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FINAL REGISTRATION REPORT

Part A

Risk Management

Product code: BAS 758 00 F

Product name(s): REVYFLEX PLUS

Chemical active substance(s):

Mefentrifluconazole, 66.6 g/L
Metrafenone, 100.0 g/L

Pyraclostrobin, 80.0 g/L

Central Zone

Zonal Rapporteur Member State: Poland

NATIONAL ASSESSMENT Poland

(authorization)

Applicant: BASF

Submission date: March 2022

MS Finalisation date: 15/06/2023

Version history

When	What
03/2022	Initial dRR – BASF DocID 2021/2031096
04/2022	Dossier sent for evaluation
10/2022	zRMS evaluation of dRR
January 2023	Final version prepared by zRMS after Commenting period
June 2023	zRMS updated finalised evaluation

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PART A

RISK MANAGEMENT

1 Details of the application

This document describes the acceptable use conditions required for the national registration of BAS 758 00 F, containing 66.67 g/L Mefentrifluconazole, 80.0 g/L Pyraclostrobin and 100.0 g/L Metrafenone in Poland.

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10 and Part C as well as in the national addendum where appropriate.

The Registration Report includes the assessment of further data or information as required for a registration at national level in accordance with the conclusions from the EU review of the active substance. It also includes assessment of data and information relating to BAS 758 00 F where that data has not been considered in the EU review.

Appendix 1 of this document provides a copy of the final product authorization in Poland.

Appendix 2 of this document is a copy of the approved product label for Poland.

Appendix 3 of this document contains copies of the letters of access to third party data needed for evaluation of the formulation (not applicable for this formulation).

Appendix 4 of this document contains the lists of data considered for national authorization.

1.1 Application background

Applicant:

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The application was submitted for the approval of BAS 758 00 F, an EC formulation containing 66.67 g/L Mefentrifluconazole, 80.0 g/L Pyraclostrobin and 100.0 g/L Metrafenone for the use in cereals.

1.2 Letters of Access

Not necessary

1.3 Justification for submission of tests and studies

BAS 758 00 F is a new plant protection product.

Testing is conducted according to the data requirements for the authorisation of plant protection products and is conducted in compliance with national and international animal welfare regulations. The testing strategy takes into account methods compliant with the 3R concept for refinement, reduction and replacement of animal testing where applicable and acceptable.

Reasoning is provided in Section B documents.

Testing has been conducted in order to fulfil the data requirements for plant protection products and in order to demonstrate an acceptable use of the plant protection product.

1.4 Data protection claims

Data protection is claimed in accordance with Article 59 of Regulation (EC) No. 1107/2009 as provided for in the list of references in Appendix 4.

2 Details of the authorization decision

2.1 Product identity

Product code	BAS 758 00 F
Product name in MS	Revyflex Plus
Authorization number	Not yet assigned
Function	Fungicide
Applicant	BASF
Active substance(s) (incl. content)	Mefentrifluconazole; 66.67 g/L Metrafenone, 100.0 g/L Pyraclostrobin; 80.0 g/L
Formulation type	Emulsifiable concentrate [Code: EC]
Packaging	See following table, professional user
Coformulants of concern for national authorizations	Not applicable
Restrictions related to identity	For detailed information see Part B section 1.2.3
Mandatory tank mixtures	Not applicable
Recommended tank mixtures	Not applicable

Packaging:

BAS 758 00 F is to be marketed in high-density polyethylene (HDPE) containers with an inner barrier, e.g., polyamide (PA/PE) or fluorination (f-HDPE), with a minimum wall thickness of 0.7 mm. They are sealed by foil seals or gasket, protected by screw caps of polyethylene.

Packaging information for 0.15 litre bottle

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	cylindrical / approx. 63 mm diameter x 92 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Packaging information for 0.25 litre bottle

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	cylindrical / approx. 63 mm diameter x 127 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Packaging information for 0.5 litre bottle

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	cylindrical / approx. 69 mm diameter x 185.5 mm
Opening:	42 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Packaging information for 1 litre eco-bottle

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	cylindrical / approx. 88.5 mm diameter x 234 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Packaging information for 5 litre eco-container

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	rectangular / approx. 185 mm x 136 mm x 313 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Packaging information for 10 litre eco-container

Type	Description
Material:	PA/PE (Coex) or f-HDPE
Shape/size:	rectangular / approx. 230 mm x 187 mm x 358 mm
Opening:	54 mm inner diameter
Closure:	screw cap
Seal:	Induction sealed or gasket

Packaging information for 20 litre container

Type	Description
Material:	f-HDPE (fluorinated)
Shape/size:	Rectangular / approx.. 285 x 237 x 424 mm
Opening:	52 mm inner diameter
Closure:	screw cap
Seal:	Gasket

Packaging information for 50 litre container

Type	Description
Material:	f-HDPE (fluorinated)
Shape/size:	cylindrical / approx. 380 mm x 618 mm (d x h)
Opening:	52 mm inner diameter
Closure:	screw cap or valve
Seal:	Gasket

2.2 Conclusion

The evaluation of the application for Revyflex Plus (BAS 758 00 F) resulted in the decision to grant the authorization (see the GAP in a table of paragraph 2.6).

2.3 Substances of concern for national monitoring

No further information is required.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

The following classification is proposed in accordance with Regulation (EC) No 1272/2008:

Hazard class(es), categories:	Acute Tox. 4 (oral)

	Acute Tox. 4 (inhalation – mist) Skin ~~Corr./~~Irrit. 2 Eye Dam./~~Irrit.~~ 1 Skin Sens. 1 STOT SE 3 Aquatic Acute 1 Aquatic Chronic 1

The following labelling information is derived from the classification and to be mentioned in the safety data sheet. The information which is determined for the **label is formatted bold:**

Hazard pictograms:	 **GHS05**, **GHS07**, **GHS09**
Signal word:	Danger
Hazard statement(s):	**H318: Causes serious eye damage** **H315: Causes skin irritation** **H317: May cause an allergic skin reaction** **H335: May cause respiratory irritation** **H302 + H332: Harmful if swallowed or inhaled** **H400: Very toxic to aquatic life** **H410: Very toxic to aquatic life with long lasting effects**
Precautionary statement(s):	P101: If medical advice is needed, have product container or label at hand P102: Keep out of reach of children P103: Read carefully and follow all instructions
Preventions	P260: Do not breathe mist or vapour P264: Wash contaminated body parts thoroughly after handling P270: Do not eat, drink or smoke when using this product **P271: Use only outdoors or in a well-ventilated area** P272: Contaminated work clothing should not be allowed out of the workplace **P280: Wear protective gloves and eye protection or face protection**
Response	**P310: Immediately call a POISON CENTER or physician** **P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.** P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing P302 + P352: IF ON SKIN: Wash with plenty of soap and water P330: Rinse mouth P391: Collect spillage P362 + P364: Take off contaminated clothing and wash it before reuse
Storage	**P403 + P233: Store in a well-ventilated place. Keep container tightly closed.** P405: Store locked up
Disposal	**P501: Dispose of contents and container to hazardous or special waste collection point.**
Additional labelling phrases:	To avoid risks to human health and the environment, comply with the instructions for use. [EUH401].

See Part C for justifications of the classification and labelling proposals.

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application

	equipment near surface water/Avoid contamination via drains from farmyards and roads).
SPe3	1-2 x 1.0 L/ha To protect aquatic organisms respect an unsprayed buffer zone of 5 m or 75% drift-reducing nozzles 1-2 x 1.5 L/ha To protect aquatic organisms respect an unsprayed buffer zone of 10 m to surface water bodies including a 10 m vegetated filter strip

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

2.5.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Operator protection:	
-	Workwear due to exposure calculations. Protective clothing, protective gloves, face/eye protection during handling, mixing and loading due to hazard characterisation
Worker protection:	
-	Work wear (arms, body and legs covered)
Environmental protection	
	1-2 x 1.0 L/ha To protect aquatic organisms respect an unsprayed buffer zone of 5 m or 75% drift-reducing nozzles 1-2 x 1.5 L/ha To protect aquatic organisms respect an unsprayed buffer zone of 10 m to surface water bodies including a 10 m vegetated filter strip
Other specific restrictions	
	No additional specific restrictions apply.

The authorization of the PPP is linked to the following conditions (voluntary labelling):

None proposed.

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None proposed.

2.6 Intended uses (only NATIONAL GAP)

GAP rev., date: 2021-12-17

PPP (product name/code):	Revyflex Plus/BAS 758 00 F	Formulation type:	EC (a, b)
Active substance 1:	mefentrifluconzole*	Conc. of as 1:	66.67 g/L (c)
Active substance 2:	metrafenone**	Conc. of as 2:	100 g/L (c)
Active substance 3:	pyraclostrobin***	Conc. of as 3:	80 g/L (c)
Safener:	n.a.	Conc. of safener:	n.a. (c)
Synergist:	n.a.	Conc. of synergist:	n.a. (c)
Applicant:	BASF	Professional use:	☒
Zone(s):	central (d)	Non professional use:	☐
Verified by MS:	yes		

Field of use: fungicide

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)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	PL	wheat TRZAW	F	*Oculimacula spp.* - PSDCHE *Blumeria graminis* - ERYSGR *Zymoseptoria tritici* - SEPTTR *Puccinia triticina* - PUCCRT *Puccinia striiformis* - PUCCST *P. tritici-repentis* - PYRNTR	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** / 0,120*** b) 0,200* / 0,300** / 0,240***	100 - 300	56	For eyespot control, only one application at BBCH 30-32

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)	**Remarks:** e.g. g safener/synergist per ha [f]
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
2	PL	barley HORVW HORVS	F	*B. graminis* - ERYSGR *Pyrenophora teres* - PYRNTE *R. secalis* - RHYNSE *Puccinia hordei* - PUCCHD	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** / 0,120*** b) 0,200* / 0,300** / 0,240***	100 - 300	56	
3	PL	rye SECCW SECCS SECCE	F	*R. secalis* - RHYNSE *Puccinia recondita* - PUCCRE	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** / 0,120*** b) 0,200* / 0,300** / 0,240***	100 - 300	56	
4	PL	triticale TTLWI	F	*B. graminis* - ERYSGR *Septoria spp*. - SEPTSP *Puccinia recondita* - PUCCRE *Puccinia striiformis* - PUCCST	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** / 0,120*** b) 0,200* / 0,300** / 0,240***	100-- 300	56	
5	PL	wheat TRZAS	F	*Puccinia striiformis* - PUCCST *P. tritici-repentis* – PYRNTR	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** / 0,120*** b) 0,200* / 0,300** / 0,240***	100 - 300	56	For eyespot control, only one application at BBCH 30-32

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l
(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 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
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.
7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions

3 Background of authorization decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a yellow, clear liquid, with a moderate sweet odour. It is not explosive, has no oxidizing properties. The product has no flash point up to a temperature of 105.0°C. It has a self-ignition temperature of 275.0°C. In aqueous solution, it has a pH value around 5.6 at 23°C. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. Extrapolation of the results of the accelerated storage stability at 54°C for 14 days indicate that for a period of a least two years the product remains suitable for use and continues to comply with the specifications. Its technical characteristics are acceptable for an EC formulation.

The intended concentration of use is 0.5% to 1.5%.

Studies regarding the combination of BAS 758 00 F with other plant protection products were submitted and the application as tank mixture is acceptable. The following preparations were tested in combination with BAS 758 00 F and all were compatible and good applicability remained: Imtrex XE (BAS 700 09 F, EC), No tradename (BAS 830 01 F, EC), Proline (BAS 9314 1 F, EC), Turbo (BAS 008 00 D, GR), Medax Top (BAS 122 08 W, SC), Camposan Extra (BAS 067 10 W, SL), Medax Max (BAS 139 00 W, WG), CCC 750 (BAS 062 03 W, SL), Moddus Start (BAS 9053 7 W, DC), Calma (BAS 9053 6 W, EC), Duplosan DP (BAS 044 26 H, SL), Biathlon 4 D (BAS 812 00 H, WG), Dash EC (BAS 160 00 S, EC), Ariane C (BAS 9517 0 H, EC), Axial 50 EC (BAS 9438 1 H, EC), Adigor (BAS 9126 0 S, EC), Atlantis Flex (BAS 9583 1 H, WG), Biopower (BAS 9140 1 S, SL), Atlantis (BAS 9377 0 H, WG), Actirob B (BAS 9101 0 S, EC), Avoxa (BAS 9673 0 H, EC), Broadway (BAS 9512 0 H, WG), Pixxaro EC (BAS 9628 1 H, EC), Zypar (BAS 9647 0 H, OD), Pirimor Granulat (BAS 9005 0 I, GR), Sumicidin Alpha (BAS 314 03 I, EC), Decis forte (BAS 9034 4 I, EC), Karate Zeon (BAS 9158 2 I, CS), Teppeki (BAS 9146 0 I, WG), Broadway Netzmittel (BAS 9101 1 S, EC). Yet, according to GAP table - REVYFLEX PLUS is not intended to be used in tank mixture with other product. So, the information is considered as supplementary.

3.2 Efficacy (Part B, Section 3)

The robust data set of 203 field trials is presented. The selection of trials based on relevance of the trial to the current documentation (presented trials were mainly conducted in countries from GAP table), acceptable disease pressure on untreated plots, decent performance of the standard(s).

3.3 Efficacy data

BAS 758 00 F is to be used in cereals (wheat, barley, rye, triticale and oats). The main targets for the use of BAS 758 00 F are the pathogens: *Zymoseptoria tritici, Septoria spp., Puccinia spp., Pyrenophora tritici-repentis, Oculimacula spp., Pyrenophora teres, Blumeria graminis, Rhynchosporium secalis and Ramularia collo-cygni*. A total dataset of 203 efficacy trials on winter wheat (103), spring wheat (2), winter barley (49), spring barley (13), rye (16), triticale (17) and oats (3) were used to support the efficacy on the different diseases in Central registration zone. All the efficacy trials are performed according to GEP and EPPO-Guidelines. The data show very good effects on the various diseases. Especially the performance towards Septoria leaf blotch and brown rust is outstanding. The trials confirm the claim made in the introduction that BAS 758 00 F is a highly effective fungicide, offering a valid opportunity for the control of important pathogens of cereals.

The effectiveness of BAS 758 00 F on cereals against following diseases in PL:

winter wheat at a dose rate 1,5 L/ha	• **SEPTTR** *Zymoseptoria tritici* **(E)** • **PUCCRT** *Puccinia triticina* **(E)** • **PUCCST** *Puccinia striiformis* **(E)** • **ERYSGR** *Blumeria graminis* **(E)** • **PYRNTR** *Pyrenophora tritici – repentis* **(E)** • **PSDCHE** *Oculimacula yallundae* **(ME)**
spring wheat at a	• **PUCCST** *Puccinia striiformis* **(E)**

dose rate 1,5 L/ha	• **PYRNTR** *Pyrenophora tritici – repentis* **(E)**
winter barley at a dose rate 1,5 L/ha	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)** • **RHYNSE** *Rhynchosporium secalis* **(E)** • ***ERYSGR** Blumeria graminis **(E)***
spring barley at a dose rate 1,5 L/ha	• **PYRNTE** *Pyrenophora teres* **(E)** • **PUCCHD** *Puccinia hordei* **(E)** • **RHYNSE** *Rhynchosporium secalis* **(E)** • **ERYSGR** *Blumeria graminis* **(E)**
winter triticale at a dose rate 1,5 L/ha	• **SEPTTR** *Septoria tritici* **(E)** • **PUCCRE** *Puccinia recondita* **(E)** • **PUCCST** *Puccinia striiformis* **(E)** • **ERYSGR** *Blumeria graminis* **(E)**
rye at a dose rate 1,5 L/ha	• **PUCCRE** *Puccinia recondita* **(E)** • **RHYNSE** *Rhynchosporium secalis* **(E)**

BAS 758 00 F effectively controlled diseases in cereals at dose rate 1,5 l/ha applied one time in season, in trials presented for the NE EPPO climate zone (PL). In trials on winter wheat against PSDCHE the product performed medium effectively.

The Applicant is requesting max 2 applications of the product per season (for *Oculimacula spp*. only one application), with a minimum of 14 days between applications and between growth stages 30-59. For PSDCHE application time is BBCH 30-32 of wheat.

To confirm the efficacy of BAS 758 00 F at different application dates, the Applicant has submitted an extensive package of efficacy trials, with treatments carried out at a wide range of developmental stages of crops, taking into account the different requirements of individual pathogens as to the developmental stages of plants at which they are usually infected.

The presented number of trials against ERYSGR on winter barley and spring barley does not meet the registration requirements in Poland. Nevertheless, the product performed efficiently and at similar efficiency level at a dose of 1.5 l/ha in the Maritime zone. That is why it is proposed to be conditionally present on the label until the number of trials is completed.

Two applications may prove necessary in practice, for example, at the onset of pressure from another disease when the long-term efficacy of the first fungicide dose has come to an end. An example is the control of cereal eyespot, at the early growth stage of winter wheat BBCH 30-32 and brown rust occurring at BBCH 49-59. In such a situation, a treatment carried out at an earlier stage - BBCH 30-32 against cereal eyespot may no longer be effective against brown rust. It will therefore be necessary to carry out a second treatment of the season.
The Applicant has not submitted trials with two applications for the NE zone. However, in several trials in the Maritime zone (in DE- 13 trials and in CZ – 1 trial) effectiveness of the product was evaluated after 2 applications: on winter wheat (against: SEPTTR, PUCCTR, PUCCST, ERYSGR, PYRNTR) into 7 trials, on winter barley (against: PYRNTE, PUCCHD, ERYSGR, RHYNSE, RAMUCC) into 7 trials.
Trials from neighbouring countries (Germany and the Czech Republic) can be used to prove that there is no negative effect of double application of BAS 758 00 F on protected plants in Poland. These studies were conducted under agro-climatic conditions similar to those prevailing in Poland. Using the RegPest model, the Applicant presented an example comparison of agroclimatic conditions for the Lower Silesian and Warmian-Masurian provinces and regions in Germany. The similarity of agroclimatic conditions of the regions was shown to be about 80%, which, according to the model, indicates a very low risk of different behaviour of the same product in these regions.

The results in trials with two applications indicated that effectiveness of the product was prolonged as a result of the second application. The product maintained high efficacy after both 1 and 2 applications. What is more twice application of the product was safe for crops as there were no symptoms of phytotoxicity and no impact of yield, hectolitre weight of harvested grain and thousand grain weight.

Taking into account the above considerations, it may be concluded that 2 applications of the product per

season will be safe to crops and it is proposed to adopt it.

3.3.1 Information on the occurrence or possible occurrence of the development of resistance

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 758 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. BASF actively participates in the FRAC meetings for all presently established Working Groups. In this way every attempt is made to formulate and promote resistance management strategies and the rational use of its fungicides.

3.3.2 Adverse effects on treated crops

No phytotoxicity was observed in the efficacy trials after treatments with the maximum target dose rate 1.5 L/ha. For yield and quality, a positive impact is measured. The same was observed in trials without diseases. Moreover, foliar treatments with BAS 758 00 F do not have any impact on germination of harvested cereal seeds.

3.3.3 Observations on other undesirable or unintended side-effects

Result of the studies indicate that there is no necessity for restrictions in the choice of succeeding crops and adjacent crops after the application of BAS 758 00 F.

3.4 Methods of analysis (Part B, Section 5)

3.4.1 Analytical method for the formulation

The analytical method AFL1019/01 was developed for the determination of the active substances Mefentrifluconazole (Reg. 5834378), Pyraclostrobin (Reg. 304428) and Metrafenone (Reg. 4037710) in BAS 758 00 F (EC - formulation) and validated according SANCO/3030/99 rev. 5. The samples are analyzed using liquid chromatographic procedure that employs DAD/UV detection and external calibration. The separation is achieved by reversed phase chromatography using gradient conditions with acetonitrile, methanol, tetrahydrofuran, formic acid and water on a RP-C18 or ODS-H80 columns. The evaluation of the UHPLC / HPLC analyses was carried out by comparison of the peak areas with an authentic external reference item by applying bracketing calibration.

Relevant impurities:

The analytical method AFL0944/03 is used for the determination of the relevant impurity N,N-Dimethylformamide (Reg.No. 159267) in BAS 758 00 F (EC - formulation) and validated according CIPAC Guidelines on method validation, SANCO/3030/99 rev.5, EPA OPPTS 830.1000, EPA OPPTS 830.1800 and ABNT NBR 14029. The samples are analyzed using a gas chromatographic procedure that employs external standard. The separation is achieved by using gradient conditions for detection and quantification. A RTX-200 column or equivalent is used. The analyses are detectedusing a MS detector and quantified by comparing the specific response ratio of the sample with those of the standard of known quality.

The analytical method AFL1023/01 was used for the determination of the relevant impurity Toluene (Reg.No. 4005250) in BAS 758 00 F (EC - formulation) and validated according CIPAC Guidelines on method validation, SANCO/3030/99 rev.5, EPA OPPTS 830.1000, EPA OPPTS 830.1800 and ABNT NBR 14029. The samples are analyzed using a GC-MS procedure that employs external standard.The separation is achieved by using gradient conditions for detection and quantification.A RTX 200 column or equivalent is used. The analyses are detected using a MS detector and quantified by comparing the specific response ratio of the sample with those of the standard of known quality.

The analytical method AFL0977/06 was used for the determination of the relevant impurity 1,2,4-(1H)-Triazole (Reg.No. 87084) in BAS 758 00 F (EC - formulation) and validated according CIPAC Guidelines on method validation, SANCO/3030/99 rev.5, EPA OPPTS 830.1000 and EPA OPPTS 830.1800. All samples are analysed using a high-performance liquid chromatograph with MS-detector. A Synergi

Polar-RP 4 µm, 150 x 4.6 mm column (or equivalent type) is used. The separation is achieved by using isocratic conditions with water, acetonitrile and formic acid for detection and quantification followed by a rinsing step with a high acetonitrile ratio and an equilibration step. The calculation of the test item concentration is carried out by comparison of the peak area of the sample with those of an external standard series applying a linear function.
A validated method for the determination of dimethyl sulfate in "BAS 758 00 F" could not be developed. Known amounts of dimethyl sulfate spiked to both the test item and the blank formulation in the range of 0.0488 mg/kg to 4.88 mg/kg could not be detected. The water content of the test item was found to be 0.4 g/100g (The water content of the blank formulation BAS 758 00 F, however, could not be determined due to insufficient amount of substance). Therefore, it can be assumed that fortifications of both dimethyl sulfate and dimethyl-D6 sulfate were hydrolysed by residual water. This, in turn, means that it is not possible to determine dimethyl sulfate concentrations as low as required (0.05 mg/kg) in this kind of sample matrix.

3.4.2 Analytical methods for residues

Mefentrifluconazole

The analytical methods developed for mefentrifluconazole (BAS 750 F) in plant and animal matrices were already submitted and evaluated in context of the previous process of Annex I Inclusion of mefentrifluconazole excepting of a new enforcement water method with its ILV, which are submitted with the current dossier.

Plant and plant products:

The analytical method for determination of mefentrifluconazole in foodstuffs of plant origin (BASF Method L0076/09) is based on LC-MS/MS (using HPLC or UPLC) with an LOQ of 0.01 mg/kg. It was validated for a diverse range of representative plant matrices (all OECD crop groups). This method is used for data generation purposes.

An analytical LC-MS/MS method (L0295/01) based on QuEChERS was developed and validated, analyzing the parent compound with an LOQ of 0.01 mg/kg. This method based on LC-MS/MS determination is suitable for enforcement purposes. An independent laboratory validation (ILV) was carried out successfully. Therefore, this method can be use as enforcement method for BAS 750 F in plant matrices.

Food of animal origin:

An analytical LC-MS/MS method (L0272/01) was developed and validated, analyzing BAS 750 F with an LOQ of 0.01 mg/kg, for cow liver, kidney, muscle, fat, milk and cream and hen egg. This method based on LC-MS/MS determination is suitable for enforcement and data generation purposes.

An analytical GC-MS method (L0309/01) was developed and validated, analyzing the metabolite M750F022 with an LOQ of 0.01 mg/kg for animal matrices. This method based on GC-MS determination is suitable for enforcement purposes and data generation.

An independent laboratory validation (ILV) was carried out successfully for both methods (L0272/01 and L0309/01). The EU residue definition for BAS 750 F for monitoring purposes is parent only in food of animal origin.

Soil

An analytical LC-MS/MS method (L0214/01) was developed and validated, analyzing BAS 750 F with an LOQ of 0.002 mg/kg. This method based on LC-MS/MS determination is suitable for enforcement purposes and data generation. The EU residue definition for BAS 750 F for monitoring purposes is parent only.

Water

BAS 750 F can be determined using BASF analytical method L0359/01 using LC/MS/MS with a limit of quantification of 30 ng/L. An independent laboratory validation (ILV) was carried out successfully in drinking and surface water. The EU residue definition for BAS 750 F for monitoring purposes is parent only.

Air

BAS 750 F in air can be determined (L0327/01) by sucking air through adsorption tubes (ORBOTM) for about 6 hours. The tube content is then extracted with acetonitrile and analysed by LC/MS-MS. The limit of quantification corresponded to a concentration of 0.01 µg/L air.

Body Fluids

An analytical method was developed and validated for the determination of BAS 750 F in body fluids (L0339/01) with a limit of quantification of 0.01 mg/kg.

Metrafenone

The analytical methods developed for metrafenone (BAS 650 F) in plant and animal matrices were already submitted and evaluated by the RMS in the context of the ongoing AIR renewal for metrafenone.

Plant and plant products:

The analytical method for determination of metrafenone in foodstuffs of plant origin (BASF Doc ID 2011/7007816) is based on LC-MS/MS with an LOQ of 0.01 mg/kg. It was validated for a diverse range of representative plant matrices.

In addition validated BASF methods L0076/01 (HPLC MS/MS, LOQ 0.1 mg/kg) and L0339/02 (HPLC MS/MS, LOQ 0.01mg/kg) were used in the residues trials submitted with this application.

Food of animal origin:

An analytical LC-MS/MS method (BASF Doc ID 2014/1181105) was developed and validated, analyzing metrafenone with an LOQ of 0.01 mg/kg, for liver, kidney, muscle, fat, milk and egg. This method is suitable for enforcement and data generation purposes. An independent laboratory validation (ILV) was carried out successfully. The EU residue definition for metrafenone for monitoring purposes is parent only in food of animal origin.

Soil

An analytical HPLC-MS/MS method (BASF Doc ID 2014/1181107) was developed and validated, analyzing metrafenone with an LOQ of 0.005 mg/kg. This method based on LC-MS/MS determination is suitable for enforcement purposes. The EU residue definition for metrafenone for monitoring purposes is parent only.

Water

Metrafenone can be determined using BASF analytical method (BASF Doc ID 2014/1181109) using HPLC/MS/MS with a limit of quantification of 0.05 µg/L. An independent laboratory validation (ILV) was carried out successfully in drinking water. The EU residue definition for metrafenone for monitoring purposes is parent only.

Air

Metrafenone in air can be determined (BASF Doc ID 2014/1181110) by sucking air through adsorption tubes. The tube content is then extracted with acetone and analysed by HPLC/MS-MS. The limit of quantification 0.03 mg/m^3.

Body Fluids

An analytical method was developed and validated for the determination of metrafenone in body fluids (BASF Doc ID 2018/1029049) with a limit of quantification of 0.05 mg/L.

Pyraclostrobin

The analytical methods for the determination of pyraclostrobin in foodstuffs of plant and animal origin were evaluated in the previous Annex I inclusion process and during more recent evaluations performed by EFSA in the context of MRL applications.

During the re-registration process of pyraclostrobin analytical methods for residues were submitted to Germany as designed Rapporteur Member State. All analytical methods are active substance data, which were provided for the EU review of pyraclostrobin. Due to the broad use of pyraclostrobin containing formulations, the scope of the methods has been considerably expanded over the past years.

For the determination of pyraclostrobin in foodstuffs of plant origin, a single residue method using LC-MS/MS method (421/0) was evaluated and adequately validated for the determination of pyraclostrobin with an LOQ of 0.02 mg/kg in high water (wheat forage), high acidic (grapes, orange), high oil (peanut), high starch content (wheat grain) commodities (Germany, 2001). An additional method (D9904) using HPLC-UV was also evaluated and adequately validated for the determination of pyraclostrobin in high acidic (grapes, orange), high starch (wheat grain) and high oil (peanut) content plant matrices with an LOQ of 0.02 mg/kg (Germany, 2001).
The general suitability of these methods has been already confirmed by EFSA in the recently published Reasoned Opinion on MRLs (Review of established MRLs according to Reg. 396/2005 (Art. 12); EFSA Journal 2011;9(8):2344). In the context of this evaluation a data gap for a validated method in coffee beans has been identified. Therefore, in the frame of the Annex I renewal a new method validation (445/0) in combination with LC-MS/MS detection was submitted and is included in this submission as well.

Additionally, a new method (535/1) using LC-MS/MS was evaluated and adequately validated for the determination of pyraclostrobin in plant matrices with an LOQ of 0.01 mg/kg in high water (tomato, onion, lettuce), high starch (wheat grain), high acid (lemon) and high oil (oilseed rape) content commodities and included in this submission. Furthermore, a new method using LC-MS/MS in combination with enzymatic cleavage was developed for the determination of the pyraclostrobin metabolite 500M79.
Independent laboratory validations were submitted for LC-MS/MS method (421/0), including validation of difficult matrices (hops) and HPLC-UV method (D9904).
The data shows that pyraclostrobin can be enforced in food of plant origin of all categories (high water, high acid, high oil, high protein/starch content and difficult matrices) using LC-MS/MS (421/0, D9904) with an LOQ of 0.02 mg/kg.

In addition, the QuEChERS method (determination using GC-MS and/or LC-MS/MS) is sufficiently validated at the LOQ of 0.01 mg/kg for the determination of pyraclostrobin in plant matrices. The use of the multi residue method for the determination of pyraclostrobin residues is widely published in the Internet.

For food of animal origin a peer reviewed LC-UV method (439/0) exists for pyraclostrobin with a validated LOQ of 0.01 mg/kg in milk and 0.05 mg/kg in muscle, liver, kidney, fat and eggs. In order to allow an efficient enforcement of pyraclostrobin parent residues using up-to-date technology (LC-

MS/MS) method L0151/01 replaces the previously submitted LC-UV method 439/0. It was also validated in blood to cover the requirement for an analytical method for body fluids and tissues.
As required in SANCO 825/00 and the relevant OECD guidance document, the validation data include a confirmatory technique (second transition).

For data generation purposes, a common moiety method was developed in the context of the previous Annex I inclusion process. It is based in the hydrolytic degradation of BAS 500 F and its metabolites to 500M04 and 500M85. For proving the suitability of the method, which has been used in the cow feeding study, the common moiety has been newly validated for key metabolites identified in the livestock metabolism studies (BASF Method no. 446/2, L0058/03). The principle of the common moiety approach from 2000 was kept; only the final quantitation technique (LC-MS/MS instead of GC-MS) was changed.

In order to support the poultry feeding study, the common residue analytical method (D9902) used for sample analysis is provided.

Analytical methods for the determination of pyraclostrobin residues in water, soil and air were submitted in the course of the EU review.

For the quantification of pyraclostrobin in water, a new method was submitted with a LOQ of 0.003 µg/L using LC-MS/MS for analysis. The method used for determination of residues of pyraclostrobin in drinking water has been successfully confirmed by a new independent laboratory validation (ILV).

For the quantification of pyraclostrobin in air, a new method was submitted with a LOQ of 4.44 ng/L air using LC-MS/MS for analysis.

For the quantification of pyraclostrobin in soil, two new methods were submitted with a limit of quantification (LOQ) of 0.001 mg/kg using LC-MS/MS for analysis.

The methods have been considered acceptable and suitable for the determination of pyraclostrobin residues in the respective matrix.

zRMS: *accepted (please, see also the B5 section).*

3.5 Mammalian toxicology (Part B, Section 6)

BAS 758 00 F is an organic-solvent based EC-type product (emulsifiable suspension concentrate) that contains the active substances mefentrifluconazole (66.67 g/L), metrafenone (100 g/L) and pyraclostrobin (80 g/L). It is intended to be used for tractor-mounted applications to cereals.

Based on hazard properties of the product or the ingredients contained the product is to be classified for toxicological hazards with H302 “Harmful if swallowed”, H332 “Harmful if inhaled”, H315 “Causes skin irritation”, H317 “May cause an allergic skin reaction”, H318 “Causes serious eye damage” and H335 “May cause respiratory irritation”. Gloves, protective clothing and eye/face protection should be worn when handling the undiluted product.

A toxicological relevance assessment for potential groundwater metabolites of mefentrifluconazole, pyraclostrobin and metrafenone was not required, because all concentrations of parent molecules or of derived metabolites are predicted to stay below 0.1 µg/L.

Dermal absorption estimates to be used in the non-dietary risk assessment are 0.2% and 6.3% for mefentrifluconazole, 0.008% and 2.6% for pyraclostrobin and default dermal absorption estimates of 25% and 70% for metrafenone for the undiluted and spray-strength diluted product, respectively.

The relevant reference values for the non-dietary risk assessment (AOEL) are 0.035 mg/kg bw/day for mefentrifluconazole, 0.015 mg/kg bw/d for pyraclostrobin, and 0.43 mg/kg bw/day for metrafenone. For acute exposures, an AAOEL of 0.15 mg/kg bw has been derived for mefentrifluconazole. No AAOEL has been established at EU-level for pyraclostrobin or metrafenone.

3.5.1 Acute toxicity

BAS 758 00 F is harmful if swallowed or inhaled, requiring a classification with H302 and H332, but is of low toxicity by the dermal route of exposure. BAS 758 00 F is a skin irritant and can cause serious eye damage, requiring classification with Skin Irrit. 2, H315 and Eye Dam. 1, H318. Moreover, the product is considered a skin sensitizer requiring a classification with Skin Sens. 1, H317.

The acute toxicity of BAS 758 00 F was evaluated using weight-of-evidence approaches. Following the provisions of Article 56 of Reg 1107/2009, a rat acute oral toxicity study was carried out because non-additive phenomena were suspected and therefore a prediction from the product composition (no classification) was deemed potentially unreliable. The results of the oral study triggered a more severe classification of the product (i.e. harmful if swallowed). Therefore, and considering the product contains ingredients posing hazards by the inhalation route of exposure, a rat acute inhalation toxicity with BAS 758 00 F was performed subsequently, the results triggering product classification as harmful if inhaled. No concern for acute dermal toxicity was concluded based on oral-to-dermal extrapolation and evidence for low potential of the product to enhance dermal absorption.

In-vitro skin corrosion/irritation studies with the product confirmed the prediction of the calculation approach as skin irritant. The in-vitro assays for eye irritation (EpiOcular) clearly indicated an eye irritating/corrosion potential (without being capable of discriminating between eye corrosion and eye irritation), while the product indicated an eye damaging potential. Thus, taking also into consideration the classifications of components of the formulation as well as a precautionary approach BAS 758 00 F was classified with Eye Dam. 1; H318, although the results of the in-vitro test on isolated chicken eye revealed that formulation BAS 758 00 F does not require classification in this hazard class. BAS 752 00 F was considered a skin sensitizer based on the product composition.

3.5.2 Operator exposure

Operator exposure to mefentrifluconazole, pyraclostrobin and metrafenone has been assessed for application of BAS 758 00 F in cereals using downward directed vehicle mounted application equipment. The estimates are based according to EFSA guidance on the AOEM.

For an operator wearing protective clothing, protective gloves, face/eye protection during handling, mixing and loading a safe use could be demonstrated for individual exposure to the active ingredients contained as well as considering combined exposure. Thus, operators are not at risk when exposed to BAS 758 00 F.

3.5.3 Worker exposure

Re-entry worker exposure to mefentrifluconazole, pyraclostrobin and metrafenone has been assessed when applied as BAS 758 00 F in cereals. The exposure scenario considered a worker entering a field for scouting and irrigation activities that had before been treated twice with BAS 758 00 F. The estimates are based on the model proposed in the EFSA guidance.

For a worker wearing work wear with arms and legs covered a safe use could be demonstrated for individual exposure to the active ingredients contained as well as considering combined exposure. Thus, workers are not at risk when exposed to BAS 7528 00 F while entering treated fields.

3.5.4 Bystander and resident exposure

Re-entry worker exposure to mefentrifluconazole, pyraclostrobin and metrafenone has been assessed when applied as BAS 758 00 F in cereals. The exposure scenario considered a bystander and residents living by or entering a field that had before been treated twice with BAS 758 00 F. The estimates are based on the model proposed in the EFSA guidance.

For bystanders and residents, a safe use could be demonstrated for individual exposure to the active ingredients contained as well as considering combined exposure. Thus, bystanders and residents are not at risk when exposed to BAS 758 00 F under use-conditions.

3.6 Residues and consumer exposure (Part B, Section 7)

zRMS: *The applicant comments have been accepted. The data available for BAS 758 00 F are considered sufficient for risk assessment. An exceedance of the current MRL of 0.05 mg/kg (wheat, rye and triticale) and 0.6 mg/kg (barley and oat) for mefentrifluconazole and 0.07 mg/kg (wheat, rye and triticale) and 0.6 mg/kg (barley and oat) for metrafenone and 0.2 mg/kg (wheat, rye and triticale) and 1.0 mg/kg (barley and oat) for pyraclostrobin as laid down in Reg. (EU) 396/2005 is not expected.*
The chronic and the short-term intakes of mefentrifluconazole, metrafenone, pyraclostrobin, and TDMs residues are unlikely to present a public health concern.
In the absence of agreed guidance on estimating combined acute and chronic exposure (Art. 4 of Regulation (EC) No. 1107/2009), an indicative Hazard Indexes (HIs) can be derived to show specifically for the intended uses, that the combined exposure from TDMs is very low. A HI <1 indicates absence of a health concern even if dose-addition of active ingredients is assumed. All HIs obtained by the applicant were below 1 (see paragraph 7.5).
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended uses.

3.6.1 Residues

Mefentrifluconazole

The metabolism and residue studies of mefentrifluconazole (BAS 750 F) have been evaluated by the Rapporteur Member State (United Kingdom) and the EFSA in context of the Approval procedure (DAR and EFSA conclusion). Further MRLs for BAS 750 F were recently published in Europe.
BAS 758 00 F was not the representative formulation in the EU dossier of BAS 750 F. Therefore, additional studies wheat and barley are submitted to support the registration of the formulated product BAS 758 00 F.
No new MRLs are proposed for BAS 750 F for wheat and barley (including oat, rye and triticale) in this document.

Metrafenone

The metabolism and residue studies of metrafenone (BAS 560 F) have been evaluated by the Rapporteur Member State (United Kingdom) and the EFSA in context of the Approval procedure (DAR and EFSA conclusion). The MRLs for metrafenone are published in Regulation (EC) No 396/2005 amended by Reg. (EU) 2018/687.
BAS 758 00 F was not the representative formulation in the EU dossier of BAS 560 F. Therefore, additional studies wheat and barley are submitted to support the registration of the formulated product BAS 758 00 F.

No new MRLs are proposed for BAS 560 F for wheat and barley (including oat, rye and triticale) in this document.

Pyraclostrobin

The metabolism and residue studies of pyraclostrobin (BAS 500 F) have been evaluated by the Rapporteur Member State (Germany) in context of the Annex I inclusion/AIR3 procedure (RAR Rev. 1, Germany 2020). The MRLs for pyraclostrobin are published in Regulation (EC) No 396/2005 amended by Reg. (EU) 2020/1633.

BAS 758 00 F was not the representative formulation in the EU dossier of pyraclostrobin. Therefore, additional studies in wheat and barley are submitted to support the registration of the formulated product BAS 758 00 F.

No new MRLs are proposed for pyraclostrobin for wheat and barley (including oat, rye and triticale) in this document.

3.6.2 Consumer exposure

Mefentrifluconazole

The results of the IEDI calculations taking into account residues in food commodities of plant and animal origin, show that there is no chronic risk for consumers. Regarding the IESTI calculations, also no acute risk for consumers was identified.

BAS 750 F: TMDI: The TMDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.035 mg/kg bw/day applying default and established MRLs of Reg. (EU) 2021/590.
The ADI utilization ranges from 1 to 32% ADI. The highest TMDI was 32% ADI for the "NL toddler", the highest contributor are apples (12% ADI).
The TMDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

IEDI: The IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.035 mg/kg bw/day.
The ADI utilization ranges from 0.4 to 7% of the ADI. The diet with the highest IEDI is "NL toddler" with 7% of the ADI. For this diet, the highest contributor is apple with 2% of the ADI. The diet with the second highest IEDI is "DE child" with 6% of the ADI, in which also apple is the major contributor with 3% of the ADI.
The IEDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

IESTI: A refined IESTI calculation was performed with the current EFSA model (version 3.1) using an ARfD of 0.15 mg/kg bw/day.
For children, the highest ARfD utilization was 0.4% for consumption of barley and second highest for wheat (0.1%). For adults, the highest ARfD utilization was 0.3% for consumption of barley.
For processed commodities, the highest ARfD utilization was 0.4% for consumption of barley/milling (flour) for children and 0.1% for adults for consumption of oat / boiled.
In both cases the IESTI is well below the ARfD for all commodities and European sub-population groups, therefore no health effects due to acute exposure are expected.

TDMs: IEDI: The IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.023 mg/kg bw/day for 1,2,4-T, 0.3 mg/kg bw/day for TA and TLA and 1 mg/kg bw/day for TAA.
The maximum ADI utilization is 48% (NL toddler) for 1,2,4-T, 4% (NL toddler) for TA and 1% (NL toddler) for TAA and TLA of the ADI. The highest contributor is milk (cattle) (42%) for 1,2,4 T, maize, corn (1%) for TA, maize, corn (0.6%) for TAA and milk (cattle) (0.6%) for TLA.
The IEDI is well below the ADI for all European sub-population groups, therefore no

health effects due to chronic exposure are expected.

IESTI: A refined calculation was performed with the current EFSA model (version 3.1) using an ARfD of 0.1 mg/kg bw/day for 1,2,4-T, 0.3 mg/kg bw/day for TA and TLA and 1 mg/kg bw/day for TAA.
For children, the highest ARfD utilization was for consumption of wheat: 0.7% for 1,2,4-T, 3% for TA and 1% for TAA and for consumption of barley 0.1% for TLA. For adults, the highest ARfD utilization was for consumption of wheat: 0.4% for 1,2,4-T, 2% for TA, 0.7% for TAA and for consumption of barley 0.1% for TLA.

For processed commodities, the highest ARfD utilization was for consumption of wheat / milling (flour): 0.6% for 1,2,4-T, 1% for TA, 0.8% for TAA and for consumption of barley / milling (flour): 0.2% for TLA for children. For adults, the highest ARfD utilization was for 1,2,4-T 0.4% for consumption of barley / beer, for TA 0.9% for consumption of wheat / bread/pizza, 0.4% for TAA for consumption of barley / beer and 2% for TLA for consumption of barley / beer.
In all cases the IESTI is well below ARfD for all commodities and European sub-population groups, therefore no health effects due to acute exposure are expected.

Metrafenone

Since the GAP for BAS 758 00 F does not lead to higher residues in cereals than have already been assessed, no additional consumer exposure assessments have been conducted.
Chronic consumer exposure resulting from the authorised uses reported in the EFSA Article 12 review (EFSA Journal 2013; 11(12); 3498) was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 1.8% of the ADI (French all population). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.
In the present evaluation for exposure re-estimation EFSA PRIMo 3.1 obviously was used (see B7).

The proposed uses of metrafenone in the formulation BAS 758 00 F do not represent unacceptable chronic risks for the consumer.

Pyraclostrobin

The results of the IEDI calculations taking into account residues in food commodities of plant and animal origin, show that there is no chronic risk for consumers. Regarding the IESTI calculations, also no acute risk for consumers was identified.

TMDI: The TMDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.03 mg/kg bw/day applying default and established MRLs of Reg. (EU) 2020/1633.
The ADI utilization ranges from 4 to 83% ADI. The highest TMDI was 83% ADI for the “DE child”, the highest contributor are oranges (27% ADI).
The TMDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

IEDI: The IEDI calculation was performed with the current EFSA model (version 3.1) using an ADI of 0.03 mg/kg bw/day. In context of IEDI calculations the ADI utilization ranges from 2 to 31% of the ADI. The diet with the highest IEDI is "NL toddler" with 31% of the ADI. For this diet, the highest contributor is milk (cattle) with 14% of the ADI. The diet with the second highest IEDI is “DE child” with 18% of the ADI, in which apples is the major contributor with 6% of the ADI.
The IEDI is well below the ADI for all European sub-population groups, therefore no health effects due to chronic exposure are expected.

IESTI: A refined calculation was performed with the current EFSA model (version 3.1) using an ARfD of 0.03 mg/kg bw/day. For children, the highest ARfD utilization was 6% for consumption of barley and second highest for oat (1%). For adults, the highest ARfD utilization was 6% for consumption of barley.

For processed commodities, the highest ARfD utilization was 4% for consumption of oat/boiled and barley/cooked for children and 29% for adults for consumption of barley/beer.
In all cases the IESTI is well below ARfD for all commodities and European sub-population groups, therefore no health effects due to acute exposure are expected.

3.7 Environmental fate and behaviour (Part B, Section 8)

The results of the peer review on mefentrifluconazole (BAS 750 F) are available in the the EFSA Conclusion on the active substance [*EFSA (European Food Safety Authority), 2018. Conclusion on the peer review of the pesticide risk assessment of the active substance BAS 750 F (Mefentrifluconazole). EFSA Journal 2018;16(7):5379, 32 pp. doi:10.2903/j.efsa.2018.5379*].

The results of the peer review for metrafenone (BAS 560 F) are available and in the *EFSA Scientific Report (2006) 58, 1 - 72, Conclusion on the peer review of metrafenone*.

The results of the peer review for pyraclostrobin (BAS 500 F) were summarized from SANCO/1420/2001 Monograph 12945/ ECCO/BBA/01.

All parameters and procedures relevant for the exposure assessment are provided in Part B of the Core Dossier.

All exposure calculations for the three active ingredients and their metabolites were carried out under consideration of zonal and national requirements for exposure assessment and under consideration of an appropriate worst-case application scenario.

3.7.1 Predicted environmental concentrations in soil (PEC_{soil})

The PEC in soil have been assessed following the latest guidance of the FOCUS working groups on degradation kinetics, soil persistence models and groundwater scenarios. A soil bulk density of 1.5 g/cm^3 and a soil layer depth of 5 cm were assumed for the calculations. PEC values were derived with the software tool ESCAPE 2.0. Additionally, PEC_{soil} were calculated for the formulated product.

The results of the calculations are presented in Part B, Section 8 of the Core Dossier. The obtained PEC_{soil} values are suitable for subsequent ecotoxicological risk assessment.

3.7.2 Predicted environmental concentrations in groundwater (PEC_{gw})

Calculations for mefentrifluconazole, metrafenone, pyraclostrobin and their metabolites were based on the latest guidance of the FOCUS groundwater working group. The simulations were performed with the models FOCUS-PEARL 5.5.5, FOCUS-PELMO 6.6.4 and FOCUS-MACRO 5.5.4, assuming worst-case application scenarios for all national relevant FOCUS scenarios parameterized for the use in spring and winter cereals. Further details on the assessment, and detailed results are presented in Section 8 of the Core Dossier.

The groundwater risk assessment showed that the leaching of unacceptable amounts of the parent substances mefentrifluconazole, metrafenone or pyraclostrobin as well as their metabolites following application of BAS 758 00 F to the crops intended in the GAP is unlikely.

3.7.3 Predicted environmental concentrations in surface water (PEC_{sw})

The calculations for PEC in surface water (PEC_{sw}) and sediment (PEC_{sed}) were performed for worst-case application scenarios for mefentrifluconazole and its metabolites (1,2,4-triazole, M750F003, M750F005, M750F006, M750F007 and M750F008), for metrafenone and for pyraclostrobin and its metabolites (BF 500-3, BF 500-6, BF 500-7, BF 500-11, BF 500-13, BF 500-14). Calculations were carried out in a stepwise approach according to the recommendations of the FOCUS working group on surface water scenarios (FOCUS 2001, FOCUS 2015) and consider the entry pathways spray drift, drainage and runoff for the parent substance.

The software packages STEPS1-2 (version 3.2) for Step 1 and Step 2, SWASH 5.3 in combination with MACRO 5.5.4, PRZM 4.3.1 and TOXSWA 5.5.3 for Step 3 and SWAN 5.0.1 in combination with TOXSWA 5.5.3 for Step 4 were used for the calculations.

Additionally, PEC_{sw} were calculated for the formulated product assuming drift as entry pathway.

For scenarios relevant for Poland and other MS the D3, D4 and R1 scenarios were taken into consideration and relevant mitigation measures were proposed: 5 m non-sprayed strips or use of 50% nozzle reduction techniques.

Further details on the assessment, and detailed results for all relevant scenarios are presented in Part B, Section 8 of the Core Dossier. Obtained PEC_{sw} and PEC_{sed} values are suitable for subsequent ecotoxicological risk assessment.

3.7.4 Predicted environmental concentrations in air (PEC_{air})

Air is not a relevant exposure pathway either for mefentrifluconazole *(EFSA Journal 2018;16(7):5379)* or for pyraclostrobin *(Monograph 12945/ECCO/BBA/01)*. The vapour pressure at 20 °C of both active substances is $< 10^{-5}$ Pa. Hence, mefentrifluconazole and pyraclostrobin are regarded as non-volatile.

The vapour pressure at 20 °C of the active substance metrafenone is $> 10^{-4}$ Pa. Hence metrafenone may be regarded as volatile. However, it was noted in radiolabelled soil and water studies that significant radioactivity was not found in volatile traps. FOCUS SW modelling does not proceed beyond Step 3 and therefore volatilisation and deposition is not required to be considered further.

3.8 Ecotoxicology (Part B, Section 9)

Following application of BAS 758 00 F no risk or unacceptable effects are expected for birds, mammals, honeybees, non-target arthropods others than bees, non-target meso- and macrofauna, non-target higher plants and soil nitrogen transformation processes without the need for additional mitigation measures. No risk or unacceptable effects are expected for aquatic organisms if risk mitigation measures equivalent to 10 m to surface water bodies including a 10 m vegetated filter are considered.

3.8.1 Effects on terrestrial vertebrates

Effects on birds

Dietary risk assessment

Exposure to active substances separately

In the screening step, all TER_A and TER_{LT} values for mefentrifluconazole, metrafenone and pyraclostrobin exceed the triggers set by Commission Regulation (EU) 546/2011 for acceptability of effects.

Exposure to combined active substances and to the formulation

The two acute risk assessment approaches carried out (combined toxicity of the active substances as virtual compound and formulation toxicity) resulted in TER values at the screening or tier 1 level above the trigger of 10 for acceptability of effects. The combined reproductive risk assessment using the concentration addition model resulted in tier 1 $TER_{LT\ combi}$ values above the trigger of 5 for acceptability of effects.

Therefore, the acute and reproductive dietary risk to birds from BAS 758 00 F according to the proposed use pattern is acceptable.

Drinking water risk assessment

Following EFSA/2009/1438, the puddle scenario is considered relevant for application of BAS 758 00 F according to the proposed use pattern. Since the ratios of the effective application rate to the relevant

endpoints are below the value of 3000 for mefentrifluconazole, metrafenone and pyraclostrobin, a quantitative risk assessment for the proposed use pattern of BAS 758 00 F is not necessary.

Secondary poisoning and biomagnification

The log P_{ow} of the active substances mefentrifluconazole, metrafenone and pyraclostrobin are > 3, which triggers an assessment of the potential risk from secondary poisoning for all active substances. According to the tier 1 risk assessments for earthworm- and fish-eating birds, the TER values for mefentrifluconazole, metrafenone and pyraclostrobin are above the trigger value of 5, indicating an acceptable risk for the intended use of BAS 758 00 F.

Low potential for accumulation of mefentrifluconazole, metrafenone and pyraclostrobin in animal tissue was concluded in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion

It can be concluded that the risk to birds from the application of BAS 758 00 F according to good agricultural practice is acceptable.

Effects on mammals

Dietary risk assessment

Exposure to active substances separately

In the screening step and/or tier 1 risk assessment, all TER_A values for mefentrifluconazole, metrafenone and pyraclostrobin and all TER_{LT} values for mefentrifluconazole and metrafenone exceed the triggers set by Commission Regulation (EU) 546/2011 for acceptability of effects.

For pyraclostrobin, the TER_{LT} values in the tier 1 risk assessment are above the relevant trigger of 5 for acceptability of effects for all scenarios, except for the small herbivorous mammal "vole" scenario at BBCH ≥ 40. Using field foliage residue dissipation data as well as refinement of the deposition factor, the refined TER_{LT} value for the "vole" scenario is above the trigger of 5.

In conclusion, quantitative risk assessments for pyraclostrobin indicate low and acceptable acute and reproductive risks for mammals from the intended uses of BAS 758 00 F according to the proposed use pattern.

Exposure to combined active substances and to formulation

The two acute risk assessment approaches carried out (combined toxicity of the active substances as virtual compound and formulation toxicity) resulted in TER values at the screening or tier 1 level above the trigger of 10 for acceptability of effects. The combined reproductive risk assessment approach resulted in $TER_{LT\ combi}$ values above the trigger of 5 with the exception of the small herbivorous mammal "vole" scenario at BBCH ≥ 40. Using field foliage residue dissipation data for pyraclostrobin as well as refinement of the deposition factor for, the refined $TER_{LT\ combi}$ value for the small herbivorous mammal "vole" scenario at BBCH ≥ 40 is above the trigger of 5.

Therefore, the acute and reproductive dietary risk to mammals from BAS 758 00 F according to the proposed use pattern is acceptable.

Drinking water risk assessment

Following EFSA/2009/1438, the puddle scenario is the one relevant for mammals. Since the ratios of the effective application rate to the relevant endpoints are below the value of 3000 for mefentrifluconazole,

metrafenone and pyraclostrobin, a quantitative risk assessment for the proposed use pattern of BAS 758 00 F is not necessary.

Secondary poisoning and biomagnification

The log P_{ow} of the active substances mefentrifluconazole, metrafenone and pyraclostrobin are > 3, which triggers an assessment of the potential risk from secondary poisoning for all three active substances. According to the tier 1 risk assessment for earthworm- and fish-eating mammals, the TER values for mefentrifluconazole, metrafenone and pyraclostrobin are above the trigger value of 5, indicating an acceptable risk for the intended use of BAS 758 00 F.

Low potential for accumulation of mefentrifluconazole, metrafenone and pyraclostrobin in animal tissue was concluded in the respective EU reviews and therefore further evaluation of biomagnification is not necessary.

Overall conclusion

It can be concluded that the risk to mammals from the application of BAS 758 00 F according to good agricultural practice is acceptable.

3.8.2 Effects on aquatic species

The following risk assessment is based on more detailed information given in the core dossier (Section B09, chapter 9.5), considering in the addition the national requirements relevant for Poland.

The standard risk assessment for the active substances mefentrifluconazole and metrafenone indicates an acceptable risk for all groups of aquatic organisms following the intended uses of BAS 758 00 F 'in spring and winter cereals' with no need for additional mitigation measures. Regarding the active substance pyraclostrobin, acute and chronic PEC/RAC ratios for fish and aquatic invertebrates did not meet the required trigger value of 1 for application of BAS 758 00 F in 'spring and winter cereals', based on standard worst-case assumptions. However, a range of higher-tier studies and approaches (such as a mesocosm study, an SSD for acute fish) allow a refined risk assessment that indicates an acceptable risk if:

1-2 x 1.0 L/ha

- non-sprayed buffer zones of 5 m or 75% drift-reducing nozzles

1-2 x 1.5 L/ha

- non-sprayed buffer zones of 10 m to surface water bodies including a 10 m vegetated filter strip are considered.

The PEC/RAC ratios for the relevant metabolites of mefentrifluconazole, metrafenone and pyraclostrobin are significantly below the trigger of 1 based on standard worst-case assumptions or of negligible relevance in aquatic systems for all proposed uses; they are thus considered not to be of ecotoxicological relevance.

Studies performed with the formulated product BAS 758 00 F indicate no significantly higher (or unexpected) toxicity than predicted based on the results of the active substance for fish, aquatic invertebrates and algae. Toxic unit calculations for fish and aquatic invertebrates indicated that pyraclostrobin is driving the toxicity of the formulated product. The formulation risk assessment revealed an acceptable risk to algae and aquatic plants following the intended uses of BAS 758 00 F in 'spring and winter cereals' with no need for additional mitigation measures.

The standard and refined risk assessment for the fungicidal product BAS 758 00 F, the active substances mefentrifluconazole, metrafenone and pyraclostrobin as well as their major metabolites demonstrates that the application of BAS 758 00 F in 'spring and winter cereals' according to good agricultural practice is of low risk to aquatic ecosystems if:
1-2 x 1.0 L/ha - a non-sprayed buffer zone of 5 m or 75% drift-reducing nozzles are employed

1-2 x 1.5 L/ha- a non-sprayed buffer zone of 10 m to surface water bodies including a 10 m vegetated filter strip are employed.

3.8.3 Effects on bees

The risk to honey bees from the use of mefentrifluconazole, metrafenone, pyraclostrobin and BAS 758 00 F was assessed using the maximum single application rate and the LD_{50} values to calculate hazard quotients (HQ) for oral exposure (Q_{HO}) and contact exposure (Q_{HC}) [*OEPP/EPPO, 2010: Environmental risk assessment scheme for plant protection products, Chapter 10: Honeybees (PP 3/10 (3), Bulletin OEPP/EPPO Bulletin 40, 323–331*].

The hazard quotients for BAS 758 00 F and the active substances mefentrifluconazole, metrafenone and pyraclostrobin for acute oral and acute contact exposure of honey bees are considerably below the Commission Regulation (EU) 546/2011 trigger value of 50.

Based on these results it can be concluded that low risk to honey bees is expected from applications of BAS 758 00 F according to the proposed uses.

3.8.4 Effects on other arthropod species other than bees

The testing and risk assessment strategy used here follow the approach recommended in the ESCORT 2 guidance document, ESCORT 3, and the EC Guidance Document on Terrestrial Ecotoxicology (SANCO/10329, 17 October 2002). The risk assessment for BAS 758 00 F is based on Tier I tests with the standard test species *Typhlodromus pyri and Aphidius rhopalosiphi* and Tier II tests on *A. rhopalosiphi* and *Chrysoperla carnea* as well as an aged residue study on *C. carnea*. The risk assessment is based on the worst-case application rate according to the proposed use pattern.

Based on the results of the conducted first and higher tier risk assessments it can be concluded that low risk for non-target arthropods is expected from the use of BAS 758 00 F according to the proposed use pattern. No unacceptable effects on non-target arthropods are expected in in-field and off-field habitats.

3.8.5 Effects on soil organisms

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna), as well as for soil microorganisms was performed in accordance with the recommendations of the "Guidance Document on Terrestrial Ecotoxicology", as provided by the Commission Services (SANCO/10329/2002 rev 2 (final), October 17, 2002).

Effects on non-target soil meso- and macrofauna
The potential risk of BAS 758 00 F, mefentrifluconazole, metrafenone, pyraclostrobin and the relevant metabolites to earthworms and other non-target soil macro-organisms was assessed by comparing the maximum PEC_{soil} values with NOEC or EC_{10} values, to generate long-term TER values (TER_{lt}).

All TER values for BAS 758 00 F, mefentrifluconazole, metrafenone, pyraclostrobin and the relevant metabolites for chronic exposure of earthworms and other non-target soil organisms (meso- and macrofauna) are considerably higher than the Commission Regulation (EU) 546/2011 trigger value of 5. This indicates that BAS 758 00 F poses no unacceptable risk to earthworms and other non-target soil organisms (meso- and macrofauna) when applied according to the proposed use rate.

Effects on soil microbial activity
The potential risk of BAS 758 00 F, mefentrifluconazole, metrafenone, pyraclostrobin and the relevant metabolites to soil micro-organisms was assessed by comparing the maximum PEC_{soil} values with the maximum concentration with effects ≤ 25%.

For the formulation BAS 758 00 F, the active substances mefentrifluconazole, metrafenone and pyraclostrobin as well as their relevant metabolites, the maximum concentration with effects < 25%

(SANCO/10329/2002 trigger) are all above the maximum PEC_{soil} values. Therefore, it is concluded that the use of BAS 758 00 F will not pose an unacceptable risk to non-target soil micro-organisms, if applied according to good agricultural practice.

3.8.6 Effects on non-target terrestrial plants

The toxicity of BAS 758 00 F to non-target terrestrial plants has been investigated by carrying out vegetative vigour and seedling emergence studies with up to six dicotyledonous and four monocotyledonous non-target plant species. Plants showed similar sensitivity to pre- emergence exposure than to post-emergence exposure. The risk assessment is thus carried out with the respective most sensitive endpoints obtained from the vegetative vigour and seedling emergence tests.

The risk assessment is based on the "Guidance Document on Terrestrial Ecotoxicology", (SANCO/10329/2002 rev.2 final, 2002). It is restricted to off-field areas, as non-target plants are non-crop plants located outside the treated area. The amount of spray drift reaching off-crop habitats is calculated using the 90th percentile estimates in Appendix IV of ESCORT 2. For a single application to field crops and vegetables < 50 cm, 2.77% of the application rate was assumed to reach areas at 1 m from the edge of the crop (worst-case scenario). The highest single application rate of BAS 758 00 F is used to calculate the maximum off-field predicted environmental rate ($PER_{off\text{-}field}$). The potential risk of BAS 758 00 F to non-target plants was assessed by comparing the calculated PER value to the ER_{50} values in order to generate TER values (TER).

Based on the results of the greenhouse trials, all the TER values were above the standard trigger of 5.

Based on the risk assessment it can be concluded that BAS 758 00 F poses no unacceptable risk to non-target plants, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from BAS 758 00 F applications are not required for the protection of terrestrial non-target plants.

3.8.7 Effects on other terrestrial organisms (Flora and Fauna)

Not relevant.

3.9 Relevance of metabolites (Part B, Section 10)

Metabolite of mefentrtifluconazole

The metabolite 1,2,4-triazole is not predicted to occur in groundwater at concentrations above 0.1 µg/L. (for details, please refer to Section 8 of the Central Core). Thus, results of the groundwater risk assessment indicate no risk of leaching of unacceptable amounts of metabolite 1,2,4-triazole into groundwater. Thus, assessment of the relevance of metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 was therefore not required.

Metabolite of metrafenone

The metabolite CL 377160 is not predicted to occur in groundwater at concentrations above 0.1 µg/L. Calculated PEC_{gw} CL 377160 are < 0.001 µg/L in all scenarios.

Assessment of the relevance of this metabolite according to the stepwise procedure of the EC guidance document SANCO/221/2000 – rev.10 is therefore not required, and no further information is provided in this document.

Metabolite of pyraclostrobin

The metabolites BF 500-6 and BF 500-7 are not predicted to occur in groundwater at concentrations above 0.1 µg/L. Calculated PEC_{gw} of BF 500-6 and BF 500-7 are < 0.001 µg/L in all scenarios (for details, please refer to Section 8 of the Central Core).

Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance

document SANCO/221/2000 – rev.10 is therefore not required, and no further information is provided in this document.

Appendix 1 Copy of the product label

Uwagi do etykiety:
Fizykochemia – nie przedłożono do oceny badania dwuletniego przechowywania środka w temperaturze otoczenia. Badanie jest obecnie w realizacji. Po zakończeniu należy je przedłożyć do oceny w Polsce w celu potwierdzenia dwuletniego okresu ważności.
Toksykologia – zmieniono treść etykiety w zakresie klasyfikacji.
Pozostałości – brak uwag do etykiety.
Los i zachowanie w środowisku – brak uwag do etykiety.
Ekotoksykologia – wprowadzono strefę ochronną dla organizmów wodnych.
Skuteczność działania – zmieniono treść etykiety w zakresie „Stosowanie środka".

Posiadacz zezwolenia:
BASF Agro B.V. Arnhem (NL), Oddział w Freienbach, Huobstrasse 3, 8808 Pfäffikon Sz, Konfederacja Szwajcarska, tel.: xxxxxxxxxxxxxxxxxxxx

Podmiot wprowadzający środek ochrony roślin na terytorium Rzeczypospolitej Polskiej:
BASF Polska Sp. z.o.o., Al. Jerozolimskie 142B, 02-305 Warszawa, xxxxxxxxxx

Podmiot odpowiedzialny za końcowe pakowanie i etykietowanie środka ochrony roślin
Podmiot odpowiedzialny za końcowe etykietowanie środka ochrony roślin: ……..

REVYFLEX PLUS

Środek przeznaczony do stosowania przez użytkowników profesjonalnych

Zawartość substancji czynnych:

Mefentriflukonazol (substancja z grupy triazoli) –	66,67 g/l (6,10 %w/w)
Pyraklostrobina (substancja z grupy strobiluryn) –	80 g/l (7.33 %w/w)
Metrafenon (substancja z grupy pochodnych ketonu difenylowego) –	100 g/l (9.17 %w/w)

Zezwolenie MRiRW nr R- /2023 z dnia 2023r.

Niebezpieczeństwo	
H302 + H332	Działa szkodliwie po połknięciu lub w następstwie wdychania.
H315	Działa drażniąco na skórę.
H317	Może powodować reakcję alergiczną skóry.
H318	Powoduje poważne uszkodzenia oczu.
H335	Może powodować podrażnienie dróg oddechowych.
H410	Działa bardzo toksycznie na organizmy wodne, powodując długotrwałe skutki.
EUH 401	W celu uniknięcia zagrożeń dla zdrowia ludzi i środowiska, należy postępować zgodnie z instrukcją użycia.
P260	Nie wdychać pyłu/dymu/gazu/mgły/par/rozpylonej cieczy.
P271	Stosować wyłącznie na zewnątrz lub w dobrze wentylowanym pomieszczeniu.
P280	Stosować rękawice ochronne/odzież ochronną/ ochronę oczu/ochronę twarzy.
P302+P352	W PRZYPADKU DOSTANIA SIĘ NA SKÓRĘ: Umyć dużą ilością wody.
P305+P351+P338	W PRZYPADKU DOSTANIA SIĘ DO OCZU: Ostrożnie płukać wodą przez kilka

P304+P340	minut. Wyjąć soczewki kontaktowe, jeżeli są i można je łatwo usunąć. Nadal płukać. W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić mu warunki do swobodnego oddychania. Natychmiast skontaktować się z OŚRODKIEM ZATRUĆ/lekarzem.
P310	Zebrać wyciek.
P391	Zawartość/pojemnik usuwać zgodnie z lokalnymi przepisami.
P501	

OPIS DZIAŁANIA
FUNGICYD w formie koncentratu do sporządzania emulsji wodnej, o działaniu układowym, do stosowania zapobiegawczego, interwencyjnego oraz wyniszczającego w ochronie przed chorobami grzybowymi. Substancja czynna piraklostrobina należy do grupy FRAC 11, mefentriflukonazol do grupy FRAC 3, metrafenon do grupy FRAC 50.

STOSOWANIE ŚRODKA
Środek do stosowania przy użyciu samobieżnego lub ciągnikowego opryskiwacza polowego.

Pszenica ozima
Łamliwość podstawy źdźbła (średni poziom zwalczania choroby)
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do fazy 2 kolanka co najmniej 2 cm nad pierwszym kolankiem (BBCH 30-32).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 1
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Mączniak prawdziwy zbóż i traw, septorioza paskowana liści pszenicy, rdza brunatna pszenicy, rdza żółta, brunatna plamistość liści
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp pomiędzy zabiegami: 14 dni
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Pszenica jara

rdza żółta, brunatna plamistość liści
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp pomiędzy zabiegami: 14 dni
Zalecana ilość wody: 100 -300 l/ha
Zalecane opryskiwanie: drobnokropliste

Pszenżyto ozime
Mączniak prawdziwy zbóż i traw, septoriozy liści, rdza brunatna, rdza żółta
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp pomiędzy zabiegami: 14 dni
Zalecana ilość wody: 100-300 l/ha

Zalecane opryskiwanie: drobnokropliste

Żyto ozime
Rdza brunatna żyta, rynchosporioza zbóż.
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp pomiędzy zabiegami: 14 dni
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

Jęczmień ozimy, jęczmień jary
Mączniak prawdziwy zbóż i traw, rynchosporioza zbóż, plamistość siatkowa jęczmienia, rdza jęczmienia
Maksymalna /zalecana dawka dla jednorazowego zastosowania: 1,5 l/ha
Termin stosowania: Środek stosować zapobiegawczo lub z chwilą wystąpienia pierwszych objawów chorób, od początku fazy strzelania w źdźbło do końca fazy kłoszenia (BBCH 30-59).
Maksymalna liczba zabiegów w sezonie wegetacyjnym: 2
Odstęp pomiędzy zabiegami: 14 dni
Zalecana ilość wody: 100-300 l/ha
Zalecane opryskiwanie: drobnokropliste

ŚRODKI OSTROŻNOŚCI, OKRESY KARENCJI I SZCZEGÓLNE WARUNKI STOSOWANIA

Okres od ostatniego zastosowania środka do dnia zbioru rośliny uprawnej (okres karencji):
Pszenica – 56 dni
Jęczmień – 56 dni
Pszenżyto – 56 dni
Żyto – 56 dni

Środek zawiera następujące substancje czynne: **metrafenon** (związek z grupy pochodnych ketonu difenylowego – benzylofenonów, wg FRAC Grupa 50) zaburzający transport aktyn w stożkach wzrostu strzępek infekcyjnych grzybów, **piraklostrobinę** z grupy strobiluryn, która należy do inhibitorów oddychania na poziomie komórkowym grzybów (fungicydy QoI, wg FRAC Grupa 11) oraz **mefentriflukonazol** z grupy triazoli (fungicydy inhibitory biosyntezy steroli – inhibitory demetylacji SBI-DMI, wg FRAC Grupa 3). W grupie inhibitorów biosyntezy steroli, substancja należy do podgrupy inhibitorów demetylacji (DMI).

W ramach strategii antyodpornościowej środki grzybobójcze zawierające substancje czynne z tych grup należy stosować maksymalnie w dwóch zabiegach w sezonie na danej plantacji zbóż. Ponadto zaleca się:
- stosować środek głównie w zabiegach zapobiegawczych (profilaktycznie),
- stosowanie zgodnie z zaleceniami zamieszczonymi na etykiecie.

Podczas stosowania środka nie dopuścić do znoszenia cieczy użytkowej na sąsiednie plantacje roślin uprawnych.

Okres od ostatniego zastosowania środka na rośliny do dnia, w którym można siać lub sadzić rośliny uprawiane następczo:
Rośliny następcze można siać lub sadzić bez ograniczeń, także w przypadku konieczności wcześniejszej likwidacji plantacji potraktowanej środkiem,

SPORZĄDZANIE CIECZY UŻYTKOWEJ

Przed użyciem wstrząsnąć zawartością opakowania.
Przed przystąpieniem do sporządzania cieczy użytkowej dokładnie ustalić potrzebną jej objętość wraz z ilością środka. Napełniając opryskiwacz postępować zgodnie z instrukcją producenta opryskiwacza. W przypadku braku instrukcji odmierzoną ilość środka dodać do zbiornika opryskiwacza napełnionego częściowo wodą (z włączonym mieszadłem).

Opróżnione opakowania przepłukać trzykrotnie wodą, a popłuczyny wlać do zbiornika opryskiwacza z cieczą użytkową, uzupełnić wodą do potrzebnej ilości i dokładnie wymieszać. Po wlaniu środka do zbiornika opryskiwacza niewyposażonego w mieszadło hydrauliczne, ciecz mechanicznie wymieszać.
W przypadku przerw w opryskiwaniu, przed ponownym przystąpieniem do pracy ciecz użytkową w zbiorniku opryskiwacza dokładnie wymieszać.

POSTĘPOWANIE Z RESZTKAMI CIECZY UŻYTKOWEJ I MYCIE APARATURY

Resztki cieczy użytkowej należy:
- jeżeli jest to możliwe, po uprzednim rozcieńczeniu zużyć na powierzchni, na której przeprowadzono zabieg, lub
- unieszkodliwić z wykorzystaniem rozwiązań technicznych zapewniających biologiczną degradację substancji czynnych środków ochrony roślin, lub
- unieszkodliwić w inny sposób, zgodny z przepisami o odpadach.

Po pracy aparaturę dokładnie wymyć.

Z wodą użytą do mycia aparatury postąpić tak, jak z resztkami cieczy użytkowej, stosując te same środki ochrony osobistej.
W przypadku mycia aparatury przy użyciu środków myjących przeznaczonych do tego celu, z powstałymi popłuczynami należy postępować zgodnie z instrukcją dołączoną do środka myjącego.

ŚRODKI OSTROŻNOŚCI DLA OSÓB STOSUJĄCYCH ŚRODEK, PRACOWNIKÓW ORAZ OSÓB POSTRONNYCH

Przed zastosowaniem środka należy poinformować o tym fakcie wszystkie zainteresowane strony, które mogą być narażone na znoszenie cieczy użytkowej i które zwróciły się o taką informację.

Nie jeść, nie pić ani nie palić podczas używania produktu.
Stosować rękawice ochronne, ochronę oczu lub twarzy oraz odzież ochronną zabezpieczającą przed oddziaływaniem środków ochrony roślin, oraz odpowiednie obuwie (np. kalosze) w trakcie przygotowywania cieczy użytkowej oraz w trakcie wykonywania zabiegu.

Okres od zastosowania środka do dnia, w którym na obszar, na którym zastosowano środek mogą wejść ludzie oraz zostać wprowadzone zwierzęta (okres prewencji):
Nie wchodzić do czasu całkowitego wyschnięcia cieczy użytkowej na powierzchni roślin.

ŚRODKI OSTROŻNOŚCI ZWIĄZANE Z OCHRONĄ ŚRODOWISKA NATURALNEGO

Nie zanieczyszczać wód środkiem ochrony roślin lub jego opakowaniem. Nie myć aparatury w pobliżu wód powierzchniowych. Unikać zanieczyszczania wód poprzez rowy odwadniające z gospodarstw i dróg.

W celu ochrony organizmów wodnych konieczne jest wyznaczenie nieopryskiwanej, zadarnionej strefy ochronnej o szerokości 10 m od zbiorników i cieków wodnych.

W celu ochrony roślin oraz stawonogów niebędących celem działania środka konieczne jest wyznaczenie strefy ochronnej o szerokości 1 m od terenów nieużytkowanych rolniczo.

WARUNKI PRZECHOWYWANIA I BEZPIECZNEGO USUWANIA ŚRODKA OCHRONY ROŚLIN I OPAKOWANIA

Chronić przed dziećmi.
Środek ochrony roślin przechowywać:

- w oryginalnych opakowaniach,
- w dobrze wentylowanym miejscu
- pod zamknięciem
- w sposób uniemożliwiający kontakt z żywnością, napojami lub paszą, skażenie środowiska oraz dostęp osób trzecich,
- w temperaturze 0ºC - 30ºC.

Zabrania się wykorzystywania opróżnionych opakowań po środkach ochrony roślin do innych celów. Niewykorzystany środek przekazać do podmiotu uprawnionego do odbierania odpadów niebezpiecznych. Opróżnione opakowania po środku zwrócić do sprzedawcy środków ochrony roślin będących środkami niebezpiecznymi.

PIERWSZA POMOC

Antidotum: brak, stosować leczenie objawowe.
W razie konieczności zasięgnięcia porady lekarza, należy pokazać opakowanie lub etykietę.
W PRZYPADKU DOSTANIA SIĘ DO DRÓG ODDECHOWYCH: wyprowadzić lub wynieść poszkodowanego na świeże powietrze i zapewnić warunki do odpoczynku w pozycji umożliwiającej swobodne oddychanie.
W przypadku kontaktu ze skórą: Umyć dużą ilością wody z mydłem.
W przypadku wystąpienia podrażnienia skóry: Zasięgnąć porady/zgłosić się pod opiekę lekarza.
W przypadku połknięcia: niezwłocznie zasięgnij porady lekarza – pokaż opakowanie lub etykietę.
W przypadku narażenia lub styczności: Zasięgnąć porady/zgłosić się pod opiekę lekarza.

Okres ważności - 2 lata
Data produkcji - .....
Zawartość netto - .....
Nr partii - .....