FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: BAS 758 00 F

Product name(s): Revyflex Plus

Chemical active substance(s):

Mefentrifluconazole, 66.6 g/L

Metrafenone, 100 g/L

Pyraclostrobin, 80 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: BASF

Submission date: March 2022

MS Finalisation date: 27/01/2023

Version history

When	What
03/2022	Initial dRR – BASF DocID 2021/2030578
04/2022	Dossier sent for evaluation
10/2022	zRMS evaluation of dRR
January 2023	Final version prepared by zRMS after Commenting period

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Evaluator comments:
The text highlighted in grey was provided by the evaluator.

0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

The application was submitted for the approval of BAS 758 00 F, a new EC formulation containing 66.67 g/L mefentrifluconazole and 100 g/L metrafenone, 80 g/L pyraclostrobin, for the use as fungicide in cereals.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013, and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	**(if relevant) Concerned MS, MS' product name and authorization number (if applicable)**
Northern zone	Latvia	Estonia, Lithuania
Central zone	Poland	Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Netherland, Romania, Slovakia
Southern zone	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Mefentrifluconazole

Table 0.1-2: Summary of regulatory history of CAS No: 1417792-03-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Implementing Regulation (EU) No 2019/337
RMS	United Kingdom
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	20.03.2019
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	N/A
Date of final Commission (re-registration) deadline (Step 2)	N/A
Current expiration of approval	20.03.2029
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the protection of operators, ensuring that conditions of use include the application of adequate

personal protective equipment.
- the protection of aquatic organisms.

An EFSA Scientific Report was made available in July 2018.

Table 0.1-3: Information on minimum purity of Mefentrifluconazole

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity: 970 g/kg The impurity N, N-dimethylformamide shall not exceed 0,5 g/kg in the technical material. The impurity toluene shall not exceed 1 g/kg in the technical material The impurity 1,2,4-(1H)-triazole shall not exceed 1 g/kg in the technical material	

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Mefentrifluconazole	
	EU agreed endpoint from EFSA Journal 2018;16(7):5379	**Endpoint used***
Environmental fate		
DT_{50} [d] sediment	1000 (default)	163.4 (geometric mean of whole system DT_{50}, n = 2)
Ecotoxicology [1)]		
Aquatic organisms		
~~Fish acute, *Pimephales promelas*~~	~~–~~	~~LC_{50} = 0.65 mg a.s./L~~
~~Invertebrate chronic, Geomean (NOEC/EC_{10} data for 4 crustacean species)~~	~~–~~	~~$Geomean_{chronic}$ = 0.0287 mg a.s./L~~

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

1) For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

Endpoint	M750F005 (Reg. No. 6003433)	
	EU agreed endpoint from EFSA Journal 2018;16(7):5379	**Endpoint used***
Ecotoxicology [1)]		

Endpoint	M750F005 (Reg. No. 6003433)	
	EU agreed endpoint from EFSA Journal 2018;16(7):5379	**Endpoint used***
Aquatic organisms		
Fish acute, *Oncorhynchus mykiss*	--	LC_{50} > 5 mg/L

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

1) For justification for using new/revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

0.1.3.2 Metrafenone

Table 0.1-4: Summary of regulatory history of CAS No: 220899-03-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	2007/6/EC, approved as an active substance in accordance with Regulation (EC) No. 1107/2009 by the Commission Implementing Regulation (EU) No. 540/2011 amended by Regulation (EU) 2021/566 and 2022/378
RMS	Latvia (The original RMS was the UK.)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.02.2007
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	Not applicable
Date of final Commission (re-registration) deadline (Step 2)	Not applicable
Current expiration of approval	~~31.04.2022~~ 30.04.2023
Low risk substance or Candidate for Substitution?	Metrafenone has not been designed as a low risk substance. Metrafenone is not a canditate for substitution.

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

No specific provisions were stated in the first inclusion decision (Commission Directive 2007/6/ES).

Note: An application to renew the approval of metrafenone was submitted on 22 January 2014 and accepted (Refer to SANCO/10148/2014 – Rev. 3, 01 October 2014). A supplementary dossier to support the renewal of approval was submitted to the Rapporteur Member State (RMS), Latvia on 19 October 2015. The co-RMS for the renewal of approval for metrafenone is Slovakia.

The SANCO report for metrafenone (SANCO/10280/06 – 14/07/2006) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is available, 'EFSA Conclusion on the peer review of the pesticide risk assessment of the active substance metrafenone (EFSA Scientific Report (2006) 58, 1-72)'.

Table 0.1-5: Information on minimum purity of Metrafenone

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity: ≥ 940 g/kg	≥ 980 g/kg (proposed new reference specification); used in the dossier Please refer to Part C, chapters 1.1.3 and 1.2

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following tables provide the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Metrafenone	
	EU agreed endpoint from EFSA scientific report	Endpoint used*
Environmental fate		
Koc for metrafenone and metabolites	For $K_{f,oc}$ the geometric mean was used according to the latest FOCUS GW guidance [*FOCUS, 2021*]. All other endpoints were in accordance with the EU-agreed endpoints [*EFSA Conclusion, 2006*].	
Ecotoxicology [1)]		
Birds		
~~Acute oral,~~ ~~*Colinus virginianus*~~ ~~*Anas platyrhynchos*~~ ~~*Taeniopygia guttata*~~	~~LD_{50} > 2025 mg a.s./kg b.w.~~ ~~*Colinus virginianus*~~ ~~*Anas platyrhynchos*~~	~~LD_{50} (extrapolated, geometric mean) = 3807 mg/kg bw~~ ~~*Colinus virginianus*~~ ~~*Anas platyrhynchos*~~ ~~*Taeniopygia guttata*~~
~~Reproductive~~ ~~*Colinus virginianus*~~ ~~*Anas platyrhynchos*~~	~~LD_{50} > 125.4 mg a.s./kg bw/day~~ ~~(*Colinus virginianus*)~~	~~NOEL = 114.7 mg a.s./kg bw/day~~ ~~(*Anas platyrhynchos*)~~
Aquatic organisms		
Fish acute, *Oncorhynchus mykiss,* *Cyprinodon variegatus*	LC_{50} > 0.82 mg a.s./L (*Oncorhynchus mykiss*)	LC_{50} > 0.35 mg a.s./L (*Cyprinodon variegatus*)
Fish prolonged, *Pimephales promelas*	NOEC = 0.228 mg a.s./L	NOEC = 0.204 mg a.s./L (ELS study)
Invertebrate acute, *Daphnia magna*, *Crassostrea virginica*	EC_{50} > 0.92 mg a.s./L (*Daphnia magna*)	LC_{50} > 0.33 mg a.s./L (*Crassostrea virginica*)
Invertebrates prolonged, *Daphnia magna*, *Americamysis bahia*	NOEC = 0.225 mg a.s./L (*Daphnia magna*)	NOEC = 0.022 mg a.s./L (*Americamysis bahia*)
Sediment dwellers prolonged, *Chironomus riparius*	--	NOEC = 296 mg a.s./kg dry sediment
~~Algae,~~ ~~*Selenastrum capricornutum,*~~ ~~*Pseudokirchneriella*~~	~~E_bC_{50} = 0.71 mg a.s./L~~ ~~(*Selenastrum capricornutum*)~~	~~E_rC_{50} > 0.339 mg a.s./L~~ ~~(*Pseudokirchneriella subcapitata*)~~

Endpoint	Metrafenone	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
~~*subcapitata*~~		
~~Aquatic plants, *Lemna gibbba*~~	~~–~~	~~E_rC_{50} > 0.327 mg a.s./L~~
Terrestrial organisms		
~~Honey bee adults *Apis mellifera*~~	~~LD_{50} (48 h) > 73.1 µg/bee~~	~~LD_{50} (48 h) > 110.0 µg/bee~~
~~Honey bee adults *Apis mellifera*~~	~~–~~	~~NOEDD (10 d) ≥ 291 µg a.s./bee/day~~ ~~2)~~

Endpoint	Metrafenone	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
~~Honey bee larvae *Apis mellifera*~~	~~–~~	~~NOED (8 d) = 49.98 µg a.s./larvae [2)]~~
~~Earthworm *Eisenia fetida*~~	~~–~~	~~NOEC ≥ 240 mg/kg dry soil (equivalent to 101.61 mg a.s./kg dry soil) [2)]~~ ~~$NOEC_{CORR}$ ≥ 50.8 mg a.s./kg dry soil [#] [2)]~~
~~Collembola *Folsomia candida*~~	~~–~~	~~NOEC ≥ 1000 mg/kg soil dry soil (equivalent to 422.65 mg a.s./kg dry soil) [2)]~~ ~~$NOEC_{CORR}$ ≥ 211.3 mg a.s./kg dry soil [#] [2)]~~

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[#] Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.

1) For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

2) Studies conducted with BAS 560 02 F to address the new data requirements according to Commission Regulation (EU) 1107/2009.

Endpoint	Metabolite, CL 3000402	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
Ecotoxicology [1)]		
Terrestrial organisms		
~~Earthworm *Eisenia andrei*~~	~~–~~	~~**NOEC = 27.78 mg/kg dry soil**~~ ~~$NOEC_{CORR}$ = 13.89 mg/kg dry soil [#]~~
~~N-mineralisation 28 d, aerobic loamy sand~~	~~–~~	~~Nitrate formation rate at 1.00 mg/kg dry soil 17.2%~~

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[#] Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.

1) For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

Endpoint	Metabolite, CL 377160	
	EU agreed endpoint from EFSA scientific report	**Endpoint used***
Ecotoxicology [1)]		
Terrestrial organisms		
~~Earthworm *Eisenia fetida*~~	~~–~~	~~NOEC ≥ 1000 mg/kg dry soil~~ ~~$NOEC_{CORR}$ ≥ 500 mg/kg dry soil [#]~~

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[#] Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.

[1)] For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

0.1.3.3 Pyraclostrobin

Table 0.1-6: Summary of regulatory history of CAS No: 175013-18-0

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	2004/30/EC amended by Directive 2009/25/EC, and approved as an active substance in accordance with Regulation (EC) No. 1107/2009 by the Commission Implementing Regulation (EU) No. 540/2011 amended by Regulation (EU) 2021/52 and Regulation (EU) 2021/2068
RMS	Germany
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2004
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.11.2004
Date of final Commission (re-registration) deadline (Step 2)	30.11.2005
Current expiration of approval	31.01.2023
Low risk substance or Candidate for Substitution?	N/A

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- protection of aquatic organisms, especially fish,
- protection of terrestrial arthropods and earthworms.

The key documents from the EU review of Pyraclostrobin (review report SANCO/1420/2001-Final; Monograph 12945/ECCO/BBA/01, August 2001) are considered to provide the relevant review information or a reference to where such information can be found.

Table 0.1-7: Information on minimum purity of Pyraclostrobin

EU agreed minimum purity from Inclusion Directive or Implementing regulation	**(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
minimum purity: 975 g/kg The manufacturing impurity dimethyl sulfate (DMS) is condidered to be of toxicological concern and must not exceed a concentration of 0,0001 % in the technical product.	

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

The following table provides the endpoints used in the evaluation in the case that they deviate from EU endpoints.

Endpoint	Pyraclostrobin	
	EU agreed endpoint from SANCO/1420/2001 Monograph 12945/ ECCO/BBA/01	**Endpoint used***
Environmental fate		
Field DT50 of pyraclostrobin	A kinetic evaluation (including standardization to reference conditions) for the field DT_{50} values in soil (BASF DocID 2006/1007384, see Appendix 2) was considered for the PEC calculations. The geometric mean of the normalized values (20°C, pF 2) from field studies of 18 days was chosen for the calculations. This endpoint for pyraclostrobin in the risk assessment therefore differs from the EU-agreed endpoint due to changes in evaluation guidelines (which type of DT_{50} to be used). In the annex I approval process Predicted Environmental Concentrations (PECs) were derived for groundwater (GW) according to the latest standards at that time (see monograph 12945/ECCO/BBA/01), i.e. PEC_{gw} was estimated using a worst-case $DT50_{soil}$ (non-normalized) from laboratory data (DT_{50} = 100 days); field data were submitted but were not used for the evaluation. PEC_{sw} was estimated using the entry pathway spray drift only, as no degradation data in soil was required at that time. Today, the exposure assessment in surface water requires a normalized (20°C, pF2) DT_{50} in soil. To fulfill this requirement, normalized laboratory or field soil DT_{50} values are needed. As field data are available and show significant faster degradation as compared to laboratory data, field data were normalized to derive the required DT_{50} in soil to be used in the required FOCUS models. This normalization study was performed in 2006. It was submitted, evaluated and accepted in the zonal process before so that a reference to this study would suffice, without re-evaluation.	

Endpoint	Pyraclostrobin	
	EU agreed endpoint from SANCO/1420/2001 Monograph 12945/ ECCO/BBA/01	**Endpoint used***
Metabolites of pyraclostrobin for PECsw calculations	Additionally, metabolites BF 500-11, BF 500-13, BF 500-14 and BF 500-3 were found in an irradiated water/sediment study at levels exceeding 5%. DT_{50} values for water, sediment and whole system from a new kinetic evaluation (BASF DocID 2012/1021122, see Appendix 2) of the irradiated water/sediment study were therefore considered for calculating $PEC_{sw/sed}$ of pyraclostrobin metabolites BF 500-11, BF 500-14 and BF 500-3. Regarding metabolites BF 500-6 and BF 500-7, worst-case default DT_{50} values (soil, sediment) of 1000 days were used as conservative approach and not the values listed in the monograph.	
Koc for pyraclostrobin and its metabolites	The single sorption parameter values considered for the calculations were taken from the monograph 12945/ECCO/BBA/01 of pyraclostrobin. Following the current EU guidance [*EFSA (2014): EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3362*], the geometric mean of the sorption coefficient ($K_{f,oc}$) values for parent and metabolites were considered in the assessment.	
Ecotoxicology [1)]		
Birds		
~~**Acute oral,** *Colinus virginianus*~~	~~LD_{50} > 2000 mg a.s./kg b.w.~~	~~$LD_{50\ (geometric\ mean)}$ = 1701 mg/kg b.w.~~
Terrestrial vertebrates other than birds		
~~**Acute oral**~~	~~LD_{50} > 5000 mg a.s./kg b.w. (rat)~~	~~LD_{50} ~ 450 mg a.s./kg b.w. (non-standard mouse study)~~
~~**Reproductive** Rat~~	~~–~~	~~Higher Tier: NOEL $_{offspring,\ parents}$ = 8.2 mg a.s./kg b.w./d (rat, multi-generation)~~
Aquatic organisms		
~~Fish prolonged, *Cyprinodon variegatus*~~	~~--~~	~~NOEC = 0.0108 mg a.s./L (ELS study)~~
~~Fish prolonged, *Pimephales promelas*~~	~~–~~	~~NOEC = 0.00414 mg a.s./L (ELS study)~~
Sediment dwellers prolonged, *Chironomus riparius*	--	NOEC = 1.37 mg a.s./kg dry sediment
~~Aquatic plants, *Lemna gibba*~~	~~–~~	~~E_rC_{50} > 1.077 mg a.s./L~~
Terrestrial organisms		
~~Honey bee acute adults *Apis mellifera*~~	~~Oral, LD_{50} (48 h) > 73.1 µg/bee Contact, LD_{50} (48 h) > 100.0 µg/bee~~	~~Oral, LD_{50} (48 h) > 110.0 µg/bee Contact, LD_{50} (48 h) > 100.0 µg/bee~~
~~Honey bee chronic adults *Apis mellifera*~~	~~–~~	~~NOEDD (10 d) = 1.0 µg/bee/day~~

Endpoint	Pyraclostrobin	
	EU agreed endpoint from SANCO/1420/2001 Monograph 12945/ ECCO/BBA/01	**Endpoint used***
~~Honey bee chronic larvae *Apis mellifera*~~	~~--~~	~~NOED (22 d) = 12.8 µg/larva~~
~~Bumble bee acute adults *Bombus terrestris*~~	~~--~~	~~Oral, LD_{50} (96 h) > 97.0 µg/bee~~ ~~Contact, LD_{50} (96 h) > 100.0 µg/bee~~
Earthworm chronic *Eisenia fetida*	--	NOEC = 23.1 mg/kg dry soil $NOEC_{CORR}$ = 11.6 mg/kg dry soil # EC_{10} = 22.2 mg/kg dry soil $EC_{10, CORR}$ = 11.1 mg/kg dry soil #

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)
# Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.
1) For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

Endpoint	Metabolite BF 500-3	
	EU agreed endpoint from SANCO/1420/2001 Monograph 12945/ ECCO/BBA/01	**Endpoint used***
Ecotoxicology 1)		
Aquatic organisms		
Sediment dwellers prolonged, *Chironomus riparius*	--	NOEC ≥ 16.0 mg/kg dry sediment

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)
1) For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

Endpoint	Metabolite, BF 500-6	
	EU agreed endpoint from SANCO/1420/2001 Monograph 12945/ ECCO/BBA/01	**Endpoint used***
Ecotoxicology 1)		
Aquatic organisms		
~~Sediment dwellers prolonged, *Chironomus riparius*~~	~~--~~	~~NOEC = 1.2 mg/kg dry sediment~~
Terrestrial organisms		
~~Earthworm *Eisenia fetida*~~	~~--~~	~~NOEC ≥ 320 mg/kg dry soil~~ ~~$NOEC_{CORR}$ ≥ 160 mg/kg dry soil #~~
~~Collembola *Folsomia candida*~~	~~--~~	~~NOEC ≥ 800 mg/kg dry soil~~ ~~$NOEC_{CORR}$ ≥ 400 mg/kg dry soil #~~

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)
# Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.
1) For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

Endpoint	Metabolite, BF 500-7	
	EU agreed endpoint from SANCO/1420/2001 Monograph 12945/ ECCO/BBA/01	**Endpoint used***
Ecotoxicology [1)]		
Aquatic organisms		
~~Sediment dwellers prolonged, *Chironomus riparius*~~	~~–~~	~~NOEC ≥ 123.5 mg/kg dry sediment~~
Terrestrial organisms		
~~Earthworm *Eisenia fetida*~~	~~–~~	~~NOEC ≥ 320 mg/kg dry soil~~ ~~$NOEC_{CORR}$ ≥ 160 mg/kg dry soil~~ [#]
~~Collembola *Folsomia candida*~~	~~–~~	~~NOEC ≥ 800 mg/kg dry soil~~ ~~$NOEC_{CORR}$ ≥ 400 mg/kg dry soil~~ [#]

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification, confirmatory data)

[#] Corrected value derived by dividing the endpoint by a factor of 2 due to a log P_{OW} >2.

[1)] For justifications for using new / revised ecotoxicological endpoints please refer to the respective paragraphs in Part B, Section 9.

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorized.
This product was not the representative formulation.

0.2 zRMS conclusion

Section 1, 2 and 4. Identity, physical and chemical properties and further information
A two-year storage stability study is ongoing and has to be provided for evaluation in post-registration. It can be assessed at a national level.

Section 3. Efficacy
The evaluation of the application of Revyflex Plus resulted in the decision to grant authorization for use according to the GAP table.

Section 5. Analytical Methods
The analytical methods are accepted.

Section 6. Mammalian Toxicology
Classification of BAS 758 000 F: Acute Tox. 4 (oral and inhal.) (H302+H332), Skin Irrit. 2 (H315), Eye Dam. 1 (H318), Skin Sens. 1 (H317), STOS SE 3 (H335).
Operator: Protective clothing, protective gloves, face/eye protection during handling, mixing and loading due to hazard characterisation.
Worker: Workwear
Residents and Bystanders: None

Section 7. Metabolism and Residues
The evaluation of the application for Revyflex Plus (BAS 758 00 F) resulted in the decision to grant the authorization to all uses included in the authorisation request (see the GAP in Appendix 1).

Section 8. Environmental Fate
In accordance with proposed pattern use in winter and spring cereals, an exposure assessment for all active substances and their metabolites and formulation of BAS 758 00 F was submitted.
The mitigation measures were proposed, and final decision will be made in ecotoxicological section.

Section 9. Ecotoxicology
Based on the risk assessment in section of ecotoxicology it can be concluded that the proposed uses of

BAS 758 00 F poses acceptable risk to non-target organisms, if applied according to the recommended use pattern. Particular precautions to reduce the environmental concentrations resulting from BAS 758 00 F applications are required for aquatic organisms.

Section 10. Assessment of the relevance of metabolites in groundwater
No metabolites exceeded trigger value 0.1 µg/L, therefore the relevance assessment of the metabolites is not required.

Uses to be considered safe on the basis of EU methodology:
Uses in the GAP table no 1-15 are to be confirmed by cMSs, in the Efficacy section.
Uses 16-22 are considered safe for PL.

Uses to be considered non-safe on the basis of EU methodology:
Use 23 is confirmed non-safe for PL.

Appendix 1 ALL intended uses

GAP rev., date: 2021-12-17

PPP (product name/code):	Not yet determined/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/~~no~~		

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: develop-mental 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 ap-plications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	AT, BE, DE, IE, NL~~, PL~~	wheat TRZAW, TRZAS TRZDU, TRZSP	F	*Oculimacula spp.* - PSDCHE *Blumeria graminis* - ER-YSGR *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
2	AT, BE, DE, IE,	barley HORVW	F	*B. graminis* - ERYSGR *Pyrenophora teres* -	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** /	100 - 300	56	

	NL~~, PL~~	HORVS		PYRNTE *R. secalis* - RHYNSE *R. collo-cygni* - RAMUCC *Puccinia hordei* - PUC-CHD						0,120*** b) 0,200* / 0,300** / 0,240***			
3	AT, BE, DE, IE, NL~~, 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	AT, BE, DE, IE, NL~~, PL~~	triticale TTLWI TTLSO	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	AT, DE, BE, NL, IE	oat AVESA	F	*B. graminis* - ERYSGR *Puccinia coronata* - PUCCCA	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	
6	CZ	wheat TRZAW, TRZAS TRZDU, TRZSP	F	*Oculimacula spp.* - PSDCHE *Blumeria graminis* - ER-YSGR *Zymoseptoria tritici* - SEPTTR *Puccinia triticina* - PUCCRT *Puccinia striiformis* - PUCCST *P. tritici-repentis* - PYRNTR	Spraying (SP)	30 - 59	a) 1 b) 1		a) 1 - 1,5 b) 1 - 1,5	a) 0,100* / 0,150** / 0,120*** b) 0,100* / 0,150** / 0,120***	100 - 300	56	For eyespot control, only one application at BBCH 30-32
7	CZ	barley HORVW HORVS	F	*B. graminis* - ERYSGR *Pyrenophora teres* - PYRNTE *R. secalis* - RHYNSE *R. collo-cygni* - RAMUCC *Puccinia hordei* - PUC-CHD	Spraying (SP)	30 - 59	a) 1 b) 1		a) 1 - 1,5 b) 1 - 1,5	a) 0,100* / 0,150** / 0,120*** b) 0,100* / 0,150** / 0,120***	100 - 300	56	

8	CZ	rye SECCW SECCS SECCE	F	*R. secalis* - RHYNSE *Puccinia recondita* - PUCCRE	Spraying (SP)	30 - 59	a) 1 b) 1		a) 1 - 1,5 b) 1 - 1,5	a) 0,100* / 0,150** / 0,120*** b) 0,100* / 0,150** / 0,120***	100 - 300	56	
9	CZ	triticale TTLWI TTLSO	F	*B. graminis* - ERYSGR *Septoria spp.* - SEPTSP *Puccinia recondita* - PUCCRE *Puccinia striiformis* – PUCCST	Spraying (SP)	30 - 59	a) 1 b) 1		a) 1 - 1,5 b) 1 - 1,5	a) 0,100* / 0,150** / 0,120*** b) 0,100* / 0,150** / 0,120***	100 - 300	56	
10	CZ	oat AVESA	F	*B. graminis* - ERYSGR *Puccinia coronata* – PUCCCA	Spraying (SP)	30 - 59	a) 1 b) 1		a) 1 - 1,5 b) 1 - 1,5	a) 0,100* / 0,150** / 0,120*** b) 0,100* / 0,150** / 0,120***	100 - 300	56	
11	HU, RO, SK	wheat TRZAW, TRZAS TRZDU, TRZSP	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) 0,5 - 1 b) 0,5 - 2	a) 0,067* / 0,100** / 0,080*** b) 0,133* / 0,200** / 0,160***	100 - 300	56	For eyespot control, only one application at BBCH 30-32
12	HU, RO, SK	barley HORVW HORVS	F	*B. graminis* - ERYSGR *Pyrenophora teres* - PYRNTE *Puccinia hordei* – PUCCHD	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 0,5 - 1 b) 0,5 - 2	a) 0,067* / 0,100** / 0,080*** b) 0,133* / 0,200** / 0,160***	100 - 300	56	
13	HU, RO, SK	rye SECCW SECCS SECCE	F	*R. secalis* - RHYNSE *Puccinia recondita* - PUCCRE	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 0,5 - 1 b) 0,5 - 2	a) 0,067* / 0,100** / 0,080*** b) 0,133* / 0,200** / 0,160***	100 - 300	56	

14	HU, RO, SK	triticale TTLWI TTLSO	F	*B. graminis* - ERYSGR *Septoria spp.* - SEPTSP *Puccinia recondita* - PUCCRE *Puccinia striiformis* – PUCCST	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 0,5 - 1 b) 0,5 - 2	a) 0,067* / 0,100** / 0,080*** b) 0,133* / 0,200** / 0,160***	100 - 300	56	
15	HU, RO, SK	oat AVESA	F	*B. graminis* - ERYSGR *Puccinia coronata* - PUCCCA	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 0,5 - 1 b) 0,5 - 2	a) 0,067* / 0,100** / 0,080*** b) 0,133* / 0,200** / 0,160***	100 - 300	56	
16	PL	wheat TRZAW, ~~TRZDU, TRZSP~~	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
17	PL	wheat TRZAS	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
18	PL	barley HORVW	F	~~*B. graminis* - ERYSGR~~ *Pyrenophora teres* - PYRNTE *R. secalis* - RHYNSE ~~*R. collo-cygni* - RAMUCC~~ *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	
19	PL	barley HORVS	F	~~*B. graminis* - ERYSGR~~ *Pyrenophora teres* -	Spraying (SP)	30 - 59	a) 2 b) 2	14	a) 1,5 b) 3	a) 0,100* / 0,150** /	100 - 300	56	

				PYRNTE *R. secalis* - RHYNSE ~~*R. collo-cygni* - RAMUCC~~ *Puccinia hordei* - PUC-CHD						0,120*** b) 0,200* / 0,300** / 0,240***			
20	PL	Barley HORVW barley HORVS	F	*B. graminis - ERYSGR*	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	
21	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	
22	PL	triticale TTLWI	F	*B. graminis* - ERYSGR *Septoria spp.* - SEPTTR *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	
~~23~~	~~PL~~	~~triticale TTLSO~~	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~~	
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
Minor uses according to Article 51 (zonal uses)													
Minor uses according to Article 51 (interzonal uses)													

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