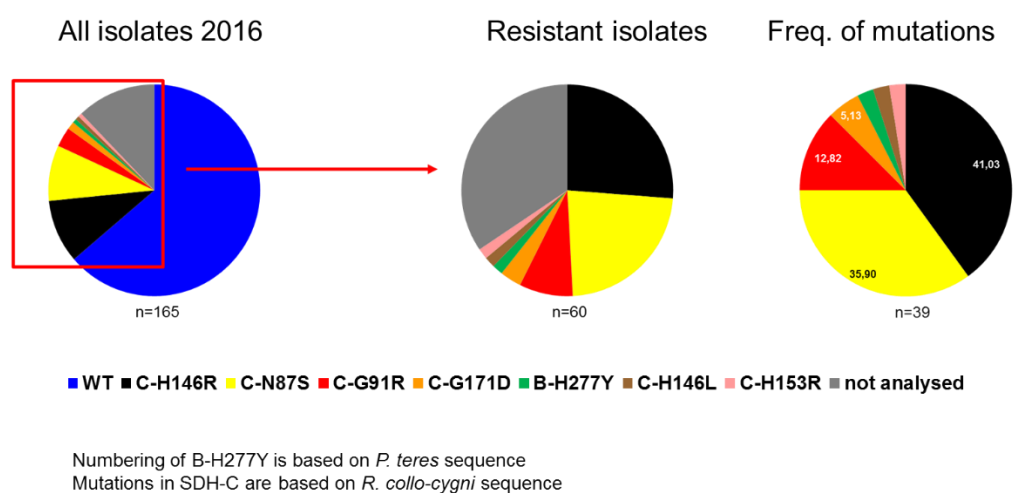


Figure 7: Frequency of SDHI mutations in the SDH-B and SDH-C subunits from isolates outside the baseline from 2016. Not all isolates were analysed (grey part). All registered SDHIs are more or less affected by the mutations that were found.

FRAC statement

FRAC summary of the status of SDHI resistance in *Ramularia collo-cygni* based on all available data from the different members of the FRAC SDHI Working Group (status August 2021):

Barley - Ramularia leaf spot (*Ramularia collo-cygni*) (BASF, Sumitomo, Syngenta)

Data from **2020** showed no mutations in Czech Republic and Slovakia.

Low frequency has been found in Hungary, Italy, Spain and Switzerland.

A heterogeneous situation, ranging from low to high (frequency of mutations and sensitivity), was observed in Germany, Denmark, France, Lithuania, Sweden and the United Kingdom.

Moderate to high frequencies of mutations were detected in Ireland.

Significantly decreased sensitivity is mainly associated with the mutations C-G91R, C-H146R/L, C-G171D or C-H153R. Additionally, mutations linked to lower resistance factors (C-N87S, B-T267I, B-N224T) were detected.

B. Azoxystrobin

Baseline studies

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

B1. Zymoseptoria tritici

Monitoring data

High frequencies of G143A mutation have been detected in intensive wheat growing areas in North-Western Europe. The situation in Southern and Eastern European countries is much more favourable, where QoI resistance is still absent or present at lower levels (Figure 8).

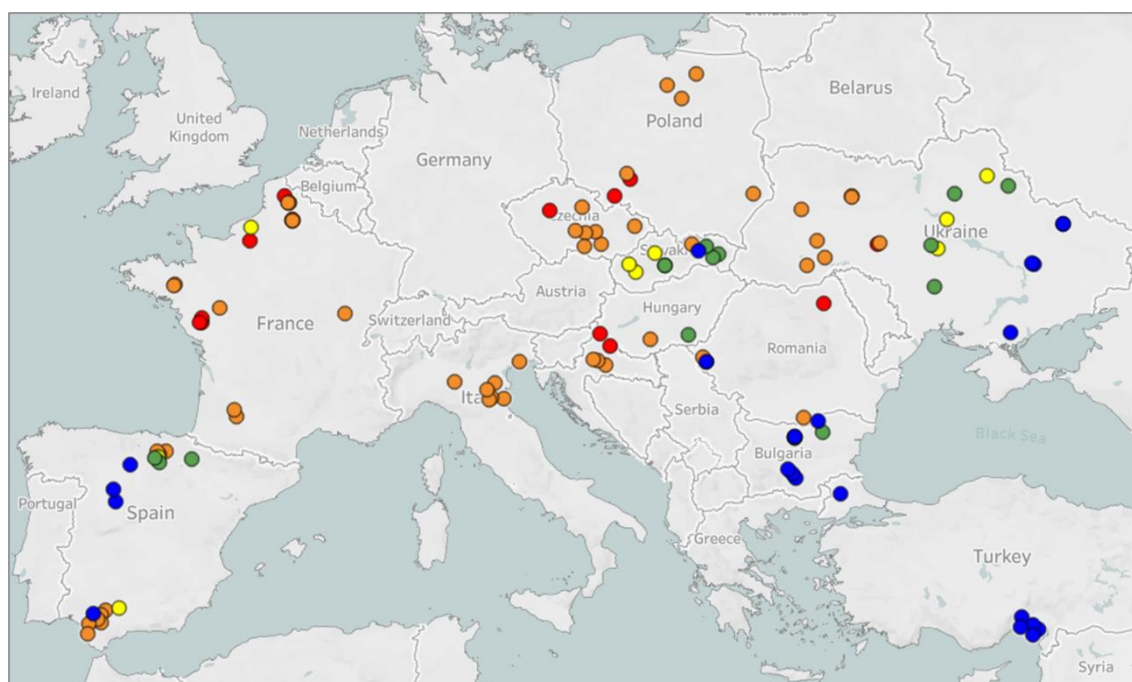


Figure 8: Monitoring of QoI sensitivity of *Zymoseptoria tritici* in 2020. Each dot represents a sample (N=122), which was analysed for frequency of G143A mutation by real-time PCR (blue: 0-2, green 3-10, yellow 11-30, orange 31-75, red 76-100% frequency of G143A).

FRAC statement

FRAC summary of the status of QoI resistance in *Zymoseptoria tritici* based on all available data from the different members of the FRAC QoI Working Group (August 2021):

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

Companies: BASF, Syngenta

Monitoring data based on molecular data showed in 2020 the following situation:

In France, Germany, Denmark, Ireland, Latvia, Lithuania, Sweden, and United Kingdom widespread resistance over all these countries at high levels were detected.

Medium to high resistance level was detected in Croatia, Czech Republic and Poland.

In Austria, Italy, Spain, Switzerland and Ukraine populations were showing in average moderate levels of resistance with high variability.

Low to moderate levels were reported in Hungary, Romania, Russia, Slovakia and Ukraine.

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

B2. Puccinia triticina (syn. Puccinia recondita) and other Puccinia species

Monitoring data

No reduced sensitivity has been detected for *Puccinia triticina* towards QoIs in any sample in BASF monitoring studies since market introduction up to now. Latest data are from the 2020 season (Figure 9), performed by the company Epilagic.

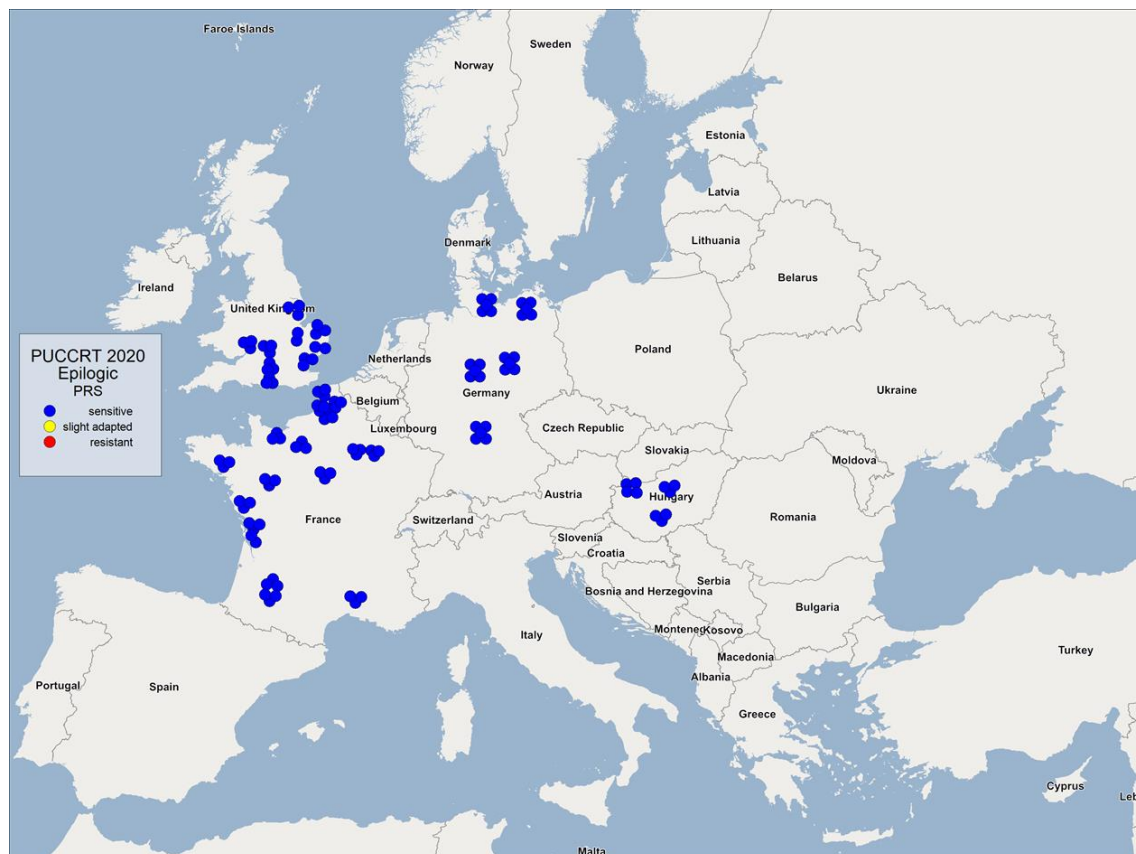


Figure 9: Monitoring of QoI sensitivity of *Puccinia triticina* in 2020. Each blue dot represents an isolate (N=110) which was analysed for QoI sensitivity in detached leaf tests with a discriminatory dose of the QoI pyraclostrobin. All isolates from all samples were QoI-sensitive.

FRAC statements

FRAC summary of the status of QoI resistance in *Puccinia* species based on all available data from the different members of the FRAC QoI Working Group (status August, 2021):

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

Companies: BASF, Bayer and Syngenta

The monitoring in 2020 based on bioassay confirmed the sensitive situation reported already in previous years.

Countries tested included Denmark, France, Germany, Hungary, Poland and United Kingdom.

In 2020, performance of QoI fungicides against brown rust was good.

Yellow rust (*Puccinia striiformis*), wheat

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Companies: Bayer and Syngenta

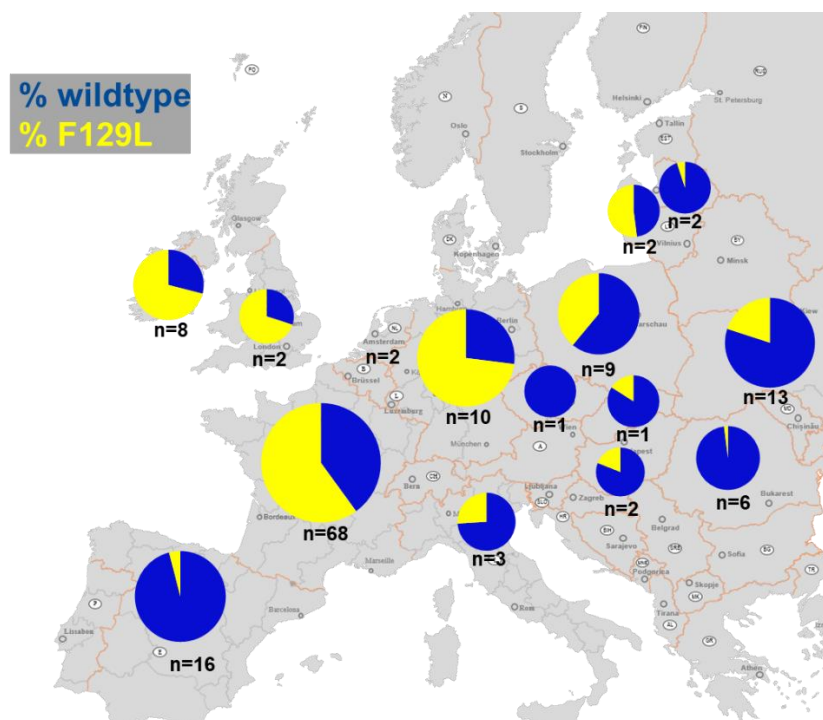
The monitoring in 2020 based on bioassay confirmed the sensitive situation reported already in previous years.

Countries included: Belgium, Denmark, France, Germany, Poland, Spain, United Kingdom.

B3. *Pyrenophora teres*

Monitoring data

In 2020, the mutation F129L dominates the population in UK, Ireland, France and Germany, in other European countries this mutation is less frequent (Figure 10). The BASF method used was a quantitative pyrosequencing assay. Other mutations have not been found in 2020. The F129L leads in general to lower resistance levels to QoIs than the G143A mutation.



FRAC statement

FRAC summary of the status of QoI resistance in *Pyrenophora teres* based on all available data from the different members of the FRAC QoI Working Group (status August, 2021):

Net blotch (*Pyrenophora teres*), barley

Companies: BASF, Bayer, Syngenta

Field performance of QoI-containing fungicides against net blotch was good.

Additional information: Mainly the F129L mutation was found. As already observed with other pathogens, resistance factors are significantly lower in comparison with the G143A mutation and field performance of products used according to FRAC and Manufacturers' recommendations remains good (for differences between QoI mutations see also the respective FRAC document titled "Mutations associated with QoI resistance" available on the FRAC website under QoI fungicides →Quick references).

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

Monitoring in 2020 based on bioassay and molecular studies showed the following situation:

Medium to high levels were found in Belgium, Germany, Ireland, Netherland and United Kingdom.

Medium levels were detected in Denmark, France, Lithuania, Sweden, Switzerland and Poland.

No to low levels were reported in Austria, Hungary, Italy, Latvia, Poland, Romania, Russia, Slovakia, Spain and Ukraine.

No resistance of mutation was found in Bulgaria, Czech Republic and Greece.

B4. *Rhynchosporium secalis* (syn. *Rhynchosporium commune*)

Monitoring data

Sensitivity monitoring (detection of G143A, F129L and G137R by pyrosequencing) on *Rhynchosporium secalis* did not show up any QoI-resistance in 2020 at any site analysed (Figure 11). Additionally, various isolates were made from the samples. Such isolates were tested in microtiter tests for their sensitivity towards the QoI pyraclostrobin in order to identify if another mechanism, the AOX overexpression, is present, which is with the molecular genetic methods used in our *Rhynchosporium secalis* monitoring not detectable. In 2020 only one isolate (0.7%) with AOX overexpression was found (Figure 12, Figure 13). Since AOX overexpression leads to a low QoI adaptation, the data show that the European population of *Rhynchosporium secalis* is still sensitive to the QoI pyraclostrobin. Since the correlation between QoIs is very high for the G143A mutation (the only mutation so far found in *Rhynchosporium secalis*) and for AOX overexpression, the data from the pyraclostrobin monitoring are also valid for azoxystrobin.

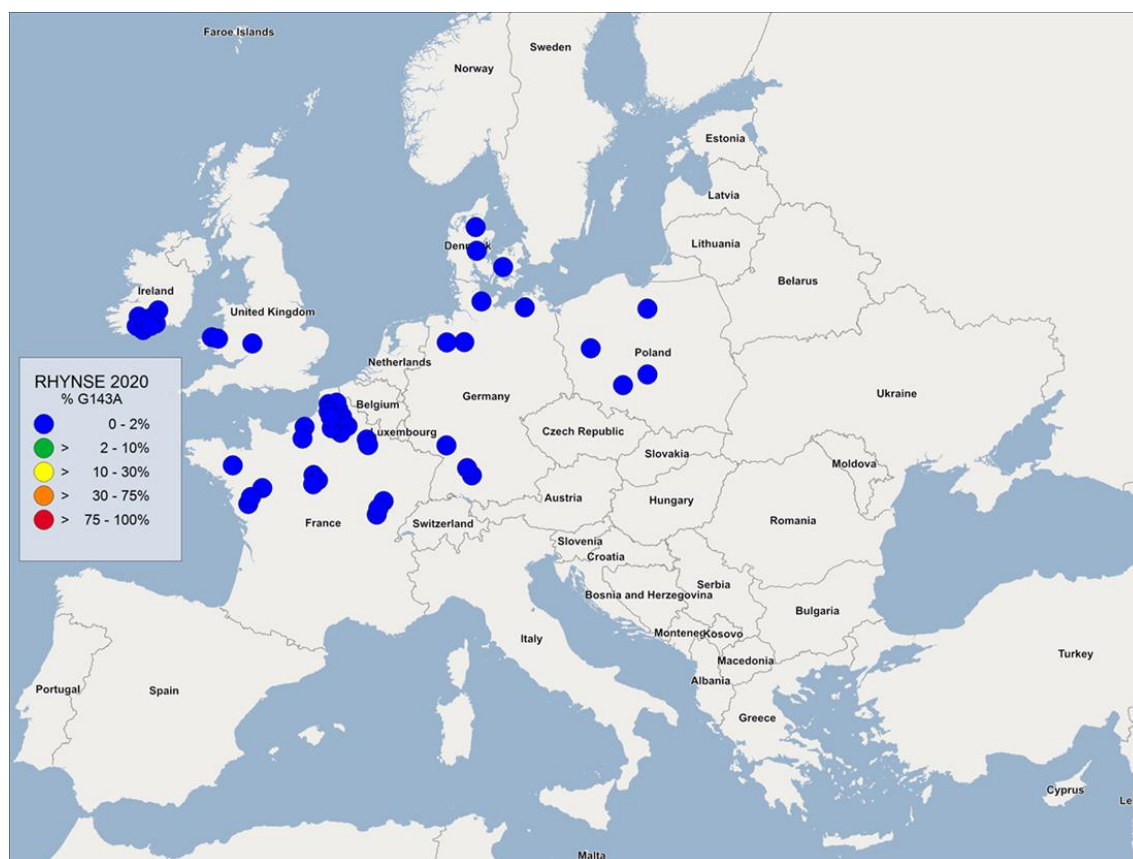


Figure 11: Monitoring of QoI sensitivity of *Rhynchosporium secalis* in 2020. Each blue dot represents a sample (N=49), which was analysed for QoI sensitivity by G143A, F129L and G137R analysis by pyrosequencing. All samples showed wild type sequences and were therefore classified as sensitive to QoIs.

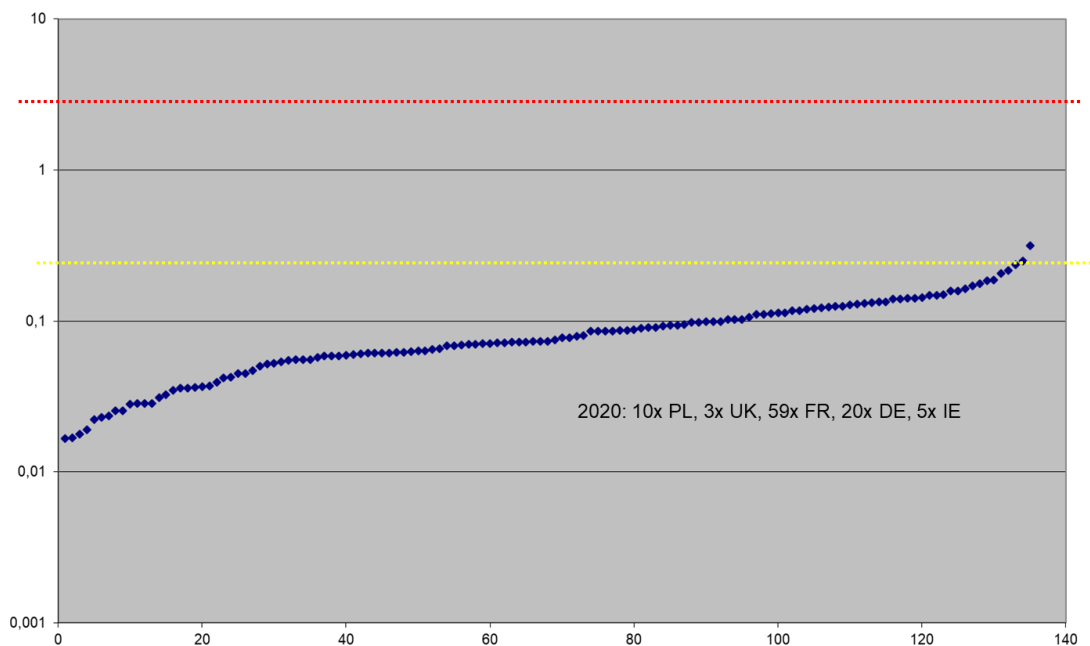


Figure 12: Monitoring of QoI sensitivity of isolates of *Rhynchosporium secalis* in 2020. Each dot represents the EC50 value of an isolate (N=135) for pyraclostrobin (ppm), determined by a microtiter assay. Lower dotted line represents the threshold for AOX overexpression, upper dotted line for G143A mutation. The thresholds were determined and confirmed in previous years with various experiments. In 2020 no isolate was found with the G143A mutation and only one with an AOX overexpression.

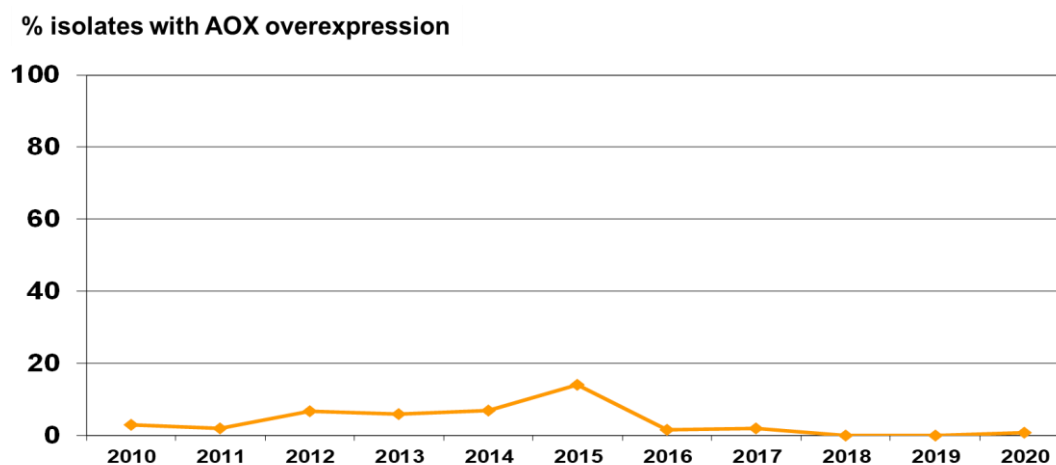


Figure 13: Frequency of isolates of *Rhynchosporium secalis* with an AOX overexpression from 2010 to 2020. The analysis show that the frequency is not increasing and at very low levels.

FRAC statement

FRAC summary of the status of QoI resistance in *Rhynchosporium secalis* based on all available data from the different members of the FRAC QoI Working Group (status August, 2021):

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

Companies: BASF, Bayer and Syngenta

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

In 2020 monitoring based on bioassay and molecular studies showed full sensitivity in Denmark, Germany, France, Hungary, Ireland, Latvia, Netherland, Poland, Slovakia, Spain and United Kingdom.

Findings in 2019:

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

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

B5. Blumeria graminis

Monitoring data

In 2020, 16 sites in Poland, Czech Republic, Hungary and Bulgaria were analysed for the frequency of the G143A in *Blumeria graminis*.

Four samples were from rye from Poland and with 0% G143A and therefore classified as full sensitive. Twelve samples were from wheat, samples from Bulgaria were with low to moderate frequency, from Czech Republic and Hungary with moderate frequency and from Poland with higher frequencies of the G143A.

FRAC statement

FRAC summary of the status of QoI resistance in cereal powdery mildews based on all available data from the different members of the FRAC QoI Working Group (status August, 2021):

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

Companies: BASF, Bayer

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Monitoring based on molecular data in 2020 for samples collected from wheat showed low to moderate frequency of G143A BG, moderate in HU, CZ and high in PL.

Samples collected from rye in 2020 from PL were all sensitive, based on molecular analysis.

Findings in 2019:

Monitoring has been carried out in Czech Republic, Latvia, Lithuania and Poland with medium to high frequencies of resistance.

Low to medium were reported in Czech Republic.

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

No monitoring in 2020

Companies: Bayer

Limited monitoring in 2019

Findings:

No to Low in Latvia and Lithuania.

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

B6. *Parastagonospora nodorum* (syn. *Leptosphaeria nodorum*, *Phaeosphaeria nodorum* or *Septoria nodorum*)

Monitoring data

No data from the last years are available. The last monitoring for this fungal species was carried out in 2010 by the company Epilogic. Most samples were full sensitive; only 6 out of 30 samples contained the G143A mutation at low to high frequency (Figure 14).

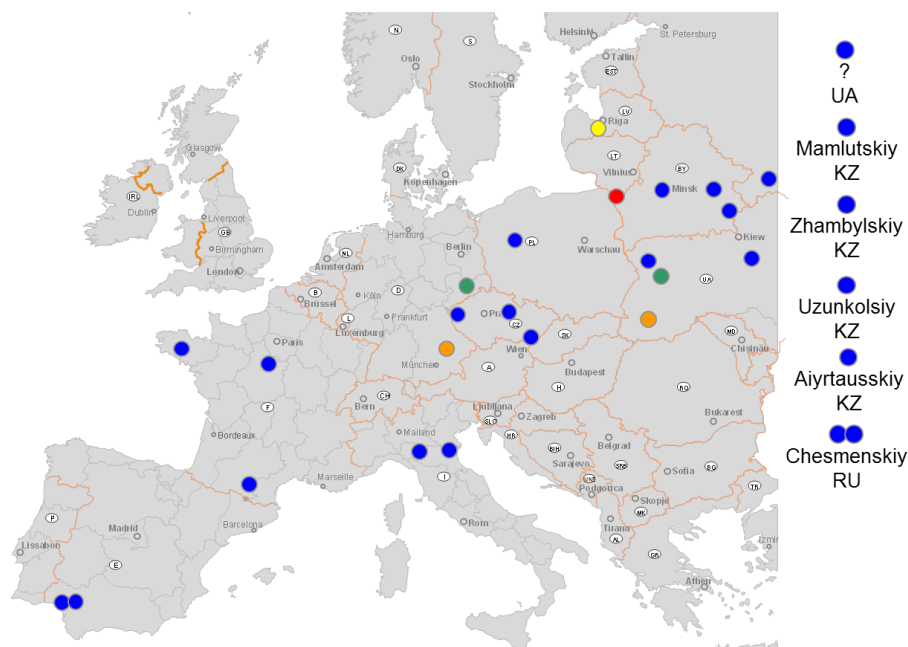


Figure 14: Monitoring of QoI sensitivity of *Parastagonospora nodorum* in 2010. Each dot represents a sample (N=30) which was analysed for frequency of G143A mutation by real-time PCR (blue: 0-2, green 3-10, yellow 11-30, orange 31-75, red 76-100% frequency of G143A). Dots on the right end are from samples outside the map segment.

FRAC statement

Parastagonospora nodorum is listed as a pathogen where the G143A mutation has been detected (FRAC 2021, Blixt et al. 2009). A current overview of the distribution and frequency of resistance is not available on the FRAC webpage.

B7. *Pyrenophora tritici-repentis*

Monitoring data

The G143A, F129L and (seldom) the G137R mutations were detected in Europe in the last years. The most important mutation is the G143A because of its higher frequency and higher impact on the sensitivity loss. The data on the current distribution over Europe in 2020 is shown in Figure 15. The G143A mutation was detected in different countries and fields with different levels.

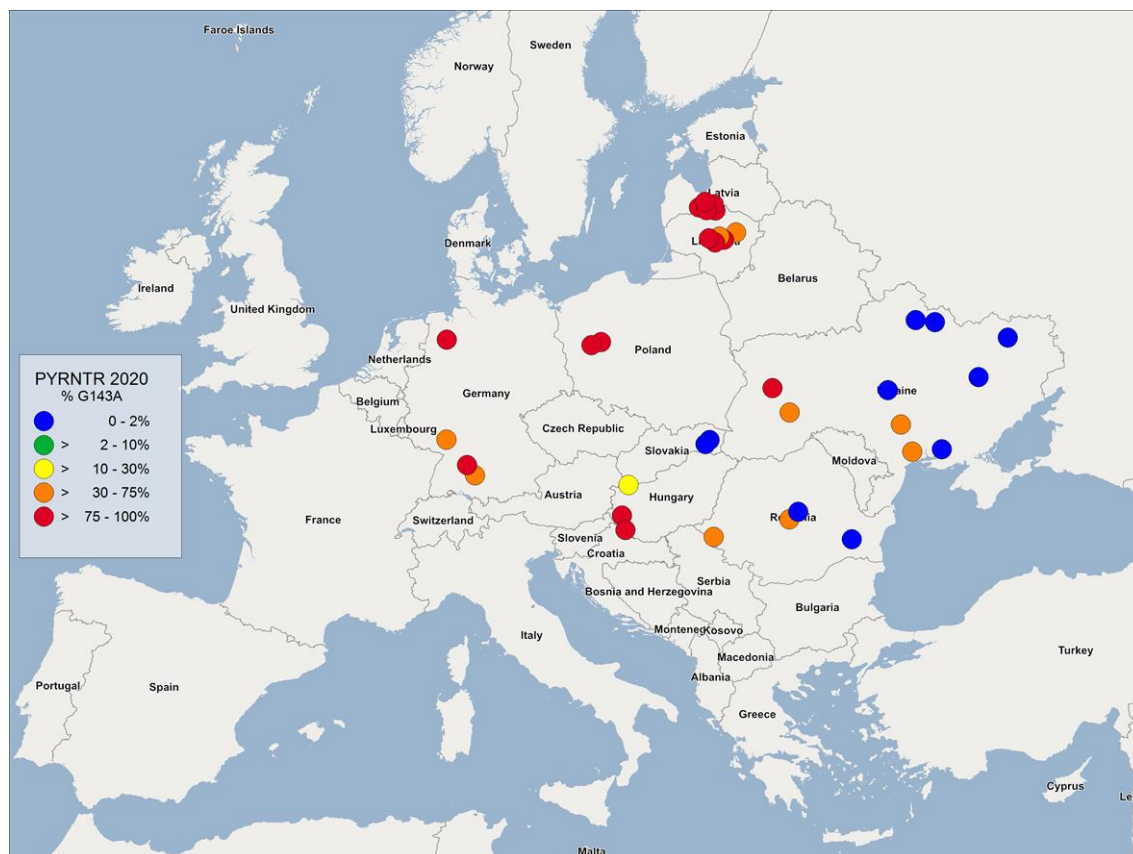


Figure 15: Monitoring of QoI sensitivity of *Pyrenophora tritici-repentis* in 2020. Each dot represents a sample (N=36), which was analysed for frequency of the G143A mutation by pyrosequencing (blue: 0-2, green 3-10, yellow 11-30, orange 31-75, red 76-100% frequency of G143A).

FRAC statement

FRAC summary of the status of QoI resistance in *Pyrenophora tritici-repentis* based on all available data from the different members of the FRAC QoI Working Group (status August, 2021):

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

Companies: BASF, Syngenta

Monitoring in 2020 based on molecular studies measuring frequency of G143A, F129L and G137R and bioassay data showed the following situation.

High levels of resistance were detected in Denmark, Hungary and Latvia,
moderate to high in Poland,

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moderate in Germany,

low in Austria, Czech Republic, Romania and Ukraine and

no resistance detected in B.

Single resistant samples/isolates were found in Russia and Sweden.

B8: Ramularia collo-cygni

QoI resistance is widespread in the European populations since more than 15 years. In 2020, 147 monosporic isolates from 27 samples (fields) from France, Germany, Ireland and UK were analysed. From these, 12 isolates were QoI sensitive and 135 QoI resistant. The sensitive isolates came from different sites in Germany. Test system was a Petri dish assay with growth of the isolates at different fungicide concentrations and subsequent EC50 calculation. Studies were performed by Agrotest Fyto.

FRAC statement

FRAC summary of the status of QoI resistance in *Ramularia collo-cygni* based on all available data from the different members of the FRAC QoI Working Group (status August, 2021):

Ramularia leaf spot (*Ramularia collo-cygni*), barley

Companies: BASF, Syngenta

Monitoring in 2020 based on bioassay and molecular quantification G143A showed the following results.

High frequency of resistance was found in Czech Republic, Denmark, Hungary, Ireland, Latvia, Slovakia, Sweden and United Kingdom,
moderate to high frequency in Germany and France,

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moderate frequency in Switzerland and

low frequency in Spain.

Resistance risk assessment under unrestricted use pattern

Use pattern

BAS 736 00 F is intended for registration for control of the above-mentioned diseases in cereals with a maximum rate per application of 2 l/ha. Maximum number of applications is 2, with a minimum of 21 days between applications. Applications are intended for registration between growth stages 30-69.

Fungicide risk

Fluxapyroxad: FRAC describes the SDHI fungicides in general as medium to high-risk compounds (FRAC 2021) according to the principles described in FRAC Monographs 1 and 2 (Brent 2007, Brent and Hollomon 2007).

Azoxystrobin: FRAC describes the QoI fungicides in general as high-risk compounds (FRAC 2021) according to the principles described in FRAC Monographs 1 and 2 (Brent 2007, Brent and Hollomon 2007).

Pathogen risk

Classification of the fungicides was made according FRAC.

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. Generally, the risk increases when a pathogen undergoes many and short disease cycles per season, the dispersal through spores over time and space is high and the competitive ability of resistant individuals is high in the absence of selection pressure. Furthermore, the risk is considered as high when resistance evolved already after few years of product use.

High risk pathogens:

Blumeria graminis
Ramularia collo-cygni

Medium risk pathogens:

Zymoseptoria tritici
Parastagonospora nodorum
Pyrenophora tritici-repentis
Pyrenophora teres

Low risk pathogens:

Puccinia spp.
Rhynchosporium secalis

Combined pathogen-fungicide risk

The combined risks of pathogens and fungicides are visualized in Figures 16 and 17.

benzimidazoles dicarboximides phenylamides <u>QoI</u>	high (x 3)	3	6	9
<u>SDHIs</u>				
metrafenone DMIs MBIs phenylpyrroles anilinopyrimidines morpholines CAA	medium (x 2)	2	4	6
chlorothalonil dithianon copper dithiocarbamates phthalimides sulphur SAR-inducers	low (x 0.5)	0.5	1	1.5
↑ basic fungicide risk		low (1)	medium (2)	high (3)
		<i>Puccinia coronata</i> <i>Puccinia hordei</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Puccinia triticina</i> <i>Rhynchosporium secalis</i>	<i>Zymoseptoria tritici</i> <i>Parastagonospora nodorum</i> <i>Pyrenophora teres</i> <i>Pyrenophora tritici-repentis</i>	<i>Blumeria graminis</i> <i>Ramularia collo-cygni</i>
	→ basic disease risk			

Figure 16: Combined risk analysis (modified after Brent and Hollomon 2007)

<u>Score</u>	<u>Risk class</u>
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 17. The positions were allocated considering the current knowledge and experience on the fungicides and pathogens.

- 1: SDHI on *Puccinia* spp.
- 2: SDHI on *Rhynchosporium secalis*, *Parastagonospora nodorum*
- 3: SDHI on *Zymoseptoria tritici*, *Pyrenophora tritici-repentis*, *Pyrenophora teres*
- 4: SDHI on *Blumeria graminis*, *Ramularia collo-cygni*
- 5: QoI on *Puccinia* spp.
- 6: QoI on *Pyrenophora teres*
- 7: QoI on *Rhynchosporium secalis*, *Parastagonospora nodorum*
- 8: QoI on *Zymoseptoria tritici*, *Pyrenophora tritici-repentis*,
- 9: QoI on *Blumeria graminis*, *Ramularia collo-cygni*

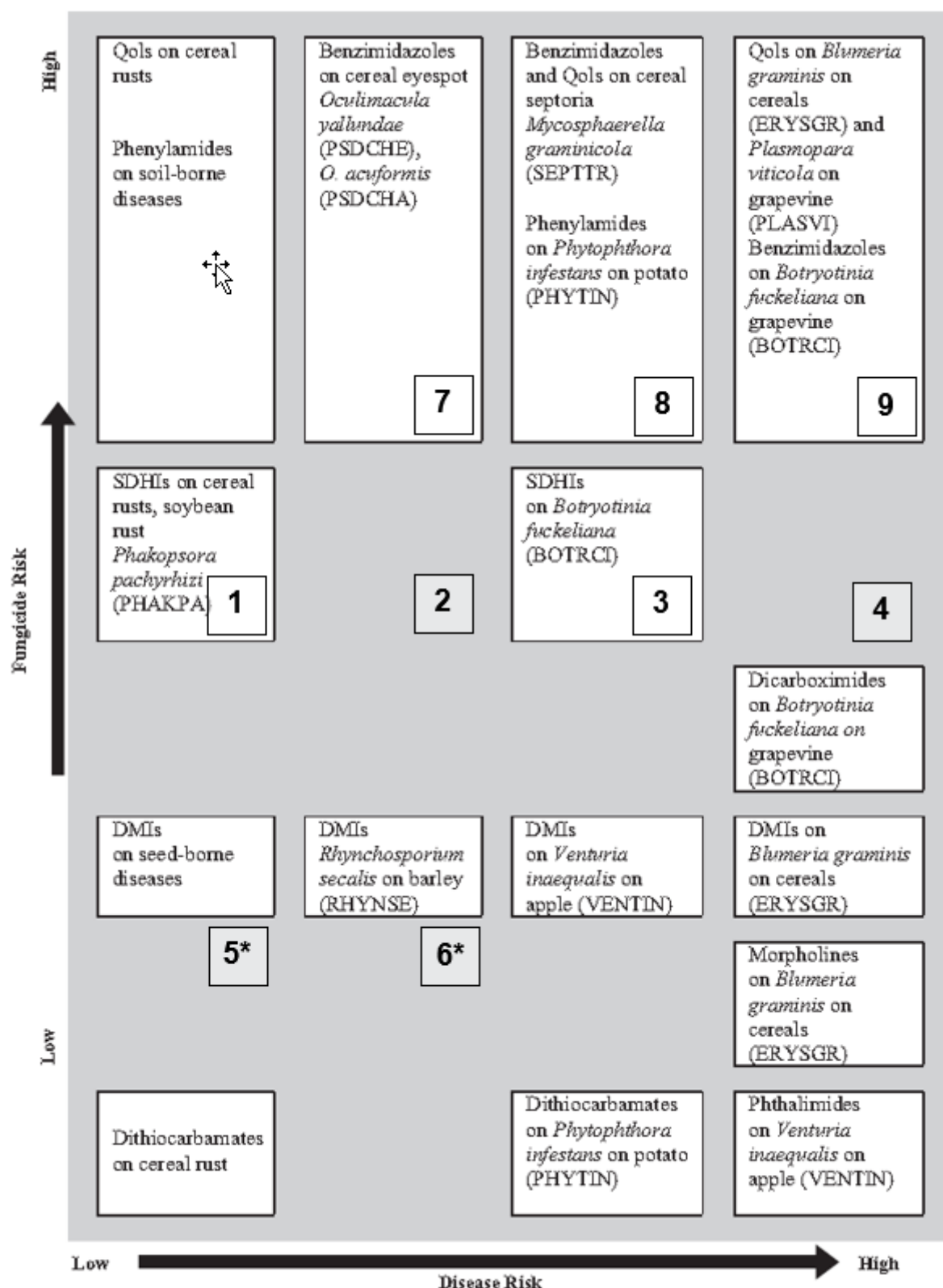


Figure 17: Scheme for visualizing the combined resistance risk (EPPO 2015). *5 and *6 are on a lower level for QoIs, because *Puccinia* species and *Pyrenophora teres* have lower QoI resistance risk because of presence of an intron after codon 143 in the cytochrome b gene (please see chapter “Mechanism of resistance”).

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

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

SDHI x pathogen ...

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

QoI x pathogen ...

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

Test methods

A. Methods for Resistance risk assessment

Pathogen resistance risk

Classification of the pathogens was made according to FRAC

Fungicide risk

Classification of the fungicides was made according FRAC.

Combined pathogen x fungicide risk

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

B. Methods for sensitivity analysis

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

Acceptability of the resistance risk assessment under unrestricted use

The analysis of the combined resistance risk showed that the risk is not acceptable for the medium-risk and high-risk pathogens under unrestricted use of BAS 736 00 F, therefore resistance management strategies need to be implemented.

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

Management strategy

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

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

Limiting the number of sprays is also an important factor in delaying the build-up of resistant pathogen populations (van den Berg et al. 2016). The number of BAS 736 00 F applications will be restricted to 2 applications per season

A further tool is the use of fungicide mixtures. Recent studies showed that especially mixtures help in delaying the selection of resistance (Hobbelen et al. 2013, 2014, van den Bosch et al. 2014). BAS 736 00 F is already a mixture of two compounds with different modes of action, which are active against most target organisms and provides therefore a build-in resistance management.

Since population size of pathogens is lower at disease onset than when already established in the field, selection pressure is less when using preventive applications rather than curative or eradication spray schemes. Therefore, BAS 736 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 SDHI Working Group and will promote effective anti-resistance management strategies. The current FRAC recommendations for resistance management of SDHI fungicides are:

General guidelines for using SDHI fungicides (all crops)

Strategies for the management of SDHI fungicide resistance, in all crops, are based on the statements listed below. These statements serve as a fundamental guide for the development of local resistance management programs. Resistance management strategies have been designed to be proactive and to prevent or delay the development of resistance to SDHI fungicides.

- A fundamental principle that must be adhered to when applying resistance management strategies for SDHI fungicides is that:

The SDHI fungicides (benodanil, benzovindiflupyr, bixafen, boscalid, carboxin, fenfuram, fluindapyr, fluopyram, flutolanil, fluxapyroxad, furametpyr, inpyrfluxam, isofetamid, isoflucypram, isopyrazam, mepronil, oxycarboxin, penflufen, penthiopyrad, pydiflumetofen, sedaxane, thifluzamide) are in the same cross-resistance group.

- Fungicide programs must deliver effective disease management. Apply SDHI fungicide based products at effective rates and intervals according to manufacturers' recommendations.
- Effective disease management is a critical component to delay the build-up of resistant pathogen populations.
- The number of applications of SDHI fungicide based products within a total disease management program must be limited.
- When mixtures are used for SDHI fungicide resistance management, applied as tank mix or as a co-formulated mixture, the mixture partner: should provide satisfactory disease control when used alone on the target disease and must have a different mode of action.
- Mixtures of two or more SDHI fungicides can be applied to provide good biological efficacy; however, they do not provide an antiresistance strategy and must be treated as a solo SDHI for resistance management. Each application of such a mixture when used in a spray program counts as one SDHI application.
- SDHI fungicides should be used preventively or at the early stages of disease development.
- Please refer to FRAC Recommendations for Mixtures - January 2010 for more information on fungicide mixtures for resistance management.
- Species can carry different mutations which affect SDHIs. A few mutations can lead to different sensitivities depending on the chemical structure of the active ingredient.
- As SDHIs are cross-resistant, resistance management must be the same for all SDHIs.
- All monitoring and guideline related statements refer to the entire group of SDHIs.

SDHI - Guidelines for using SDHI fungicides on cereal crops

Foliar applications

- Apply SDHI fungicides always in mixtures
- The mixture partner:
 - ✓ should provide satisfactory disease control when used alone on the target disease
 - ✓ must have a different mode of action
- Apply a maximum of 2 SDHI fungicide containing sprays per cereal crop.

Apply the SDHI fungicide preventively or as early as possible in the disease cycle. Do not rely only on the curative potential of SDHI fungicides. Strongly reduced rate programs including multiple applications must not be used. Refer to manufacturers' recommendations for rates.

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

General guidelines for using QoI fungicides (all crops)

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

Guidelines for using QoI fungicides on cereal crops

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

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

Implementation of the management strategy

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

Monitoring, reporting and reacting to changes in performance

The sensitivity and/or the presence of target site mutations in *Zymoseptoria tritici*, *Puccinia triticina*, *Pyrenophora teres*, *Ramularia collo-cygni* and *Rhynchosporium secalis* to SDHIs are monitored by BASF on an annual or biannual basis in extensive monitoring studies over all important European cereal growing areas.

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

In case of field failure of BAS 736 00 F, which cannot be explained by other agronomic parameters, the sensitivity of the target pathogens of this Resistance Risk Analysis to fluxapyroxad and azoxystrobin 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:	<p><u>Risk of possible occurrence of the development of resistance</u></p> <p>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.</p> <p>BAS 736 00 F (Miralon) contains the two active substances: fluxapyroxad and azoxystrobin. Fluxapyroxad belongs to the fungicide group succinate dehydrogenase inhibitors (SDHI, mode of action class C2) (FRAC code 7) and its mode of action at the molecular level is the inhibition of the enzyme succinate dehydrogenase (SDH), also known as complex II in the mitochondrial electron transport chain. Azoxystrobin belongs to the group C (respiration), subgroup C3 (inhibition of complex III) with the target site cytochrome bc1 at QoI site (FRAC code 11) with the group name QoI (Quinone outside inhibitors) fungicides. The mode of action of QoI fungicides is the inhibition of mitochondrial respiration.</p> <p>The applicant provided a detailed description of both active substances included in BAS 736 00 F fungicide, their mode of action, discussed the risk of resistance, and presented known cases of resistance to individual active substances used as a single products.</p> <p>The plant pathogens describing in this report are recognized as showing a high to low risk of development of resistance to fungicides, and it depends on pathogen, disease pressure, country and location of field. According to FRAC Pathogen Risk List (september, 2019) the plant pathogens such as: <i>Blumeria graminis</i> (powdery mildew), <i>Ramularia collo-cygni</i> (Ramularia leaf spot) are recognized as showing a high risk of development of resistance to fungicides, <i>Zymoseptoria tritici</i> (Septoria leaf blotch), <i>Pyrenophora tritici-repentis</i> (tan spot), <i>Pyrenophora teres</i> (net blotch) are recognized as showing a medium</p>
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risk and *Puccinia triticina* (brown rust), *Puccinia striiformis* (yellow rust), *Puccinia hordei*, *Puccinia recondita* and *Puccinia coronata* (rusts), *Rhynchosporium secalis* (leaf scald) and *Parastagonospora nodorum* (glume blotch) as showing a low risk of development of resistance to fungicides.

BAS 736 00 F may be used twice a year on the same field and this increases the risk of resistance development. Therefore, the product label should include a complete strategy of risk development. For the use of BAS 736 00 F the key to resistance management is to reduce selection pressure by using a combination of the following techniques: crops rotation, cultural techniques (non-chemical weed control methods), herbicide rotation and herbicide mixtures. The risk management strategy to reduce the risk of resistance development to fluxapyroxad and azoxystrobin should be based on Good Agricultural Practices (GAP) and recommendations of FRAC to apply the label recommended rate, the proper application time relative to risk for disease development, the use of fungicides with different mode of actions, checking the performance of the crop protection products to ensure adequate efficacy is achieved, and also the use of the non-chemical methods of prevention and protection against diseases, including cultural and agronomic methods depending on the soil and climatic conditions.

Conclusion. The modified risk and the resistance management strategy proposed by the applicant seems to be sufficient to manage the risk to an acceptable level. This strategy is in line with recommendations of the HRAC and there is no need of any additional specific recommendations to avoid resistance. The full recommendations for minimize the risk of resistance development on fluxapyroxad and azoxystrobin, should be included in the label of tested product.

3.4 Adverse effects on treated crops (KCP 6.4)

In this chapter, results from all trials (with or without diseases) are presented for the phytotoxicity (3.4.2). Concerning yield and quality data, only results from efficacy trials without diseases, which situation is equivalent to selectivity trials, are presented here in order to provide supporting evidence. Results from efficacy trials with disease were presented in chapter 3.2.

Trials with no disease or trials with disease below the infection threshold in the untreated are considered as trials without disease for purpose of this chapter.

Information on trials submitted (3.4: Adverse effects on treated crops)

This information concerns trials which are considered as disease free. Trial methodology and standard products used in the trials without disease were the same as in the trials with disease which were presented in chapter 3.2 of the BAD.

Altogether 7 trials without disease in wheat, 5 trials in barley, 1 trial in triticale and 3 trials in oats are presented in this section.

All trials were conducted between 2019 and 2020. The target dose rate was the same as in the efficacy trials: 2 L/ha of BAS 736 00 F was applied according to the GAP.

BAS 9314 1 F known as Proline at the dose rate of 0.8 L/ha (prothioconazole 250 g/L) or its UK version BAS 9314 4 F at 0.72 L/ha (prothioconazole 275 g/L) were applied.

The distribution of trials by country and year and by EPPO zone is provided in Table 3.4-1.

Table 3.4-1: Distribution of trials by location and year; Trials without disease

Crop	EPPO Zone	Country	Year		TOTAL
			2019	2020	per country
Wheat	Maritime	CZ	2	0	2
		FR	2	1	3
		UK	0	1	1
	North East	PL	0	1	1
Barley	Maritime	UK	1	3	4
	North East	LT	1	0	1
Triticale	North East	PL	1	0	1
Oats	Maritime	UK	3	0	3
Total ALL					16

3.4.1 Phytotoxicity to host crop (KCP 6.4.1)

Phytotoxicity to the host crop was tested in a large number of trials with or without disease in wheat (113), barley (82), rye (21), triticale (21) and oats (6). Trials were carried out on a wide range of commercially grown varieties.

No symptom of phytotoxicity was recorded in any trial.

In conclusion, BAS 736 00 F at the target dose rate according to the GAP can be considered perfectly selective of wheat, barley, rye, triticale and oats.

Table 3.4-2: Phytotoxicity of BAS 736 00 F, Wheat

Number of trials with...		Efficacy trials (113 trials)			
		with disease (106 trials)		without disease (7 trials)	
		BAS 736 00 F	Standard	BAS 736 00 F	Standard
		2 L/ha	1 N	2 L/ha	1 N
Maximum of phytotoxicity recorded during the trials	0% to 5%	106	106	7	7
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	106	106	7	7
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-

Table 3.4-3: Phytotoxicity of BAS 736 00 F, Barley

Number of trials with...		Efficacy trials (82 trials)			
		with disease (77 trials)		without disease (5 trials)	
		BAS 736 00 F	Standard	BAS 736 00 F	Standard
		2 L/ha	1 N	2 L/ha	1 N
Maximum of phytotoxicity recorded during the trials	0% to 5%	77	77	5	5
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	77	77	5	5
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-

Table 3.4-4: Phytotoxicity of BAS 736 00 F, Rye

Number of trials with...		Efficacy trials with disease (21 trials)	
		BAS 736 00 F	Standard
		2 L/ha	1 N
Maximum of phytotoxicity recorded during the trials	0% to 5%	21	21
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-
Level of symptoms at the last assessments	0% to 5%	21	21
	>5% to 10%	-	-
	>10% to 15%	-	-
	>15 %	-	-

Table 3.4-5: Phytotoxicity of BAS 736 00 F, Triticale

Number of trials with...		Efficacy trials (21 trials)			
		with disease (20 trials)		without disease (1 trial)	
		BAS 736 00 F	Standard	BAS 736 00 F	Standard
		2 L/ha	1 N	2 L/ha	1 N
Maximum of phytotoxicity recorded during the trials	0% to 5%	20	20	1	1
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	20	20	1	1
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-

Table 3.4-6: Phytotoxicity of BAS 736 00 F, Oats

Number of trials with...		Efficacy trials (6 trials)			
		with disease (3 trials)		without disease (3 trials)	
		BAS 736 00 F	Standard	BAS 736 00 F	Standard
		2 L/ha	1 N	2 L/ha	1 N
Maximum of phytotoxicity recorded during the trials	0% to 5%	3	3	3	3
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-
Level of symptoms at the last assessments	0% to 5%	3	3	3	3
	>5% to 10%	-	-	-	-
	>10% to 15%	-	-	-	-
	>15 %	-	-	-	-

Comments of zRMS	Phytotoxicity to host crop
	The selectivity of BAS 736 00 F (Miralon) was tested in the trials with or without diseases: in total 113 trials in wheat, 82 in barley, 21 in rye, 21 in triticale and 6 in oat. Among those trials there were 7 trials without disease in wheat, 5 trials in barley, 1 trial in triticale and 3 trials in oat. The trials without disease or trials with disease below the infection threshold in the untreated were considered as trials without disease. The selectivity was assessed in all efficacy trials.
	All the trials were carried out by the contractor companies and official Research Institutes officially recognized for efficacy testing of plant protection products by the authorities of relevant countries, according to GEP, in accordance with EPPO general guidelines: PP 1/135 (4), PP 1/152 (4), PP 1/181 (4), PP 1/223 (2), PP 1/239 (2) and specific guidelines: EPPO PP 1/26 (4) and CEB n°218. No major deviation from the EPPO guidelines was observed.
	ZRMS confirms that the trials were conducted with the proper methods, there was no deviations from EPPO guidelines. The level of infestation by pathogens was considered as acceptable to validate the trials.
	The results of the trials both with and without disease did not show any phytotoxicity of tested fungicide to all tested cereal crops. It should be concluded that BAS 736 00 F at the target dose rates according to the GAP table can be considered completely selective to wheat, barley, rye, triticale and oats.

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

Yield data from efficacy trials with disease were provided in chapter 3.2.4. Results from disease free trials (including the trials with very low infection below the minimum infection threshold) in wheat, barley and triticale are presented in this chapter. No disease-free trials are available in rye and oats. In the tables, the effect of the maximum dose of 2 L/ha which represents the worst case scenario is compared to the effect of the reference.

Wheat

A total of 7 trials on wheat with no or very low symptoms of disease, carried out between 2019 and 2020 in Germany, France, Poland and the United Kingdom, have been harvested to confirm the yield response of BAS 736 00 F in the absence of diseases.

A summary of the data from is presented in Table 3.4-7.

Across all trials, the results with 2 L/ha of BAS 736 00 F demonstrate no statistically significant negative impact on the yield in dt/ha in comparison to the untreated.

Table 3.4-7: Yield in absence of disease (in dt/ha and % of UTC), Wheat; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 6	mean (min-max)	88.4 (43.9-119.9)	90.7 (47.6-118.8)	103.4 (99.1-109.4)	89.9 (45.4-118.2)	101.9 (98.6-107.7)
North east	n = 1	mean (min-max)	90.1 (90.1-90.1)	96.3 (96.3-96.3)	106.9 (106.9-106.9)	89.7 (89.7-89.7)	99.5 (99.5-99.5)
Total ALL	n = 7	mean (min-max)	88.7 (43.9-119.9)	91.5 (47.6-118.8)	103.9 (99.1-109.4)	89.9 (45.4-118.2)	101.6 (98.6-107.7)

In conclusion, BAS 736 00 F at the proposed label rate of 2 L/ha has no negative effect on the yield of the treated wheat.

Barley

A total of 5 trials on wheat with no or very low symptoms of disease, carried out between 2019 and 2020 in Lithuania and the United Kingdom, have been harvested to confirm the yield response of BAS 736 00 F in the absence of diseases.

A summary of the data from is presented in Table 3.4-8

Across all trials, the results with 2 L/ha of BAS 736 00 F demonstrate no statistically significant negative impact on the yield in dt/ha in comparison to the untreated.

Table 3.4-8: Yield in absence of disease (in dt/ha and % of UTC), Barley; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 4	mean (min-max)	77.6 (36.1-111.8)	81.9 (37.9-119.4)	104.8 (98.4-109)	81.3 (32.9-117.3)	101.2 (91.1-110.3)
North east	n = 1	mean (min-max)	46.0 (46-46)	48.8 (48.8-48.8)	106.1 (106.1-106.1)	47.2 (47.2-47.2)	102.5 (102.5-102.5)
Total ALL	n = 5	mean (min-max)	71.3 (36.1-111.8)	75.3 (37.9-119.4)	105.1 (98.4-109)	74.5 (32.9-117.3)	101.4 (91.1-110.3)

In conclusion, BAS 736 00 F at the proposed label rate of 2 L/ha has no negative effect on the yield of the treated barley.

Triticale

One trial on triticale with no symptoms of disease, carried in the harvest year 2019 in Poland, have been harvested to confirm the yield response of BAS 736 00 F in the absence of diseases.

A summary of the data is presented in Table 3.4-10.

The results with 2 L/ha of BAS 736 00 F demonstrate no statistically significant negative impact on the yield in dt/ha in comparison to the untreated.

Table 3.4-9: Yield in absence of disease (in dt/ha and % of UTC), Triticale; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC
North east	n = 1	mean	72.7	72.8	100.1	74.7	102.6

In conclusion, BAS 736 00 F at the proposed label rate of 2 L/ha has no negative effect on the yield of the treated triticale.

Oats

A total of 3 trials on ~~oat wheat~~ with no or very low symptoms of disease, carried ~~out~~ in the harvest year 2019 in the United Kingdom, have been harvested to confirm the yield response of BAS 736 00 F in the absence of diseases.

A summary of the data is presented in Table 3.4-10.

Across all trials, the results with 2 L/ha of BAS 736 00 F demonstrate no statistically significant negative impact on the yield in dt/ha in comparison to the untreated.

Table 3.4-10: Yield in absence of disease (in dt/ha and % of UTC), Oats; summary

Eppo Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			dt/ha	dt/ha	%UTC	dt/ha	%UTC
Maritime	n = 3	mean (min-max)	113.6 (76.9-186.3)	116.9 (74.5-190.7)	103.2 (96.1-111.1)	119.7 (79.9-196.2)	105.5 (103.9-107.2)

In conclusion, BAS 736 00 F at the proposed label rate of 2 L/ha has no negative effect on the yield of the treated oats.

Comments of zRMS	<u>Effect on the yield of treated plants or plant product</u>
	Yield from the trials without disease
	Concerning the yield and its quality the trials with disease include all trials for efficacy and the trials without diseases can be concern as selectivity trials.
	The applicant submitted the yield data from disease free trials (including the trials with very low infection below the minimum infection threshold) carried out in wheat (Maritime Eppo zone - 6 trials, N-E zone - 1 trial), in barley (Maritime zone - 4 trials, N-E zone - 1 trial) in triticale (N-E zone - 1 trial) and in oats (Maritime zone - 3 trials in UK).
	BAS 736 00 F (Miralon) at the proposed label rate of 2 L/ha has no negative effect on the yield of wheat, barley and triticale. The yield of wheat and barley was higher than both from untreated plots and treated by standard product, while in triticale was comparable to untreated and to the standard. The yield of oats (obtained in UK) was slightly lower than the yield from the standard and higher than from untreated. Considering that the UK left the EU on January 31, 2020 and the studies has been started earlier, the results from this country should be considered in assessment.
	ZRMS confirms that BAS 736 00 F at the proposed label rate of 2 L/ha has no negative effect on the yield of the treated wheat, barley and triticale.

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

Yield data from efficacy trials with disease were provided in chapter 3.2.4. Results from disease free trials (including the trials with very low infection below the minimum infection threshold) in wheat, barley and triticale are presented in this chapter. No disease-free trials are available in rye and oats. In the tables, the effect of the maximum dose of 2 L/ha which represents the worst case scenario is compared to the effect of the reference.

Wheat

A total of 6 trials on wheat with no or very low symptoms of disease, carried out between 2019 and 2020, are presented in this chapter. All 6 trials provided data on hectolitre weight, 5 trials provided also data on thousand grain weight of the grains harvested from the treated wheat.

A summary of the data is presented in Table 3.4-11 and in Table 3.4-12.

Across all trials, the results with 2 L/ha of BAS 736 00 F demonstrate no negative impact on the thousand grains weight and the hectolitre weight in comparison to the untreated.

Table 3.4-11: Thousand grain weight in absence of disease (in g and % of UTC), Wheat; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC
Maritime	n = 4	mean (min-max)	38.3 (34.2-43.6)	40.7 (37.5-44.9)	106.5 (100.3-117.3)	39.3 (35.9-44.4)	102.6 (100.7-105.2)
North east	n = 1	mean (min-max)	49.8 (49.8-49.8)	50.1 (50.1-50.1)	100.5 (100.5-100.5)	50.6 (50.6-50.6)	101.6 (101.6-101.6)
Total ALL	n = 5	mean (min-max)	40.6 (34.2-49.8)	42.6 (37.5-50.1)	105.3 (100.3-117.3)	41.5 (35.9-50.6)	102.4 (100.7-105.2)

Table 3.4-12: Hectolitre weight in absence of disease (in kg and % of UTC), Wheat; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC
Maritime	n = 5	mean (min-max)	79.0 (74.8-82.3)	79.9 (75.5-84.4)	101.1 (100.1-102.6)	79.1 (74.3-81.7)	100.0 (99.3-100.9)
North east	n = 1	mean (min-max)	80.9 (80.9-80.9)	81.1 (81.1-81.1)	100.2 (100.2-100.2)	80.7 (80.7-80.7)	99.8 (99.8-99.8)
Total ALL	n = 6	mean (min-max)	79.3 (74.8-82.3)	80.1 (75.5-84.4)	101.0 (100.1-102.6)	79.3 (74.3-81.7)	100.0 (99.3-100.9)

In conclusion, BAS 736 00 F at the proposed maximum label rate of 2 L/ha has no effect on the thousand grain weight and hectolitre weight of the treated wheat.

Barley

A total of 5 trials on barley with no or very low symptoms of disease, carried out between 2019 and 2020, are presented in this chapter. All trials provided data on hectolitre weight and 3 trials provided also data on thousand grain weight of the grains harvested from the treated barley.

A summary of the data is presented in Table 3.4-13 and in Table 3.4-14.

Across all trials, the results with 2 L/ha of BAS 736 00 F demonstrate no negative impact on the thousand grains weight and the hectolitre weight in comparison to the untreated.

Table 3.4-13: Thousand grain weight in absence of disease (in g and % of UTC), Barley; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC
Maritime	n = 2	mean	50.1	51.3	102.1	49.8	99.2
		(min-max)	(44.6-55.6)	(45.1-57.5)	(100.9-103.3)	(45.3-54.3)	(97.6-100.9)
North east	n = 1	mean	59.4	60.8	102.4	60.0	101.1
		(min-max)	(59.4-59.4)	(60.8-60.8)	(102.4-102.4)	(60-60)	(101.1-101.1)
Total ALL	n = 3	mean	53.2	54.4	102.2	53.2	99.9
		(min-max)	(44.6-59.4)	(45.1-60.8)	(100.9-103.3)	(45.3-60)	(97.6-101.1)

Table 3.4-14: Hectolitre weight in absence of disease (in kg and % of UTC), Barley; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC
Maritime	n = 4	mean	62.0	61.8	99.7	61.2	98.6
		(min-max)	(54.1-68)	(52.7-68.3)	(97.5-100.8)	(50.6-68)	(93.5-100.8)
North east	n = 1	mean	63.2	63.5	100.5	63.2	100.0
		(min-max)	(63.2-63.2)	(63.5-63.5)	(100.5-100.5)	(63.2-63.2)	(100-100)
Total ALL	n = 5	mean	62.2	62.2	99.8	61.6	98.9
		(min-max)	(54.1-68)	(52.7-68.3)	(97.5-100.8)	(50.6-68)	(93.5-100.8)

In conclusion, BAS 736 00 F at the proposed maximum label rate of 2 L/ha has no effect on the thousand grain weight and hectolitre weight of the treated barley.

Triticale

One trial on triticale with no symptoms of disease, carried in the harvest year 2019 in Poland is presented in this chapter.

Assessments of the thousand grain weight and the hectolitre weight we conducted. A summary of the data is presented in Table 3.4-15 and Table 3.4-16.

The results with 1 trial in triticale demonstrate no negative impact of the treatment with 2 L/ha of BAS 736 00 F on the thousand grains weight and the hectolitre weight in comparison to the untreated.

Table 3.4-15: Thousand grain weight in absence of disease (in g and % of UTC), Triticale; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC
North east	n = 1	mean	46.7	48.0	102.9	48.3	103.4

Table 3.4-16: Hectolitre weight in absence of disease (in kg and % of UTC), Triticale; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC
North east	n = 1	mean	77.5	77.2	99.5	77.2	99.5

In conclusion, BAS 736 00 F at the proposed label rate of 2 L/ha has no negative effect on thousand grain weight and hectolitre weight of the treated triticale.

Oats

A total of 3 trials on wheat with no or very low symptoms of disease, carried in the harvest year 2019 in the United Kingdom are presented in this chapter.

Assessments of the thousand grain weight and the hectolitre weight we conducted. A summary of the data from is presented in Table 3.4-7 and in Table 3.4-18.

Across all trials, the results with 2 L/ha of BAS 736 00 F demonstrate no negative impact on the thousand grains weight and the hectolitre weight in comparison to the untreated.

Table 3.4-17: Thousand grain weight in absence of disease (in g and % of UTC), Oats; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			g	g	%UTC	g	%UTC
Maritime	n = 3	mean (min-max)	43.5 (39.7-49.8)	44.0 (41.4-49.2)	101.4 (98.8-104.3)	44.8 (41.6-49.6)	103.2 (99.4-105.6)

Table 3.4-18: Hectolitre weight in absence of disease (in kg and % of UTC), Oats; summary

EPPO Zone climatic			Untreated	BAS 736 00 F 2.0 L/ha		Standard	
			kg	kg	%UTC	kg	%UTC
Maritime	n = 3	mean (min-max)	50.8 (50.4-51.1)	51.4 (50.9-51.7)	101.3 (101.1-101.5)	51.0 (50.1-51.9)	100.4 (99.4-101.9)

In conclusion, BAS 736 00 F at the proposed label rate of 2 L/ha has no negative effect on the thousand grain weight and hectolitre weight of the treated oats.

Comments of zRMS	Effect on the quality of plants or plant products
	In the trials with no or with very low symptoms of diseases the thousand grain weight and hectolitre weight in harvested wheat, barley, triticale and oat grains were determined. The thousand grain weight was determined in 5 trials in wheat (Maritime zone – 4, N-E zone – 1), in 3 trials in barley (Maritime zone – 2, N-E zone – 1), in 1 trials in triticale (North-East EPPO zone) and in 3 trials in oat (Maritime EPPO zone). The hectolitre weight was determined in 6 trials in wheat (Maritime zone – 5, N-E zone – 1), in 5 trials in barley (Maritime zone – 4, N-E zone – 1), in 1 trials in triticale (North-East EPPO zone) and in 3 trials in oat (Maritime EPPO zone).
	The results of the trials in wheat, barley, triticale and rye, treated with BAS 736 00 F at the rate of 2 L/ha demonstrate no negative impact on the thousand grains weight and the hectolitre weight in comparison to the untreated. The data were similar or higher to those obtained from the reference product.
	ZRMS agree with applicant that « BAS 736 00 F at the proposed label rate of 2.0 L/ha has no negative effect on the thousand grain weight and hectolitre weight of the treated oats”.

3.4.4 Effects on transformation processes (KCP 6.4.4)

Bread making study

The impact of BAS 736 00 F on wheat processing procedure was performed in 6 French trials in 2019 and 2020. These studies were carried out according the recommendations of the French guidance CEB n°218 (2012): Method for the study of unintended effects of plant protection products on soft wheat quality and transformed products from wheat.

BAS 736 00 F was applied at 2 L/ha in comparison standard product BAS 9314 1 F 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

Hagberg's falling time index:

The test measures the falling time of wheat, using ground wheat in suspension in water. A good milling wheat has a high falling time, and wheat with low falling times is not normally used in milling.

This index measures indirectly the activity of the amylases which can become excessive in the presence of grains which are germinated or in germination phase. It is expressed in seconds. The scale is the following one:

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

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

Zeleny test

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

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

Chopin alveograph

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

The alveogram is characterized by the following parameters:

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

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

Source: Arvalis

Bread-making

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

- A **dough index** representing the characteristics of elasticity, viscosity, holding to the oven of the dough. A difference of 5 is considered as significant by the laboratory 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 indexes 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 summarized in Table 3.4-19.

In terms of yield, BAS 736 00 F at 2 L/ha achieved a gain of 3,7 dt/ha in comparison with the untreated control, and + 2 dt/ha compared to standard.

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 736 00 F nor the reference.

Table 3.4-19: Yield, hectoliter weight, protein content, thousand grains weight, moisture content and germination rate – bread-making trials

Mean values of 6 trials	Untreated	BAS 73600 F 2 L/ha	BAS 9314 1 F 0.8 L/ha
Yield (dt/ha)	103,8	107,5	105,5
Hectolitre weight (kg/hL))	80,2	80,5	80,0
Protein content (%)	11,9	12,0	12,0
Thousand grains weight (g)	42,0	43,7	43,1
Moisure content (%)	12,8	12,9	12,9
Germination rate (%)	99,0	98,3	99,0

● Results of the processing procedure studies

The bread making results are presented in Table 3.4-20.

Results show that BAS 736 00 F does not lead to significant modifications of ZELENY index, Hagberg's falling time index or the Chopin alveograph. BAS 736 00 F at the dose rate of 2 L/ha does not show any significant difference in comparison to the references on the processing procedure for bread-making.

To conclude, all the studies and analysis confirm that BAS 736 00 F has no negative effect on wheat quality and processing procedures.

Table 3.4-20: Yield – bread-making trials

Mean values of 6 trials	Untreated	BAS 73600 F 2 L/ha	BAS 9314 1 F 0,8 L/ha	Difference BAS 73600F/ BAS 9314 1 F	Acceptable diff.
Hagberg falling time (s)	388,7	390,9	392,3	-0,4	<10%
Sedimentation value (mm) - Zélény	40,0	39,7	39,7	0,0	<10%
Chopin Alveogram					
G	21,2	20,0	20,4	-1,6	<10%
P	68,6	70,2	72,2	-2,9	<15%
P/L	0,9	1,0	1,1	-5,6	-
W	211,0	201,7	205,3	-1,8	<20%
Bread Making					
Dough index	89,2	89,8	89,8	0,0	<5 points
Bread index	60,5	58,0	58,8	-0,8	<10 points
Bread index making	249,7	247,8	248,7	-0,8	<15 points

Brewing study

To demonstrate that BAS 736 00 F had no negative impact on brewing, a study was conducted by the IFBM (Institut Français de la Brasserie et Malterie) in 2020. Grains samples have been taken in 4 trials: 2 trials on winter barley and 2 trials on spring barley.

Results are summarised in Table 3.4-21

Conclusion

For winter barley, the results are similar between the reference and the treated samples.

For spring barley, the quantity of filtered wort (filtration test) is higher for the treated samples, but it is a positive effect. The head retention value is higher for the beer of the treated samples, but it is a positive effect. All the other results are similar between the reference and the treated samples.

Table 3.4-21: Qualitative analysis on barley

Analysis	Winter barley				Spring barley			
	Reference (Proline)	BAS 736 00 F 2 L/ha	Difference BAS 736 00 F - reference	Tolerance	Reference (Proline)	BAS 736 00 F 2 L/ha	Difference BAS 736 00 F - reference	Tolerance
Barley analysis								
Proteins content (%)	10.0	10.0	0.0	1	10.4	10.4	0.0	1
Germination index	9.6	9.6	0.0	1	9.6	9.6	0.0	1
Kernel size (%>2,5 mm)	83.5	83.9	0.4	15	91.8	91.6	-0.2	15
Deoxynivalenol (µg/kg)	15	15	0	50	0	0	0	50
T2 + HT2 (µg/kg)	0.00	2.25	2.25		84.50	132.20	47.70	
Ergosterol	8.4	7.3	-1.1	2.0	4.2	4.1	-0.1	2.0
Enniatins (µg/kg)	0.0	2.5	2.5		57.0	27.5	-29.5	
Malt analysis								
Fine grind extract (% dry matter)	79.7	79.8	0.1	1	83.6	83.9	0.3	0.5
Viscosity (mPas)	1.640	1.622	-0.018	0.1	1.508	1.498	-0.010	0.05
Soluble proteins (% dry matter)	3.48	3.48	0.00	0.2	4.68	4.70	0.02	0.2
α-amylases (D.U)	50	50	0	7	65	64	-1	7
β-glucans (mg/L)	361	357	-4	50	74	73	-1	30
Friability (% flour)	78	77	-1	10	94	94	0	10
Calcoflur: % modification	92	93	1	10	98	99	1	10
% homogeneity	80	83	3	10	94	94	0	10
Malting study								
Quantity of wort (g)	387	386	-1	10	378	395	17	10
Filtration rate (g/min)	28	29	1	15	12	17	5	10
Washing rate (g/mn)	30	30	0	15	20	28	8	10
Attenuation limit (%)	78.3	78.3	0.0	1.5	79.1	78.8	-0.3	1.5
Apparent gravity (°plato)	5.6	5.6	0.0	1	5.5	5.8	0.3	1
Brewing study								
Duration of wort filtration (min)	67	74	7	10	81	74	-7	10
Attenuation limit (%)	80.8	81.3	0.5	1.5	84.4	85.5	1.1	1.5
Free amino nitrogen (mg/l)	172	169	-3	20	254	253	-1	20
Fermentation number	1	2	1	2	1	2	1	2
Time to ferment 5°plato (h)	99	72	99	77	83	74	73	65
Time to reach 95% of fermentation extract (h)	163	139	161	142	143	134	139	115
Attenuation at 7 th day (%)	96.6	98.9	97.7	96.6	98.9	98.9	98.9	98.9
Harvested yeast viability (10 ⁸ /g)	16	18	17	22	16	22	11	19

	Winter barley						Spring barley					
Analysis	Reference (Proline)		BAS 736 00 F		Difference BAS 736 00 F - ref- erence	Toler- ance	Reference (Proline)		BAS 736 00 F		Difference BAS 736 00 F - ref- erence	Toler- ance
			2 L/ha						2 L/ha			
Apparent extract at the end of maturation (°plato)	2.4	2.8	2.4	2.4	-0.2	1	2.3	2.4	2.1	2.2	-0.2	1
Apparent attenuation at the end of maturation (%)	78.4	76.1	78.6	78.6	1.3	1.5	79.8	79.3	81.9	80.2	1.5	1.5
Beer analysis												
Alcohol (% V/V)	4.92		4.82		-0.10	0.2	4.89		4.83		-0.06	0.2
Apparent extract (plato)	2.35		2.29		-0.06	0.25	2.29		2.21		-0.08	0.25
Coulour (EBC)	4.4		4.3		-0.1	2	5.4		5.1		-0.3	2
Head retention	234		230		-4	15	227		254		27	15
Tasting												
No significant difference between reference and treated												

Comments of zRMS	Effects on transformation processes
	Bread making study
	The impact of BAS 736 00 F applied at the rate of 2 L/ha on bread making was performed in 6 trials carried out in France. During the studies the test measures the falling time of wheat, using ground wheat in water suspension, the Hagberg's falling time index, measures indirectly the activity of the amylases and also Zeleny test and Chopin alveograph were determined. During bread making the dough index, the bread index and total bread-making index were given.
	ZRMS agree with applicant statement "all the studies and analysis confirm that BAS 736 00 F has no negative effect on wheat quality and processing procedures".
	Brewing study
	The brewing studies were conducted by the IFBM in 2 trials on winter barley and 2 trials on spring barley. The studies included the barley analysis, malt analysis, malting study, brewing study, beer analysis.
	In the studies conducted by the IFBM no negative impact of BAS 736 00 F on brewing was found. ZRMS agree with applicant conclusions.

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 736 00 F because after the treatments in the efficacy trials no phytotoxic effects were seen. However, the specific case study was conducted. A summary of results is presented below.

Material and methods

Six winter wheat trials were conducted in Belgium, France, Germany, Hungary, Poland and Spain. Five winter barley trials were conducted in France (2 trials), the Netherlands, Poland and Spain. The crops were treated twice with 2,0 L/ha BAS 736 00 F at the crop growth stages BBCH 49 and 69. Then samples were collected and tested for germination capacity.

100 grains per treatment and 4 replications each were placed in small pots (16 x 26 cm) in sand and covered with 1 cm sand. The trials were carried out in a greenhouse chamber at a temperature of 20°C with 16 h

light per day. Water was applied to the crops by hand as necessary. The treated and harvested wheat and barley grains from the season 2019 were tested for seedling germination 15 to 30 weeks after harvest.

Evaluation for germination by counting the seedlings in three classes was done according to the ISTA-methods (chapter 5, The Germination Test, 2006) at growth stage (GS) 12.

- 1 – normal seedling germination
- 2 – abnormal seedling germination
- 3 – not germinated

In the absence of specific EPPO guidelines for germination trials, the studies with harvested grains have been conducted according to ISTA-methods (chapter 5, The Germination Test, 2006). This is in line with the EPPO guideline PP 1/135 (4), which refers to standard seed testing methods (ISTA) testing of propagating material. The design of the germination trials is in accordance to EPPO guideline PP 1/152 (4). Therewith the trials are valid for the evaluation of harvested grains.

Results

The untreated check of the wheat showed germination rates between 85,0 and 99,3 %, in barley it ranged between 82,8 and 98,8 %.

No significant difference in germination of the harvested seeds was determined between the grains from BAS 736 00 F treated and the untreated plots in any of the wheat or barley trials.

Table 3.4-22: Germination behaviour of wheat and barley seeds

N o	Crop	Treatment	Dose rate		Germinated plants (GS 12)					
			product	active ingredient	normal %	Tukey test	abnormal %	Tukey test	not germinated %	Tukey test
			L/ha	g/ha						
1	Wheat winter	Untreated	-	-	95,5	a	1,3	a	3,3	a
		BAS 736 00 F	2	250	94,8	a	1,8	a	3,5	a
2	Wheat winter	Untreated	-	-	96,5	a	1,0	a	2,5	a
		BAS 736 00 F	2	250	96,5	a	0,5	a	3,0	a
3	Wheat winter	Untreated	-	-	85,0	a	1,8	a	13,3	a
		BAS 736 00 F	2	250	85,0	a	2,8	a	12,3	a
4	Wheat winter	Untreated	-	-	99,3	a	0,5	a	0,3	a
		BAS 736 00 F	2	250	98,5	a	0,5	a	1,0	a
5	Wheat winter	Untreated	-	-	98,5	a	0,8	a	0,8	a
		BAS 736 00 F	2	250	98,8	a	0,8	a	0,5	a
6	Wheat winter	Untreated	-	-	96,0	a	0,8	a	3,3	a
		BAS 736 00 F	2	250	98,0	a	1,3	a	0,8	a
7	Barley winter	Untreated	-	-	82,8	a	4,0	a	13,3	a
		BAS 736 00 F	2	250	81,0	a	4,0	a	15,0	a
8	Barley winter	Untreated	-	-	98,8	a	0,8	a	0,5	a
		BAS 736 00 F	2	250	99,0	a	0,8	a	0,3	a
9	Barley winter	Untreated	-	-	91,5	a	2,5	a	6,0	a
		BAS 736 00 F	2	250	93,8	a	3,3	a	3,0	a
10	Barley winter	Untreated	-	-	98,0	a	0,8	a	1,3	a
		BAS 736 00 F	2	250	98,3	a	1,0	a	0,8	a
11	Barley winter	Untreated	-	-	90,8	a	2,3	a	7,0	a
		BAS 736 00 F	2	250	86,8	a	2,8	a	10,5	a

Conclusion

In conclusion of the germination study, previous foliar treatments with BAS 736 00 F do not have any impact on germination of the harvested wheat and barley seeds.

Comments of zRMS	<p>Impact on treated plants or plant products to be used for propagation</p> <p>The applicant submitted 6 trials with winter wheat (from 6 countries) and 5 trials with winter barley (from 4 countries), carried out in a greenhouse chamber, aimed for determination of grains germination capacity. The studies have been conducted according to ISTA-methods, which are in line with the EPPO guideline PP 1/135 (4).</p> <p>In the trials the germination capacity of winter wheat and winter barley seeds, treated twice with BAS 736 00 F, at the rate of 2.0 L/ha, was conducted and normal seedlings, abnormal and not germinated were counted.</p> <p>In winter wheat, in 3 trials the germination capacity (normal seedlings) was at the same level or comparable to untreated, in 2 trial was higher and in 1 trial was lower by 2%, in comparison to untreated. In winter barley the germination capacity in 2 trials was at the same level as from untreated, in 1 trials was higher and in 2 trial was lower, even by 4%.</p> <p>ZRMS confirms that BAS 736 00 F do not have any negative impact on germination of the harvested wheat and barley seeds.</p>
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Summary and conclusion on 3.4

No phytotoxicity was observed in any efficacy trials with or without disease after treatments with the maximum target dose rate 2.0 L/ha.

Altogether 16 trials without disease or with the disease symptoms below the threshold (7 in wheat, 5 in barley, 1 in triticale and 3 in oats) were presented and demonstrated no statistically significant negative impact on yield and qualitative parameters such as the thousand grain weight and the hectolitre weight.

Moreover foliar treatments with BAS 736 00 F do not have any impact on germination of harvested cereal seeds.

Bread making and brewing studies confirmed no negative effect on transformation processes.

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

3.5.1 Impact on succeeding crops (KCP 6.5.1)

A study has been conducted to evaluate the effect of BAS 736 00 F on different succeeding crops. The germination and growth of different crops grown in substrate treated with BAS 736 00 F has been evaluated in pot trials in the glasshouse in order to simulate the replanting of various crops following a field failure of a crop treated with BAS 736 00 F.

Guidelines covered in the succeeding crops study:

- 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 AUG 2014.docx

The following 10 species were tested:

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

Before cultivation of the crops, BAS 736 00 F was incorporated into the substrate. According to the PEC soil calculation a dose rate of 4.0 l/ha BAS 736 00 F (= 500 g active ingredient/ha fluxapyroxad+azoxystrobin) 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 light per day. The crops were watered by hand as necessary.

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.

Predicted Environmental Concentration (PEC) of BAS 736 00 F

Maximum, actual and accumulation concentrations in soil (PEC_{soil,max}, PEC_{soil,act}, PEC_{soil,acu}) were calculated for fluxapyroxad and for azoxystrobin. The calculations were carried out based on the approach given in the guidances of the FOCUS workgroup.

PECs in the field (“GAP” scenario) were calculated considering the worst-case use pattern of the formulation BAS 736 00 F and the geometry proposed by the FOCUS workgroup. PEC in succeeding crop experiments were calculated for two times higher application rate (“SOP-2” scenario), than the worst-case

use rate of BAS 736 00 F, considering the geometry of the containers used for the application in the experiments.

Table 3.5-1: PEC_{soil} of Fluxapyroxad and Azoxystrobin after yearly, multi-year application of BAS 736 00 F to cereals (GAP scenario) and maximum concentration after application in the succeeding crop experiment at twice the application rate (SOP 2)

Substance	GAP scenario			SOP 2 scenario
	PEC _{soil,plateau} [mg/kg] (20 cm tillage)	PEC _{soil,max} [mg/kg]	PEC _{soil,accu,max} [mg/kg]	PEC _{soil,act} [mg/kg]
Xemium	0.027	0.050	0.077	0.154
Azoxystrobin	0.058	0.079	0.137	0.231

Bold + grey field: relevant for the comparison between GAP scenario and the SOP-2 scenario

Results

Neither of the tested crops showed crop injury, when grown in substrate treated with BAS 736 00 F.

None of the tested crops grown in substrate treated with BAS 736 00 F exhibited a negative influence on germination rate in relation to the untreated substrate.

No negative effect on plant weight or height was observed between the crops grown in substrate treated with BAS 736 00 F and the crops grown in untreated substrate for all of the tested crops.

Conclusion

As a conclusion of all studies conducted, BAS 736 00 F does not have any negative impact on the cultivation of the tested succeeding crops.

No signs are to be found in any glasshouse or field trials that BAS 736 00 F had negative effects on following crops. This indicates that the product BAS 736 00 F presents an extremely small risk of damage to any following crop. It may therefore be concluded that there are no grounds for expecting a risk of damage to following crops due to application of BAS 736 00 F.

There is no necessity for restrictions in the choice of following crops, even in the event of crop failure on a field which has been treated with BAS 736 00 F.

Comments of zRMS	<u>Impact on succeeding crops</u>
	<p>The germination and growth of different crops, grown in substrate treated with BAS 736 00 F has been evaluated in pot trials in the glasshouse, in order to simulate the replanting of various crops following a field failure of a crop treated with BAS 736 00 F. In the studies the crop species such as: sugar beet, oilseed rape, carrot, sunflower, winter barley, pea, potato, winter wheat, broad bean and maize were sown five weeks after substrate application. BAS 736 00 F was incorporated with the substrate at the rate of twice higher than on the label. The phytotoxicity, the germination rate and the plant height in cm (for monocots) and plant weight (fresh matter) in g/plant for all crops were measured at GS 12.</p> <p>BAS 736 00 F did not have any negative impact on the crops tested for replanting crops, following a field failure of a crop treated with BAS 736. The parameters of tested crops grown in substrate treated with BAS 736 00 F were not lower than of the untreated substrate</p> <p>ZRMS agree with applicant that is no necessity for restrictions in the choice of succeeding crops.</p>

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).

Executive Summary

In a vegetative vigor test, six species of dicotyledonous plants (carrot, lettuce, oilseed rape, cabbage, soya bean, tomato) and four species of monocotyledonous plants (onion, rye grass, wheat, corn) were exposed to BAS 736 00 F to evaluate potential for adverse effects. BAS 736 00 F was applied post-emergence at growth stage BBCH 12 – 14 at 2.0 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 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 736 00 F applied at BBCH 12-14 with a rate of 2.0 L/ha did not cause effects to plant survival and plant length for all tested plant species.

Slight visual phytotoxic effects could be detected for oilseed rape and soybean.

No influence of BAS 736 00 F applied at rate of 2.0 L/ha on plant dry biomass was observed for all tested plant species, except for carrot and tomato with significant reduced biomass, but at levels of only 6 % and 5 %, respectively.

Since only a single rate was tested, no ER50 can be calculated, however, as only slight effects were observed, the ER50 is clearly > 2.0 L/ha for all species and endpoints measured.

The NOER for plant survival and plant length reduction is equal or higher than the tested rate of BAS 736 00 F. For all tested species the NOER for plant dry biomass reduction is equal or higher than the tested rate of BAS 736 00 F, except for carrot and tomato. For carrot and tomato the NOER is lower than the tested rate of 2.0 L/ha BAS 736 00 F. For all tested species the estimated NOER for plant phytotoxicity is equal or higher than the tested rate of BAS 736 00 F, except for oilseed rape and soybean. For oilseed rape and soybean, the NOER is lower than the tested rate of 2.0 L/ha BAS 736 00 F. Lower dose rates were not tested. As the observed effects are marginal, and the ER50 values are all > 2.0 L/ha in those worst-case test conditions, a practical impact is considered negligible at the maximum expected exposure level of 3% for adjacent crops after application in cereals.

Table 3.5-2: Effect of BAS 736 00 F on plant survival (% to untreated control) - 21 DAT

Plant species	Rate BAS 736 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
	2.0	6.0	6.0	6.0	100
Lettuce	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Cabbage	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Oilseed rape	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Tomato	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Soybean	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Onion	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Ryegrass	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Wheat	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100
Corn	0.0	6.0	6.0	6.0	100
	2.0	6.0	6.0	6.0	100

Treatment not significantly different to control

Table 3.5-3: Effect of BAS 736 00 F on plant length and biomass (% to untreated control) - 21 DAT

Plant species	Plant length		Biomass (dry)	
	Rate - BAS 736 00 F [L/ha] 0.0	2.0	Rate - BAS 736 00 F [L/ha] 0.0	2.0
Carrot	100.0	98.1	100.0	94.0*
Lettuce	100.0	102.1	100.0	103.4
Cabbage	100.0	105.2	100.0	97.3
Oilseed rape	100.0	102.3	100.0	101.5
Tomato	100.0	100.3	100.0	95.4*
Soybean	100.0	101.8	100.0	100.8
Onion	100.0	101.1	100.0	106.5
Ryegrass	100.0	101.1	100.0	97.9
Wheat	100.0	95.1	100.0	93.4
Corn	100.0	97.1	100.0	94.2

* significant different to the untreated control (Student t-test, one-sided smaller $\alpha=0.05$) - based on the plant length or biomass data

Table 3.5-4: No observed effects rates (NOER) (L/ha) for plant survival, phytotoxicity, plant length and biomass reduction 21 days after application of BAS 736 00 F at BBCH stage 12-14

Plant species	NOER			
	Plant survival	Phytotoxicity*	Plant length	Biomass
Carrot	≥ 2.0	≥ 2.0	≥ 2.0	< 2.0
Lettuce	≥ 2.0	≥ 2.0	≥ 2.0	≥ 2.0
Cabbage	≥ 2.0	≥ 2.0	≥ 2.0	≥ 2.0
Oilseed rape	≥ 2.0	< 2.0	≥ 2.0	≥ 2.0
Tomato	≥ 2.0	≥ 2.0	≥ 2.0	< 2.0
Soybean	≥ 2.0	< 2.0	≥ 2.0	≥ 2.0
Onion	≥ 2.0	≥ 2.0	≥ 2.0	≥ 2.0
Ryegrass	≥ 2.0	≥ 2.0	≥ 2.0	≥ 2.0
Wheat	≥ 2.0	≥ 2.0	≥ 2.0	≥ 2.0
Corn	≥ 2.0	≥ 2.0	≥ 2.0	≥ 2.0

* estimated from assessment data

Conclusion

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 2.0 L/ha BAS 736 00 F provides sufficient margins for the conclusion that no adverse effects on adjacent crops are expected from the envisioned uses of BAS 736 00 F.

Therefore, the data presented within this Annex Point justifies the recommendation of no restrictions on adjacent crops after the application of BAS 736 00 F.

Comments of zRMS	<p>Impact on other plants including adjacent crops</p> <p>In a vegetative vigor test six species of dicotyledonous plants (carrot, lettuce, oilseed rape, cabbage, soya bean, tomato) and four species of monocotyledonous plants (onion, rye grass, wheat, corn) were exposed to BAS 736 00 F to evaluate potential for adverse effects. The data did not show a negative effect of BAS 736 00 F on tested crops. ZRMS agree with applicant that the presented data justifies the recommendation of no restrictions on adjacent crops after BAS 736 00 F application.</p>
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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 summarised in Part B, Section 9 (Ecotoxicology).

3.6 Other/special studies

Tank cleaning

A study was conducted to demonstrate that residues of the plant protection product BAS 736 00 F do not remain in the spray tank after cleaning such that there is a risk to the operator or crops.

Test design

A calculation was carried out to estimate the effectiveness cleaning of spray application equipment after the use of BAS 736 00 F.

For the calculation, the maximum permissible application rate of product was used in the lowest recommended water quantity, which is 2.0 L of formulation per hectare in 100 L of water per ha, or 250 g active ingredient per ha.

To dilute the active ingredient, which remains in the technical residual quantity, to such an extent, that no plant damage occurs during a subsequent application, a “Double rinse Procedure” without any cleaning agent was supposed for the calculation. The amount of water for each cleaning cycle is 10% of the tank volume.

Summary and conclusion

In the cleaning procedure, the active ingredient is diluted to such an extent that the simulated “Double rinse Procedure” is proved to be efficient enough.

The amount of active substance that could be carried over into a following application is 0.56 g a.i./ha with a water rate of 400 L/ha. After cleaning, the active ingredient was reduced by a factor of 1:1800.

Even if a large amount of water and thus a large volume per hectare is sprayed out in the next application, which leads to a high concentration of the displaced active ingredient per hectare, no plant damage will occur.

Common agricultural practice implies cleaning of application equipment direct after use. If the field sprayer is cleaned with water immediately after the use of BAS 736 00 F, even in the most unfavorable case, the contamination in the immediately following application is negligible. Therefore, cleaning the sprayer solely with water may be regarded as completely adequate in the case of BAS 736 00 F. It is not necessary to add cleaning agents.

Protective clothing will be cleaned effectively when washed with usual laundry detergents, by the reason that agrochemical formulations are designed for excellent mixing with water.

Comments of zRMS	Tank cleaning ZRMS agree with the cleaning procedure provided by applicant.
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Physical and chemical compatibility

Data on the tank-mix compatibility have been generated for an aqueous mixture of BAS 736 00 F with other plant protection products.

The physical and chemical properties were determined on a mixture of BAS 736 00 F with 7 other plant protection products were tested. The ASTM Method E 1518-05 was followed.

The mixtures were prepared at application rates recommended for the tank mixture. The tank mix partners tested are presented in Table 3.6-1.

Table 3.6-1: Tested tank mix partners

Trade Name	BAS Code	Batch-No.	Type	Content registered
Medax Max	BAS 139 00 W	FD-171205-0009	WG	5 % Prohexadione-Calcium + 7,5 % Trinexapac-ethyl
Revysol	BAS 750 01 F	FD-170906-0008	EC	100 g/l Mefentrifluconazole
- / -	BAS 832 00 F	FD-180208-0009	EC	30 g/l Metiltetraprole + 50 g/l Mefentrifluconazole
Actirob	BAS 9101 0 S	F469G1E001	EC	842 g/l Rapsölmethylester
Adigor	BAS 9126 0 S	ALT0C02	EC	none (Adjuvant-System)
Atlantis	BAS 9377 0 H	EFKK003982	WG	0,6 % Iodosulfuron-methyl-natrium + 3 % Mesosulfuron-methyl
Axial 50	BAS 9438 1 H	CHE7B00037	EC	12,5 g/l Cloquintocet-mexyl + 50 g/l Pixonaden

The results of the tests carried out are given in Table 3.6-2.

Table 3.6-2: Tested mixtures and results of the compatibility tests

Test No.	Trade Name	BAS Code	Dose Rate	Appl. Rate	Order	pH Value	Result
1	No Tradename	736 00 F	2.000 L/ha	100 l/ha	1	6.9	compatible using agitator, shear test done
	Revysol	750 01 F	1.500 l/ha		2		
2	No Tradename	736 00 F	2.000 l/ha	100 l/ha	1	6.3	compatible using agitator, shear test done
	No Tradename	832 00 F	2.000 l/ha		2		
3	No Tradename	736 00 F	2.000 l/ha	100 l/ha	2	5.2	compatible using agitator, shear test done
	Medax Max	139 00 W	1.500 kg/ha		1		
4	No Tradename	736 00 F	2.000 l/ha	100 l/ha	1	5.9	compatible using agitator, shear test done
	Axial 50	9438 1 H	1.200 l/ha		2		
	Adigor	9126 0 S	1.000 l/ha		3		
5	No Tradename	736 00 F	2.000 l/ha	100 l/ha	2	6.9	compatible using agitator, shear test done, foaming possible
	Atlantis	9377 0 H	0.500 kg/ha		1		
	Actirob	9101 0 S	1.000 l/ha		3		

All mixtures were determined to be physically compatible and can be used in spray applications. In all mixtures no lumping and no flocculation occurred. The mixtures appeared to be homogeneous. BAS 736 00 F is apparently physically compatible with the tested products.

Azoxystrobin and fluxapyroxad, the ingredients of BAS 736 00 F, are stable in diluted aqueous conditions. Therefore, none of the functional groups are likely to react under normal tank mix conditions. The tank mix partners described in Table 3.6-1 are approved commercial products for applications in various tank mixtures as they are sufficiently stable in aqueous conditions. No indication of any chemical reaction between the mixed products was observed. Therefore BAS 736 00 F is apparently chemically compatible with the tested products.

Summary and conclusion

The tank mixtures of BAS 736 00 F with the other plant protection products described in the study were found to be homogeneous with good physical user properties at the recommended use rates. BAS 736 00 F is therefore physical compatible with the other plant protection products described in the study under normal tank mix conditions.

The physicochemical data of each mixing component, the chemical stability of the ingredients and the stable pH of the mixtures indicate that BAS 736 00 F are apparently chemically compatible with the other plant protection products described in the report.

Comments of zRMS	ZRMS agree with applicant.
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Water volumes comparison

BAS 736 00 F has been tested in the different registration trials with different water volumes to prove efficacy under a range of water volumes: 100 L/ha, 140 L/ha, 150 L/ha, 180 L/ha, 190 L/ha, 200 L/ha, 240 L/ha, 250 L/ha and 300 L/ha. The tested water volumes cover the range of 100-300 L/ha which is stated in the GAP.

In this section the performance from trials using 100, 140 or 150 L/ha representing low water volumes is compared to the performance from trials using 300 L/ha, representing high water volumes in order to demonstrate that no efficacy drop should be expected when using low water volumes.

In addition, a specific water volume trial was conducted in winter wheat in order to confirm the performance of BAS 736 00 F applied with 3 different water volumes – 100, 200 and 300 L/ha – in an orthogonal comparison.

a) Efficacy with different water volumes in efficacy trials

Efficacy of BAS 736 00 F at 1.2 and 2.0 L/ha obtained in the efficacy trials using low water volumes (100, 140 and 150 L/ha) and from the trials using high water volume (300 L/ha) is compared in this section.

The most frequent diseases of wheat and/or barley – Septoria leaf blotch, brown rust and net blotch – have been chosen for the demonstration. The same assessments are presented here as in the main efficacy section of this BAD.

The data summaries are available in Table 3.6-3 (wheat) and Table 3.6-4 (barley).

It was demonstrated on chosen efficacy trials that high efficacies of BAS 736 00 F were reached in the trials using low water volumes. No tendency to lower performance was observed at low water volumes. On the contrary, the average performance of BAS 736 00 F obtained in the trials with 300 L/ha was, on some diseases, lower compared to the performance from the trials with 100-150 L water/ha.

It should however be considered that above presented results were not obtained from orthogonal testing but from different trials with various conditions. Therefore, no general conclusions on relation between the water volume and the efficacy should be drawn.

Conclusion

It can be concluded that there was no performance drop when lower water volumes of 100 L/ha were applied. Therefore, it is justified to have a water volume range from 100-300 L/ha.

Table 3.6-3: Efficacy of BAS 736 00 F at different water volumes, TRZAW; summary

Disease					Water volume		Untreated	BAS 736 00 F				Standard	
							infect	1.2 L/ha		2.0 L/ha		infect efficacy	
								infect	efficacy	infect	efficacy	infect	efficacy
SEPTTR	2.0 vs std	100 L/ha	n = 1	mean	100.0	-	-	6.5	93.5	3.8	96.3		
		150 L/ha	n = 6	mean (min-max)	41.7 (14.3-83.1)	-	-	7.3 (0.7-19.4)	89.6 (78.7-97.2)	18.9 (1.5-52.4)	69.5 (40.9-92.2)		
		300 L/ha	n = 8	mean (min-max)	48.3 (13.3-99.8)	-	-	9.6 (3.6-24.4)	80.6 (71.7-92.3)	21.8 (4.5-70.6)	63.4 (29.2-86.6)		
	1.2 vs 2.0 vs std	100 L/ha	n = 1	mean	100.0	4.8	95.3	6.5	93.5	3.8	96.3		
		150 L/ha	n = 5	mean (min-max)	35.5 (14.3-83.1)	6.0 (0.9-22.5)	89.8 (76.9-95.8)	5.1 (0.7-19.4)	91.8 (79.9-97.2)	14.6 (1.5-52.4)	73.3 (40.9-92.2)		
		300 L/ha	n = 6	mean (min-max)	55.4 (19.4-99.8)	16.9 (4.9-37.6)	72.7 (62-84.5)	10.3 (3.6-24.4)	83.3 (75.4-92.3)	26.6 (4.5-70.6)	62.1 (29.2-86.6)		
PUCRT	1.2 vs 2.0 vs std	150 L/ha	n = 2	mean (min-max)	14.1 (14.1-14.2)	0.9 (0-1.8)	93.7 (87.6-99.8)	0.5 (0-1)	96.4 (92.9-99.8)	4.7 (1.4-8)	66.7 (43.4-90)		
		300 L/ha	n = 5	mean (min-max)	24.5 (5.8-48.8)	2.5 (0-9.6)	94.3 (80.4-100)	1.3 (0-6.2)	97.1 (87.2-100)	7.4 (0-19)	77.7 (58.2-100)		

b) Efficacy with different water volumes in a special water volume trial

To prove that BAS 736 00 F is working in the given range of water volumes a special water volumes trial was conducted in winter wheat in Germany in 2020. The trial was 4 times replicated and fully randomized. BAS 736 00 F was applied at the dose rate of 2.0 L/ha twice, at BBCH 31-32 and at BBCH 37-39, the spray interval was 16 days. The treatment was targeting *Zymoseptoria tritici*. The disease was assessed visually by estimating the intensity of attack on the leaves. The assessment at 38 DALT, BBCH 71-73 was considered for the comparison.

The tested water volumes were 100 L/ha, 200 L/ha and 300 L/ha. In comparison the standard Proline at 0.8 L/ha was tested as well.

The efficacies on *Zymoseptoria tritici* at 38 DALT achieved with water volumes 100, 200 and 300 L/ha were 84.4 %, 82.6 and 85.5% respectively. The results prove that the efficacy of BAS 736 00 F stays on a comparable level independently from the water volume the product is applied with. The level of efficacy observed in this special trial with all three water volumes corresponds to the average efficacy observed on *Zymoseptoria tritici* in wheat (as presented in efficacy chapter).

A slightly different trend was observed for the standard Proline applied at 0.8 L/ha. Here the efficacy was slightly lower when the water volume was increased.

Conclusion

The efficacy of BAS 736 00 F is comparable at the different water volumes requested in the GAP. No trend to lower efficacy at lower water volumes was observed for BAS 736 00 F.

Comments of zRMS	Water volume. ZRMS agree with applicant`s conclusion that there was no efficacy drop when lower water volumes of 100 L/ha were applied. The efficacy of BAS 736 00 F applied at the rate of 2.0 L/ha, at lower rates of water for SEPTTR control on wheat and PYRNTE and PUCCHD control on barley was higher than that of higher dose of water and this tendency was comparable to the standard product.
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RegPest Model

For some uses defended in this BAD, the number of trials available per climatic zone according to guidance given by EPPO PP 1/241 may be insufficient. Therefore, in some cases trials have been extrapolated between the zones. The key factor of extrapolation was indication from the RegPest model.

A detailed study using RegPest was done in the Biological assessment dossier in order to prove comparability of data conducted in different regions.

The RegPest analysis was used to support available data on *Puccinia striiformis* and *Blumeria graminis* in wheat, and on *Puccinia hordei*, *Rhynchosporium secalis* and *Blumeria graminis* in barley. An overview is provided in Table 3.6-5.

Table 3.6-5: Overview of proposed extrapolations between the zones in cereals

Crop	Disease	Extrapolation			
		from (region with data)			to
		EPPO	country	number of trials	EPPO
wheat	PUCCSI	North east	PL	5	South east
		Maritime	DE	6	North east
	ERYSGR	Maritime	DE	3	North east
		North east	PL	4	Maritime
barley	PUCCHD	North east	PL	6	South east
	RHYNSE	Maritime	DE	3	North east
	ERYSGH	Maritime	DE	1	North east
		South east	SK	2	North east

In the analysis, the conditions (13 indicators) of the available trials, from which the extrapolation is requested, were compared to the chosen representative regions of the concerned member states in the EPPO zone to which the extrapolation is done. From each concerned member state, to which extrapolation was done, the regions where cereal production is most concentrated were selected for analysis.

In the North east zone, Poland is the only member state relevant in the Central registration zone. Extrapolations were done from the trials out of the neighbouring countries in the Maritime (DE, CZ) or in the South east (SK) zones. The available trials were compared to 5 Polish regions which were identified as the regions with the highest cereal production area in Poland: Lubelskie, Dolnoslaskie, Wielkopolskie, Kujawsko-Pomorskie and Zachodniopomorskie.

In case of extrapolations from the North-East to the South-East zone, the following regions were identified as the region with the highest cereal production:

- Slovakia: Zapadni Slovensko
- Hungary: Dél-Alföld, Észak-Alföld and Dél-Dunántúl
- Romania: Sud – Muntenia, Sud-Est and Sud-Vest Oltenia

For *Blumeria graminis* in wheat, an extrapolation from the North east zone to the Maritime zone is proposed. As the Maritime zone consists of many different member states it was considered difficult and useless to compare the available trials to a representative region(s) of each member state. Instead, the comparison was conducted to representative regions of 3 nearest (to Poland) countries – Germany, the Czech Republic and Austria. It is proposed that each of the concerned member states of the Maritime zone decides if the extrapolation is acceptable in its case.

The following representative regions were chosen for the Maritime EPPO zone based on statistics:

- Germany: Sachsen-Anhalt and Mecklenburg-Vorpommern and Lüneburg
- Czech Republic: Jihovýchod, Stredni Cechy, Jihozapad
- Austria: Niederösterreich, Burgenland

In Germany, the information on level of NUTS2 was not available, the statistics were collected from larger subregions which in majority of cases cover several NUTS2. Exceptions where the statistical region corresponds with NUTS2 and includes large wheat areas are the region Sachsen-Anhalt and Mecklenburg-Vorpommern. In addition to it, the region Lüneburg which covers large part of Niedersachsen was chosen as one of the representative regions of Germany.

All compared regions showed similarity between 70.15-88.49%.

Comments of zRMS	<p><u>Data extrapolation</u></p> <p>ZRMS accept the data extrapolation between the zones proposed by applicant and suggest the cMS to decide by own. The extrapolation is justified by high similarity of results in the zones and close neighborhood of the individual regions (countries) for which the extrapolation is proposed.</p>
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3.7 List of test facilities including the corresponding certificates

Table 3.7-1: List of test facilities

Country	Institute/ Organisation	Address	GEP Doc ID
BG	Eurofins EOOD	Zar Kalojan 5 5570 Letniza	2015/1143221
CZ	BASF spol. s r.o.	Sokolovska 668/136d 186 00, Praha	2016/1351528
	ADW AGRO, a.s.	Krahulov 76 Okrisky 675 21	2019/2046744
	InTec Agro Trials, s.r.o.	Blatnicka 179 687 24 Uhersky Ostroh	2019/2055093
	Zemservis Domaninek	K Zamecku 1231 Bystrice nad Pernstejnem	2016/1350607
	Zkusebni stanice Nechanice	Stolbova 319, Nechanice	2020/2095629
	Zkusebni Stanice Trutnov	Volanovska 409 541 01 Trutnov	2017/1156065
DE	BASF SE	Agrarzentrum Limburgerhof Spreyerer Strasse 2 67117 Limburgerhof	2013/1412362 2018/1238674
	Hetterich Fieldwork GbR	Bambergerstraße Schwarzach-Düllstadt 97359	2019/2041586
DK	AARHUS UNIVERSITY	Department of Agroecology DK-4200 Slagelse	2014/1321454 2020/2104176
	AGROLAB DENMARK A/S	Røjleskovvej 18 DK-5500 Middelfart	2014/1327634
	BASF A/S	KALVEBOD BRYGGE 45 2. S. 1560 COPENHAGEN V	2014/1048395 2020/2079424
FI	LUKE	Tietotie 4, 31600 Jokioinen	2017/1229043
	NSL	Elisabetsgatan 21 B 8, 00170 Helsingfors	2020/2100984
FR	BASF France SAS	Division Agro, 21 Chemin de la Sauvegarde, Ecully	2017/1023856 2019/1054949
HU	BASF Hungária Kft.	Központi major. 6710 Szeged-Szentmihály	2017/1077283
IE	Crop Plot Trials	Ballinaparnon, Buck Leary Glanmire, Co.Cork	2019/2050392
	Teagasc	OakPark, Co. Carlow	2020/2099299
LT	Institute of Agriculture	Instituto ave 1 Akademija, LT-58344	2013/1418041 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
NL	BASF Nederland B.V.	Groningensingel 1, Arnhem, the Netherlands	2019/2047841
PL	UTP in Bydgoszcz	ul. Ks. Kordeckiego 20 85-225 Bydgoszcz	2010/1226832
	IPP-NRI Sosnowice	ul. Gliwicka 29 44-153 Sosnowice	2010/1226834
	IOR PIB Poznań	ul. Władysława Węgorka 20 60-318 Poznań	2011/1269209

Country	Institute/ Organisation	Address	GEP Doc ID
	Staphyt Sp. z o.o	ul. Ziębicka 2 60-164 Poznań	2011/1269203
	BASF Polska Sp. z o.o.	Al. Jerozolimskie 154 02-326 Warszawa	2011/1269204 2021/2012841
	Eurofins Agroscience Serv	Parkowa 6 Kaźmierz 64-530	2016/1318743
	SGS Polska Sp. z o.o.	Bema 83 01-233 Warsaw	2016/1350127
	Agreco Sp. z o.o.	Lipowa 21/1 53-124 Wrocław	2018/1181238
RO	AgroProspect SRL	Hoghiz Fantana Village nr. 1 Brasov country cod 507099	2013/1399864
	SGS Romania S.A.	Strada Bucovina 56 300668 Timisoara	2019/2038531
	BASF SRL	Morii, 21 917250 Tamadau Mare	2016/1135081
SE	Agrolab Sverige AB	Eslöv och Kölback	2016/1354368
SK	Blumeria Consulting s.r.o.	Ľ. Okánika 590/4 Nitra	2016/1352169
	Berberis s.r.o.	Boliarov 54 044 47 Boliarov	2017/1224930
	Vyskumny ustav rastlinnej výroby Piestany	Bratislavská cesta 122 921 68 Piestany	2017/1226421
UK	BASF Plc	WINDMILL AVENUE WOOLPIT Suffolk GL7 5PU	2018/1015310
	Eurofins Agroscience Serv	Slade Lane Wilson Melbourne DE73 8AG	2018/1103451
	Cropworks Ltd.	Bankfoot Perth PH1 4AQ	2020/2036579

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6/1	Neradova, D.	2021	Biological Assessment Dossier - BAS 736 00 F - Central Zone - zRMS: Poland 2021/2015967 BASF spol. s.r.o., Prague, Czech Republic no Unpublished	No	BASF
KCP 6.1/1	Neradova, D.	2021	Justification of the co-formulated mixture BAS 736 00 F for cereals 2021/2036686 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.2/1	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in wheat (113 trials) 2021/2042887 <none> yes Unpublished	No	BASF
KCP 6.2/2	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in barley (82 trials) 2021/2042888 <none> yes Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.2/3	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in rye (21 trials) 2021/2042890 <none> yes Unpublished	No	BASF
KCP 6.2/4	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in triticale (21 trials) 2021/2042891 <none> yes Unpublished	No	BASF
KCP 6.2/5	Anonymous	2021	Dossier Trial Data Reports: BAS 736 00 F - Efficacy trials in oats (6 trials) 2021/2042892 <none> yes Unpublished	No	BASF
KCP 6.3/1	Stammler, G.	2021	BAS 736 00 F - Resistance Risk Analysis 2021/2031889 BASF SE, Limburgerhof, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 6.4.5/1	Schuster, A.	2021	Germination trials with harvested grains from Wheat and Barley treated with BAS 736 00 F 2021/2004014 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.5.1/1	Brahm, L.	2019	Cultivation of different crops in substrate treated with BAS 736 00 F (Succeeding crops study) 2019/1067468 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.5.2/1	Maleck, A.	2019	Effect of BAS 736 00 F on vegetative vigour of ten species of terrestrial plants under greenhouse conditions 2019/1061112 Agro-Check Dr. Teresiak & Erdmann GbR, Lentzke, Germany Fed.Rep. yes Unpublished	No	BASF
KCP 6.6/1	Nord, S.	2020	Effectiveness of Procedures for Cleaning Application Equipment and Protective Clothing BAS 736 00 F 2020/2036309 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.6/2	Schlotterbeck, U.	2019	Physical and Chemical Compatibility in aqueous tank mixtures of BAS 736 00 F 2021/2004054 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.6/3	Anonymous	2021	BAS 736 00 F: Summary report on comparison of regions 2021/2042893 <none> yes Unpublished	No	BASF
KCP 6.6/4	Lopatka, A., Koza, P., Siebielec, G., Lysiak, M.	2012	Expert report regarding division of Europe into regions characterized by homogenous soil and climatic conditions, within the boundaries of which the results of efficacy evaluation of pesticides can be relevant for the entire region 2012/1368202 IUNG - Institute of Soil Science and Plant Cultivation - State Research Institute, Pulawy, Poland no Unpublished	No	BASF
KCP 6.6/5	Anonymous	2015	GEP Certificate: Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria - 2015 2015/1143221 Eurofins Agroscience Services EOOD, Letnitsa, Bulgaria no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.6/6	Anonymous	2016	GEP Certificate: BASF spol. s r.o., Praha, Czech Republic 2016/1351528 BASF spol. s.r.o., Prague, Czech Republic no Unpublished	No	BASF
KCP 6.6/7	Anonymous	2018	GEP Certificate - ADW Agro As Krahulov Czech Republic - 2018 2019/2046744 ADW Agro A.s., Krahulov, Czech Republic no Unpublished	No	BASF
KCP 6.6/8	Anonymous	2018	Rozhodnutí InTec Agro Trials spol sro, Uhersky Ostroh, Czech Republic 2019/2055093 InTec Agro Trials spol sro, Uhersky Ostroh, Czech Republic no Unpublished	No	BASF
KCP 6.6/9	Anonymous	2016	GEP Certificate: Zemservis zkusebni stanice Domaninek s.r.o., Bystrice nad Pernštejnem, Czech Republic - 2016 2016/1350607 Zemservis zkusebni stanice Domaninek s.r.o, Bystrice nad Pernštejnem, Czech Republic no Unpublished	No	BASF
KCP 6.6/10	Anonymous	2016	GEP Certificate: Zkusebni stanice Nechanice, s.r.o., Nechanice, Czech Republic - 2016 2020/2095629 Zkusebni stanice Nechanice s.r.o., Nechanice, Czech Republic no Unpublished	No	BASF
KCP 6.6/11	Anonymous	2016	GEP Certificate - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic - 2017 2017/1156065 ZST - Zkusebni Stanice Trutnov s.r.o, Trutnov, Czech Republic no Unpublished	No	BASF

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 6.6/12	Anonymous	2013	GEP Certificate: BASF SE Agrarzentrum Limburgerhof, Germany, 2013 2013/1412362 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.6/13	Anonymous	2018	GEP Certificate - BASF SE Agrarzentrum Limburgerhof Germany - 2018 2018/1238674 BASF SE, Limburgerhof, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.6/14	Anonymous	2019	GEP Certificate - Hetterich Fieldwork GbR Schwarzach - Germany 2019/2041586 Hetterich Fieldwork GbR, Schwarzach, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.6/15	Anonymous	2013	GEP Certificate - Aarhus University (diseases and pests), Slagelse, Denmark 2014-2019 2014/1321454 University of Aarhus, Slagelse, Denmark no Unpublished	No	BASF
KCP 6.6/16	Anonymous	2020	GEP Certificate - Aarhus University - Department of Agroecology (diseases and pests), Flakkebjerg, Denmark - 2020 2020/2104176 Aarhus University, Aarhus, Denmark no Unpublished	No	BASF
KCP 6.6/17	Anonymous	2013	GEP Certificate: Agrolab A/S, Field Trials, Middelfart, Denmark, 2014 2014/1327634 Agrolab A/S, Middelfart, Denmark no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.6/18	Anonymous	2014	GEP Certificate: BASF A/S, Copenhagen, Denmark, 2014 2014/1048395 BASF Denmark A/S, Copenhagen, Denmark no Unpublished	No	BASF
KCP 6.6/19	Anonymous	2020	GEP certificate BASF A/S Kobenhavn Denmark 2020 2020/2079424 BASF Denmark A/S, Copenhagen, Denmark no Unpublished	No	BASF
KCP 6.6/20	Anonymous	2017	GEP Certificate - Luke Jokionen Finland - 2016-2023 2017/1229043 Natural Resources Institute Finland (Luke), Jokioinen, Finland no Unpublished	No	BASF
KCP 6.6/21	Anonymous	2017	GEP Certificate - Nylands Svenska Lantbrukssällskap (NSL) Finland 2016-2023 2020/2100984 Nylands Svenska Lantbrukssällskap (NSL), Helsingfors, Finland no Unpublished	No	BASF
KCP 6.6/22	Anonymous	2017	GEP Certificate - BASF France SAS Ecully France - 2017 2017/1023856 BASF Agro SAS, Ecully, France no Unpublished	No	BASF
KCP 6.6/23	Anonymous	2019	GEP Certificate: BASF France SAS, Ecully, France, 2019 2019/1054949 BASF France SAS, Ecully, France no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.6/24	Anonymous	2017	GEP Certificate - BASF Hungaria Kft - Budapest - Hungaria - 2017 2017/1077283 BASF Hungaria Kft., Budapest, Hungary no Unpublished	No	BASF
KCP 6.6/25	Anonymous	2019	Trials permit certificate - Crop-Plot Trials C/O Buck Leary's Cross, Ballinaperson, Glanmire, Co. Cork, Ireland - 2019 2019/2050392 <none> no Unpublished	No	BASF
KCP 6.6/26	Anonymous	2020	Trials permit certificate - Teagasc Carlow Ireland - renewal 2020 2020/2099299 Teagasc, Carlow, Ireland no Unpublished	No	BASF
KCP 6.6/27	Anonymous	2013	GEP certificate - Lithuanian Institute of Agriculture, Akademija Lithuania - 2013-2019 2013/1418041 Lithuanian Institute of Agriculture, Akademija, Lithuania no Unpublished	No	BASF
KCP 6.6/28	Anonymous	2019	GEP certificates for Institute of Agriculture - LAMMC- Lithuania 2020/2105312 Department of Soil and Crop Management - Institut of Agriculture, LAMMC, Akademija, Lithuania no Unpublished	No	BASF
KCP 6.6/29	Anonymous	2017	GEP Certificate: UAB Agrolab Baltic, Vilnius, Lithuania, 2017 2017/1014490 UAB Agrolab Baltic, Vilnius, Lithuania no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.6/30	Anonymous	2016	GEP Certificate - Latvijas Augu aizsardzības pētniecības centrs, Rīga, LV 2016/1350437 Latvian State Centre of Plant Protection, Riga, Latvia no Unpublished	No	BASF
KCP 6.6/31	Anonymous	2019	GEP Certificate: SIA Baltic Trial Station, Riga, Latvia, 2019 - 2024 2020/2079667 SIA Agrolab Baltic, Riga, Latvia no Unpublished	No	BASF
KCP 6.6/32	Anonymous	2019	GEP Certificate - BASF Nederland BV Arnhem 2019 2019/2047841 BASF Nederland BV, Arnhem, Netherlands no Unpublished	No	BASF
KCP 6.6/33	Anonymous	2010	GEP Certificate - Uniwersytet Technologiczno - Przyrodniczy im. Jana i Jędrzeja Śniadeckich - Wydział Rolnictwa i Biotechnologii - Katedra Fitopatologii i Mikologii Molekularnej, Bydgoszcz, Poland 2010/1226832 <none> no Unpublished	No	BASF
KCP 6.6/34	Anonymous	2010	GEP Certificate - Institute of Plant Protection - National Research Institute in Poznań - Sosnowice Branch - Pesticide Efficacy Testing Department, Poland 2010/1226834 <none> no Unpublished	No	BASF
KCP 6.6/35	Anonymous	2011	GEP Certificate - Instytut of Plant Protection - National Research Institute - Department of Plant Protection Products - Team for Fungicide Investigation, Poznań, Poland 2011/1269209 Institute of Plant Protection - National Research Institute, Poznań, Poland no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.6/36	Anonymous	2011	GEP Certificate - Agrostat Sp. z.o.o., Poland 2011/1269203 Agrostat Sp. z o.o., Poznan, Poland no Unpublished	No	BASF
KCP 6.6/37	Anonymous	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 6.6/38	Anonymous	2021	GEP Certificate - BASF Polska Spolka zo.o Warszawa - Poland - 2021 2021/2012841 BASF Polska Sp. z o.o., Warsaw, Poland no Unpublished	No	BASF
KCP 6.6/39	Anonymous	2016	GEP Certificate - Eurofins Agroscience Service GmbH 2016 2016/1318743 Eurofins Agroscience Services GmbH, Stade, Germany Fed.Rep. no Unpublished	No	BASF
KCP 6.6/40	Laczynski, T.	2016	GEP Certificate - SGS Polska Sp. zo.o Warswa Poland - Translation 2016/1350127 SGS Polska Sp. zo.o., Warsaw, Poland no Unpublished	No	BASF
KCP 6.6/41	Anonymous	2018	GEP Certificate: AGRECO Sp. z o.o., Wroclaw, Poland 2018 2018/1181238 AGRECO Sp. z o.o., Wroclaw, Poland no Unpublished	No	BASF

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 6.6/42	Anonymous	2013	GEP Certificate - SC AgroProspect SRL Brasov, Romania, 2013 2013/1399864 SC AgroProspect Srl, Brasov, Romania no Unpublished	No	BASF
KCP 6.6/43	Anonymous	2018	GEP Certificate - SGS Romania SA - AFL seed & Crop - 2018 2019/2038531 SGS Romania SA - AFL seed & Crop, Timisoara, Romania no Unpublished	No	SGS
KCP 6.6/44	Anonymous	2016	GEP Certificate - S.C. BASF SRL Calarasi Romania - 2016 2016/1135081 S.C. BASF SRL, Calarasi, Romania no Unpublished	No	BASF
KCP 6.6/45	Anonymous	2016	GEP Certificate - Agrolab Sverige AB - Eslov - Sweden - 2016 2016/1354368 Agrolab Sverige AB, Eslov, Sweden no Unpublished	No	BASF
KCP 6.6/46	Anonymous	2016	GEP Certificate: Blumeria consulting sro, Nitra, Slovakia, 2016-2021 2016/1352169 Blumeria consulting s.r.o., Nitra, Slovakia no Unpublished	No	BASF
KCP 6.6/47	Anonymous	2017	GEP Certificate - Berberis s.r.o., Boliarov, Slovakia 2017/1224930 Berberis s.r.o., Boliarov, Slovakia no Unpublished	No	BASF

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 6.6/48	Anonymous	2017	GEP Certificate - NPPC - Vyskumny ustav rastlinnej vyroby Piestany, Piestany, Slovakia 2017 2017/1226421 VURV - Vyskumny Ustav Rastlinnej Vyroby Piestany, Piestany, Slovakia no Unpublished	No	BASF
KCP 6.6/49	Anonymous	2018	GEP Certificate: BASF plc, United Kingdom, 2018 2018/1015310 BASF plc, Cheadle Cheshire SK8 6QG, United Kingdom no Unpublished	No	BASF
KCP 6.6/50	Anonymous	2018	GEP Certificate - Eurofins Agrosience Services Ltd. - United Kingdom - 2018-2022 2018/1103451 Eurofins Agrosience Services Ltd., Melbourne Derbyshire DE73 8AG, United Kingdom no Unpublished	No	BASF
KCP 6.6/51	Anonymous	2020	GEP Certificate - Cropworks Limited, UK, April 2020 - Feb 2025 2020/2036579 Cropworks Ltd., Bankfoot Perth PH1 4AQ, United Kingdom 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 studies submitted with this section.

The following tables are to be completed by MS

List of data submitted by the applicant and not 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 XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

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 XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner