

FINAL REGISTRATION REPORT

Part B

Section 9

Ecotoxicology

Detailed summary of the risk assessment

Product code: GLOB2021dF

Product name: PIRLANKO

Chemical active substances:

Prothioconazole, 156 g/L

Boscalid, 156 g/L

Central Zone

Zonal Rapporteur Member State:

Poland

CORE ASSESSMENT

(authorization)

Applicant: GLOBACHEM NV

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When	What
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January 2025	zRMS evaluation
May 2025	Following commenting period
June 2025	Verification of reference list
April 2026	Fixing small GAP-related mistake – applicant proposal
May 2026	zRMS conclusion regarding GAP mistake
June 2026	Final Report

Table of Contents

9	Ecotoxicology (KCP 10).....	7
9.1	Critical GAP and overall conclusions.....	8
9.1.1	Overall conclusions.....	10
9.1.1.1	Table 9.1-3 Metabolites of Prothioconazole.....	10
9.1.1.2	Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3).....	10
9.1.1.3	Effects on aquatic organisms (KCP 10.2).....	10
9.1.1.4	Effects on bees (KCP 10.3.1).....	11
9.1.1.5	Effects on arthropods other than bees (KCP 10.3.2)	11
9.1.1.6	Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)	11
9.1.1.7	Effects on non-target terrestrial plants (KCP 10.6)	11
9.1.1.8	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	12
9.1.2	Grouping of intended uses for risk assessment.....	12
9.1.3	Consideration of metabolites	12
9.2	Effects on birds (KCP 10.1.1).....	14
9.2.1	Toxicity data	14
9.2.1.1	Justification for new endpoints	15
9.2.2	Risk assessment for spray applications.....	15
9.2.2.1	First-tier assessment (screening/generic focal species)	15
(a)	Boscalid.....	15
(b)	Prothioconazole.....	19
(c)	Prothioconazole-desthio.....	21
(d)	GLOB2021dF	25
9.2.2.2	Higher-tier risk assessment.....	29
9.2.2.3	Drinking water exposure.....	29
9.2.2.4	Effects of secondary poisoning.....	30
9.2.2.5	Biomagnification in terrestrial food chains.....	34
9.2.3	Risk assessment for baits, pellets, granules, prills or treated seed.....	34
9.2.4	Overall conclusions.....	35
9.3	Effects on terrestrial vertebrates other than birds (KCP 10.1.2).....	36
9.3.1	Toxicity data	36
9.3.1.1	Justification for new endpoints	36
9.3.2	Risk assessment for spray applications.....	37
9.3.2.1	First-tier assessment (screening/generic focal species)	37
(a)	Boscalid.....	37
(b)	Prothioconazole.....	40
(c)	Prothioconazole-desthio.....	42
(d)	GLOB2021dF	45
9.3.2.2	Higher-tier risk assessment.....	52
9.3.2.3	Drinking water exposure.....	52
9.3.2.4	Effects of secondary poisoning.....	53
9.3.2.5	Biomagnification in terrestrial food chains.....	57
9.3.3	Risk assessment for baits, pellets, granules, prills or treated seed.....	57
9.3.4	Overall conclusions.....	57

9.4	Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)	58
9.5	Effects on aquatic organisms (KCP 10.2).....	58
9.5.1	Toxicity data	58
9.5.1.1	Justification for new endpoints	61
9.5.2	Risk assessment	61
9.5.2.1	Boscalid.....	62
9.5.2.2	Prothioconazole 1.....	72
9.5.2.3	Prothioconazole 2.....	88
9.5.2.4	Prothioconazole-desthio 1.....	104
9.5.2.5	Prothioconazole-desthio 2.....	116
9.5.2.6	Prothioconazole: S-methyl and 1,2,4-triazole.....	127
9.5.2.7	Step 4: Prothioconazole-desthio	139
9.5.2.8	Combination toxicity assessment.....	146
9.5.3	Summary of mitigation measures	166
9.5.4	Overall conclusions.....	168
9.6	Effects on bees (KCP 10.3.1).....	171
9.6.1	Toxicity data	171
9.6.1.1	Justification for new endpoints	172
9.6.2	Acute Risk assessment.....	172
9.6.2.1	Hazard quotients for bees.....	172
9.6.2.2	Acute risk assessment (KCP 10.3.1.1) according to EFSA 2013.....	172
9.6.2.3	Higher-tier risk assessment for bees (tunnel test, field studies).....	173
9.6.3	Chronic Risk Assessment	173
9.6.3.1	Chronic risk assessment (KCP 10.3.1.1) according to EPPO 2010.....	173
9.6.3.2	Chronic risk assessment (KCP 10.3.1.1) according to EFSA 2013.....	175
9.6.4	Effects on bumblebees	179
9.6.4.1	Hazard quotients for bumblebees.....	179
9.6.4.1	Acute risk assessment (KCP 10.3.1.1) to bumblebees according to EFSA 2013.....	179
9.6.5	Effects on solitary bees	182
9.6.6	Overall conclusions.....	182
9.7	Effects on arthropods other than bees (KCP 10.3.2)	183
9.7.1	Toxicity data	183
9.7.1.1	Justification for new endpoints	185
9.7.2	Risk assessment	185
9.7.2.1	Risk assessment for in-field exposure.....	185
9.7.2.2	Risk assessment for off-field exposure	186
9.7.2.3	Additional higher-tier risk assessment.....	188
9.7.2.4	Risk mitigation measures	188
9.7.3	Overall conclusions.....	188
9.8	Effects on non-target soil meso- and macrofauna (KCP 10.4)	188
9.8.1	Toxicity data	188
9.8.1.1	Justification for new endpoints	191
9.8.2	Risk assessment	191
9.8.2.1	First-tier risk assessment.....	191
9.8.2.2	Higher-tier risk assessment.....	197
9.8.3	Overall conclusions.....	198
9.9	Effects on soil microbial activity (KCP 10.5).....	199

9.9.1	Toxicity data	199
9.9.1.1	Justification for new endpoints	200
9.9.2	Risk assessment	200
9.9.3	Overall conclusions.....	202
9.10	Effects on non-target terrestrial plants (KCP 10.6)	203
9.10.1	Toxicity data	203
9.10.1.1	Justification for new endpoints	203
9.10.2	Risk assessment	203
9.10.2.1	Tier-1 risk assessment (based screening data)	203
9.10.2.2	Tier-2 risk assessment (based on dose-response data).....	204
9.10.2.3	Higher-tier risk assessment	204
9.10.2.4	Risk mitigation measures	205
9.10.3	Overall conclusions.....	205
9.11	Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)	207
9.12	Monitoring data (KCP 10.8)	207
9.13	Classification and Labelling	207
Appendix 1	Lists of data considered in support of the evaluation	209
Appendix 2	Detailed evaluation of the new studies	215
A 2.1	KCP 10.2 Effects on aquatic organisms	215
A 2.2	KCP 10.3 Effects on arthropods	220
A 2.3	KCP 10.4 Effects on non-target soil meso- and macrofauna.....	239
A 2.4	KCP 10.5 Effects on soil nitrogen transformation.....	244
A 2.5	KCP 10.6 Effects on terrestrial non-target higher plants.....	245

9 Ecotoxicology (KCP 10)

9.1 Critical GAP and overall conclusions

Table 9.1-1: Table of critical GAPs

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
Use-No. *	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	Conclusion						
					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	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Birds	Mammals	Aquatic organisms	Bees	Non-target arthro-	Soil organisms	Non-target plants
Zonal uses (field or outdoor uses, certain types of protected crops)																				
1	PL, CZ, DE, HU, RO, SK, BE	Oilseed Rape	F	Leptma Alternaria Sclerotinia	Foliar Spray	BBCH 14-18	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	N/A	1 application in autumn and 1 application not in autumn.							
2						BBCH 21-64 69	a) 1 b) 2						2 applications in spring.							
3-16	PL, CZ, DE, HU, RO, SK, BE	Cereals	F	Fusarium Rust Powdery mildew Leaf blotch, leaf spot	Foliar Spray	BBCH 25 - 69	a) 1 b) 2	21	a) 0.8 L/ha b) 1.6 L/ha	a) Prothioconazole : 0.125 Boscalid : 0.125 b) Prothioconazole : 0.250 Boscalid : 0.250	100 - 300	N/A	/							

Explanation for column 15 – 21 “Conclusion”

A	Acceptable, Safe use
R	Further refinement and/or risk mitigation measures required

C	To be confirmed by eMS
N	No safe use

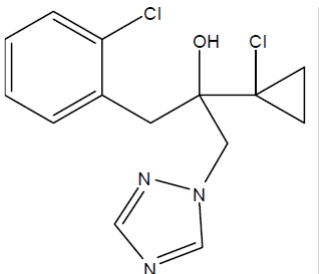
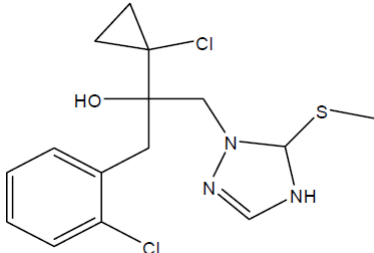
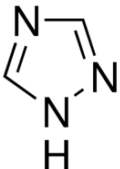
Remarks table:

- | | |
|---|---|
| <ul style="list-style-type: none"> (1) Numeration necessary to allow references (2) Use official codes/nomenclatures of EU (3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> 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 <u>and</u> 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 | <ul style="list-style-type: none"> (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 |
|---|---|

zRMS conclusion: The GAP change for oilseed rape from BBCH 61 to 69 is already covered by the existing risk assessment for non-target organisms.

9.1.1 Overall conclusions

9.1.1.1 Table 9.1-3 Metabolites of Prothioconazole

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Prothioconazole-desthio		312.2 g/mol	Soil: > 10 % of a.s. Sediment/water: > 10 % of a.s.	Yes, aquatic organisms and soil organisms
Prothioconazole-S-methyl (M01)		358.3 g/mol	Soil: > 10 % of a.s.	Yes, aquatic organisms and soil organisms
1,2,4- triazole (M13)		69.065 g/mol	Sediment/water: > 10 % of a.s.	Yes, aquatic organisms

9.1.1.2 Effects on birds (KCP 10.1.1), Effects on terrestrial vertebrates other than birds (KCP 10.1.2), Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

The TER_a value is greater than the Annex VI trigger of 10, indicating low acute risk to birds from boscalid, prothioconazole and metabolites following application of GLOB2021dF at the intended GAP. The TER_{lt} value for boscalid, prothioconazole and metabolites is greater than the Annex VI trigger of 5, indicating that GLOB2021dF presents no unacceptable long-term risk to birds when applied according to the proposed GAP.

9.1.1.3 Effects on aquatic organisms (KCP 10.2)

The TER_a and TER_{lt} for GLOB2021dF, the active substances and the metabolites are above the Annex VI trigger values, indicating that GLOB2021dF poses low acute and chronic risk to aquatic organisms when the following risk mitigation measures are taken into account:
Appropriate risk mitigation measures are given in section 9.5.

Winter oilseed rape 2 x 125g boscalid and 125g prothioconazole/ ha:

~~5m vegetated filter strip~~

~~Spring oilseed rape 2 x 125g boscalid and 125g prothioconazole/ ha:~~
~~5m vegetated filter strip~~

~~Winter cereals 2 x 125g boscalid and 125g prothioconazole/ ha:~~
~~5m vegetated filter strip~~

~~Spring cereals 2 x 125g boscalid and 125g prothioconazole/ ha:~~
~~- /~~

9.1.1.4 Effects on bees (KCP 10.3.1)

HQ values for oral and dermal exposure are below the relevant trigger. Therefore, it can be assumed that the intended uses of GLOB2021dF represent low acute risk exposure to honeybees and bumblebee.

The chronic TERs for honey bee adults and larvae are higher than the trigger of 1, indicating that the proposed uses according to the intended GAP of GLOB2021dF poses an acceptable chronic risk to honey bee larvae and adults.

Based on the EFSA 2013 guidance for the risk assessments on bees, the use of the proposed refinements results in an acceptable risk towards bees.

9.1.1.5 Effects on arthropods other than bees (KCP 10.3.2)

The PER values all fall below the relevant trigger value indicating an acceptable risk for non-target arthropods for the intended use of GLOB2021dF.

9.1.1.6 Effects on non-target soil meso- and macrofauna (KCP 10.4), Effects on soil microbial activity (KCP 10.5)

The TER values together with the higher tier field study indicate an acceptable risk for earthworms and other non-target soil organisms for the intended use of GLOB2021dF.

As the $PEC_{\text{soil, accumulation}}$ of boscalid, prothioconazole, its metabolites and the formulation are all lower than the concentration at which no significant effects are detected, it can be concluded that the risk of GLOB2021dF to soil micro-organisms is acceptable in accordance with the intended use.

9.1.1.7 Effects on non-target terrestrial plants (KCP 10.6)

First tier risk assessment indicates that there is no unacceptable risk from GLOB2021dF for non-target plants when applied according to the proposed use rates.

9.1.1.8 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Not relevant.

9.1.2 Grouping of intended uses for risk assessment

The following table documents the grouping of the intended uses to support application of the risk envelope approach (according to SANCO/11244/2011).

GLOB21dF is intended to be used twice on winter and spring oilseed rape and twice on winter and spring cereals against various fungal diseases. The highest possible dose rate is 0.8 L/ha for all crops. Different grouping of the uses is performed in the risk assessment:

- For birds the use in oilseed rape covers also cereals.
- For mammals, all uses are considered separately for the risk assessment.
- For the aquatic organisms, all uses are considered separately for the risk assessment.
- For the bees and the other non-target arthropods, all uses are covered by the use on oilseed rape.
- For soil dwelling organisms, oilseed rape cover the use in cereals.

9.1.3 Consideration of metabolites

A list of metabolites found in environmental compartments is provided below. The need for conducting a metabolite-specific risk assessment in the context of the evaluation of GLOB2021dF is indicated in the table.

Table 9.1-2 Metabolites of Boscalid

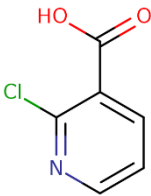
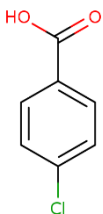
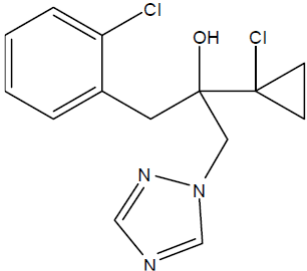
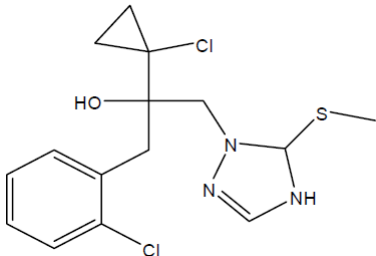
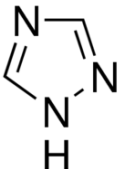
Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
M510F47		157.6	Soil: anaerobic conditions. 2.6 % after 3 d, 6 % after 62 d, 5.9 % after 90 d, 6.7 % after 120 d	No
M510F64		156.56	Sediment: under outdoor conditions 7.3 % after 7 d 9 % after 14 d 9.4 % after 30 d 1.9 % after 120 d	No

Table 9.1-3 Metabolites of Prothioconazole

Metabolite	Chemical structure	Molar mass	Maximum occurrence in compartments	Risk assessment required?
Prothioconazole-desthio		312.2 g/mol	Soil: > 10 % of a.s. Sediment/water: > 10 % of a.s.	Yes, aquatic organisms and soil organisms
Prothioconazole-S-methyl (M01)		358.3 g/mol	Soil: > 10 % of a.s.	Yes, aquatic organisms and soil organisms
1,2,4- triazole (M13)		69.065 g/mol	Sediment/water: > 10 % of a.s.	Yes, aquatic organisms

9.2 Effects on birds (KCP 10.1.1)

9.2.1 Toxicity data

Avian toxicity studies have been carried out with boscalid, prothioconazole and the major plant metabolite prothioconazole-desthio. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on birds from GLOB2021dF were not evaluated as part of the EU assessment of boscalid or prothioconazole. However, the provision of further data on the GLOB2021dF is not considered essential, because active substance data on toxicity to birds can be used and additional formulation data are not considered essential.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.2-1: Endpoints and effect values relevant for the risk assessment for birds

Species	Substance	Exposure System	Results	Reference
<i>Colinus virginianus</i>	Boscalid	Oral Acute	LD₅₀ > 2000 mg/kg bw	EFSA 2008
<i>Anas platyrhynchos</i> L. <i>Colinus virginianus</i>	Boscalid	Dietary Short-term	LC ₅₀ > 5000 mg/kg feed	EFSA 2008
<i>Colinus virginianus</i>	Boscalid	Dietary Reproductive toxicity	NOEL = 24.1 mg/kg bw/d	EFSA 2008
Bobwhite quail	Prothioconazole	Oral 1 d, Acute	LD ₅₀ > 2000 mg as/kg bw	EFSA 2007
Bobwhite quail	Prothioconazole	Dietary 5 d	LC ₅₀ > 5000 mg a.s./kg diet Calc LD₅₀ > 1413 mg a.s./kg bw/d	EFSA 2007
Mallard duck	Prothioconazole	Dietary 5 d	LC ₅₀ > 5000 mg a.s./kg diet Calc LD ₅₀ > 2457 mg a.s./kg bw/d	EFSA 2007
Bobwhite quail	Prothioconazole-desthio	Oral 1 d, Acute	LD ₅₀ > 2000 mg as/kg bw	EFSA 2007
Bobwhite quail	Prothioconazole-desthio (M04)	Dietary 5 d	LC ₅₀ = 4090 mg p.m./kg diet Calc LD₅₀¹ > 297 mg p.m./kg bw/d	EFSA 2007
Bobwhite quail	Prothioconazole	Subchronic and reproductive toxicity	NOEC ≥ 1000 mg a.s./kg diet Calc NOEL ≥ 86 mg a.s./kg bw/d	EFSA 2007
Mallard duck	Prothioconazole	Subchronic and reproductive toxicity	NOEC = 700 mg a.s./kg diet Calc NOEL = 78 mg a.s./kg bw/d	EFSA 2007
Bobwhite quail	Prothioconazole-desthio	Subchronic and reproductive toxicity	NOEC ≥ 173 mg p.m./kg diet	EFSA 2007

Species	Substance	Exposure System	Results	Reference
			Calc NOEL $\geq$ 14.8 mg p.m./kg bw/d	
Mallard duck	Prothioconazole-desthio (M04)	Subchronic and reproductive toxicity	NOEC $\geq$ 500 mg p.m./kg diet Calc NOEL = 63 mg p.m./kg bw/d	EFSA 2007

9.2.1.1 Justification for new endpoints

According to the Guidance EFSA/2009/1438, where the dietary LC₅₀ is lower than the acute LD₅₀, the dietary value should be used in the acute risk assessment. Therefore, LC₅₀ > 1413 mg prothioconazole/kg bw and LD₅₀ > 297 mg prothioconazole-desthio/kg bw was used in the acute risk assessment as a worst case for active substance prothioconazole and metabolite prothioconazole-desthio.

9.2.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Birds and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.2.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

(a) Boscalid

Multiple applications

Table 9.2-2: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from boscalid due to the use of GLOB2021dF in oilseed rape (2 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Boscalid				
Application rate (g/ha)		2 x 125				
Acute toxicity (mg/kg bw)		>2000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1.1	21.84	91.60	
Reprod. toxicity (mg/kg bw/d)		24.1				
TER criterion		5				

Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Screening					
-	Small omnivorous bird	64.8	0.636	5.15	4.68
Tier 1					
late - late with seeds (BBCH 30-99)	Small insectivorous bird "dunnock"	2.7	0.636	0.21	112.28
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.636	0.87	27.81
BBCH 30-39	Small omnivorous bird "lark"	3.3	0.636	0.26	91.86
BBCH ≥ 40	Small omnivorous bird "lark"	2.7	0.636	0.21	112.28
BBCH 20-29	Medium herbivorous/granivorous bird "pigeon"	3.5	0.636	0.28	86.61
BBCH 30-39	Medium herbivorous/granivorous bird "pigeon"	1.1	0.636	0.09	275.59
BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"	0.9	0.636	0.07	336.83
~~10 - 19~~	~~Small insectivorous bird "woodlark"~~	~~5.1~~	~~0.636~~	~~0.41~~	~~59.44~~
~~20 - 29~~	~~Small insectivorous bird "wagtail"~~	~~2.4~~	~~0.636~~	~~0.19~~	~~126.31~~
Oilseed rape early (shoots) (BBCH 10- 19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	15.9			19.1
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7			13.4
Oilseed rape BBCH 20 - 29	Small insectivorous bird "wagtail" ground invertebrates with interception 100% soil dwelling invertebrates	2.8			108.3
Oilseed rape BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9			51.4

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-3: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from boscalid due to the use of GLOB2021dF in cereals (2 x 125 g/ha)

Intended use	Cereals
Active substance/product	Boscalid

Application rate (g/ha)	2 x 125				
Acute toxicity (mg/kg bw)	>2000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Screening step	Small omnivorous bird	158.8	1.1	21.84	91.60
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Screening					
-	Small omnivorous bird	64.8	0.636	5.15	4.68
Tier 1					
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.636	0.87	27.81
BBCH 30-39	Small omnivorous bird "lark"	5.4	0.636	0.43	56.14
BBCH ≥40	Small herbivorous bird "lark"	3.3	0.636	0.26	91.86
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" Grass + cereals 100% cereal shoots	16.2			18.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Single application

Table 9.2-4: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from boscalid due to the use of GLOB2021dF in oilseed rape (1 x 125 g/ha)

Intended use	Oilseed rape				
Active substance/product	Boscalid				
Application rate (g/ha)	1 x 125				
Acute toxicity (mg/kg bw)	>2000				
TER criterion	10				
Crop scenario	Indicator/generic focal species	SV₉₀	MAF₉₀	DDD₉₀ (mg/kg bw/d)	TER_a
Growth stage					
Screening step	Small omnivorous bird	158.8	1	19.85	100.76
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{lt}
Growth stage					
Screening					
-	Small omnivorous bird	64.8	0.53	4.293	5.61
Tier 1					

late - late with seeds (BBCH 30-99)	Small insectivorous bird "dunnock"	2.7	0.53	0.18	134.73
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.53	0.72	33.37
BBCH 30-39	Small omnivorous bird "lark"	3.3	0.53	0.22	110.23
BBCH ≥ 40	Small omnivorous bird "lark"	2.7	0.53	0.18	134.73
BBCH 20-29	Medium herbivorous/granivorous bird "pigeon"	3.5	0.53	0.23	103.94
BBCH 30-39	Medium herbivorous/granivorous bird "pigeon"	1.1	0.53	0.07	330.70
BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"	0.9	0.53	0.06	404.19
~~10 - 19~~	~~Small insectivorous bird "woodlark"~~	~~5.1~~	~~0.53~~	~~0.34~~	~~71.33~~
~~20 - 29~~	~~Small insectivorous bird "wagtail"~~	~~2.4~~	~~0.53~~	~~0.16~~	~~151.57~~
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	15.9			22.9
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7			16.0
Oilseed rape BBCH 20 - 29	Small insectivorous bird "wagtail" ground invertebrates with interception 100% soil dwelling invertebrates	2.8			129.9
Oilseed rape BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9			61.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-5: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from boscalid due to the use of GLOB2021dF in cereals (1 x 125 g/ha)

Intended use	Cereals				
Active substance/product	Boscalid				
Application rate (g/ha)	1 x 125				
Acute toxicity (mg/kg bw)	>2000				
TER criterion	10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a

Screening step	Small omnivorous bird	158.8	1	19.85	100.76
Reprod. toxicity (mg/kg bw/d)	24.1				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Screening					
-	Small omnivorous bird	64.8	0.53	4.293	5.61
Tier 1					
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.53	0.72	33.37
BBCH 30-39	Small omnivorous bird "lark"	3.3	0.53	0.22	110.23
BBCH ≥ 40	Small omnivorous bird "lark"	2.7	0.53	0.18	134.73
Cereals Early (shoots) autumn- winter BBCH 10-29	Large herbivorous bird "goose" Grass + cereals 100% cereal shoots	16.2			22.5

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER:

(b) Prothioconazole

Multiple applications

Table 9.2-6: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole due to the use of GLOB2021dF in oilseed rape (2 x 125 g/ha)

Intended use		Oilseed rape			
Active substance/product		Prothioconazole			
Application rate (g/ha)		2 x 125			
Acute toxicity (mg/kg bw)		>1413			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Screening step	Small omnivorous bird	158.8	1.2 1.1	23.82-21.84	59.32 64.7
Reprod. toxicity (mg/kg bw/d)	78				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Screening					
-	Small omnivorous bird	64.8	0.742-0.636	6.040 5.15	12.98 15.1

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-7: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole due to the use of GLOB2021dF in cereals (2 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Prothioconazole				
Application rate (g/ha)		2 x 125				
Acute toxicity (mg/kg bw)		>1413				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1.1	21.84	64.71	
Reprod. toxicity (mg/kg bw/d)		78				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small omnivorous bird	64.8	0.636	5.15	15.14	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Single application

Table 9.2-8: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole due to the use of GLOB2021dF in oilseed rape (1 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Prothioconazole				
Application rate (g/ha)		1 x 125				
Acute toxicity (mg/kg bw)		>1413				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1	19.85	71.84	
Reprod. toxicity (mg/kg bw/d)		78				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small omnivorous bird	64.8	0.53	4.293	18.17	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-9: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole due to the use of GLOB2021dF in cereals (1 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Prothioconazole				
Application rate (g/ha)		1 x 125				
Acute toxicity (mg/kg bw)		>1413				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1	19.85	100.756	
Reprod. toxicity (mg/kg bw/d)		78				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small omnivorous bird	64.8	0.53	4.293	18.17	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER:

(c) Prothioconazole-desthio

Multiple applications

Table 9.2-10: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole-desthio due to the use of GLOB2021dF in oilseed rape (2 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Prothioconazole-desthio				
Application rate (g/ha)		2 x 113.75				
Acute toxicity (mg/kg bw)		>297				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1.1	19.87	14.95	
Reprod. toxicity (mg/kg bw/d)		14.8				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}	
Growth stage						
Screening						
-	Small omnivorous bird	64.8	0.636	4.69	3.16	

Tier 1					
late - late with seeds (BBCH 30-99)	Small insectivorous bird "dunnock"	2.7	0.636	0.20	75.77
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.636	0.79	18.77
BBCH 30-39	Small omnivorous bird "lark"	3.3	0.636	0.24	61.99
BBCH ≥ 40	Small omnivorous bird "lark"	2.7	0.636	0.20	75.77
BBCH 20-29	Medium herbivorous/granivorous bird "pigeon"	3.5	0.636	0.25	58.45
BBCH 30-39	Medium herbivorous/granivorous bird "pigeon"	1.1	0.636	0.08	185.98
BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"	0.9	0.636	0.07	227.31
10 - 19	Small insectivorous bird "woodlark"	5.1	0.636	0.37	40.11
20 - 29	Small insectivorous bird "wagtail"	2.4	0.636	0.17	85.24
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	15.9			12.9
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7			9.0
Oilseed rape BBCH 20 - 29	Small insectivorous bird "wagtail" ground invertebrates with interception 100% soil dwelling invertebrates	2.8			73.1
Oilseed rape BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9			34.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-11: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole-desthio due to the use of GLOB2021dF in cereals (2 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Prothioconazole-desthio				
Application rate (g/ha)		2 x 113.75				
Acute toxicity (mg/kg bw)		>297				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀	TER _a	

Growth stage				(mg/kg bw/d)	
Screening step	Small omnivorous bird	158.8	1.1	19.87	14.95
Reprod. toxicity (mg/kg bw/d)	14.8				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Screening					
-	Small omnivorous bird	64.8	0.636	4.69	3.16
Tier 1					
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.636	0.87	17.08 18.8
BBCH 30-39	Small omnivorous bird "lark"	5.4	0.636	0.43	34.47 37.9
BBCH ≥40	Small herbivorous bird "lark"	3.3	0.636	0.26	56.41 62.0
Cereals Early (shoots) autumn- winter BBCH 10-29	Large herbivorous bird "goose" Grass + cereals 100% cereal shoots	16.2			12.6

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Single application

Table 9.2-12: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole-desthio due to the use of GLOB2021dF in oilseed rape (1 x 125 g/ha)

Intended use		Oilseed rape			
Active substance/product		Prothioconazole-desthio			
Application rate (g/ha)		1 x 113.75			
Acute toxicity (mg/kg bw)		>297			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Screening step	Small omnivorous bird	158.8	1	18.06	16.44
Reprod. toxicity (mg/kg bw/d)	14.8				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{it}
Screening					
-	Small omnivorous bird	64.8	0.53	3.91	3.79
Tier 1					
late - late with seeds (BBCH 30-99)	Small insectivorous bird "dunnock"	2.7	0.53	0.16	90.92
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.53	0.66	22.52
BBCH 30-39	Small omnivorous bird "lark"	3.3	0.53	0.20	74.39

BBCH ≥ 40	Small omnivorous bird "lark"	2.7	0.53	0.16	90.92
BBCH 20-29	Medium herbivorous/granivorous bird "pigeon"	3.5	0.53	0.21	70.14
BBCH 30-39	Medium herbivorous/granivorous bird "pigeon"	1.1	0.53	0.07	223.17
BBCH ≥ 40	Medium herbivorous/granivorous bird "pigeon"	0.9	0.53	0.05	272.77
~~10 - 19~~	~~Small insectivorous bird "woodlark"~~	~~5.1~~	~~0.53~~	~~0.31~~	~~48.14~~
~~20 - 29~~	~~Small insectivorous bird "wagtail"~~	~~2.4~~	~~0.53~~	~~0.14~~	~~102.29~~
Oilseed rape early (shoots) (BBCH 10-19)	Large herbivorous bird "goose" Non-grass herbs 100% crop shoots	15.9			15.4
Oilseed rape BBCH 10 - 19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	22.7			10.8
Oilseed rape BBCH 20 - 29	Small insectivorous bird "wagtail" ground invertebrates with interception 100% soil dwelling invertebrates	2.8			87.7
Oilseed rape BBCH 10 - 19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	5.9			41.6

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.2-13: Screening and first-tier assessment of the acute and long-term/reproductive risk for birds from prothioconazole-desthio due to the use of GLOB2021dF in cereals (1 x 125 g/ha)

Intended use		Cereals			
Active substance/product		Prothioconazole-desthio			
Application rate (g/ha)		1 x 113.75			
Acute toxicity (mg/kg bw)		>297			
TER criterion		10			
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Growth stage	Small omnivorous bird	158.8	1	18.06	16.44
Reprod. toxicity (mg/kg bw/d)		14.8			
TER criterion		5			
Crop scenario	Indicator/generic focal species	SV _m	MAF _m ×	DDD _m	TER _{it}

Growth stage			TWA	(mg/kg bw/d)	
Screening					
-	Small omnivorous bird	64.8	0.53	3.91	3.79
Tier 1					
BBCH 10-29	Small omnivorous bird "lark"	10.9	0.53	0.66	22.52
BBCH 30-39	Small omnivorous bird "lark"	5.4	0.53	0.33	45.46
BBCH ≥40	Small herbivorous bird "lark"	3.3	0.53	0.20	74.39
Cereals Early (shoots) autumn-winter BBCH 10-29	Large herbivorous bird "goose" Grass + cereals 100% cereal shoots	16.2			15.2

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER:

(d) GLOB2021dF

Combined risk assessment was performed for Boscalid, Prothioconazole and its metabolite Prothioconazole-desthio (M04). As a worst-case approach, assuming the toxicity of the mixture to be entirely additive (i.e. no synergism), a theoretical endpoint for the mixture can be calculated from the appropriate LD₅₀ and NOEC/NOEL values for each of the active substances, resp. metabolite by applying Finney's formula (following Appendix B of EFSA/2009/1438).

In order to determine the ratio of the metabolite Prothioconazole-desthio (M04) within the mixture, the maximum formation fraction of the metabolite was adjusted for molecular weight to get the following:

- The molecular weight conversion is carried out by taking the molecular weight of the metabolite (312.2g/mol) divided by the molecular weight of the parent (344.3g/mol) = 0.91
- multiplied by the formation fraction of 1.0 of parent = 0.91 x 1.0 = 0.91

Therefore in the case of the combination assessment for birds and mammals, out of a total of 125 g of prothioconazole, 113.75 of that will degrade to Prothioconazole-desthio (M04).

Approach 1

Assessment presented for both active substances Boscalid and Prothioconazole.

Acute risk

For the assessment of the acute risk to birds, the following formula is used to derive a surrogate LD₅₀ for the mixture of active substances with known toxicity assuming additivity:

$$LD_{50}(\text{mix}) = \left(\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} \right)^{-1}$$

With:

X(a.s._i) = fraction of active substance [i] in the mixture;
(please note that the sum $\sum X(a.s._i)$ must be 1)

LD₅₀(a.s._i) = acute toxicity value for active substance [i]

For GLOB2021dF, the LD₅₀ (mix) amounts to 1656.02 mg/kg bw = ((0.5/2000) + (0.5/1413))⁻¹

Multiple applications

Table 9.2-14: Screening and first-tier assessment of the acute risk for birds due to the use of GLOB2021dF in oilseed rape (2 x 893 g/ha)

Intended use		Oilseed rape				
Active substance/product		GLOB2021dF				
Application rate (g/ha)		2 x 893* 2 x 0.250				
Acute toxicity (mg/kg bw)		1656.02				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1.1	155.99 43.67	10.62 37.9	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger. *Based on a density of 1.1168 mg/mL.

Single application

Table 9.2-15: Screening and first-tier assessment of the acute risk for birds due to the use of GLOB2021dF in oilseed rape (1 x 893 g/ha)

Intended use		Oilseed rape				
Active substance/product		GLOB2021dF				
Application rate (g/ha)		1 x 893* 1 x 250				
Acute toxicity (mg/kg bw)		1656.02				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1	141.808 39.7	11.69 41.7	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger. *Based on a density of 1.1168 mg/mL.

Based on the screening step and Tier 1, the combined acute risk is acceptable for the use on oilseed rape, covering use on cereal. Therefore, no further risk assessment was performed for combination of active substances.

Long-term risk

A calculated NOEL for the mixture is unlikely to constitute a reliable measure of toxicity as NOEL values may represent varying risk or response levels for different compounds. It is therefore not the current practice to derive a surrogate NOEL for the mixture of active substances as has been done for the acute risk. Alternatively, to assess the long-term risk to birds, a common accepted approach by different member states is to calculate a combined TER(mix) for each exposure scenario (bare soil and oilseed rape) using the following equation:

$$TER_{(mix)} = \left(\sum_i \frac{1}{TER_{(a.s._i)}} \right)^{-1}$$

where:

$TER_{(a.s._i)}$ = calculated TER for the active substance i

Multiple applications

$$\begin{aligned} TER_{(mix) \text{ chronic oilseed rape}} &= ((1/27.81 \text{ 13.4}) + (1/15.14 \text{ 2.98}))^{-1} = 8.85 \text{ 7.09} \\ TER_{(mix) \text{ chronic cereals}} &= ((1/27.81 \text{ 18.7}) + (1/15.14 \text{ 2.98}))^{-1} = 8.85 \text{ 8.35} \end{aligned}$$

Single applications

$$\begin{aligned} TER_{(mix) \text{ chronic oilseed rape}} &= ((1/33.37 \text{ 16.0}) + (1/18.17))^{-1} = 11.76 \text{ 8.5} \\ TER_{(mix) \text{ chronic cereals}} &= ((1/33.37 \text{ 22.5}) + (1/18.17))^{-1} = 11.76 \text{ 10.05} \end{aligned}$$

In case the use of the TER resulting from the screening step did not indicate an acceptable risk, the lowest TER value calculated at tier 1 is used, as. Both chronic $TER_{(mix)}$ are higher than the trigger of 5, therefore the combined long-term risk is acceptable.

Approach 2

Assessment presented for Boscalid and metabolite Prothioconazole-desthio (M04).

This conservative approach will assume that 100% of the 125 g/ha of the active substance Prothioconazole will degrade to 113.75 g/ha of the metabolite, Prothioconazole-desthio (M04).

$$LD_{50} (mix) = \left(\sum_i \frac{X(a.s._i)}{LD_{50} (a.s._i)} \right)^{-1}$$

With:

$X(a.s._i)$ = fraction of active substance [i] in the mixture;
(please note that the sum $\sum X(a.s._i)$ must be 1)

$LD_{50}(a.s._i)$ = acute toxicity value for active substance [i]

For Boscalid and Prothioconazole-desthio (M04), $LD_{50} (mix)$ amounts to 517.20 mg/kg bw = $((0.5/2000)+(0.5/297))^{-1}$

Table 9.2-11: Screening step and first tier assessment of the acute combined risk for birds due to the use of GLOB2021dF in oilseed rape based on a surrogate LD_{50}

Intended use		Oilseed rape (covering cereals)				
Active substance/product		GLOB2021dF				
Application rate (g/ha)		2 x 893* 2 x 238.75				
Acute toxicity (mg/kg bw)		517.20				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small omnivorous bird	158.8	1.1	155.99	3.32	

				41.7	12.4
Tier 1					
BBCH 30-99	Small insectivorous bird "dunnoek"	7.4	1.1	7.27	71.15
BBCH 10-29	Small herbivorous bird "lark"	24.0	1.1	23.58	21.94
BBCH 30-39	Small herbivorous bird "lark"	7.2	1.1	7.07	73.13
BBCH ≥40	Small herbivorous bird "lark"	6.0	1.1	5.89	87.75
BBCH 20-29	Small herbivorous/granivorous bird "pigeon"	4.0	1.1	3.93	131.63
BBCH 30-39	Small herbivorous/granivorous bird "pigeon"	2.4	1.1	2.36	219.38
BBCH ≥40	Small herbivorous/granivorous bird "pigeon"	2.0	1.1	1.96	263.26
BBCH 20-29	Small insectivorous bird "wagtail"	7.7	1.1	7.56	68.38
Oilseed rape BBCH 10-19	medium herbivorous/granivorous bird "pigeon" Non-grass herbs 100% crop shoots	55.6	1.1		9.5
Oilseed rape BBCH 10-19	Small insectivorous bird "wagtail" ground invertebrates without interception 100% soil dwelling invertebrates	10.9	1.1		48.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger. *Based on a density of 1.1168 mg/mL.

A calculated NOEL for the mixture is unlikely to constitute a reliable measure of toxicity as NOEL values may represent varying risk or response levels for different compounds. Therefore, to assess the long-term risk to birds a combined TER(mix) for each exposure scenario was calculated using the following equation:

$$TER_{(mix)} = \left(\sum_i \frac{1}{TER_{(a.s._i)}} \right)^{-1}$$

where:

TER_(a.s._i) = calculated TER for the active substance i

Multiple applications

$$TER_{(mix) \text{ chronic oilseed rape}} = ((1/27.81 \ 13.4) + (1/18.77 \ 9.0))^{-1} = 11.21 \ 5.38$$

$$TER_{(mix) \text{ chronic cereals}} = ((1/27.81 \ 18.7) + (1/17.08 \ 12.6))^{-1} = 10.58 \ 7.53$$

Single application

$$TER_{(mix) \text{ chronic oilseed rape}} = ((1/18.17 \ 16.0) + (1/22.52 \ 10.8))^{-1} = 13.45 \ 6.44$$

$$TER_{(mix) \text{ chronic cereals}} = ((1/18.17 \ 22.5) + (1/22.52 \ 15.2))^{-1} = 13.45 \ 9.07$$

For Boscalid and Prothioconazole-desthio the chronic TER_(mix) for oilseed rape and cereals are higher than the trigger of 5, therefore the combined long-term risk is acceptable.

Conclusion

An acceptable acute and long-term combined risk to birds can be concluded.

9.2.2.2 Higher-tier risk assessment

No refinement needed, since the risk was found to be acceptable at a lower tier.

9.2.2.3 Drinking water exposure

When necessary, the assessment of the risk for birds due to uptake of contaminated drinking water is conducted for a small granivorous bird with a body weight of 15.3 g (*Carduelis cannabina*) and a drinking water uptake rate of 0.46 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Leaf scenario

Since GLOB2021dF is not intended to be applied on leafy vegetables forming heads or crop plants with comparable water collecting structures at principal growth stage 4 or later, the leaf scenario does not have to be considered.

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances ($K_{oc} < 500$ L/kg) or 3000 in the case of more sorptive substances ($K_{oc} \geq 500$ L/kg).

With a $K(f)_{oc}$ of 771.2 for Boscalid and a $K(f)_{oc}$ of 1765 mL/g and 573.5 mL/g for prothioconazole and prothioconazole-desthio respectively, both active substances and metabolite belong to the group of more sorptive substances ($K_{oc} \geq 500$ L/kg).

The calculations of oilseed rape with two applications (and thus a MAF of 1.2) at 0.8 L product/ha which covers also the use in cereals. For the metabolite the same application rate of the parent is used, but with a correction for the molecular weight.

Multiple applications

Boscalid

Effective application rate (g/ha)	=	125 x 1.2 = 150	Application rate x MAF
Acute toxicity (mg/kg bw)	=	2000	quotient = 0.075
Reprod. toxicity (mg/kg bw/d)	=	24.1	quotient = 6.224

Prothioconazole

Effective application rate (g/ha)	=	125 x 1.2 = 150	Application rate x MAF
Acute toxicity (mg/kg bw)	=	1413	quotient = 0.11
Reprod. toxicity (mg/kg bw/d)	=	78	quotient = 1.92

Prothioconazole desthio

Effective application rate (g/ha)	=	113.35 x 1.2 = 136.02	Application rate x MAF
Acute toxicity (mg/kg bw)	=	297	quotient = 0.46
Reprod. toxicity (mg/kg bw/d)	=	14.8	quotient = 9.19

Single applications

Boscalid

Effective application rate (g/ha)	=	125 x 1 = 125	Application rate x MAF
Acute toxicity (mg/kg bw)	=	2000	quotient = 0.063
Reprod. toxicity (mg/kg bw/d)	=	24.1	quotient = 5.187

Prothioconazole

Effective application rate (g/ha)	=	125 x 1 = 125	Application rate x MAF
Acute toxicity (mg/kg bw)	=	1413	quotient = 0.088
Reprod. toxicity (mg/kg bw/d)	=	78	quotient = 1.603

Prothioconazole desthio

Effective application rate (g/ha)	=	113.35 x 1 = 113.35	Application rate x MAF
Acute toxicity (mg/kg bw)	=	297	quotient = 0.38
Reprod. toxicity (mg/kg bw/d)	=	14.8	quotient = 7.659

The ratio of the effective application rate to the acute and long term toxicity endpoint is less than 3000 for Boscalid, Prothioconazole and Prothioconazole-desthio. Therefore, it is considered that there is low risk of acute/long term toxicity to birds from the uptake of contaminated drinking water and no further assessment is required.

The resulting acute and chronic ratio are less than the trigger value for both active substances and its metabolite. No further consideration of the risk to birds via drinking water is therefore required. In conclusion, GLOB2021dF poses low acute and long-term risks to birds drinking contaminated water for all intended uses.

9.2.2.4 Effects of secondary poisoning

The log P_{ow} of Boscalid amounts to 2.96 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required for this active.

The log P_{ow} of Prothioconazole, Prothioconazole-desthio, Prothioconazole-S-methyl amounts to 3.82, 3.04 and 4.3, respectively, thus exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore required.

Risk assessment for earthworm-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous birds is assessed for a bird of 100 g body weight with a daily food consumption of 104.6 g. Bioaccumulation in earthworms is estimated based on predicted concentrations in soil.

The risk is only calculated with the two times application on ~~oilseed rape~~ cereals, providing the highest PEC_{soil} values which covers the use in cereals.

Table 9.2-16: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in oilseed rape cereals (2 x 125 g as/ha)

Parameter	Prothioconazole-desthio		Comments
	single multiple	single multiple	
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0174 0.0278	0.0174 0.0256	
log P _{ow} / P _{ow}	3.04/1096.48 3.82/6607		
Koc	573.5 575.4 1765		Mean (n = 4), EFSA Scientific Report (2007)
foc	0.02		Default
BCF _{worm}	1.2204 2.2698		BCF _{worm/soil} = (PEC _{worm,ww} /PEC _{soil,dw}) = (0.84 + 0.012 × P _{ow}) / foc × Koc
PEC _{worm}	0.0212 0.1164 0.0631	0.0212 0.07664 0.05811	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.0223 0.08047 0.08689 0.066	0.0223 0.08047 0.06101	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	14.8 95.6		Review report Prothioconazole
TER _{lt}	663.79 183.91 1448	663.79 183.91 1566	TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.2-17: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole-desthio via bioaccumulation in earthworms (secondary poisoning) for the intended use in oilseed rape cereals (2 x 125 g as/ha)

Parameter	Prothioconazole-desthio		Comments
	multiple	single	
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0174 0.0628	0.0174 0.0628	
log P _{ow} / P _{ow}	3.04/1096.48		
Koc	573.5 575.4		Mean (n = 4), EFSA Scientific Report (2007)
foc	0.02		
BCF _{worm}	1.2204		

Parameter	Prothioconazole-desthio		Comments
	multiple	single	
PEC _{worm}	0.0212 0.07664	0.0212 0.07664	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.0223 0.08047	0.0223 0.08047	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	14.8		
TER _{lt}	663.79 183.91	663.79 183.91	TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.2-18: Assessment of the risk for earthworm-eating birds due to exposure to S-methyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in oilseed rape cereals (2 x 125 g as/ha)

Parameter	S-methyl		Comments
	multiple	single	
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0625 0.0174	0.0668 0.0177	
log P _{ow} / P _{ow}	4.19/15488.17		
Koc	2526 2556.3		Mean (n = 4), EFSA Scientific Report (2007) 106, 1-98
foc	0.02		
BCF _{worm}	3.6955		
PEC _{worm}	0.0610 0.0643	0.1220 0.06541	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.0640 0.06752	0.1281 0.06868	DDD = PEC _{worm} × 1.05
NOEL (mg/kg bw/d)	7.4 7.8		
TER _{lt}	115.58 115	57.79 113	TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Since all calculated TER_{lt} are higher than 5, the risk for earthworm-eating birds from prothioconazole, as well as Prothioconazole-desthio and Prothioconazole-S-methyl exposure is acceptable.

Risk assessment for fish-eating birds via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous birds is assessed for a bird of 1000 g body weight with a daily food consumption of 159 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water. The risk is only calculated for the use with the highest PEC_{sw} as this covers all other uses, which was the use in cereals for boscalid and prothioconazole-desthio and oilseed rape for prothioconazole.

Table 9.2-19: Assessment of the risk for fish-eating birds due to exposure to Boscalid Prothioconazole via bioaccumulation in fish (secondary poisoning) for the intended uses in oilseed rape (2 x 125 g/ha)

Parameter	Prothioconazole		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.0063 0.021		Max. PEC _{sw} oilseed rape Step 2
BCF _{fish}	92		EFSA conclusion Prothioconazole
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.58		PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.09		DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	24.1		EFSA conclusion Prothioconazole
TER _{it}	261.5		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.2-20: Assessment of the risk for fish-eating birds due to exposure to Prothioconazole via bioaccumulation in fish (secondary poisoning) for the intended uses in oilseed rape (2 x 125 g/ha)

Parameter	Prothioconazole		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.0011 0.001289		Max. PEC _{sw} oilseed rape Step 2
BCF _{fish}	18.8 19.7		EFSA conclusion Prothioconazole
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.021 0.025		PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0033 0.004		DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	78		EFSA conclusion Prothioconazole
TER _{it}	23721.8 19318		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.2-21: Assessment of the risk for fish-eating birds due to exposure to Prothioconazole-desthio via bioaccumulation in fish (secondary poisoning) for the intended use in oilseed rape winter cereals (2 x 125 g/ha)

Parameter	Prothioconazole-desthio		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.0007 0.00899		Max. PEC _{sw} oilseed rape winter cereals Step 2

Parameter	Prothioconazole-desthio		Comments
	Multiple	Single	
BCF _{fish}	45 65		EFSA conclusion Prothioconazole
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.032 0.58435		PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0050 0.0929		DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	14.8		EFSA conclusion Prothioconazole
TER _{lt}	2955.0 159		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.2-22: Assessment of the risk for fish-eating birds due to exposure to Prothioconazole-S-methyl via bioaccumulation in fish (secondary poisoning) for the intended use in oilseed rape winter cereals (2 x 125 g/ha)

Parameter	Prothioconazole-S-methyl		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.000042 0.00084		Max. PEC _{sw} oilseed rape winter cereals Step 2
BCF _{fish}	1995		EFSA conclusion Prothioconazole worse-case whole fish BCF values for prothioconazole-S-methyl (M01) taken from the prothioconazole RAR (2018).
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.0083 1.6758		PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.159 0.26645		DDD = PEC _{fish} × 0.159
NOEL (mg/kg bw/d)	7.8		EFSA conclusion Prothioconazole
TER _{lt}	6555.6 29		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

9.2.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.2.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.2.4 Overall conclusions

The TER_a value is greater than the Annex VI trigger of 10, indicating low acute risk to birds from boscalid, prothioconazole and metabolites following application of GLOB2021dF at the intended GAP. The TER_{LT} value for boscalid, prothioconazole and metabolites is greater than the Annex VI trigger of 5, indicating that GLOB2021dF presents no unacceptable long-term risk to birds when applied according to the proposed GAP.

Combined risk assessment was performed for both active substances Boscalid and Prothioconazole (approach 1) and for metabolite Prothioconazole-desthio (M04) and Boscalid (approach 2). All TER_{mix} values were above the trigger values.

The risk assessment for secondary poisoning, required for Prothioconazole and its metabolites as well as Boscalid, showed that the risk for earthworm-eating and fish-eating birds is acceptable following use of GLOB1820F according to the proposed use pattern.

Furthermore, the risk assessment for exposure to Prothioconazole and Boscalid *via* drinking water also showed an acceptable risk.

zRMS Comments:	The risk assessment to birds was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438). The results of the ‘screening phase’ acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed and accepted in core assessment endpoints for most sensitive species for the active substances and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for birds resulting from acute and long-term exposure to active substances and metabolites following use of GLOB1820F in compliance with proposed GAP. A quantitative drinking water risk assessment is not triggered for the proposed use pattern of GLOB1820F according to EFSA/2009/1438 criteria and therefore the risk to birds via drinking water is acceptable. Since the acceptability criterion of $TER \geq 5$ is achieved for all active substances and metabolites, an acceptable risk to earthworm-eating and fish-eating birds via secondary poisoning can be concluded for all intended uses. No risk mitigation measures are required. Conclusion According to the performed risk assessment there is no potential of risk to birds resulting from exposure to active substances and metabolites following use of Pirlanko (GLOB1820F) in compliance with proposed GAP.
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9.3 Effects on terrestrial vertebrates other than birds (KCP 10.1.2)

9.3.1 Toxicity data

Mammalian toxicity studies have been carried out with boscalid, prothioconazole and the major plant metabolite prothioconazole-desthio. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on mammals from GLOB2021dF were not evaluated as part of the EU assessment of boscalid or prothioconazole. However, the provision of further data on the GLOB2021dF is not considered essential, because active substance data on toxicity to birds can be used and additional formulation data are not considered essential.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.3-1: Endpoints and effect values relevant for the risk assessment for mammals

Species	Substance	Exposure System	Results	Reference
Rat	Boscalid	Oral 1 d Acute	LD₅₀ > 5000 mg/kg bw	EFSA 2008
Rat	Boscalid	Dietary Reproductive toxicity Two-generation study	NOAED = 67 mg/kg bw/d	EFSA 2008
Rat	Prothioconazole	Oral Acute	LD₅₀ > 6200 mg/kg bw/d	EFSA 2007
Rat	Prothioconazole-desthio	Oral Acute	LD ₅₀ (female) = 2506 mg p.m./kg bw/d LD ₅₀ (male) = 2806 mg p.m./kg bw/d	EFSA 2007
Mouse	Prothioconazole-desthio	Oral Acute	LD ₅₀ (female) = 3459 mg p.m./kg bw/d LD ₅₀ (male) = 2235 mg p.m./kg bw/d	EFSA 2007
Rat	Prothioconazole	Chronic study	NOEL _{parental} = 9.7 mg a.s./kg bw/d NOEL _{reproduction} = 95.6 mg a.s./kg bw/d	EFSA 2007
Rat	Prothioconazole-desthio	Chronic study	NOEL _{parental} = 2.5 mg p.m./kg bw/d NOEL _{reproduction} = 10 mg p.m./kg bw/d	EFSA 2007

9.3.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.3.2 Risk assessment for spray applications

The risk assessment is based on the methods presented in the Guidance Document on Risk Assessment for Mammals and Mammals on request from EFSA (EFSA Journal 2009; 7(12): 1438; hereafter referred to as EFSA/2009/1438).

9.3.2.1 First-tier assessment (screening/generic focal species)

The results of the acute and reproductive first-tier risk assessments are summarised in the following tables.

(a) Boscalid

Multiple applications

Table 9.3-2: Screening of the acute and long-term/reproductive risk for mammals from boscalid due to the use of GLOB2021dF in oilseed rape (2 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Boscalid				
Application rate (g/ha)		2 x 125				
Acute toxicity (mg/kg bw)		>5000				
TER criterion		10				
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Screening step	Small herbivorous mammal	118.4	1.1	16.28	307.13	
Reprod. toxicity (mg/kg bw/d)		67				
TER criterion		5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{It}	
Screening						
-	Small herbivorous mammal	48.3	0.636	3.84	17.45	
Tier 1						
Oilseed rape BBCH ≥20	small insectivorous mammal "shrew"	1.9	0.636	0.15	443.56	
Oilseed rape BBCH ≥40	small insectivorous mammal "shrew"	18.1	0.636	1.44	46.56	
all season	Large herbivorous mammal "lagomorph"	14.3	0.636	1.14	58.93	
BBCH 10-29	small omnivorous mammal "mouse"	7.8	0.636	0.62	108.05	
BBCH 30-39	small omnivorous mammal "mouse"	2.3	0.636	0.18	366.42	

BBCH >=40	small omnivorous mammal "mouse"	1.9	0.636	0.15	443.56
BBCH 10 - 19	Small insectivorous mammal "shrew"	4.2	0.636	0.33	200.7

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-3: Screening of the acute and long-term/reproductive risk for mammals from boscalid due to the use of GLOB2021dF in cereals (2 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Boscalid				
Application rate (g/ha)		2 x 125				
Acute toxicity (mg/kg bw)		>5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1.1	16.28	307.13	
Reprod. toxicity (mg/kg bw/d)		67				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.636	3.84	17.45	
Tier 1						
BBCH >20	Small insectivorous mammal “shrew”	5.4 1.9	0.636	0.43	156.07 443.6	
BBCH >40	Small herbivorous mammal “vole”	40.9 21.7	0.636	3.25	20.61 38.8	
Early shoots	Large herbivorous mammal “lagomorph”	42.1 22.3	0.636	3.35	20.02 37.8	
BBCH 10-29	Small omnivorous mammal “mouse”	17.2 7.8	0.636	1.37	49.00 108.0	
BBCH 30-39	Small omnivorous mammal “mouse”	8.6 3.9	0.636	0.68	98.00 216.1	
BBCH >40	Small omnivorous mammal “mouse”	5.2 2.3	0.636	0.41	162.07 366.4	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Single application

Table 9.3-4: Screening of the acute and long-term/reproductive risk for mammals from boscalid due to the use of GLOB2021dF in oilseed rape (1 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Boscalid				
Application rate (g/ha)		1 x 125				
Acute toxicity (mg/kg bw)		>5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1	14.80	337.84	
Reprod. toxicity (mg/kg bw/d)		67				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.53	3.20	20.94	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-5: Screening of the acute and long-term/reproductive risk for mammals from boscalid due to the use of GLOB2021dF in cereals (1 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Boscalid				
Application rate (g/ha)		1 x 125				
Acute toxicity (mg/kg bw)		>5000				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1	14.80	337.84	
Reprod. toxicity (mg/kg bw/d)		67				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.53	3.20	20.94	
Tier 1						
BBCH >20	Small insectivorous mammal “shrew”	5.4 1.9	0.53	0.36	187.28 532.3	
BBCH >40	Small herbivorous mammal “vole”	40.9 18.1 21.7	0.53	2.71	24.73 55.9 46.6	

Early shoots All season	Large herbivorous mammal “lagomorph”	42.1 14.3 22.3	0.53	2.79	24.02 70.7 45.35
BBCH 10-29	Small omnivorous mammal “mouse”	17.2 7.8	0.53	1.14	58.80 129.7
BBCH 30-39	Small omnivorous mammal “mouse”	8.6 2.3	0.53	0.57	117.60 439.7
BBCH >40	Small omnivorous mammal “mouse”	5.2 1.9	0.53	0.34	194.48 532.3

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER:

(b) Prothioconazole

Multiple applications

Table 9.3-6: Screening of the acute and long-term/reproductive risk for mammals from prothioconazole due to the use of GLOB2021dF in oilseed rape (2 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Prothioconazole				
Application rate (g/ha)		2 x 125				
Acute toxicity (mg/kg bw)		>6200				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1.2 1.1	17.76 16.28	349.10 380.8	
Reprod. toxicity (mg/kg bw/d)		95.6				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.742 0.636	4.48 3.84	21.34 24.9	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-7: Screening of the acute and long-term/reproductive risk for mammals from prothioconazole due to the use of GLOB2021dF in cereals (2 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Prothioconazole				
Application rate (g/ha)		2 x 125				
Acute toxicity (mg/kg bw)		>6200				

TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1.1	16.28	380.84	
Reprod. toxicity (mg/kg bw/d)		95.6				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.636	3.84	24.90	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Single application

Table 9.3-8: Screening of the acute and long-term/reproductive risk for mammals from prothioconazole due to the use of GLOB2021dF in oilseed rape (1 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Prothioconazole				
Application rate (g/ha)		1 x 125				
Acute toxicity (mg/kg bw)		>6200				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1	14.80	337.84 418.9	
Reprod. toxicity (mg/kg bw/d)		95.6				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.53	3.20	29.88	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-9: Screening of the acute and long-term/reproductive risk for mammals from prothioconazole due to the use of GLOB2021dF in cereals (1 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Prothioconazole				
Application rate (g/ha)		1 x 125				
Acute toxicity (mg/kg bw)		>6200				
TER criterion		10				

Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Screening step	Small herbivorous mammal	118.4	1	14.80	337.84 418.9
Reprod. toxicity (mg/kg bw/d)	95.6				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Screening					
-	Small herbivorous mammal	48.3	0.53	3.20	29.88

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER:

(c) Prothioconazole-desthio

Multiple applications

Table 9.3-10: Screening and first-tier assessment of the acute and long-term/reproductive risk for mammals from prothioconazole-desthio due to the use of GLOB2021dF in oilseed rape (2 x 125 g/ha)

Intended use		Oilseed rape			
Active substance/product		Prothioconazole-desthio			
Application rate (g/ha)		2 x 113.75			
Acute toxicity (mg/kg bw)		2235			
TER criterion		10			
Crop scenario Growth stage	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a
Screening step	Small herbivorous mammal	118.4	1.1	14.81	150.86
Reprod. toxicity (mg/kg bw/d)	10				
TER criterion	5				
Crop scenario Growth stage	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}
Screening					
-	Small herbivorous mammal	48.3	0.636	3.49	2.86
Tier 1					
Oilseed rape BBCH ≥20	small insectivorous mammal "shrew"	1.9	0.636	0.14	72.75
Oilseed rape BBCH ≥40	small insectivorous mammal "shrew"	18.1	0.636	1.31	7.64
all season	Large herbivorous mammal "lagomorph"	14.3	0.636	1.03	9.67
BBCH 10-29	small omnivorous mammal	7.8	0.636	0.56	17.72

	"mouse"				
BBCH 30-39	small omnivorous mammal "mouse"	2.3	0.636	0.17	60.10
BBCH >=40	small omnivorous mammal "mouse"	1.9	0.636	0.14	72.75

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-11: Screening and first-tier assessment of the acute and long-term/reproductive risk for mammals from prothioconazole-desthio due to the use of GLOB2021dF in cereals (2 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Prothioconazole-desthio				
Application rate (g/ha)		2 x 113.75				
Acute toxicity (mg/kg bw)		2235				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1.1	14.81	150.86	
Reprod. toxicity (mg/kg bw/d)		10				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.636	3.49	2.86	
Tier 1						
BBCH 20+	small insectivorous mammal "shrew"	1.9	0.636	0.14	72.75	
BBCH 40+	small insectivorous mammal "vole"	21.7	0.636	1.57	6.37	
BBCH 30-39	small omnivorous mammal "mouse"	3.9	0.636	0.28	35.44	
BBCH 40+	small omnivorous mammal "mouse"	2.3	0.636	0.17	60.10	
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	7.8	0.53	0.565	17.7	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Single application

Table 9.3-12: Screening and first-tier assessment of the acute and long-term/reproductive risk for mammals from prothioconazole-desthio due to the use of GLOB2021dF in oilseed rape (1 x 125 g/ha)

Intended use		Oilseed rape				
Active substance/product		Prothioconazole-desthio				
Application rate (g/ha)		1 x 113.75				
Acute toxicity (mg/kg bw)		2235				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1	13.420	166.541	
Reprod. toxicity (mg/kg bw/d)		10				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.53	2.902	3.446	
Tier 1						
late – late with seeds (BBCH 30-99)	small insectivorous mammal "shrew"	4.2	0.53	0.25	39.49	
BBCH 10-29	small insectivorous mammal "shrew"	1.9	0.53	0.11	87.30	
BBCH 30-39	small insectivorous mammal "shrew"	18.1	0.53	1.09	9.16	
BBCH ≥ 40	Large herbivorous mammal "lagomorph"	14.3	0.53	0.86	11.60	
BBCH 20-29	small omnivorous mammal "mouse"	7.8	0.53	0.47	21.27	
BBCH 30-39	small omnivorous mammal "mouse"	2.3	0.53	0.14	72.12	
BBCH ≥ 40	small omnivorous mammal "mouse"	1.9	0.53	0.11	87.30	
Cereals BBCH ≥ 20	Small insectivorous mammal "shrew"	1.9			87.3	
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"	21.7			7.6	
Cereals BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3			72.1	
Cereals BBCH 10-29	Small omnivorous mammal "mouse"	7.8			21.3	
Cereals BBCH 30-39	Small omnivorous mammal "mouse"	3.9			42.5	

Cereals BBCH ≥ 40	Small omnivorous mammal "mouse"	2.3			72.1
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SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

Table 9.3-13: Screening and first-tier assessment of the acute and long-term/reproductive risk for mammals from prothioconazole-desthio due to the use of GLOB2021dF in cereals (1 x 125 g/ha)

Intended use		Cereals				
Active substance/product		Prothioconazole-desthio				
Application rate (g/ha)		1 x 113.75				
Acute toxicity (mg/kg bw)		2235				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1	13.420	166.541	
Reprod. toxicity (mg/kg bw/d)		10				
TER criterion		5				
Crop scenario	Indicator/generic focal species	SV _m	MAF _m × TWA	DDD _m (mg/kg bw/d)	TER _{lt}	
Growth stage						
Screening						
-	Small herbivorous mammal	48.3	0.53	2.902	3.43	
Tier 1						
BBCH 20+	small insectivorous mammal "shrew"	1.9	0.53	0.16-0.115	62.36-87.3	
BBCH 40+	small insectivorous mammal "vole"	21.7	0.53	1.83-1.32	5.46-7.6	
BBCH 30-39	small omnivorous mammal "mouse"	3.9	0.53	0.33-0.235	30.38-42.5	
BBCH 40+	small omnivorous mammal "mouse"	2.3	0.53	0.19-0.139	51.51-72.1	
Cereals BBCH 10-29	Small omnivorous mammal “mouse”	7.8	0.53	0.469	21.3	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER:

(d) GLOB2021dF

Combined risk assessment was performed for Boscalid, Prothioconazole and its metabolite Prothioconazole-desthio (M04). As a worst-case approach, assuming the toxicity of the mixture to be entirely additive (i.e. no synergism), a theoretical endpoint for the mixture can be calculated from the appropriate LD₅₀ and NOEC/NOEL values for each of the active substances, resp. metabolite by applying Finney's formula (following Appendix B of EFSA/2009/1438).

In order to determine the ratio of the metabolite Prothioconazole-desthio (M04) within the mixture, the maximum formation fraction of the metabolite was adjusted for molecular weight to get the following:

- The molecular weight conversion is carried out by taking the molecular weight of the metabolite (312.2g/mol) divided by the molecular weight of the parent (344.3g/mol) = 0.91
- multiplied by the formation fraction of 1.0 of parent = 0.91 x 1.0 = 0.91

Therefore in the case of the combination assessment for birds and mammals, out of a total of 125 g of prothioconazole, 113.75 of that will degrade to Prothioconazole-desthio (M04).

Approach 1

Assessment presented for both active substances Boscalid and Prothioconazole.

Acute risk

For the assessment of the acute risk to birds, the following formula is used to derive a surrogate LD₅₀ for the mixture of active substances with known toxicity assuming additivity:

$$LD_{50}(\text{mix}) = \left(\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} \right)^{-1}$$

With:

X(a.s._i) = fraction of active substance [i] in the mixture;
(please note that the sum $\sum X(a.s._i)$ must be 1)

LD₅₀(a.s._i) = acute toxicity value for active substance [i]

For GLOB2021dF, the LD₅₀ (mix) amounts to 5535.71 2767.86-mg/kg bw = ((0.5/5000) + (0.5/6200))⁻¹

No single substance is identified as the driver of the risk assessment.

Multiple applications

Table 9.3-14: Screening and first-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of GLOB2021dF in oilseed rape (2 x 893 g/ha)

Intended use		Oilseed rape				
Active substance/product		GLOB2021dF				
Application rate (g/ha)		2 x 893* 2 x 250				
Acute toxicity (mg/kg bw)		5535.71				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1.1 1.2	116.30 35.52	47.60 155.8	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger. *Based on a density of 1.1168 mg/mL.

Single application

Table 9.3-15: Screening and first-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of GLOB2021dF in oilseed rape (1 x 893 g/ha)

Intended use		Oilseed rape				
Active substance/product		GLOB2021dF				
Application rate (g/ha)		1 x 893* 1 x 250				
Acute toxicity (mg/kg bw)		5535.714				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1	105.731 29.6	52.36 187.0	

SV: shortcut value; MAF: multiple application factor; TWA: time-weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger. *Based on a density of 1.1168 mg/mL.

Based on the screening step, the combined acute risk of a small herbivorous mammal is acceptable for the use on oilseed rape, covering use on cereal. Therefore, no further risk assessment was performed for combination of active substances.

Long-term risk

A calculated NOEL for the mixture is unlikely to constitute a reliable measure of toxicity as NOEL values may represent varying risk or response levels for different compounds. It is therefore not the current practice to derive a surrogate NOEL for the mixture of active substances as has been done for the acute risk. Alternatively, to assess the long-term risk to mammals, a common accepted approach by different member states is to calculate a combined TER(mix) for each exposure scenario (bare soil and oilseed rape) using the following equation:

$$TER_{(mix)} = \left(\sum_i \frac{1}{TER_{(a.s._i)}} \right)^{-1}$$

where:

TER_(a.s._i) = calculated TER for the active substance i

Multiple applications

$$\begin{aligned} TER_{(mix)chronic \text{ oilseed rape}} &= ((1/17.45) + (1/21.34 \text{ } 24.9))^{-1} &= 9.60 \text{ } 10.26 \\ TER_{(mix)chronic \text{ cereals}} &= ((1/17.45) + (1/24.30 \text{ } 24.9))^{-1} &= 10.16 \text{ } 10.26 \end{aligned}$$

Single applications

$$\begin{aligned} TER_{(mix) \text{ chronic oilseed rape}} &= ((1/20.94) + (1/29.88))^{-1} &= 12.31 \\ TER_{(mix)chronic \text{ cereals}} &= ((1/20.94) + (1/29.88))^{-1} &= 12.31 \end{aligned}$$

In case the use of the TER resulting from the screening step did not indicate an acceptable risk, the lowest TER value calculated at tier 1 is used, as. Both chronic TER_(mix) are higher than the trigger of 5, therefore the combined long-term risk is acceptable.

Approach 2

Assessment presented for metabolite Prothioconazole-desthio (M04).

This conservative approach will assume that 100% of the 125 g/ha of the active substance Prothioconazole will degrade to 113.75g/ha of the metabolite, Prothioconazole-desthio (M04). This value is based on molar masses of Prothioconazole (358.3 g/mol) and Prothioconazole-desthio (M04) (312.2)

$$LD_{50}(\text{mix}) = \left(\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} \right)^{-1}$$

With:

$X(a.s._i)$ = fraction of active substance [i] in the mixture;
(please note that the sum $\sum X(a.s._i)$ must be 1)

$LD_{50}(a.s._i)$ = acute toxicity value for active substance [i]

For Boscalid and Prothioconazole-desthio (M04), $LD_{50}(\text{mix})$ amounts to 3089.15 mg/kg bw = $((0.5/5000) + (0.5/2235))^{-1}$

No single substance is identified as the driver of the risk assessment.

Table 9.3-16: Screening step of the acute combined risk for mammals due to the use of GLOB2021dF in oilseed rape based on a surrogate LD_{50}

Intended use		Oilseed rape (covering cereals)				
Active substance/product		GLOB2021dF				
Application rate (g/ha)		2 x 893* 2 x 238.75				
Acute toxicity (mg/kg bw)		3089.15				
TER criterion		10				
Crop scenario	Indicator/generic focal species	SV ₉₀	MAF ₉₀	DDD ₉₀ (mg/kg bw/d)	TER _a	
Growth stage						
Screening step	Small herbivorous mammal	118.4	1.1 1.2	126.88 33.92	26.56 91.1	

Based on the screening, the combined acute risk of a small granivorous mammal is acceptable for the oilseed rape scenario which covers all other intended scenarios.

To assess the long-term risk to mammals a combined TER(mix) for each exposure scenario was calculated using the following equation:

$$TER(\text{mix}) = \left(\sum_i \frac{1}{TER(a.s._i)} \right)^{-1}$$

where:

$TER_{(a.s._i)}$ = calculated TER for the active substance i

Small insectivorous mammal "shrew", BBCH >40

Multiple applications

$$TER_{(\text{mix})\text{chronic oilseed rape}} = ((1/46.56) + (1/7.64))^{-1} = 6.56$$

Single application

$$TER_{(mix)chronic\ oilseed\ rape} = ((1/20.94) + (1/9.16))^{-1} = 6.37$$

Small insectivorous mammal "vole", BBCH >40

Multiple applications

$$TER_{(mix)chronic\ cereals} = ((1/20.61\ 38.8) + (1/6.37))^{-1} = 4.87\ 5.47$$

Single application

$$TER_{(mix)chronic\ cereals} = ((1/24.73\ 20.94) + (1/5.46\ 7.6))^{-1} = 4.47\ 5.79\ 5.58$$

Large herbivorous mammal "lagomorph"

Multiple applications

$$TER_{(mix)chronic\ oilseed\ rape} = ((1/58.93) + (1/9.67))^{-1} = 8.31$$

Single application

$$TER_{(mix)chronic\ oilseed\ rape} = ((1/20.02) + (1/11.60))^{-1} = 7.34$$

Higher tier risk assessment

Small herbivorous mammal "vole", BBCH ≥ 40, TER_{it} mix 4.87

The diet for the common vole in this scenario is 100% grass. It can therefore be assumed that animals feeding on grass at ground level will not be exposed to 100% of the product residues and crop interception can be considered. The level of interception is based on crop BBCH growth stage. Crop interception is considered a realistic refinement as it minimizes residues from the product on food items. These interception values are in the first instance taken from Appendix A of the EFSA Guidance (2009) and then from the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (2014). In Appendix A of the EFSA Guidance (2009) the interception factor for this scenario is 0.80. To refine the risk assessment further a deposition factor of 0.1 from the FOCUSgw guidance has been applied for cereals, BBCH ≥ 40.

For GLOB2021dF, the NOEC(mix) amounts to 17.4 mg/kg bw/d = ((0.5/67 + (0.5/10))⁻¹

Table 9.3-29: Higher tier assessment of the long-term/reproductive risk for mammals – mixture (approach 2)

Intended use		Oilseed rape							
Active substance/product		Boscalid and prothioconazole -desthio (M04)							
Application rate (g/ha)		2 x 179							
Reprod. toxicity (mg/kg bw/d)		17.4							
TER criterion		5							
Crop Scenario	Focal species	Food category, % in diet	FIR/bw	RUD_m	DF	MAF_x TWA	PT	DDD_m (mg/kg bw/d)	TER_{it}
Cereals	Common vole (<i>Microtus arvalis</i>)	Grass (100%)	1.33	54.2	0.10*	1.2 x 0.53	1	0.82	21.25

SV: shortcut value; MAF: multiple application factor; TWA: time weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

*Refined deposition factor of 90 for spring and winter cereals BBCH 40-69, taken from the Generic Guidance for Tier 1 FOCUS Ground Water Assessments (2014).

The TER above exceeds the trigger value of 5, demonstrating GLOB2021dF poses an acceptable risk to small herbivorous mammals via dietary exposure. No further consideration is required.

Conclusion

An acceptable acute and long-term combined risk to mammals can be concluded.

In accordance with EFSA Scientific Report (2007) 106, 1-98, the refinement parameter proposed for prothioconazole-desthio (JAU 6476-desthio) (M04), was DT₅₀ of 3.2 days in foliage and the maximum measured residue of 3.7 mg/kg that allowed to calculate new MAF and/or fTWA values.

Assuming first-order kinetics, the MAF and fTWA can be calculated according to the following formulas (EFSA Journal 2009; 7(12):1438):

$$\text{MAF}_m = \frac{1 - e^{-nki}}{1 - e^{-ki}}$$

With:

$k = \ln(2)/\text{DT}_{50}$ (rate constant)

$n =$ number of applications

$i =$ application interval (d)

$$\text{TWA} = \frac{1 - e^{-ki}}{ki}$$

With:

$k = \ln(2)/\text{DT}_{50}$ (rate constant)

$i =$ averaging interval

The calculated MAF and fTWA values are:

— for winter and spring cereals (2 applications, 14d interval) **MAF_m = 1.05d** and **fTWA = 0.313**

— winter oilseed rape (2 applications, 21d interval) **MAF_m = 1.01d** and **fTWA = 0.217**.

The refined risk assessment for small herbivorous mammal (*Common vole*) with new MAF_m and fTWA values are presented in below tables.

Table 9.3-7: Higher-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Prothioconazol 300 EC (prothioconazole-desthio (JAU 6476-desthio) (M04), winter cereals and spring cereals use no 1-6)

Intended use	winter cereals, spring cereals
Active substance	prothioconazole-desthio (JAU 6476-desthio) (M04)
Application rate (g/ha)	2 × 195 [†] , interval: 14d

Reprod. toxicity (mg/kg bw/d)		10			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	1.05 × 0.313	1.4	7.1

SV: shortcut value; MAF: multiple application factor; TWA: time weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

[†] assumed total dose of the parent and 100% conversion from parent (worst case)

Table 9.3-8: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Protiokonazol 300 EC (prothioconazole-desthio (JAU 6476-desthio) (M04), winter oilseed rape use no 8)

Intended use		winter oilseed rape			
Active substance		prothioconazole-desthio (JAU 6476-desthio) (M04)			
Application rate (g/ha)		2 × 180 [†] , interval: 21d			
Reprod. toxicity (mg/kg bw/d)		10			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	1.01 × 0.217	0.7	14.3

SV: shortcut value; MAF: multiple application factor; TWA: time weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

[†] assumed total dose of the parent and 100% conversion from parent (worst case)

[‡] MAF for 2 applications and 14d interval (worst case) since MAF for 21d interval is not provided

The calculated MAF and fTWA values are calculated using moving time window approach:
— for winter and spring cereals (2 applications, 14d interval) MAF_m × TWA = 0.220

The refined risk assessment for small herbivorous mammal (*Common vole*) with new MAF_m and fTWA values are presented in below tables:

Table 9.3-8: First-tier assessment of the acute and long-term/reproductive risk for mammals due to the use of Protiokonazol 300 EC (prothioconazole-desthio (JAU 6476-desthio) (M04), winter oilseed rape use no 8)

Intended use		winter oilseed rape			
Active substance		prothioconazole-desthio (JAU 6476-desthio) (M04)			
Application rate (g/ha)		2 × 113.75			
Reprod. toxicity (mg/kg bw/d)		10			
TER criterion		5			
Crop scenario Growth stage	Indicator/generic focal species	SV_m	MAF_m × TWA	DDD_m (mg/kg bw/d)	TER_{it}
Cereals BBCH ≥ 40	Small herbivorous mammal "vole"	21.7	0.220	0.544	18.4
Oilseed rape BBCH ≥ 40	Small herbivorous mammal "vole"	18.1	0.220	0.454	22

SV: shortcut value; MAF: multiple application factor; TWA: time weighted average factor; DDD: daily dietary dose; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.

[†] assumed total dose of the parent and 100% conversion from parent (worst case)

As refined TER_{it} for vole is higher than for mouse:
Multiple applications

$$TER_{(mix)chronic\ cereals} = \frac{1}{((1/20.61) + (1/11.7 (mouse)))^+} = 7.46$$

The TER above exceeds the trigger value of 5, demonstrating GLOB2021dF poses an acceptable risk to small herbivorous mammals via dietary exposure. No further consideration is required.

zRMS comment:

Vole

BBCH $\geq$ 40

Small herbivorous mammal
"vole"

The refinement long-term risk assessment for vole was accepted by RMS. based on DT₅₀ value for cereals and refined parameter of ftwa according to EFSA Conclusion 2007.

9.3.2.2 Higher-tier risk assessment

No refinement needed since the risk was found to be acceptable at a lower tier.

9.3.2.3 Drinking water exposure

When necessary, the assessment of the risk for mammals due to uptake of contaminated drinking water is conducted for a small omnivorous mammal with a body weight of 21.7 g (*Apodemus sylvaticus*) and a drinking water uptake rate of 0.24 L/kg bw/d (cf. Appendix K of EFSA/2009/1438).

Puddle scenario

Due to the characteristics of the exposure scenario in connection with the standard assumptions for water uptake by animals, no specific calculations of exposure and TER are necessary when the ratio of effective application rate (in g/ha) to relevant endpoint (in mg/kg bw/d) does not exceed 50 in the case of less sorptive substances (Koc < 500 L/kg) or 3000 in the case of more sorptive substances (Koc $\geq$ 500 L/kg).

With a K(f)oc of 771.2 for Boscalid and a K(f)oc of 1765 mL/g and 573.5 mL/g for prothioconazole and prothioconazole-desthio respectively, both active substances and metabolite belong to the group of more sorptive substances (Koc $\geq$ 500 L/kg).

The calculations of oilseed rape with two applications (and thus a MAF of 1.4 1.2) at 0.8 L product/ha which covers also the use in cereals. For the metabolite the same application rate of the parent is used, but with a correction for the molecular weight.

Multiple applications

Boscalid

Effective application rate (g/ha)	=	125 x 1.4 1.2 = 150	Application rate x MAF
Acute toxicity (mg/kg bw)	=	5000	quotient = 0.030
Reprod. toxicity (mg/kg bw/d)	=	67	quotient = 2.239

Prothioconazole

Effective application rate (g/ha)	=	125 x 1.4 1.2 = 150	Application rate x MAF
Acute toxicity (mg/kg bw)	=	6200	quotient = 0.024
Reprod. toxicity (mg/kg bw/d)	=	95.6	quotient = 1.569

Prothioconazole desthio

Effective application rate (g/ha)	=	$113.35 \times 1.4 \times 1.2 = 136.02$	= Application rate x MAF
Acute toxicity (mg/kg bw)	=	2235	quotient = 0.061
Reprod. toxicity (mg/kg bw/d)	=	4-10	quotient = 34.01

Single applications

Boscalid

Effective application rate (g/ha)	=	125 x 1 = 125	Application rate x MAF
Acute toxicity (mg/kg bw)	=	5000	quotient = 0.025
Reprod. toxicity (mg/kg bw/d)	=	24.1	quotient = 1.866

Prothioconazole

Effective application rate (g/ha)	=	125 x 1 = 125	Application rate x MAF
Acute toxicity (mg/kg bw)	=	6200	quotient = 0.020
Reprod. toxicity (mg/kg bw/d)	=	95.6	quotient = 1.308

Prothioconazole desthio

Effective application rate (g/ha)	=	113.35 x 1 = 113.35	Application rate x MAF
Acute toxicity (mg/kg bw)	=	2235	quotient = 0.051
Reprod. toxicity (mg/kg bw/d)	=	4	quotient = 28.338

The ratio of the effective application rate to the acute and long term toxicity endpoint is less than 3000 for Boscalid, Prothioconazole and Prothioconazole-desthio. Therefore, it is considered that there is low risk of acute/long term toxicity to mammals from the uptake of contaminated drinking water and no further assessment is required.

The resulting acute and chronic ratio are less than the trigger value for both active substances and its metabolite. No further consideration of the risk to mammals via drinking water is therefore required. In conclusion, GLOB2021dF poses low acute and long-term risks to mammals drinking contaminated water for all intended uses.

9.3.2.4 Effects of secondary poisoning

The log P_{ow} of Boscalid amounts to 2.96 and thus does not exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is not required for this active.

The log P_{ow} of Prothioconazole, Prothioconazole-desthio, Prothioconazole-S-methyl amounts to 3.82, 3.04 and 4.3, respectively, thus exceed the trigger value of 3. A risk assessment for effects due to secondary poisoning is therefore required.

Risk assessment for earthworm-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for vermivorous mammals is assessed for a small mammal of 10 g body weight with a daily food consumption of 12.8 g. Bioaccumulation in earthworms is estimated based on measured/predicted concentrations in soil/porewater / is based on experimental data.

The risk is only calculated with the two times application on oilseed rape, providing the highest PEC_{soil} values which covers the use in cereals.

Table 9.3-17: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole via bioaccumulation in earthworms (secondary poisoning) for the intended use in oilseed rape cereals (2 x 125 g as/ha)

Parameter	Prothioconazole		Comments
	single multiple	single multiple	
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0165 0.0072 0.0278	0.0330 0.0256	
log P _{ow} / P _{ow}	3.82/6607		
Koc	1765		
foc	0.02		Default
BCF _{worm}	2.2698		$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.087 0.063	0.044 0.05811	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.111 0.0807	0.056 0.07438	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	95.6		Review report Prothioconazole
TER _{lt}	1994.23 1184	997.12 1285	TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.3-18: Assessment of the risk for earthworm-eating birds due to exposure to Prothioconazole-desthio via bioaccumulation in earthworms (secondary poisoning) for the intended use in oilseed rape cereals (2 x 125 g as/ha)

Parameter	Prothioconazole-desthio		Comments
	single	multiple	
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0174 0.0628	0.0174 0.0628	
log P _{ow} / P _{ow}	3.04/1096.48		
Koc	573.5 575.4		Mean (n = 4), EFSA Scientific Report (2007)
foc	0.02		Default
BCF _{worm}	1.2204		$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / foc \times Koc$
PEC _{worm}	0.076 0.077	0.057 0.077	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.098	0.073 0.098	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	10		Review report Prothioconazole
TER _{lt}	367.91 102	367.91 102	TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.3-19: Assessment of the risk for earthworm-eating birds due to exposure to S-methyl via bioaccumulation in earthworms (secondary poisoning) for the intended use in oilseed rape cereals (2 x 125 g as/ha)

Parameter	S-methyl		Comments
	single	multiple	
PEC _{soil} (twa = 21 d) (mg/kg soil)	0.0625 0.0174	0.0668 0.0177	
log P _{ow} / P _{ow}	4.19/15488.17		
K _{oc}	2526 2556.3		Mean (n = 4), EFSA Scientific Report (2007) 106, 1-98
f _{oc}	0.02		Default
BCF _{worm}	3.6955		$BCF_{worm/soil} = (PEC_{worm,ww}/PEC_{soil,dw}) = (0.84 + 0.012 \times P_{ow}) / f_{oc} \times K_{oc}$
PEC _{worm}	0.142 0.0643	0.071 0.0654	PEC _{worm} = PEC _{soil} × BCF _{worm/soil}
Daily dietary dose (mg/kg bw/d)	0.181 0.0823	0.091 0.08373	DDD = PEC _{worm} × 1.28
NOEL (mg/kg bw/d)	9.56		Review report Prothioconazole
TER _{lt}	122.49 116	61.24 114	TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Since all calculated TER_{lt} are higher than 5, the risk for earthworm-eating mammals from prothioconazole, as well as Prothioconazole-desthio and Prothioconazole-S-methyl exposure is acceptable.

Risk assessment for fish-eating mammals via secondary poisoning

According to EFSA/2009/1438, the risk for piscivorous mammals is assessed for a mammal of 3000 g body weight with a daily food consumption of 425 g. Bioaccumulation in fish is estimated based on predicted concentrations in surface water. The risk is only calculated for the use with the highest PEC_{sw} as this covers all other uses.

Table 9.3-20: Assessment of the risk for fish-eating mammals due to exposure to boscalid via bioaccumulation in fish (secondary poisoning) for all uses (2 x 125 g/ha) covering the intended single application use (1 x 125 g/ha)

Parameter	Boscalid		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.0063		Max. PEC _{sw} winter cereals
BCF _{fish}	92		EFSA conclusion Boscalid
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.66		$PEC_{fish} = PEC_{water} \times BCF_{fish}$
Daily dietary dose (mg/kg bw/d)	0.094		DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	67		EFSA conclusion Boscalid

Parameter	Boscalid		Comments
	Multiple	Single	
TER _{it}	814.1		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.3-21: Assessment of the risk for fish-eating mammals due to exposure to Prothioconazole via bioaccumulation in fish (secondary poisoning) for all uses (2 x 125 g/ha) covering the intended single application use (1 x 125 g/ha)

Parameter	Prothioconazole		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.0011 0.001289		Max. PEC _{sw} oilseed rape
BCF _{fish}	18.8 19.7		EFSA conclusion Prothioconazole
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.020 0.025		PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0028 0.004		DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	95.6		EFSA conclusion Prothioconazole
TER _{it}	32555.1 26512		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.3-22: Assessment of the risk for fish-eating mammals due to exposure to Prothioconazole-desthio via bioaccumulation in fish (secondary poisoning) for all uses (2 x 125 g/ha winter cereals) covering the intended single application use (1 x 125 g/ha)

Parameter	Prothioconazole-desthio		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.0007 0.00899		Max. PEC _{sw} oilseed rape winter cereals Step 2
BCF _{fish}	45 65		EFSA conclusion Prothioconazole
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	0.4048 0.58435		PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.0575 0.083		DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	10		EFSA conclusion Prothioconazole
TER _{it}	2235.6 120		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Table 9.3-23: Assessment of the risk for fish-eating mammals due to exposure to Prothioconazole-S-methyl via bioaccumulation in fish (secondary poisoning) for all uses (2 x 125 g/ha winter cereals) covering the intended single application use (1 x 125 g/ha)

Parameter	Prothioconazole-S-methyl		Comments
	Multiple	Single	
PEC _{sw} (mg/L)	0.000042 0.00084		Max. PEC _{sw} oilseed rape winter cereals Step 2
BCF _{fish}	1995		EFSA conclusion Prothioconazole worse-case whole fish BCF values for prothioconazole-S-methyl (M01) taken from the prothioconazole RAR (2018).
BMF	-		biomagnification factor (relevant for BCF ≥ 2000)
PEC _{fish}	2.56 1.66758		PEC _{fish} = PEC _{water} × BCF _{fish}
Daily dietary dose (mg/kg bw/d)	0.364 0.238		DDD = PEC _{fish} × 0.142
NOEL (mg/kg bw/d)	9.56		EFSA conclusion Prothioconazole
TER _{lt}	26.28 32		TER = NOEC/DDD

TER values shown in bold fall below the relevant trigger.

Since all calculated TER_{lt} are higher than 5, the risk for fish-eating mammals from Boscalid and Prothioconazole, as well as Prothioconazole-desthio and Prothioconazole-S-methyl exposure is acceptable.

9.3.2.5 Biomagnification in terrestrial food chains

Not relevant.

9.3.3 Risk assessment for baits, pellets, granules, prills or treated seed

Not relevant.

9.3.4 Overall conclusions

The TER_a value is greater than the Annex VI trigger of 10, indicating low acute risk to mammals from boscalid, prothioconazole and metabolites following application of GLOB2021dF at the intended GAP. The TER_{lt} value for boscalid, prothioconazole and metabolites is greater than the Annex VI trigger of 5, indicating that GLOB2021dF presents no unacceptable long-term risk to mammals when applied according to the proposed GAP.

zRMS Comments:	The risk assessment to mammals was performed in accordance with the recommendation of Guidance Document on Risk Assessment for Birds & Mammals on request from EFSA (EFSA Journal 2009; 7(12):1438).
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	The results of the ‘screening phase’ acute dietary risk assessment and Tier-1 long term dietary risk assessment - Toxicity Exposure Ratios (TER_A and TER_{LT}) were calculated taking into account the EU agreed and accepted in core assessment endpoints for most sensitive species for the active substances and using the EFSA Bird and Mammal risk assessment calculator for the higher predicted application rate than it is foreseen in GAP exceeding the trigger set by Commission regulation (EU) 546/2011 for acceptability of effects. Revealed that there is no potential of risk for mammals resulting from acute and long-term exposure to active substances and metabolites following use of GLOB1820F in compliance with proposed GAP. A quantitative drinking water risk assessment is not triggered for the proposed use pattern of GLOB1820F according to EFSA/2009/1438 criteria and therefore the risk to wild mammals via drinking water is acceptable. Since the acceptability criterion of $TER \geq 5$ is achieved for all active substances and metabolites, an acceptable risk to earthworm-eating and fish-eating birds via secondary poisoning can be concluded for all intended uses. No risk mitigation measures are required. Conclusion According to the performed risk assessment there is no potential of risk to wild mammals resulting from exposure to active substances and metabolites following use of Pirlanko (GLOB1820F) in compliance with proposed GAP.
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The GAP change for oilseed rape from BBCH 61 to 69 is already covered by the existing risk assessment for Birds and Mammals.

9.4 Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) (KCP 10.1.3)

Not relevant.

9.5 Effects on aquatic organisms (KCP 10.2)

9.5.1 Toxicity data

Studies on the toxicity to aquatic organisms have been carried out with boscalid, prothioconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on aquatic organisms of GLOB2021dF were not evaluated as part of the EU assessment of boscalid and prothioconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.5-1: Endpoints and effect values relevant for the risk assessment for aquatic organisms – boscalid

Species	Substance	Exposure System	Results	Reference
Fish				
<i>Oncorhynchus mykiss</i>	Boscalid	96 h, s	EC ₅₀ = 2.7 mg a.s./L	EFSA 2008
<i>Oncorhynchus mykiss</i>	Boscalid	97 d, f	NOEC = 0.125 mg a.s./L	EFSA 2008
Daphnia				
<i>Daphnia magna</i>	Boscalid	48 h, s	EC ₅₀ = 5.33 mg a.s./L	EFSA 2008
<i>Daphnia magna</i>	Boscalid	21 d, ss	NOEC = 1.31 mg a.s./L	EFSA 2008
Freshwater algae				
<i>Pseudokirchneriella subcapitata</i>	Boscalid	96 h, s	EC ₅₀ = 1.34 mg a.s./L	EFSA 2008
Sediment organisms				
<i>Chironomus riparius</i>	Boscalid	28 d, s	NOEC = 1 mg a.s./L (spiked water)	EFSA 2008
<i>Chironomus riparius</i>	Boscalid	28 d, s	NOEC = 23.26 mg/kg dry sediment (spiked sediment)	Addendum 2 to DAR 2006
Higher-tier studies (micro- or mesocosm studies)				
-				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-2: Endpoints and effect values relevant for the risk assessment for aquatic organisms – prothioconazole and metabolites

Species	Substance	Exposure System	Results	Reference
Fish				
<i>Oncorhynchus mykiss</i>	Prothioconazole	Acute	LC ₅₀ /EC ₅₀ = 1.83 mg a.s./L	EFSA 2007
<i>Lepomis macrochirus</i>	Prothioconazole	Acute	LC ₅₀ = 4.59 mg a.s./L	EFSA 2007
<i>Cyprinus carpio</i>	Prothioconazole	Acute	LC ₅₀ = 6.91 mg a.s./L	EFSA 2007
<i>Oncorhynchus mykiss</i>	Prothioconazole-desthio	Acute	LC ₅₀ /EC ₅₀ = 6.63 mg metab/L	EFSA 2007
<i>Leuciscus idus melanotus</i>	Prothioconazole-desthio	Acute	LC ₅₀ = 13.2 mg p.m./L	EFSA 2007
<i>Oncorhynchus mykiss</i>	Prothioconazole-S-methyl	Acute	LC ₅₀ /EC ₅₀ = 1.8 mg metab/L	EFSA 2007
<i>Oncorhynchus</i>	1,2,4-Triazole	Acute	LC ₅₀ = 498 mg met/L	EFSA 2007

Species	Substance	Exposure System	Results	Reference
<i>mykiss</i>				
<i>Oncorhynchus mykiss</i>	Prothioconazole	Chronic	NOEC = 0.308 mg as/L	EFSA 2007
<i>Oncorhynchus mykiss</i>	Prothioconazole-desthio	Chronic	NOEC = 0.00334 mg metab/L	EFSA 2007
<i>Oncorhynchus mykiss</i>	1,2,4-Triazole	Chronic	NOEC = 3.2 mg metab/L	EFSA 2007
Daphnia				
<i>Daphnia magna</i>	Prothioconazole	acute	LC ₅₀ = 1.3 mg as/L	EFSA 2007
<i>Daphnia magna</i>	Prothioconazole-desthio	acute	LC ₅₀ > 10 mg met/L	EFSA 2007
<i>Daphnia magna</i>	Prothioconazole-S-methyl	acute	LC ₅₀ = 2.8 mg met/L	EFSA 2007
<i>Daphnia magna</i>	1,2,4-Triazole	acute	LC ₅₀ = 900 mg met/L	EFSA 2007
<i>Daphnia magna</i>	Prothioconazole	chronic	NOEC = 0.56 mg a.s./L	EFSA 2007
<i>Daphnia magna</i>	Prothioconazole-desthio	chronic	NOEC = 0.1 mg metab./L	EFSA 2007
Freshwater algae				
<i>Pseudokirchneriella subcapitata</i>	Prothioconazole	72h	EbC ₅₀ = 1.10 mg as/L ErC ₅₀ = 2.18 mg as/L	EFSA 2007
<i>Scenedesmus subspicatus</i>	Prothioconazole-desthio	72h	EbC ₅₀ = 0.073 mg metab/L ErC ₅₀ = 0.55 mg metab./L	EFSA 2007
<i>Pseudokirchneriella subcapitata</i>	Prothioconazole-S-methyl	72h	EbC ₅₀ = 3.77 mg metab/L ErC ₅₀ = 47.4 mg metab./L	EFSA 2007
<i>Pseudokirchneriella subcapitata</i>	1,2,4-Triazole	72h	EbC ₅₀ = 8.2 mg metab/L ErC ₅₀ = 22.5 mg metab./L	EFSA 2007
Sediment organisms				
<i>Chironomus riparius</i>	Prothioconazole	28d	NOEC = 9.14 mg as/L	EFSA 2007
<i>Chironomus riparius</i>	Prothioconazole-desthio	28d	NOEC = 2.0 mg metab./L	EFSA 2007

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations; im: based on initial measured concentrations

Table 9.5-3: Endpoints and effect values relevant for the risk assessment for aquatic organisms – GLOB2021dF

Species	Substance	Exposure System	Results	Reference
<i>Oncorhynchus mykiss</i>	GLOB2021dF	96h, s	LC ₅₀ = 30.04 mg/L	Shankarlal S., 2024
<i>Daphnia magna</i>	GLOB2021dF	48 h, s	EC ₅₀ = 5.352 mg/L	Kubisiak K., 2023a Zaworska K., 2023
<i>Raphidocelis subcapitata</i>	GLOB2021dF	72 h, s	E _r C ₅₀ = 8.262 mg/L E _y C ₅₀ = 3.914 mg/L	Zaworska K., 2023 Kubisiak K., 2023a
Higher-tier studies (micro- or mesocosm studies)				
-				

s: static; ss: semi-static; f: flow-through; nom: based on nominal concentrations; mm: based on mean measured concentrations

9.5.1.1 Justification for new endpoints

Not relevant as there is no deviation to the EU agreed endpoints.

9.5.2 Risk assessment

The evaluation of the risk for aquatic and sediment-dwelling organisms was performed in accordance with the recommendations of the “Guidance document on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters in the context of Regulation (EC) No 1107/2009”, as provided by the Commission Services (SANTE-2015-00080, 15 January 2015).

The relevant global maximum FOCUS 3 PEC_{SW} for risk assessments covering the proposed use pattern and the resulting PEC/RAC ratios are presented in the tables below.

In the table below the D and R scenarios considered relevant for zRMS (Czech) and cMS countries (Poland and Germany) are shown. For completeness all PEC_{sw} and PEC_{sed, accumulation} results for the 10 FOCUS scenarios are presented in this core dossier but the scenarios not relevant for these countries are shown in font light grey.

D and R scenarios considered relevant for each country

Country	Scenarios
Poland (zRMS)	D3, D4, R1
Czech Republic	D4, R1
Germany	National Specific models
Hungary	D3, D5, R1, R3, R4
Romania	D3, D5, R1, R3, R4
Slovakia	D3, D5, R1

In the following table, the ratios between predicted environmental concentrations in surface water bodies (PEC_{sw}, PEC_{sed}) and regulatory acceptable concentrations (RAC) for aquatic organisms are given per intended use for each FOCUS scenario and each organism group.

9.5.2.1 Boscalid

Multiple Applications

Table 9.5-4: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in winter oilseed rape

Group		Fish acute	Fish pro-longed	Inver-teb. acute	Inver-teb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	E _r C ₅₀ /E _y C ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 14									
D2/ditch	5.374	0.1990	0.4299	0.1008	0.0410	0.0401	0.0537	72.577	0.0312

Group		Fish acute	Fish pro-longed	Inver-teb. acute	Inver-teb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
D2/stream	3.356	0.1243	0.2685	0.0630	0.0256	0.0250	0.0336	42.131	0.0181
D3/ditch	0.694	0.0257	0.0555	0.0130	0.0053	0.0052	0.0069	1.346	0.0006
D4/pond	0.372	0.0138	0.0298	0.0070	0.0028	0.0028	0.0037	9.605	0.0041
D4/stream	0.787	0.0291	0.0630	0.0148	0.0060	0.0059	0.0079	3.08	0.0013
D5/pond	0.23	0.0085	0.0184	0.0043	0.0018	0.0017	0.0023	6.776	0.0029
D5/stream	0.638	0.0236	0.0510	0.0120	0.0049	0.0048	0.0064	1.29	0.0006
R1/pond	0.104	0.0039	0.0083	0.0020	0.0008	0.0008	0.0010	3.223	0.0014
R1/stream	0.905	0.0335	0.0724	0.0170	0.0069	0.0068	0.0091	1.087	0.0005
R3/stream	1.154	0.0427	0.0923	0.0217	0.0088	0.0086	0.0115	2.042	0.0009
BBCH 21									
D2/ditch	6.207	0.2299	0.4966	0.1165	0.0474	0.0463	0.0621	102.847	0.0442
D2/stream	3.884	0.1439	0.3107	0.0729	0.0296	0.0290	0.0388	61.27	0.0263
D3/ditch	0.691	0.0256	0.0553	0.0130	0.0053	0.0052	0.0069	1.079	0.0005
D4/pond	0.587	0.0217	0.0470	0.0110	0.0045	0.0044	0.0059	14.519	0.0062
D4/stream	1.037	0.0384	0.0830	0.0195	0.0079	0.0077	0.0104	4.79	0.0021
D5/pond	0.464	0.0172	0.0371	0.0087	0.0035	0.0035	0.0046	11.296	0.0049
D5/stream	0.653	0.0242	0.0522	0.0123	0.0050	0.0049	0.0065	2.368	0.0010
R1/pond	0.25	0.0093	0.0200	0.0047	0.0019	0.0019	0.0025	5.136	0.0022
R1/stream	1.753	0.0649	0.1402	0.0329	0.0134	0.0131	0.0175	3.182	0.0014
R3/stream	1.565	0.0580	0.1252	0.0294	0.0119	0.0117	0.0157	3.508	0.0015
BBCH 61									
D2/ditch	6.322	0.2341	0.5058	0.1186	0.0483	0.0472	0.0632	102.62	0.0441
D2/stream	3.942	0.1460	0.3154	0.0740	0.0301	0.0294	0.0394	60.514	0.0260
D3/ditch	0.693	0.0257	0.0554	0.0130	0.0053	0.0052	0.0069	1.26	0.0005
D4/pond	0.388	0.0144	0.0310	0.0073	0.0030	0.0029	0.0039	9.937	0.0043
D4/stream	0.722	0.0267	0.0578	0.0135	0.0055	0.0054	0.0072	3.172	0.0014
D5/pond	0.443	0.0164	0.0354	0.0083	0.0034	0.0033	0.0044	10.603	0.0046
D5/stream	0.638	0.0236	0.0510	0.0120	0.0049	0.0048	0.0064	2.252	0.0010
R1/pond	0.246	0.0091	0.0197	0.0046	0.0019	0.0018	0.0025	5.177	0.0022
R1/stream	1.634	0.0605	0.1307	0.0307	0.0125	0.0122	0.0163	3.276	0.0014
R3/stream	1.563	0.0579	0.1250	0.0293	0.0119	0.0117	0.0156	3.503	0.0015

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-5: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in spring oilseed rape

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	E _r C ₅₀ /E _y C ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 14									
D1/ditch	4.311	0.1597	0.3449	0.0809	0.0329	0.0322	0.0431	110.572	0.0475
D1/stream	2.778	0.1029	0.2222	0.0521	0.0212	0.0207	0.0278	62.534	0.0269
D3/ditch	0.692	0.0256	0.0554	0.0130	0.0053	0.0052	0.0069	1.248	0.0005
D4/pond	0.538	0.0199	0.0430	0.0101	0.0041	0.0040	0.0054	13.32	0.0057
D4/stream	0.874	0.0324	0.0699	0.0164	0.0067	0.0065	0.0087	4.402	0.0019
D5/pond	0.515	0.0191	0.0412	0.0097	0.0039	0.0038	0.0052	11.545	0.0050
D5/stream	0.646	0.0239	0.0517	0.0121	0.0049	0.0048	0.0065	2.533	0.0011
R1/pond	0.215	0.0080	0.0172	0.0040	0.0016	0.0016	0.0022	6.318	0.0027
R1/stream	1.507	0.0558	0.1206	0.0283	0.0115	0.0112	0.0151	4.23	0.0018
BBCH 61									
D1/ditch	4.1510	0.1537	0.3321	0.0779	0.0317	0.0310	0.0415	105.486	0.0454
D1/stream	2.6640	0.0987	0.2131	0.0500	0.0203	0.0199	0.0266	59.68	0.0257
D3/ditch	0.695	0.0257	0.0556	0.0130	0.0053	0.0052	0.0070	1.812	0.0008
D4/pond	0.504	0.0187	0.0403	0.0095	0.0038	0.0038	0.0050	12.511	0.0054
D4/stream	0.953	0.0353	0.0762	0.0179	0.0073	0.0071	0.0095	3.981	0.0017
D5/pond	0.353	0.0131	0.0282	0.0066	0.0027	0.0026	0.0035	7.445	0.0032
D5/stream	0.638	0.0236	0.0510	0.0120	0.0049	0.0048	0.0064	1.739	0.0007
R1/pond	0.278	0.0103	0.0222	0.0052	0.0021	0.0021	0.0028	7.304	0.0031
R1/stream	1.595	0.0591	0.1276	0.0299	0.0122	0.0119	0.0160	6.499	0.0028

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-6: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in winter cereals

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	E _r C ₅₀ /E _y C ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 25									
D1/ditch	5.211	0.1930	0.4169	0.0978	0.0398	0.0389	0.0521	126.085	0.0542
D1/stream	3.303	0.1223	0.2642	0.0620	0.0252	0.0246	0.0330	71.916	0.0309
D2/ditch	6.936	0.2569	0.5549	0.1301	0.0529	0.0518	0.0694	112.4660	0.0484
D2/stream	4.329	0.1603	0.3463	0.0812	0.0330	0.0323	0.0433	66.5580	0.0286
D3/ditch	0.692	0.0256	0.0554	0.0130	0.0053	0.0052	0.0069	1.2000	0.0005
D4/pond	0.636	0.0236	0.0509	0.0119	0.0049	0.0047	0.0064	15.3850	0.0066
D4/stream	1.057	0.0391	0.0846	0.0198	0.0081	0.0079	0.0106	5.0270	0.0022
D5/pond	0.505	0.0187	0.0404	0.0095	0.0039	0.0038	0.0051	12.1920	0.0052
D5/stream	0.705	0.0261	0.0564	0.0132	0.0054	0.0053	0.0071	2.6280	0.0011
D6/ditch	1.596	0.0591	0.1277	0.0299	0.0122	0.0119	0.0160	3.6560	0.0016
R1/pond	0.252	0.0093	0.0202	0.0047	0.0019	0.0019	0.0025	6.2860	0.0027
R1/stream	1.652	0.0612	0.1322	0.0310	0.0126	0.0123	0.0165	6.5010	0.0028
R3/stream	1.797	0.0666	0.1438	0.0337	0.0137	0.0134	0.0180	2.7050	0.0012
R4/stream	3.347	0.1240	0.2678	0.0628	0.0255	0.0250	0.0335	4.0040	0.0017
BBCH69									
D1/ditch	3.302	0.122	0.264	0.062	0.025	0.025	0.033	81.664	0.035
D1/stream	2.067	0.077	0.165	0.039	0.016	0.015	0.021	44.619	0.019
D2/ditch	4.192	0.155	0.335	0.079	0.032	0.031	0.042	76.203	0.033
D2/stream	2.615	0.097	0.209	0.049	0.020	0.020	0.026	44.775	0.019
D3/ditch	0.694	0.026	0.056	0.013	0.005	0.005	0.007	1.514	0.001
D4/pond	0.4182	0.015	0.033	0.008	0.003	0.003	0.004	10.593	0.005

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
D4/stream	0.7408	0.027	0.059	0.014	0.006	0.006	0.007	3.354	0.001
D5/pond	0.4505	0.017	0.036	0.008	0.003	0.003	0.005	10.442	0.004
D5/stream	0.6384	0.024	0.051	0.012	0.005	0.005	0.006	2.308	0.001
D6/ditch	1.123	0.042	0.090	0.021	0.009	0.008	0.011	2.837	0.001
R1/pond	0.2691	0.010	0.022	0.005	0.002	0.002	0.003	6.622	0.003
R1/stream	1.724	0.064	0.138	0.032	0.013	0.013	0.017	6.996	0.003
R3/stream	1.978	0.073	0.158	0.037	0.015	0.015	0.020	3.776	0.002
R4/stream	1.782	0.066	0.143	0.033	0.014	0.013	0.018	3.904	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-7: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in spring cereals

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	E _r C ₅₀ /E _y C ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 25									
D1/ditch	3.995	0.1480	0.3196	0.0750	0.0305	0.0298	0.0400	101.021	0.0434
D1/stream	2.527	0.0936	0.2022	0.0474	0.0193	0.0189	0.0253	57.08	0.0245
D3/ditch	0.692	0.0256	0.0554	0.0130	0.0053	0.0052	0.0069	1.208	0.0005
D4/pond	0.743	0.0275	0.0594	0.0139	0.0057	0.0055	0.0074	17.862	0.0077
D4/stream	1.139	0.0422	0.0911	0.0214	0.0087	0.0085	0.0114	6.078	0.0026
D5/pond	0.448	0.0166	0.0358	0.0084	0.0034	0.0033	0.0045	10.56	0.0045
D5/stream	0.598	0.0221	0.0478	0.0112	0.0046	0.0045	0.0060	2.231	0.0010
R4/stream	2.895	0.1072	0.2316	0.0543	0.0221	0.0216	0.0290	5.233	0.0022

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
BBCH69									
D1/ditch	3.992	0.148	0.319	0.075	0.030	0.030	0.040	100.908	0.043
D1/stream	2.525	0.094	0.202	0.047	0.019	0.019	0.025	57.052	0.025
D3/ditch	0.6933	0.026	0.055	0.013	0.005	0.005	0.007	1.518	0.001
D4/pond	0.5993	0.022	0.048	0.011	0.005	0.004	0.006	14.037	0.006
D4/stream	0.9376	0.035	0.075	0.018	0.007	0.007	0.009	4.278	0.002
D5/pond	0.4343	0.016	0.035	0.008	0.003	0.003	0.004	12.493	0.005
D5/stream	0.5981	0.022	0.048	0.011	0.005	0.004	0.006	2.642	0.001
R4/stream	1.787	0.066	0.143	0.034	0.014	0.013	0.018	4.605	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Single Application

Table 9.5-8: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in winter oilseed rape

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	ErC ₅₀ /EyC ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 14									
D2/ditch	5.3740	0.1990	0.4299	0.1008	0.0410	0.0401	0.0537	71.897	0.0309
D2/stream	3.3560	0.1243	0.2685	0.0630	0.0256	0.0250	0.0336	42.181	0.0181
D3/ditch	0.794	0.0294	0.0635	0.0149	0.0061	0.0059	0.0079	1.532	0.0007
D4/pond	0.373	0.0138	0.0298	0.0070	0.0028	0.0028	0.0037	9.368	0.0040
D4/stream	0.787	0.0291	0.0630	0.0148	0.0060	0.0059	0.0079	3.082	0.0013
D5/pond	0.299	0.0111	0.0239	0.0056	0.0023	0.0022	0.0030	7.553	0.0032

Group		Fish acute	Fish pro-longed	Inver-teb. acute	Inver-teb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
D5/stream	0.738	0.0273	0.0590	0.0138	0.0056	0.0055	0.0074	1.593	0.0007
R1/pond	0.078	0.0029	0.0062	0.0015	0.0006	0.0006	0.0008	1.746	0.0008
R1/stream	0.638	0.0236	0.0510	0.0120	0.0049	0.0048	0.0064	0.878	0.0004
R3/stream	1.129	0.0418	0.0903	0.0212	0.0086	0.0084	0.0113	2.435	0.0010
BBCH 21									
D2/ditch	2.871	0.1063	0.2297	0.0539	0.0219	0.0214	0.0287	51.877	0.0223
D2/stream	1.786	0.0661	0.1429	0.0335	0.0136	0.0133	0.0179	30.799	0.0132
D3/ditch	0.789	0.0292	0.0631	0.0148	0.0060	0.0059	0.0079	0.864	0.0004
D4/pond	0.241	0.0089	0.0193	0.0045	0.0018	0.0018	0.0024	6.365	0.0027
D4/stream	0.614	0.0227	0.0491	0.0115	0.0047	0.0046	0.0061	2.055	0.0009
D5/pond	0.202	0.0075	0.0162	0.0038	0.0015	0.0015	0.0020	4.919	0.0021
D5/stream	0.534	0.0198	0.0427	0.0100	0.0041	0.0040	0.0053	1.049	0.0005
R1/pond	0.129	0.0048	0.0103	0.0024	0.0010	0.0010	0.0013	2.787	0.0012
R1/stream	0.86	0.0319	0.0688	0.0161	0.0066	0.0064	0.0086	1.838	0.0008
R3/stream	0.952	0.0353	0.0762	0.0179	0.0073	0.0071	0.0095	1.547	0.0007
BBCH 61									
D2/ditch	2.882	0.1067	0.2306	0.0541	0.0220	0.0215	0.0288	49.409	0.0212
D2/stream	1.793	0.0664	0.1434	0.0336	0.0137	0.0134	0.0179	28.885	0.0124
D3/ditch	0.792	0.0293	0.0634	0.0149	0.0060	0.0059	0.0079	1.198	0.0005
D4/pond	0.122	0.0045	0.0098	0.0023	0.0009	0.0009	0.0012	3.451	0.0015
D4/stream	0.667	0.0247	0.0534	0.0125	0.0051	0.0050	0.0067	1.044	0.0004
D5/pond	0.211	0.0078	0.0169	0.0040	0.0016	0.0016	0.0021	5.056	0.0022
D5/stream	0.676	0.0250	0.0541	0.0127	0.0052	0.0050	0.0068	1.086	0.0005
R1/pond	0.129	0.0048	0.0103	0.0024	0.0010	0.0010	0.0013	2.787	0.0012
R1/stream	0.86	0.0319	0.0688	0.0161	0.0066	0.0064	0.0086	1.838	0.0008
R3/stream	1.029	0.0381	0.0823	0.0193	0.0079	0.0077	0.0103	2.06	0.0009

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-9: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in spring oilseed rape

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae	Sed. dwell. prolonged		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	E _r C ₅₀ /E _y C ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 24 14									
D1/ditch	2.536	0.0939	0.2029	0.0476	0.0194	0.0189	0.0254	71.096	0.0306
D1/stream	1.603	0.0594	0.1282	0.0301	0.0122	0.0120	0.0160	40.465	0.0174
D3/ditch	0.791	0.0293	0.0633	0.0148	0.0060	0.0059	0.0079	1.075	0.0005
D4/pond	0.278	0.0103	0.0222	0.0052	0.0021	0.0021	0.0028	7.197	0.0031
D4/stream	0.648	0.0240	0.0518	0.0122	0.0049	0.0048	0.0065	2.299	0.0010
D5/pond	0.233	0.0086	0.0186	0.0044	0.0018	0.0017	0.0023	5.397	0.0023
D5/stream	0.63	0.0233	0.0504	0.0118	0.0048	0.0047	0.0063	1.182	0.0005
R1/pond	0.11	0.0041	0.0088	0.0021	0.0008	0.0008	0.0011	2.97	0.0013
R1/stream	0.852	0.0316	0.0682	0.0160	0.0065	0.0064	0.0085	1.523	0.0007
BBCH 61									
D1/ditch	1.6080	0.0596	0.1286	0.0302	0.0123	0.0120	0.0161	45.749	0.0197
D1/stream	1.0040	0.0372	0.0803	0.0188	0.0077	0.0075	0.0100	25.491	0.0110
D3/ditch	0.794	0.0294	0.0635	0.0149	0.0061	0.0059	0.0079	1.418	0.0006
D4/pond	0.128	0.0047	0.0102	0.0024	0.0010	0.0010	0.0013	3.433	0.0015
D4/stream	0.684	0.0253	0.0547	0.0128	0.0052	0.0051	0.0068	1.041	0.0004
D5/pond	0.244	0.0090	0.0195	0.0046	0.0019	0.0018	0.0024	4.882	0.0021
D5/stream	0.738	0.0273	0.0590	0.0138	0.0056	0.0055	0.0074	1.194	0.0005
R1/pond	0.219	0.0081	0.0175	0.0041	0.0017	0.0016	0.0022	4.39	0.0019
R1/stream	1.02	0.0378	0.0816	0.0191	0.0078	0.0076	0.0102	4.994	0.0021

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-10: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in winter cereals

Group		Fish acute	Fish pro-longed	Inver-teb. acute	Inver-teb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	ErC ₅₀ /EyC ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 25									
D1/ditch	2.4790	0.0918	0.1983	0.0465	0.0189	0.0185	0.0248	65.219	0.0280
~~D1/stream~~	~~3.197~~	~~0.1184~~	~~0.2558~~	~~0.0600~~	~~0.0244~~	~~0.0239~~	~~0.0320~~	~~55.8550~~	~~0.0240~~
D2/ditch stream	1.996	0.0739	0.1597	0.0374	0.0152	0.0149	0.0200	32.7880	0.0141
~~D2/stream~~ D3/ditch	0.791	0.0293	0.0633	0.0148	0.0060	0.0059	0.0079	1.0190	0.0004
~~D3/ditch~~ D4/pond	0.253	0.0094	0.0202	0.0047	0.0019	0.0019	0.0025	6.5680	0.0028
~~D4/pond~~ D4/stream	0.585	0.0217	0.0468	0.0110	0.0045	0.0044	0.0059	2.0580	0.0009
~~D4/stream~~ D5/pond	0.225	0.0083	0.0180	0.0042	0.0017	0.0017	0.0023	5.5060	0.0024
~~D5/pond~~ D5/stream	0.634	0.0235	0.0507	0.0119	0.0048	0.0047	0.0063	1.1920	0.0005
~~D5/stream~~ D6/ditch	1.015	0.0376	0.0812	0.0190	0.0077	0.0076	0.0102	2.0430	0.0009
~~D6/ditch~~ R1/pond	0.122	0.0045	0.0098	0.0023	0.0009	0.0009	0.0012	2.9580	0.0013
~~R1/pond~~ R1/stream	0.863	0.0320	0.0690	0.0162	0.0066	0.0064	0.0086	1.7740	0.0008
~~R1/stream~~ R3/stream	1.025	0.0380	0.0820	0.0192	0.0078	0.0076	0.0103	2.1000	0.0009
R4/stream	1.461							1.897	
BBCH69									
D1/ditch	1.306	0.048	0.104	0.025	0.010	0.010	0.013	37.922	0.016

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
D1/stream	0.8168	0.030	0.065	0.015	0.006	0.006	0.008	20.377	0.009
D2/ditch	1.623	0.060	0.130	0.030	0.012	0.012	0.016	30.698	0.013
D2/stream	1.017	0.038	0.081	0.019	0.008	0.008	0.010	18.321	0.008
D3/ditch	0.7931	0.029	0.063	0.015	0.006	0.006	0.008	1.32	0.001
D4/pond	0.1237	0.005	0.010	0.002	0.001	0.001	0.001	3.341	0.001
D4/stream	0.6841	0.025	0.055	0.013	0.005	0.005	0.007	0.999	0.000
D5/pond	0.1612	0.006	0.013	0.003	0.001	0.001	0.002	3.7	0.002
D5/stream	0.7381	0.027	0.059	0.014	0.006	0.006	0.007	0.847	0.000
D6/ditch	0.7954	0.029	0.064	0.015	0.006	0.006	0.008	1.601	0.001
R1/pond	0.1425	0.005	0.011	0.003	0.001	0.001	0.001	3.613	0.002
R1/stream	1.059	0.039	0.085	0.020	0.008	0.008	0.011	4.778	0.002
R3/stream	0.9803	0.036	0.078	0.018	0.007	0.007	0.010	1.072	0.0004
R4/stream	1.78	0.066	0.142	0.033	0.014	0.013	0.018	3.733	0.002

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-11: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Boscalid for each organism group based on FOCUS Steps 1, 2 and 3 calculations for the use of GLOB2021dF in spring cereals

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>	<i>Chironomus riparius</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		EC ₅₀ 2700	NOEC 125	EC ₅₀ 5330	NOEC 1310	E _r C ₅₀ /E _y C ₅₀ 1340	NOEC 1000		NOEC 23260
AF		100	10	100	10	10	10		10
RAC (µg/L)		27	12.5	53.30	131	134	100		2326
FOCUS Scenario	PEC _{gl-max} (µg/L)							PEC _{gl-max} (µg/kg)	
Step 3									
BBCH 25									
D1/ditch	2.311	0.0856	0.1849	0.0434	0.0176	0.0172	0.0231	64.569	0.0278
D1/stream	1.47	0.0544	0.1176	0.0276	0.0112	0.0110	0.0147	36.82	0.0158
D3/ditch	0.791	0.0293	0.0633	0.0148	0.0060	0.0059	0.0079	1.029	0.0004

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae	Sed. dwell. pro-longed		Sed. dwell. pro-longed
D4/pond	0.349	0.0129	0.0279	0.0065	0.0027	0.0026	0.0035	8.857	0.0038
D4/stream	0.606	0.0224	0.0485	0.0114	0.0046	0.0045	0.0061	2.919	0.0013
D5/pond	0.233	0.0086	0.0186	0.0044	0.0018	0.0017	0.0023	5.592	0.0024
D5/stream	0.631	0.0234	0.0505	0.0118	0.0048	0.0047	0.0063	1.188	0.0005
R4/stream	1.692	0.0627	0.1354	0.0317	0.0129	0.0126	0.0169	3.422	0.0015
BBCH69									
D1/ditch	1.227	0.045	0.098	0.023	0.009	0.009	0.012	39.843	0.017
D1/stream	0.7658	0.028	0.061	0.014	0.006	0.006	0.008	22.018	0.009
D3/ditch	0.7923	0.029	0.063	0.015	0.006	0.006	0.008	1.321	0.001
D4/pond	0.1759	0.007	0.014	0.003	0.001	0.001	0.002	4.488	0.002
D4/stream	0.6821	0.025	0.055	0.013	0.005	0.005	0.007	1.282	0.001
D5/pond	1.789	0.066	0.143	0.034	0.014	0.013	0.018	5.388	0.002
D5/stream	1.227	0.045	0.098	0.023	0.009	0.009	0.012	39.843	0.017
R4/stream	0.7658	0.028	0.061	0.014	0.006	0.006	0.008	22.018	0.009

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

zRMS comments:

PEC_{sw} and PEC_{sed} values are missing for the D5 pond and D5 stream scenarios, in Part B8, therefore the PEC/RAC ratios values have been deleted. Member States should consider this.

9.5.2.2 Prothioconazole 1

Serie 1 (whole system DT50 to the water compartment)
Multiple applications

Table 9.5-12: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter cereals (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	13.9276	0.0152 0.0014
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
S-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	12.7992	0.0140 0.0014
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	12.7992	0.0140 0.0014
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
Step 3								
BBCH 25								
D1/ditch	0.6995	0.0382	0.0227	0.0538	0.0125	0.0032	1.5560	0.0017 0.0008
D1/stream	0.5898	0.0322	0.0191	0.0454	0.0105	0.0027	0.1053	0.0004 0.0006
D2/ditch	0.7037	0.0385	0.0228	0.0541	0.0126	0.0032	1.5060	0.0017 0.0008
D2/stream	0.6121	0.0334	0.0199	0.0471	0.0109	0.0028	1.1440	0.0013 0.0007
D3/ditch	0.6920	0.0378	0.0225	0.0532	0.0124	0.0032	0.4434	0.0005 0.0008
D4/pond	0.0354	0.0019	0.0011	0.0027	0.0006	0.0002	0.1753	0.0002 0.00004
D4/stream	0.5228	0.0286	0.0170	0.0402	0.0093	0.0024	0.0202	0.0000 0.0006
D5/pond	0.0376	0.0021	0.0012	0.0029	0.0007	0.0002	0.1740	0.0005 0.00004
D5/stream	0.6089	0.0333	0.0198	0.0468	0.0109	0.0028	0.0533	0.0004 0.00007
D6/ditch	0.6975	0.0381	0.0226	0.0537	0.0125	0.0032	1.1450	0.0017 0.0008
R1/pond	0.0340	0.0019	0.0011	0.0026	0.0006	0.0002	0.1605	0.0002 0.00004

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
R1/stream	0.4507	0.0246	0.0146	0.0347	0.0080	0.0021	0.0955	0.0001 0.0005
R3/stream	0.6370	0.0348	0.0207	0.0490	0.0114	0.0029	0.2029	0.0002 0.0007
R4/stream	0.4526	0.0247	0.0147	0.0348	0.0081	0.0021	0.0720	0.0001 0.0005
BBCH69								
D1/ditch	1.019	0.056	0.033	0.078	0.018	0.005	3.36	0.004 0.001
D1/stream	0.106	0.006	0.003	0.008	0.002	0.000	0.982	0.001 0.0001
D2/ditch	0.606	0.033	0.020	0.047	0.011	0.003	0.352	0.000 0.0007
D2/stream	0.013	0.001	0.000	0.001	0.000	0.000	0.059	0.000 0.00001
D3/ditch	0.727	0.040	0.024	0.056	0.013	0.003	2.346	0.003 0.0008
D4/pond	0.08	0.004	0.003	0.006	0.001	0.000	0.895	0.001 0.00009
D4/stream	0.617	0.034	0.020	0.047	0.011	0.003	1.573	0.002 0.0007
D5/pond	0.059	0.003	0.002	0.005	0.001	0.000	0.557	0.001 0.00006
D5/stream	0.694	0.038	0.023	0.053	0.012	0.003	0.568	0.001 0.0008
D6/ditch	0.008	0.000	0.000	0.001	0.000	0.000	0.016	0.000 0.000009
R1/pond	0.034	0.002	0.001	0.003	0.001	0.000	0.154	0.000 0.00004
R1/stream	0.008	0.000	0.000	0.001	0.000	0.000	0.147	0.000 0.000009
R3/stream	0.592	0.032	0.019	0.046	0.011	0.003	0.12	0.000 0.0006
R4/stream	0.007	0.000	0.000	0.001	0.000	0.000	0.007	0.000 0.000008

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-13: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 an 3 calculations for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.030
Step 2								
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	12.7992	0.0140 0.0014
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
Step 3								
BBCH 25								
D1/ditch	1.0190	0.0557	0.0331	0.0784	0.0182	0.0047	2.3600	0.0033 0.0012
D1/stream	0.6057	0.0331	0.0197	0.0466	0.0108	0.0028	0.3520	0.0004 0.0007
D3/ditch	0.6922	0.0378	0.0225	0.0532	0.0124	0.0032	0.4564	0.0005 0.0008
D4/pond	0.0366	0.0020	0.0012	0.0028	0.0007	0.0002	0.1573	0.0002 0.00004
D4/stream	0.5809	0.0317	0.0189	0.0447	0.0104	0.0027	0.0762	0.0001 0.0006
D5/pond	0.0351	0.0019	0.0011	0.0027	0.0006	0.0002	0.1691	0.0003 0.00004
D5/stream	0.5972	0.0326	0.0194	0.0459	0.0107	0.0027	0.0326	0.0000 0.0007

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
R4/stream	0.4980	0.0272	0.0162	0.0383	0.0089	0.0023	0.4233	0.0005
BBCH69								
D1/ditch	1.019	0.056	0.033	0.078	0.018	0.005	2.36	0.004 0.0011
D1/stream	0.106	0.006	0.003	0.008	0.002	0.000	0.961	0.001 0.0001
D3/ditch	0.606	0.033	0.020	0.047	0.011	0.003	0.352	0.000 0.0007
D4/pond	0.013	0.001	0.000	0.001	0.000	0.000	0.062	0.000 0.00001
D4/stream	0.693	0.038	0.023	0.053	0.012	0.003	0.518	0.001 0.0008
D5/pond	0.006	0.000	0.000	0.000	0.000	0.000	0.011	0.000
D5/stream	0.034	0.002	0.001	0.003	0.001	0.000	0.154	0.000 0.00004
R4/stream	0.008	0.000	0.000	0.001	0.000	0.000	0.14	0.000

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-14: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
Test species		<i>On- corhyn- chus mykiss</i>	<i>On- corhyn- chus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo- kirchn. subcapi- tata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl- max} (µg/L)						PEC _{gl- max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.030
Step 2								
N-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
S-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0014
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0014
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.3167	0.0113 0.0014
Step 3								
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								
D2/ditch	0.7004	0.0383	0.0227	0.0539	0.0125	0.0032	1.4870	0.0018 0.0008
D2/stream	0.6166	0.0337	0.0200	0.0474	0.0110	0.0028	1.3074	0.0018 0.0007
D3/ditch	0.6944	0.0379	0.0225	0.0534	0.0124	0.0032	0.5239	0.0006 0.0008
D4/pond	0.0245	0.0013	0.0008	0.0019	0.0004	0.0001	0.1594	0.0002 0.00003
D4/stream	0.5918	0.0323	0.0192	0.0455	0.0106	0.0027	0.1142	0.0001 0.0006
D5/pond	0.0253	0.0014	0.0008	0.0019	0.0005	0.0001	0.1309	0.0003 0.00003
D5/stream	0.6385	0.0349	0.0207	0.0491	0.0114	0.0029	0.1305	0.0008 0.0007
R1/pond	0.0251	0.0014	0.0008	0.0019	0.0004	0.0001	0.1541	0.0002 0.00003
R1/stream	0.4525	0.0247	0.0147	0.0348	0.0081	0.0021	0.0655	0.0001 0.0005
R3/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1583	0.0002 0.0007
BBCH 21 (no applications in autumn)								
D2/ditch	0.7035	0.0384	0.0228	0.0541	0.0126	0.0032	1.3970	0.0018 0.0008
D2/stream	0.6166	0.0337	0.0200	0.0474	0.0110	0.0028	1.0810	0.0018 0.0007
D3/ditch	0.6913	0.0378	0.0224	0.0532	0.0123	0.0032	0.4112	0.0004 0.0008
D4/pond	0.0375	0.0020	0.0012	0.0029	0.0007	0.0002	0.1818	0.0002 0.00004

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
D4/stream	0.5315	0.0290	0.0173	0.0409	0.0095	0.0024	0.0212	0.0000 0.0006
D5/pond	0.0328	0.0018	0.0011	0.0025	0.0006	0.0002	0.1253	0.0002 0.00004
D5/stream	0.5545	0.0303	0.0180	0.0427	0.0099	0.0025	0.0139	0.0003 0.0006
R1/pond	0.0372	0.0020	0.0012	0.0029	0.0007	0.0002	0.1670	0.0002 0.00004
R1/stream	0.4499	0.0246	0.0146	0.0346	0.0080	0.0021	0.0656	0.0001 0.0005
R3/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1793	0.0002 0.0007
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.7062	0.0386	0.0229	0.0543	0.0126	0.0032	1.5300	0.0013 0.0008
D2/stream	0.6167	0.0337	0.0200	0.0474	0.0110	0.0028	1.1500	0.0013 0.0007
D3/ditch	0.6927	0.0379	0.0225	0.0533	0.0124	0.0032	0.4766	0.0005 0.0008
D4/pond	0.0347	0.0019	0.0011	0.0027	0.0006	0.0002	0.1666	0.0002 0.00004
D4/stream	0.5767	0.0315	0.0187	0.0444	0.0103	0.0026	0.0634	0.0001 0.0006
D5/pond	0.0375	0.0020	0.0012	0.0029	0.0007	0.0002	0.1253	0.0002 0.00004
D5/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1625	0.0002 0.0007
R1/pond	0.0434	0.0024	0.0014	0.0033	0.0008	0.0002	0.2153	0.0002 0.00005
R1/stream	0.4523	0.0247	0.0147	0.0348	0.0081	0.0021	0.2748	0.0003 0.0005
R3/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1660	0.0002 0.0007

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-15: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.030
Step 2								
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0014
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.3167	0.0113 0.0014
Step 3								
BBCH 14 (early application)								
D1/ditch	1.0190	0.0557	0.0331	0.0784	0.0182	0.0047	3.3603	0.0022 0.0011
D1/stream	0.6057	0.0331	0.0197	0.0466	0.0108	0.0028	0.3520	0.0004 0.0007
D3/ditch	0.6925	0.0378	0.0225	0.0533	0.0124	0.0032	0.4717	0.0005 0.0008
D4/pond	0.0366	0.0020	0.0012	0.0028	0.0007	0.0002	0.1574	0.0002 0.00004
D4/stream	0.5823	0.0318	0.0189	0.0448	0.0104	0.0027	0.0799	0.0004 0.0006
D5/pond	0.0351	0.0019	0.0011	0.0027	0.0006	0.0002	0.1691	0.0002 0.00004
D5/stream	0.5979	0.0327	0.0194	0.0460	0.0107	0.0027	0.0302	0.0003 0.0007

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
R1/pond	0.0337	0.0018	0.0011	0.0026	0.0006	0.0002	0.4575	0.0002 0.00004
R1/stream	0.4507	0.0246	0.0146	0.0347	0.0080	0.0021	0.0753	0.0001 0.0005
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	0.9983	0.0546	0.0324	0.0768	0.0178	0.0046	5.4059	0.0035 0.0011
D1/stream	0.6057	0.0331	0.0197	0.0466	0.0108	0.0028	0.3504	0.0006 0.0007
D3/ditch	0.6954	0.0380	0.0226	0.0535	0.0124	0.0032	0.6747	0.0007 0.0008
D4/pond	0.0360	0.0020	0.0012	0.0028	0.0006	0.0002	0.1539	0.0002 0.00004
D4/stream	0.5918	0.0323	0.0192	0.0455	0.0106	0.0027	0.1319	0.0001 0.0006
D5/pond	0.0365	0.0020	0.0012	0.0028	0.0007	0.0002	0.1584	0.0002 0.00004
D5/stream	0.6385	0.0349	0.0207	0.0491	0.0114	0.0029	0.1809	0.0002 0.0007
R1/pond	0.0473	0.0026	0.0015	0.0036	0.0008	0.0002	0.2682	0.0003 0.00005
R1/stream	0.4527	0.0247	0.0147	0.0348	0.0081	0.0021	0.8128	0.0009 0.0005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Single applications

Table 9.5-16: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914

BBCH 21 (no applications in autumn)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
D2/ditch	0.8015	0.0438	0.0260	0.0617	0.0143	0.0037	1.4363	0.0016 0.0009
D2/stream	0.7130	0.0390	0.0231	0.0548	0.0127	0.0033	1.2508	0.0014 0.0008
D3/ditch	0.7893	0.0431	0.0256	0.0607	0.0141	0.0036	0.3469	0.0004 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1137	0.0001 0.00003
D4/stream	0.6146	0.0336	0.0200	0.0473	0.0110	0.0028	0.0245	0.0000 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1072	0.0001 0.00003
D5/stream	0.5126	0.0280	0.0166	0.0394	0.0092	0.0024	0.0064	0.0000 0.0006
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1014	0.0001 0.00003
R1/stream	0.5203	0.0284	0.0169	0.0400	0.0093	0.0024	0.0650	0.0001 0.0006
R3/stream	0.7374	0.0403	0.0239	0.0567	0.0132	0.0034	0.1335	0.0000 0.0008
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.8015	0.0438	0.0260	0.0617	0.0143	0.0037	1.4363	0.0016 0.0009
D2/stream	0.7130	0.0390	0.0231	0.0548	0.0127	0.0033	1.2508	0.0014 0.0008
D3/ditch	0.7925	0.0433	0.0257	0.0610	0.0142	0.0036	0.4732	0.0005 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.0993	0.0001 0.00003
D4/stream	0.6668	0.0364	0.0216	0.0513	0.0119	0.0031	0.0701	0.0001 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1008	0.0001 0.00003
D5/stream	0.6748	0.0369	0.0219	0.0519	0.0121	0.0031	0.0354	0.0000 0.0007
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1014	0.0001 0.00003
R1/stream	0.5203	0.0284	0.0169	0.0400	0.0093	0.0024	0.0650	0.0001 0.0006
R3/stream	0.7312	0.0400	0.0237	0.0562	0.0131	0.0034	0.1424	0.0001 0.0008

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-17: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
N-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	6.8965	0.0075 0.0013
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0014
S-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.5736	0.0083 0.0013
Step 3								
BBCH 14 (early application)								
D1/ditch	0.8007	0.0438	0.0260	0.0616	0.0143	0.0037	3.0309	0.0032 0.0009
D1/stream	0.7003	0.0383	0.0227	0.0539	0.0125	0.0032	0.3114	0.0008 0.0008
D3/ditch	0.7915	0.0433	0.0257	0.0609	0.0141	0.0036	0.4283	0.0005 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.0983	0.0004 0.00003
D4/stream	0.6480	0.0354	0.0210	0.0498	0.0116	0.0030	0.0438	0.0000 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1027	0.0004 0.00003
D5/stream	0.6281	0.0343	0.0204	0.0483	0.0112	0.0029	0.0123	0.0000 0.0007

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.0988	0.0001 0.00003
R1/stream	0.5211	0.0285	0.0169	0.0401	0.0093	0.0024	0.0680	0.0001 0.0006
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	0.8007	0.0438	0.0260	0.0616	0.0143	0.0037	1.9818	0.0023 0.0009
D1/stream	0.7003	0.0383	0.0227	0.0539	0.0125	0.0032	0.5413	0.0004 0.0008
D3/ditch	0.7939	0.0434	0.0258	0.0611	0.0142	0.0036	0.5555	0.0006 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.0939	0.0001 0.00003
D4/stream	0.6843	0.0374	0.0222	0.0526	0.0122	0.0031	0.1319	0.0001 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	1.0906	0.0001 0.00003
D5/stream	0.7379	0.0403	0.0240	0.0568	0.0132	0.0034	0.1788	0.0003 0.0009
R1/pond	0.0486	0.0027	0.0016	0.0037	0.0009	0.0002	0.1930	0.0002 0.00005
R1/stream	0.5235	0.0286	0.0170	0.0403	0.0093	0.0024	0.8154	0.0009 0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-18: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

[illegible]

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.00297
Step 2								
N-Europe Oct-Feb	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	11.1844	0.0122 0.0016
N-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.7992	0.0085 0.0016
N-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.7992	0.0085 0.0016
S-Europe Oct-Feb	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	10.0560	0.0110 0.0016
S-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	10.0560	0.0110 0.0016
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
Step 3								
BBCH 25								
D1/ditch	0.7937	0.0434	0.0258	0.0611	0.0142	0.0036	0.5751	0.0006 0.0009
D1/stream	0.6168	0.0337	0.0200	0.0474	0.0110	0.0028	0.0052	0.0000 0.0007
D2/ditch	0.7972	0.0436	0.0259	0.0613	0.0142	0.0037	1.0000	0.0011 0.0009
D2/stream	0.6595	0.0360	0.0214	0.0507	0.0118	0.0030	0.0052	0.0000 0.0007
D3/ditch	0.7904	0.0432	0.0257	0.0608	0.0141	0.0036	0.3852	0.0004 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1082	0.0001 0.00003
D4/stream	0.5842	0.0319	0.0190	0.0449	0.0104	0.0027	0.0169	0.0000 0.0006
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1004	0.0000 0.00003
D5/stream	0.6314	0.0345	0.0205	0.0486	0.0113	0.0029	0.0130	0.0000 0.0007
D6/ditch	0.7982	0.0436	0.0259	0.0614	0.0143	0.0037	1.0000	0.0011 0.0009
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1005	0.0001 0.00003
R1/stream	0.5211	0.0285	0.0169	0.0401	0.0093	0.0024	0.0679	0.0001 0.0006
R3/stream	0.7320	0.0400	0.0238	0.0563	0.0131	0.0034	0.1361	0.0000 0.0008

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
R4/stream	0.5161	0.0282	0.0168	0.0397	0.0092	0.0024	0.0004	0.0006
BBCH69								
D1/ditch	0.801	0.044	0.026	0.062	0.014	0.004	2.039	0.002 0.0009
D1/stream	0.7	0.038	0.023	0.054	0.013	0.003	0.33	0.000 0.0008
D2/ditch	0.802	0.044	0.026	0.062	0.014	0.004	2.225	0.002 0.0009
D2/stream	0.713	0.039	0.023	0.055	0.013	0.003	1.81	0.002 0.0008
D3/ditch	0.793	0.043	0.026	0.061	0.014	0.004	0.51	0.001 0.0009
D4/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.094	0.000 0.00003
D4/stream	0.684	0.037	0.022	0.053	0.012	0.003	0.12	0.000 0.0007
D5/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.103	0.000 0.00003
D5/stream	0.738	0.040	0.024	0.057	0.013	0.003	0.167	0.000 0.0009
D6/ditch	0.795	0.043	0.026	0.061	0.014	0.004	0.765	0.001 0.0009
R1/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.09	0.000 0.00003
R1/stream	0.523	0.029	0.017	0.040	0.009	0.002	0.065	0.000 0.0006
R3/stream	0.736	0.040	0.024	0.057	0.013	0.003	0.152	0.000 0.0008
R4/stream	0.523	0.029	0.017	0.040	0.009	0.002	0.068	0.000 0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-19: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	ErC ₅₀		NOEC

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
(µg/L)		1830	308	1300	560	2180		9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.7992	0.0085 0.0013
N-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.7992	0.0085 0.0013
S-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	10.0560	0.0110 0.0013
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
Step 3								
BBCH 25								
D1/ditch	0.8007	0.0438	0.0260	0.0616	0.0143	0.0037	2.0330	0.0023 0.0088
D1/stream	0.7003	0.0383	0.0227	0.0539	0.0125	0.0032	0.3418	0.0004 0.0008
D3/ditch	0.7910	0.0432	0.0257	0.0608	0.0141	0.0036	0.4103	0.0004 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.0982	0.0001 0.00003
D4/stream	0.6473	0.0354	0.0210	0.0498	0.0116	0.0030	0.0431	0.0000 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.4076	0.0001 0.00003
D5/stream	0.6285	0.0343	0.0204	0.0483	0.0112	0.0029	0.0174	0.0000 0.0007
R4/stream	0.5225	0.0286	0.0170	0.0402	0.0093	0.0024	0.1874	0.0002 0.0006
BBCH69								
D1/ditch	0.801	0.044	0.026	0.062	0.014	0.004	2	0.002 0.0009
D1/stream	0.7	0.038	0.023	0.054	0.013	0.003	0.33	0.000 0.0008
D3/ditch	0.793	0.043	0.026	0.061	0.014	0.004	0.464	0.001 0.0009

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.2.3 Prothioconazole 2

Table 9.5-20: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter cereals (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapi-tata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.484 0.0297
Step 2								

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
N-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	13.9276	0.0152 0.0014
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
S-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	12.7992	0.0140 0.0014
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	12.7992	0.0140 0.0014
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
Step 3								
BBCH 25								
D1/ditch	0.6994	0.0382	0.0227	0.0538	0.0125	0.0032	1.5410	0.0012 0.0008
D1/stream	0.5898	0.0322	0.0191	0.0454	0.0105	0.0027	0.1049	0.0004 0.0006
D2/ditch	0.7034	0.0384	0.0228	0.0541	0.0126	0.0032	1.4750	0.0016 0.0008
D2/stream	0.6121	0.0334	0.0199	0.0471	0.0109	0.0028	1.1100	0.0013 0.0007
D3/ditch	0.6920	0.0378	0.0225	0.0532	0.0124	0.0032	0.4326	0.0005 0.0008
D4/pond	0.0368	0.0020	0.0012	0.0028	0.0007	0.0002	0.1760	0.0002 0.00004
D4/stream	0.5228	0.0286	0.0170	0.0402	0.0093	0.0024	0.0200	0.0000 0.0006
D5/pond	0.0394	0.0022	0.0013	0.0030	0.0007	0.0002	0.1823	0.0003 0.00004
D5/stream	0.6089	0.0333	0.0198	0.0468	0.0109	0.0028	0.0520	0.0004 0.0007
D6/ditch	0.6975	0.0381	0.0226	0.0537	0.0125	0.0032	1.1460	0.0013 0.0008
R1/pond	0.0368	0.0020	0.0012	0.0028	0.0007	0.0002	0.1649	0.0002 0.00004
R1/stream	0.4507	0.0246	0.0146	0.0347	0.0080	0.0021	0.0882	0.0001 0.0005
R3/stream	0.6370	0.0348	0.0207	0.0490	0.0114	0.0029	0.1004	0.0003 0.0007
R4/stream	0.4526	0.0247	0.0147	0.0348	0.0081	0.0021	0.0712	0.0001 0.0005
BBCH69								

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D1/ditch	1.065	0.058	0.035	0.082	0.019	0.005	3.264	0.004 0.001
D1/stream	0.606	0.033	0.020	0.047	0.011	0.003	0.329	0.000 0.0007
D2/ditch	0.728	0.040	0.024	0.056	0.013	0.003	2.204	0.002 0.0008
D2/stream	0.617	0.034	0.020	0.047	0.011	0.003	1.567	0.002 0.0007
D3/ditch	0.694	0.038	0.023	0.053	0.012	0.003	0.531	0.001 0.0008
D4/pond	0.038	0.002	0.001	0.003	0.001	0.000	0.168	0.000 0.00002
D4/stream	0.592	0.032	0.019	0.046	0.011	0.003	0.107	0.000 0.0006
D5/pond	0.039	0.002	0.001	0.003	0.001	0.000	0.182	0.000 0.00004
D5/stream	0.639	0.035	0.021	0.049	0.011	0.003	0.147	0.000 0.0007
D6/ditch	0.695	0.038	0.023	0.053	0.012	0.003	0.783	0.001 0.0008
R1/pond	0.037	0.002	0.001	0.003	0.001	0.000	0.156	0.000 0.00004
R1/stream	0.452	0.025	0.015	0.035	0.008	0.002	0.073	0.000 0.0005
R3/stream	0.637	0.035	0.021	0.049	0.011	0.003	0.138	0.000 0.0007
R4/stream	0.453	0.025	0.015	0.035	0.008	0.002	0.079	0.000 0.0005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-21: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	ErC ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.5424	0.0115 0.0014
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	12.7992	0.0140 0.0014
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
Step 3								
BBCH 25								
D1/ditch	1.0650	0.0582	0.0346	0.0819	0.0190	0.0049	3.2640	0.0046 0.0011
D1/stream	0.6057	0.0331	0.0197	0.0466	0.0108	0.0028	0.3203	0.0004 0.0007
D3/ditch	0.6921	0.0378	0.0225	0.0532	0.0124	0.0032	0.4415	0.0005 0.0008
D4/pond	0.0394	0.0022	0.0013	0.0030	0.0007	0.0002	0.1690	0.0002 0.00004
D4/stream	0.5809	0.0317	0.0189	0.0447	0.0104	0.0027	0.0751	0.0001 0.0006
D5/pond	0.0379	0.0021	0.0012	0.0029	0.0007	0.0002	0.1771	0.0003 0.00004
D5/stream	0.5972	0.0326	0.0194	0.0459	0.0107	0.0027	0.0382	0.0004 0.0007
R4/stream	0.4981	0.0272	0.0162	0.0383	0.0089	0.0023	0.4700	0.0003 0.0005
BBCH69								
D1/ditch	1.065	0.058	0.035	0.082	0.019	0.005	3.264	0.004 0.0012
D1/stream	0.606	0.033	0.020	0.047	0.011	0.003	0.329	0.000 0.0007
D3/ditch	0.693	0.038	0.023	0.053	0.012	0.003	0.488	0.001 0.0008
D4/pond	0.038	0.002	0.001	0.003	0.001	0.000	0.167	0.000 0.00004
D4/stream	0.59	0.032	0.019	0.045	0.011	0.003	0.096	0.000 0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
Test species		<i>On- corhyn- chus mykiss</i>	<i>On- corhyn- chus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo- kirchn. subcapi- tata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	ErC ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl- max} (µg/L)						PEC _{gl- max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0137
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0137
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0137
S-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0137
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0137
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.3167	0.0113 0.0137
Step 3								

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								
D2/ditch	0.7004	0.0383	0.0227	0.0539	0.0125	0.0032	1.4990	0.0013 0.0008
D2/stream	0.6166	0.0337	0.0200	0.0474	0.0110	0.0028	1.3170	0.0014 0.0007
D3/ditch	0.6944	0.0379	0.0225	0.0534	0.0124	0.0032	0.5230	0.0006 0.0008
D4/pond	0.0261	0.0014	0.0008	0.0020	0.0005	0.0001	0.1571	0.0002 0.00003
D4/stream	0.5918	0.0323	0.0192	0.0455	0.0106	0.0027	0.1140	0.0001 0.0006
D5/pond	0.0270	0.0015	0.0009	0.0021	0.0005	0.0001	0.1451	0.0002 0.00003
D5/stream	0.6385	0.0349	0.0207	0.0491	0.0114	0.0029	0.1501	0.0002 0.0007
R1/pond	0.0269	0.0015	0.0009	0.0021	0.0005	0.0001	0.1527	0.0002 0.00003
R1/stream	0.4525	0.0247	0.0147	0.0348	0.0081	0.0021	0.0654	0.0001 0.0005
R3/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1546	0.0002 0.0007
BBCH 21 (no applications in autumn)								
D2/ditch	0.7032	0.0384	0.0228	0.0541	0.0126	0.0032	1.4650	0.0015 0.0008
D2/stream	0.6166	0.0337	0.0200	0.0474	0.0110	0.0028	1.0849	0.0012 0.0007
D3/ditch	0.6913	0.0378	0.0224	0.0532	0.0123	0.0032	0.4045	0.0004 0.0008
D4/pond	0.0387	0.0021	0.0013	0.0030	0.0007	0.0002	0.1833	0.0002 0.00004
D4/stream	0.5315	0.0290	0.0173	0.0409	0.0095	0.0024	0.0212	0.0000 0.0006
D5/pond	0.0352	0.0019	0.0011	0.0027	0.0006	0.0002	0.1723	0.0002 0.00004
D5/stream	0.5545	0.0303	0.0180	0.0427	0.0099	0.0025	0.0172	0.0000 0.0006
R1/pond	0.0388	0.0021	0.0013	0.0030	0.0007	0.0002	0.1713	0.0002 0.00004
R1/stream	0.4499	0.0246	0.0146	0.0346	0.0080	0.0021	0.0645	0.0001 0.0005
R3/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1536	0.0002 0.0007

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.7057	0.0386	0.0229	0.0543	0.0126	0.0032	1.5043	0.0016 0.0008
D2/stream	0.6167	0.0337	0.0200	0.0474	0.0110	0.0028	1.4550	0.0013 0.0007
D3/ditch	0.6927	0.0379	0.0225	0.0533	0.0124	0.0032	0.4640	0.0005 0.0008
D4/pond	0.0374	0.0020	0.0012	0.0029	0.0007	0.0002	0.1720	0.0002 0.00004
D4/stream	0.5767	0.0315	0.0187	0.0444	0.0103	0.0026	0.0628	0.0001 0.0006
D5/pond	0.0394	0.0022	0.0013	0.0030	0.0007	0.0002	0.1823	0.0002 0.00004
D5/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1520	0.0002 0.0007
R1/pond	0.0463	0.0025	0.0015	0.0036	0.0008	0.0002	0.2199	0.0002 0.00005
R1/stream	0.4523	0.0247	0.0147	0.0348	0.0081	0.0021	0.2740	0.0003 0.0005
R3/stream	0.6377	0.0348	0.0207	0.0491	0.0114	0.0029	0.1613	0.0002 0.0007

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-23: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.00297

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
Step 2								
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
N-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0014
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.3167	0.0113 0.0014
Step 3								
BBCH 14 (early application)								
D1/ditch	1.0650	0.0582	0.0346	0.0819	0.0190	0.0049	8.9250	0.0037 0.0012
D1/stream	0.6057	0.0331	0.0197	0.0466	0.0108	0.0028	8.3405	0.0003 0.0007
D3/ditch	0.6925	0.0378	0.0225	0.0533	0.0124	0.0032	0.4535	0.0005 0.0008
D4/pond	0.0394	0.0022	0.0013	0.0030	0.0007	0.0002	0.1692	0.0002 0.00004
D4/stream	0.5823	0.0318	0.0189	0.0448	0.0104	0.0027	0.0789	0.0001 0.0006
D5/pond	0.0379	0.0021	0.0012	0.0029	0.0007	0.0002	0.1574	0.0002 0.00004
D5/stream	0.5979	0.0327	0.0194	0.0460	0.0107	0.0027	0.0339	0.0003 0.0007
R1/pond	0.0364	0.0020	0.0012	0.0028	0.0007	0.0002	0.1621	0.0002 0.0005
R1/stream	0.4507	0.0246	0.0146	0.0347	0.0080	0.0021	0.0701	0.0001 0.0005
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	1.0520	0.0575	0.0342	0.0809	0.0188	0.0048	8.3801	0.0033 0.0012
D1/stream	0.6057	0.0331	0.0197	0.0466	0.0108	0.0028	8.3323	0.0003 0.0007
D3/ditch	0.6953	0.0380	0.0226	0.0535	0.0124	0.0032	0.6363	0.0007 0.0008
D4/pond	0.0396	0.0022	0.0013	0.0030	0.0007	0.0002	0.1780	0.0002 0.00004
D4/stream	0.5918	0.0323	0.0192	0.0455	0.0106	0.0027	0.1276	0.0001 0.0006
D5/pond	0.0399	0.0022	0.0013	0.0031	0.0007	0.0002	0.1554	0.0003 0.00004

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
D5/stream	0.6385	0.0349	0.0207	0.0491	0.0114	0.0029	0.1254	0.3002 0.0007
R1/pond	0.0572	0.0031	0.0019	0.0044	0.0010	0.0003	0.2774	0.0003 0.00006
R1/stream	0.4527	0.0247	0.0147	0.0348	0.0081	0.0021	0.8069	0.0009 0.0005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Single applications

Table 9.5-24: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC gl-max (µg/L)						PEC gl-max (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Oct-Feb	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
N-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	6.8965	0.0075 0.0013
N-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	6.8965	0.0075 0.0013
S-Europe Oct-Feb	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	8.2506	0.0090 0.0013
S-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	8.2506	0.0090 0.0013

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.3167	0.0113 0.0014
Step 3								
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								
D2/ditch	0.8015	0.0438	0.0260	0.0617	0.0143	0.0037	1.7160	0.0014 0.0009
D2/stream	0.7130	0.0390	0.0231	0.0548	0.0127	0.0033	1.5230	0.0013 0.0008
D3/ditch	0.7946	0.0434	0.0258	0.0611	0.0142	0.0036	0.5985	0.0007 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1269	0.0001 0.00003
D4/stream	0.6843	0.0374	0.0222	0.0526	0.0122	0.0031	0.1319	0.0001 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1312	0.0001 0.00003
D5/stream	0.7383	0.0403	0.0240	0.0568	0.0132	0.0034	0.1203	0.0003 0.0008
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1118	0.0001 0.00003
R1/stream	0.5232	0.0286	0.0170	0.0402	0.0093	0.0024	0.0757	0.0001 0.0006
R3/stream	0.7315	0.0400	0.0238	0.0563	0.0131	0.0034	0.5115	0.0003 0.0008
BBCH 21 (no applications in autumn)								
D2/ditch	0.8015	0.0438	0.0260	0.0617	0.0143	0.0037	1.4340	0.0014 0.0009
D2/stream	0.7130	0.0390	0.0231	0.0548	0.0127	0.0033	1.5230	0.0013 0.0008
D3/ditch	0.7893	0.0431	0.0256	0.0607	0.0141	0.0036	0.3465	0.0004 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1160	0.0001 0.00003
D4/stream	0.6146	0.0336	0.0200	0.0473	0.0110	0.0028	0.0245	0.0000 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1114	0.0001 0.00003
D5/stream	0.5126	0.0280	0.0166	0.0394	0.0092	0.0024	0.0064	0.0000 0.0006
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1038	0.0001 0.00003

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
R1/stream	0.5203	0.0284	0.0169	0.0400	0.0093	0.0024	0.0650	0.0001 0.0006
R3/stream	0.7374	0.0403	0.0239	0.0567	0.0132	0.0034	0.1236	0.0002 0.0008
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.8015	0.0438	0.0260	0.0617	0.0143	0.0037	0.5036	0.0016 0.0009
D2/stream	0.7130	0.0390	0.0231	0.0548	0.0127	0.0033	0.3336	0.0015 0.0008
D3/ditch	0.7925	0.0433	0.0257	0.0610	0.0142	0.0036	0.4722	0.0005 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1056	0.0001 0.00003
D4/stream	0.6668	0.0364	0.0216	0.0513	0.0119	0.0031	0.0701	0.0001 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1128	0.0001 0.00003
D5/stream	0.6748	0.0369	0.0219	0.0519	0.0121	0.0031	0.0324	0.0006 0.0007
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1038	0.0001 0.00003
R1/stream	0.5203	0.0284	0.0169	0.0400	0.0093	0.0024	0.0650	0.0001 0.0006
R3/stream	0.7312	0.0400	0.0237	0.0562	0.0131	0.0034	0.1236	0.0002 0.0008

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-25: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	9.6397	0.0105 0.0014
N-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	6.8965	0.0075 0.0013
S-Europe Mar-May	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	10.9938	0.0120 0.0014
S-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.5736	0.0083 0.0013
Step 3								
BBCH 14 (early application)								
D1/ditch	0.8007	0.0438	0.0260	0.0616	0.0143	0.0037	2.3060	0.0022 0.0009
D1/stream	0.7003	0.0383	0.0227	0.0539	0.0125	0.0032	0.3413	0.0004 0.0008
D3/ditch	0.7915	0.0433	0.0257	0.0609	0.0141	0.0036	0.4278	0.0005 0.0010
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1044	0.0001 0.00003
D4/stream	0.6480	0.0354	0.0210	0.0498	0.0116	0.0030	0.0438	0.0000 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1108	0.0001 0.00003
D5/stream	0.6281	0.0343	0.0204	0.0483	0.0112	0.0029	0.0113	0.0000 0.0007
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1013	0.0001 0.00003
R1/stream	0.5211	0.0285	0.0169	0.0401	0.0093	0.0024	0.0679	0.0001 0.0006
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	0.8007	0.0438	0.0260	0.0616	0.0143	0.0037	1.9850	0.0022 0.0009
D1/stream	0.7003	0.0383	0.0227	0.0539	0.0125	0.0032	0.3405	0.0004 0.0008
D3/ditch	0.7939	0.0434	0.0258	0.0611	0.0142	0.0036	0.5543	0.0006 0.0009

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1068	0.0001 0.00003
D4/stream	0.6843	0.0374	0.0222	0.0526	0.0122	0.0031	0.1317	0.0001 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1068	0.0001 0.00003
D5/stream	0.7379	0.0403	0.0240	0.0568	0.0132	0.0034	0.1323	0.0001 0.0008
R1/pond	0.0506	0.0028	0.0016	0.0039	0.0009	0.0002	0.1978	0.0002 0.00006
R1/stream	0.5235	0.0286	0.0170	0.0403	0.0093	0.0024	0.8093	0.0009 0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-26: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	21.3982	0.0234 0.0297
Step 2								
N-Europe Oct-Feb	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	0.5705	0.0006 0.0013
N-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	0.4292	0.0005 0.0013
N-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	0.4292	0.0005 0.0013
S-Europe Oct-Feb	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	0.5234	0.0006 0.0013

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
S-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	0.5234	0.0006 0.0013
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	0.6258	0.0007 0.0014
Step 3								
BBCH 25								
D1/ditch	0.7937	0.0434	0.0258	0.0611	0.0142	0.0036	0.5535	0.0004 0.0009
D1/stream	0.6168	0.0337	0.0200	0.0474	0.0110	0.0028	0.3855	0.0004 0.0007
D2/ditch	0.7972	0.0436	0.0259	0.0613	0.0142	0.0037	1.0400	0.0011 0.0009
D2/stream	0.6595	0.0360	0.0214	0.0507	0.0118	0.0030	0.0534	0.0004 0.0007
D3/ditch	0.7904	0.0432	0.0257	0.0608	0.0141	0.0036	0.3848	0.0004 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1083	0.0001 0.00003
D4/stream	0.5842	0.0319	0.0190	0.0449	0.0104	0.0027	0.0169	0.0000 0.0006
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1139	0.0004 0.00003
D5/stream	0.6314	0.0345	0.0205	0.0486	0.0113	0.0029	0.0150	0.0004 0.0007
D6/ditch	0.7982	0.0436	0.0259	0.0614	0.0143	0.0037	1.3110	0.0011 0.0009
R1/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1029	0.0001 0.00003
R1/stream	0.5211	0.0285	0.0169	0.0401	0.0093	0.0024	0.0678	0.0001 0.0006
R3/stream	0.7320	0.0400	0.0238	0.0563	0.0131	0.0034	0.1383	0.0004 0.0008
R4/stream	0.5161	0.0282	0.0168	0.0397	0.0092	0.0024	0.0533	0.0004 0.0006
BBCH69								
D1/ditch	0.801	0.044	0.026	0.062	0.014	0.004	2.006	0.002 0.0009
D1/stream	0.7	0.038	0.023	0.054	0.013	0.003	0.329	0.000 0.0008
D2/ditch	0.802	0.044	0.026	0.062	0.014	0.004	2.186	0.002 0.0009
D2/stream	0.713	0.039	0.023	0.055	0.013	0.003	1.806	0.002 0.0008

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D3/ditch	0.793	0.043	0.026	0.061	0.014	0.004	0.508	0.001 0.0009
D4/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.107	0.000 0.0009
D4/stream	0.684	0.037	0.022	0.053	0.012	0.003	0.119	0.000 0.0007
D5/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.111	0.000 0.00003
D5/stream	0.738	0.040	0.024	0.057	0.013	0.003	0.167	0.000 0.0008
D6/ditch	0.795	0.043	0.026	0.061	0.014	0.004	0.764	0.001 0.0009
R1/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.096	0.000 0.00003
R1/stream	0.523	0.029	0.017	0.040	0.009	0.002	0.065	0.000 0.0006
R3/stream	0.736	0.040	0.024	0.057	0.013	0.003	0.151	0.000 0.0008
R4/stream	0.523	0.029	0.017	0.040	0.009	0.002	0.068	0.000 0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-27: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 1830	NOEC 308	EC ₅₀ 1300	NOEC 560	E _r C ₅₀ 2180		NOEC 9140
AF		100	10	100	10	10		10
RAC (µg/L)		18.3	30.8	13	56	218		914
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	27.1501	1.4836	0.8815	2.0885	0.4848	0.1245	442.8795	0.4846 0.0297
Step 2								
N-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.7992	0.0085 0.0013

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
N-Europe Jun-Sep	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	7.7992	0.0085 0.0013
S-Europe Mar-May	1.1496	0.0628	0.0373	0.0884	0.0205	0.0053	10.0560	0.0110 0.0013
S-Europe Jun-Sep	1.2894	0.0705	0.0419	0.0992	0.0230	0.0059	11.6708	0.0128 0.0014
Step 3								
BBCH 25								
D1/ditch	0.8007	0.0438	0.0260	0.0616	0.0143	0.0037	0.3060	0.0025 0.0009
D1/stream	0.7003	0.0383	0.0227	0.0539	0.0125	0.0032	0.3115	0.0004 0.0008
D3/ditch	0.7910	0.0432	0.0257	0.0608	0.0141	0.0036	0.4099	0.0004 0.0009
D4/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1043	0.0001 0.00003
D4/stream	0.6473	0.0354	0.0210	0.0498	0.0116	0.0030	0.0431	0.0000 0.0007
D5/pond	0.0273	0.0015	0.0009	0.0021	0.0005	0.0001	0.1168	0.0001 0.00003
D5/stream	0.6285	0.0343	0.0204	0.0483	0.0112	0.0029	0.0134	0.0000 0.0007
R4/stream	0.5225	0.0286	0.0170	0.0402	0.0093	0.0024	0.1529	0.0005 0.0006
BBCH69								
D1/ditch	0.801	0.044	0.026	0.062	0.014	0.004	1.975	0.002 0.0009
D1/stream	0.7	0.038	0.023	0.054	0.013	0.003	0.329	0.000 0.0008
D3/ditch	0.793	0.043	0.026	0.061	0.014	0.004	0.463	0.001 0.0009
D4/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.105	0.000 0.00003
D4/stream	0.682	0.037	0.022	0.052	0.012	0.003	0.108	0.000 0.0007
D5/pond	0.027	0.001	0.001	0.002	0.000	0.000	0.11	0.000 0.00003
D5/stream	0.691	0.038	0.022	0.053	0.012	0.003	0.037	0.000 0.0008
R4/stream	0.523	0.029	0.017	0.040	0.009	0.002	0.068	0.000 0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

For the intended uses in oilseed rape and cereals, calculated PEC/RAC ratios did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for invertebrates as characterised by a NOEC of 13 µg/L for species of *Daphnia magna* in connection with an assessment factor of 100) in all FOCUS Steps 1-3 scenarios. Therefore, no further assessment is necessary.

9.5.2.4 Prothioconazole-desthio 1

Serie 1 (whole system DT50 to the water compartment)
Multiple applications

Table 9.5-28: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Oct-Feb	5.6167	0.0847	16.8165	0.0562	0.5617	0.1021	31.3456	0.1567
N-Europe Mar-May	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
N-Europe Jun-Sep	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
S-Europe Oct-Feb	4.6033	0.0694	13.7823	0.0460	0.4603	0.0837	25.6085	0.1280
S-Europe Mar-May	4.6033	0.0694	13.7823	0.0460	0.4603	0.0837	25.6085	0.1280
S-Europe Jun-Sep	3.5898	0.0541	10.7479	0.0359	0.3590	0.0653	19.8714	0.0994
Step 3								
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								
D2/ditch	0.3316	0.0050	0.9928	0.0033	0.0332	0.0060	0.4527	0.0023
D2/stream	0.2088	0.0031	0.6251	0.0021	0.0209	0.0038	0.2302	0.0012
D3/ditch	0.0060	0.0001	0.0180	0.0001	0.0006	0.0001	0.0097	0.0000

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
D4/pond	0.0077	0.0001	0.0231	0.0001	0.0008	0.0001	0.0960	0.0005
D4/stream	0.0357	0.0005	0.1069	0.0004	0.0036	0.0006	0.0211	0.0001
D5/pond	0.0039	0.0001	0.0117	0.0000	0.0004	0.0001	0.0798	0.0004
D5/stream	0.0175	0.0003	0.0524	0.0002	0.0018	0.0003	0.0048	0.0000
R1/pond	0.0214	0.0003	0.0641	0.0002	0.0021	0.0004	0.3218	0.0016
R1/stream	0.1931	0.0029	0.5781	0.0019	0.0193	0.0035	0.1429	0.0007
R3/stream	0.4159	0.0063	1.2452	0.0042	0.0416	0.0076	0.3599	0.0018
BBCH 21 (no applications in autumn)								
D2/ditch	0.0258	0.0004	0.0772	0.0003	0.0026	0.0005	0.0804	0.0004
D2/stream	0.0318	0.0005	0.0952	0.0003	0.0032	0.0006	0.1007	0.0005
D3/ditch	0.0016	0.0000	0.0048	0.0000	0.0002	0.0000	0.0055	0.0000
D4/pond	0.0052	0.0001	0.0156	0.0001	0.0005	0.0001	0.1144	0.0006
D4/stream	0.0040	0.0001	0.0120	0.0000	0.0004	0.0001	0.0032	0.0000
D5/pond	0.0069	0.0001	0.0207	0.0001	0.0007	0.0001	0.1414	0.0007
D5/stream	0.0057	0.0001	0.0171	0.0001	0.0006	0.0001	0.0002	0.0000
R1/pond	0.0424	0.0006	0.1269	0.0004	0.0042	0.0008	0.3930	0.0020
R1/stream	0.4226	0.0064	1.2653	0.0042	0.0423	0.0077	0.4044	0.0020
R3/stream	0.1628	0.0025	0.4874	0.0016	0.0163	0.0030	0.1224	0.0006
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.0269	0.0004	0.0805	0.0003	0.0027	0.0005	0.1263	0.0006
D2/stream	0.0377	0.0006	0.1129	0.0004	0.0038	0.0007	0.1339	0.0007
D3/ditch	0.0044	0.0001	0.0132	0.0000	0.0004	0.0001	0.0076	0.0000
D4/pond	0.0076	0.0001	0.0228	0.0001	0.0008	0.0001	0.1416	0.0007
D4/stream	0.0036	0.0001	0.0108	0.0000	0.0004	0.0001	0.0028	0.0000
D5/pond	0.0083	0.0001	0.0249	0.0001	0.0008	0.0002	0.1571	0.0008
D5/stream	0.0071	0.0001	0.0213	0.0001	0.0007	0.0001	0.0023	0.0000
R1/pond	0.0434	0.0007	0.1299	0.0004	0.0043	0.0008	0.4147	0.0021
R1/stream	0.4109	0.0062	1.2302	0.0041	0.0411	0.0075	0.3988	0.0020
R3/stream	0.1469	0.0022	0.4398	0.0015	0.0147	0.0027	0.1116	0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-29: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	38.9059	0.5868	116.4847	0.3891	3.8906	0.7074	274.1978	1.3710
Step 2								
N-Europe Mar-May	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
N-Europe Jun-Sep	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
S-Europe Mar-May	4.6033	0.0694	13.7823	0.0460	0.4603	0.0837	25.6085	0.1280
S-Europe Jun-Sep	3.5898	0.0541	10.7479	0.0359	0.3590	0.0653	19.8714	0.0994
Step 3								
BBCH 14 (early application)								
D1/ditch	0.1060	0.0016	0.3174	0.0011	0.0106	0.0019	0.9621	0.0048
D1/stream	0.0125	0.0002	0.0374	0.0001	0.0013	0.0002	0.0535	0.0003
D3/ditch	0.0044	0.0001	0.0132	0.0000	0.0004	0.0001	0.0076	0.0000
D4/pond	0.0081	0.0001	0.0243	0.0001	0.0008	0.0001	0.1430	0.0007
D4/stream	0.0047	0.0001	0.0141	0.0000	0.0005	0.0001	0.0041	0.0000
D5/pond	0.0081	0.0001	0.0243	0.0001	0.0008	0.0001	0.1544	0.0008
D5/stream	0.0061	0.0001	0.0183	0.0001	0.0006	0.0001	0.0005	0.0000
R1/pond	0.0490	0.0007	0.1467	0.0005	0.0049	0.0009	0.3945	0.0020
R1/stream	0.3549	0.0054	1.0626	0.0035	0.0355	0.0065	0.5881	0.0029
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	0.0871	0.0013	0.2608	0.0009	0.0087	0.0016	0.8195	0.0041
D1/stream	0.0122	0.0002	0.0365	0.0001	0.0012	0.0002	0.0867	0.0004
D3/ditch	0.0099	0.0001	0.0296	0.0001	0.0010	0.0002	0.0241	0.0001
D4/pond	0.0086	0.0001	0.0257	0.0001	0.0009	0.0002	0.1508	0.0008

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D1/ditch	0.0181	0.0003	0.0542	0.0002	0.0018	0.0003	0.1036	0.0005
D1/stream	0.0109	0.0002	0.0326	0.0001	0.0011	0.0002	0.0228	0.0001
D2/ditch	0.0435	0.0007	0.1302	0.0004	0.0044	0.0008	0.1149	0.0006
D2/stream	0.0357	0.0005	0.1069	0.0004	0.0036	0.0006	0.1353	0.0007
D3/ditch	0.0039	0.0001	0.0117	0.0000	0.0004	0.0001	0.0066	0.0000
D4/pond	0.0060	0.0001	0.0180	0.0001	0.0006	0.0001	0.1227	0.0006
D4/stream	0.0037	0.0001	0.0111	0.0000	0.0004	0.0001	0.0032	0.0000
D5/pond	0.0082	0.0001	0.0246	0.0001	0.0008	0.0001	0.1563	0.0008
D5/stream	0.0063	0.0001	0.0189	0.0001	0.0006	0.0001	0.0007	0.0000
D6/ditch	0.5052	0.0076	1.5126	0.0051	0.0505	0.0092	0.1651	0.0008
R1/pond	0.0473	0.0007	0.1416	0.0005	0.0047	0.0009	0.3821	0.0019
R1/stream	0.3203	0.0048	0.9590	0.0032	0.0320	0.0058	0.6176	0.0031
R3/stream	0.3393	0.0051	1.0159	0.0034	0.0339	0.0062	0.3920	0.0020
R4/stream	0.6908	0.0104	2.0683	0.0069	0.0691	0.0126	0.4161	0.0021
BBCH69								
D1/ditch	0.106	0.002	0.317	0.001	0.011	0.002	0.982	0.001
D1/stream	0.013	0.000	0.039	0.000	0.001	0.000	0.059	0.000
D2/ditch	0.08	0.001	0.240	0.001	0.008	0.001	0.895	0.001
D2/stream	0.059	0.001	0.177	0.001	0.006	0.001	0.557	0.001
D3/ditch	0.008	0.000	0.024	0.000	0.001	0.000	0.016	0.000
D4/pond	0.008	0.000	0.024	0.000	0.001	0.000	0.147	0.000
D4/stream	0.007	0.000	0.021	0.000	0.001	0.000	0.007	0.000
D5/pond	0.008	0.000	0.024	0.000	0.001	0.000	0.159	0.000
D5/stream	0.007	0.000	0.021	0.000	0.001	0.000	0.002	0.000
D6/ditch	0.008	0.000	0.024	0.000	0.001	0.000	0.031	0.000
R1/pond	0.088	0.001	0.263	0.001	0.009	0.002	0.636	0.001
R1/stream	0.639	0.010	1.913	0.006	0.064	0.012	1.378	0.002
R3/stream	0.711	0.011	2.129	0.007	0.071	0.013	0.884	0.001
R4/stream	0.798	0.012	2.389	0.008	0.080	0.015	0.984	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-31: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-deshtio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Mar-May	3.9276	0.0592	11.7593	0.0393	0.3928	0.0714	21.7838	0.1089
N-Europe Jun-Sep	3.9276	0.0592	11.7593	0.0393	0.3928	0.0714	21.7838	0.1089
S-Europe Mar-May	7.3059	0.1102	21.8740	0.0731	0.7306	0.1328	40.9073	0.2045
S-Europe Jun-Sep	5.6167	0.0847	16.8165	0.0562	0.5617	0.1021	31.3456	0.1567
Step 3								
BBCH 25								
D1/ditch	0.1059	0.0016	0.3171	0.0011	0.0106	0.0019	0.9563	0.0048
D1/stream	0.0125	0.0002	0.0374	0.0001	0.0013	0.0002	0.0400	0.0002
D3/ditch	0.0040	0.0001	0.0120	0.0000	0.0004	0.0001	0.0070	0.0000
D4/pond	0.0081	0.0001	0.0243	0.0001	0.0008	0.0001	0.1377	0.0007
D4/stream	0.0050	0.0001	0.0150	0.0001	0.0005	0.0001	0.0046	0.0000
D5/pond	0.0081	0.0001	0.0243	0.0001	0.0008	0.0001	0.1543	0.0008
D5/stream	0.0061	0.0001	0.0183	0.0001	0.0006	0.0001	0.0005	0.0000
R4/stream	0.5743	0.0087	1.7195	0.0057	0.0574	0.0104	0.7411	0.0037
BBCH69								
D1/ditch	0.106	0.002	0.317	0.001	0.011	0.002	0.961	0.001
D1/stream	0.013	0.000	0.039	0.000	0.001	0.000	0.062	0.000
D3/ditch	0.006	0.000	0.018	0.000	0.001	0.000	0.011	0.000
D4/pond	0.008	0.000	0.024	0.000	0.001	0.000	0.14	0.000

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D4/stream	0.009	0.000	0.027	0.000	0.001	0.000	0.008	0.000
D5/pond	0.008	0.000	0.024	0.000	0.001	0.000	0.156	0.000
D5/stream	0.006	0.000	0.018	0.000	0.001	0.000	0.001	0.000
R4/stream	0.799	0.012	2.392	0.008	0.080	0.015	0.985	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Single applications

Table 9.5-32: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Oct-Feb	3.7675	0.0568	11.2799	0.0377	0.3768	0.0685	21.0356	0.1052
N-Europe Mar-May	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
N-Europe Jun-Sep	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
S-Europe Oct-Feb	3.0852	0.0465	9.2371	0.0309	0.3085	0.0561	17.1731	0.0859
S-Europe Mar-May	3.0852	0.0465	9.2371	0.0309	0.3085	0.0561	17.1731	0.0859
S-Europe Jun-Sep	2.4029	0.0362	7.1943	0.0240	0.2403	0.0437	13.3107	0.0666
Step 3								
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								
D2/ditch	0.3316	0.0050	0.9928	0.0033	0.0332	0.0060	0.4418	0.0022
D2/stream	0.2088	0.0031	0.6251	0.0021	0.0209	0.0038	0.2534	0.0013

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
D3/ditch	0.0068	0.0001	0.0204	0.0001	0.0007	0.0001	0.0110	0.0001
D4/pond	0.0083	0.0001	0.0249	0.0001	0.0008	0.0002	0.0912	0.0005
D4/stream	0.0357	0.0005	0.1069	0.0004	0.0036	0.0006	0.0212	0.0001
D5/pond	0.0042	0.0001	0.0126	0.0000	0.0004	0.0001	0.0728	0.0004
D5/stream	0.0085	0.0001	0.0254	0.0001	0.0009	0.0002	0.0027	0.0000
R1/pond	0.0203	0.0003	0.0608	0.0002	0.0020	0.0004	0.2151	0.0011
R1/stream	0.1919	0.0029	0.5746	0.0019	0.0192	0.0035	0.1226	0.0006
R3/stream	0.4196	0.0063	1.2563	0.0042	0.0420	0.0076	0.6174	0.0031
BBCH 21 (no applications in autumn)								
D2/ditch	0.0119	0.0002	0.0356	0.0001	0.0012	0.0002	0.0360	0.0002
D2/stream	0.0367	0.0006	0.1099	0.0004	0.0037	0.0007	0.1110	0.0006
D3/ditch	0.0013	0.0000	0.0039	0.0000	0.0001	0.0000	0.0028	0.0000
D4/pond	0.0029	0.0000	0.0087	0.0000	0.0003	0.0001	0.0702	0.0004
D4/stream	0.0035	0.0001	0.0105	0.0000	0.0004	0.0001	0.0013	0.0000
D5/pond	0.0036	0.0001	0.0108	0.0000	0.0004	0.0001	0.0821	0.0004
D5/stream	0.0053	0.0001	0.0159	0.0001	0.0005	0.0001	0.0001	0.0000
R1/pond	0.0203	0.0003	0.0608	0.0002	0.0020	0.0004	0.2052	0.0010
R1/stream	0.1853	0.0028	0.5548	0.0019	0.0185	0.0034	0.2192	0.0011
R3/stream	0.1238	0.0019	0.3707	0.0012	0.0124	0.0023	0.0602	0.0003
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.0227	0.0003	0.0680	0.0002	0.0023	0.0004	0.1015	0.0005
D2/stream	0.0433	0.0007	0.1296	0.0004	0.0043	0.0008	0.1413	0.0007
D3/ditch	0.0051	0.0001	0.0153	0.0001	0.0005	0.0001	0.0061	0.0000
D4/pond	0.0049	0.0001	0.0147	0.0000	0.0005	0.0001	0.0926	0.0005
D4/stream	0.0040	0.0001	0.0120	0.0000	0.0004	0.0001	0.0010	0.0000
D5/pond	0.0049	0.0001	0.0147	0.0000	0.0005	0.0001	0.0987	0.0005
D5/stream	0.0069	0.0001	0.0207	0.0001	0.0007	0.0001	0.0004	0.0000
R1/pond	0.0203	0.0003	0.0608	0.0002	0.0020	0.0004	0.2052	0.0010
R1/stream	0.1853	0.0028	0.5548	0.0019	0.0185	0.0034	0.2192	0.0011
R3/stream	0.2294	0.0035	0.6868	0.0023	0.0229	0.0042	0.3097	0.0015

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-33: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	38.9059	0.5868	116.4847	0.3891	3.8906	0.7074	274.1978	1.3710
Step 2								
N-Europe Mar-May	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
N-Europe Jun-Sep	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
S-Europe Mar-May	3.0852	0.0465	9.2371	0.0309	0.3085	0.0561	17.1731	0.0859
S-Europe Jun-Sep	2.4029	0.0362	7.1943	0.0240	0.2403	0.0437	13.3107	0.0666
Step 3								
BBCH 14 (early application)								
D1/ditch	0.0577	0.0009	0.1728	0.0006	0.0058	0.0010	0.5484	0.0027
D1/stream	0.0133	0.0002	0.0398	0.0001	0.0013	0.0002	0.0277	0.0001
D3/ditch	0.0023	0.0000	0.0069	0.0000	0.0002	0.0000	0.0040	0.0000
D4/pond	0.0048	0.0001	0.0144	0.0000	0.0005	0.0001	0.0898	0.0004
D4/stream	0.0038	0.0001	0.0114	0.0000	0.0004	0.0001	0.0015	0.0000
D5/pond	0.0046	0.0001	0.0138	0.0000	0.0005	0.0001	0.0939	0.0005
D5/stream	0.0064	0.0001	0.0192	0.0001	0.0006	0.0001	0.0002	0.0000
R1/pond	0.0245	0.0004	0.0734	0.0002	0.0025	0.0004	0.2331	0.0012
R1/stream	0.2777	0.0042	0.8314	0.0028	0.0278	0.0050	0.2521	0.0013
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	0.0618	0.0009	0.1850	0.0006	0.0062	0.0011	0.5212	0.0026
D1/stream	0.0141	0.0002	0.0422	0.0001	0.0014	0.0003	0.0151	0.0001
D3/ditch	0.0073	0.0001	0.0219	0.0001	0.0007	0.0001	0.0106	0.0001
D4/pond	0.0051	0.0001	0.0153	0.0001	0.0005	0.0001	0.0903	0.0005

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D4/stream	0.0048	0.0001	0.0144	0.0000	0.0005	0.0001	0.0035	0.0000
D5/pond	0.0054	0.0001	0.0162	0.0001	0.0005	0.0001	0.1040	0.0005
D5/stream	0.0083	0.0001	0.0249	0.0001	0.0008	0.0002	0.0026	0.0000
R1/pond	0.0428	0.0006	0.1281	0.0004	0.0043	0.0008	0.3639	0.0018
R1/stream	0.1709	0.0026	0.5117	0.0017	0.0171	0.0031	0.5631	0.0028

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-34: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desethio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Oct-Feb	6.0419	0.0911	18.0895	0.0604	0.6042	0.1099	33.9985	0.1700
N-Europe Mar-May	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
N-Europe Jun-Sep	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
S-Europe Oct-Feb	4.9047	0.0740	14.6847	0.0490	0.4905	0.0892	27.4730	0.1374
S-Europe Mar-May	4.9047	0.0740	14.6847	0.0490	0.4905	0.0892	27.4730	0.1374
S-Europe Jun-Sep	3.7675	0.0568	11.2799	0.0377	0.3768	0.0685	21.0356	0.1052
Step 3								
BBCH 25								
D1/ditch	0.0024	0.0000	0.0072	0.0000	0.0002	0.0000	0.0142	0.0001

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D1/stream	0.0108	0.0002	0.0323	0.0001	0.0011	0.0002	0.0046	0.0000
D2/ditch	0.0075	0.0001	0.0225	0.0001	0.0008	0.0001	0.0250	0.0001
D2/stream	0.0340	0.0005	0.1018	0.0003	0.0034	0.0006	0.0059	0.0000
D3/ditch	0.0020	0.0000	0.0060	0.0000	0.0002	0.0000	0.0034	0.0000
D4/pond	0.0032	0.0000	0.0096	0.0000	0.0003	0.0001	0.0718	0.0004
D4/stream	0.0033	0.0000	0.0099	0.0000	0.0003	0.0001	0.0012	0.0000
D5/pond	0.0047	0.0001	0.0141	0.0000	0.0005	0.0001	0.0960	0.0005
D5/stream	0.0065	0.0001	0.0195	0.0001	0.0007	0.0001	0.0002	0.0000
D6/ditch	0.5047	0.0076	1.5111	0.0050	0.0505	0.0092	0.1679	0.0008
R1/pond	0.0206	0.0003	0.0617	0.0002	0.0021	0.0004	0.2069	0.0010
R1/stream	0.2012	0.0030	0.6024	0.0020	0.0201	0.0037	0.2292	0.0011
R3/stream	0.2452	0.0037	0.7341	0.0025	0.0245	0.0045	0.3362	0.0017
R4/stream	0.3173	0.0048	0.9500	0.0032	0.0317	0.0058	0.2190	0.0011
BBCH69								
D1 ditch	0.057	0.001	0.171	0.001	0.006	0.001	0.527	0.001
D1 stream	0.013	0.000	0.039	0.000	0.001	0.000	0.009	0.000
D2 ditch	0.084	0.001	0.251	0.001	0.008	0.002	0.891	0.001
D2 stream	0.067	0.001	0.201	0.001	0.007	0.001	0.62	0.001
D3 ditch	0.008	0.000	0.024	0.000	0.001	0.000	0.01	0.000
D4 pond	0.005	0.000	0.015	0.000	0.001	0.000	0.092	0.000
D4 stream	0.005	0.000	0.015	0.000	0.001	0.000	0.003	0.000
D5 pond	0.005	0.000	0.015	0.000	0.001	0.000	0.103	0.000
D5 stream	0.008	0.000	0.024	0.000	0.001	0.000	0.003	0.000
D6 ditch	0.009	0.000	0.027	0.000	0.001	0.000	0.028	0.000
R1 pond	0.045	0.001	0.135	0.000	0.005	0.001	0.328	0.000
R1 stream	0.444	0.007	1.329	0.004	0.044	0.008	0.937	0.001
R3 stream	0.33	0.005	0.988	0.003	0.033	0.006	0.195	0.000
R4 stream	0.798	0.012	2.389	0.008	0.080	0.015	0.984	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-35: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desethio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	ErC ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Mar-May	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
N-Europe Jun-Sep	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
S-Europe Mar-May	4.9047	0.0740	14.6847	0.0490	0.4905	0.0892	27.4730	0.1374
S-Europe Jun-Sep	3.7675	0.0568	11.2799	0.0377	0.3768	0.0685	21.0356	0.1052
Step 3								
BBCH 25								
D1/ditch	0.0576	0.0009	0.1725	0.0006	0.0058	0.0010	0.5450	0.0027
D1/stream	0.0133	0.0002	0.0398	0.0001	0.0013	0.0002	0.0245	0.0001
D3/ditch	0.0022	0.0000	0.0066	0.0000	0.0002	0.0000	0.0037	0.0000
D4/pond	0.0048	0.0001	0.0144	0.0000	0.0005	0.0001	0.0865	0.0004
D4/stream	0.0038	0.0001	0.0114	0.0000	0.0004	0.0001	0.0017	0.0000
D5/pond	0.0046	0.0001	0.0138	0.0000	0.0005	0.0001	0.0939	0.0005
D5/stream	0.0064	0.0001	0.0192	0.0001	0.0006	0.0001	0.0002	0.0000
R4/stream	0.3497	0.0053	1.0470	0.0035	0.0350	0.0064	0.5641	0.0028
BBCH69								
D1/ditch	0.568 0.062	0.568 0.001	0.568 0.186	0.568 0.001	0.568 0.0062	0.568 0.001	0.568	0.568 0.003
D1/stream	0.024 0.013	0.024 0.0002	0.024 0.039	0.024 0.0001	0.024 0.0013	0.024 0.0002	0.024	0.024 0.00012
D3/ditch	0.006 0.005	0.006 0.0001	0.006 0.015	0.006 0.0001	0.006 0.001	0.006 0.0001	0.006	0.006 0.00003
D4/pond	0.087 0.005	0.087 0.0001	0.087 0.015	0.087 0.0001	0.087 0.001	0.087 0.0001	0.087	0.087 0.0004
D4/stream	0.004 0.005	0.004 0.0001	0.004 0.015	0.004 0.0001	0.004 0.001	0.004 0.0001	0.004	0.004 0.00002
D5/pond	0.101 0.005	0.101 0.0001	0.101 0.015	0.101 0.0001	0.101 0.001	0.101 0.0001	0.101	0.101 0.001

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D5/stream	0.000 0.007	0.000 0.0001	0.000 0.021	0.000 0.0001	0.000 0.001	0.000 0.0001	0.000	0.000
R4/stream	0.996 0.779	0.996 0.012	0.996 2.33	0.996 0.01	0.996 0.1	0.996 0.014	0.996	0.996 0.005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.2.5 Prothioconazole-desthio 2

Serie 2 (whole system DT50 to the sediment compartment)

Multiple applications

Table 9.5-36: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desmethio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	ErC ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Oct-Feb	5.6167	0.0847	16.8165	0.0562	0.5617	0.1021	31.3456	0.1567
N-Europe Mar-May	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
N-Europe Jun-Sep	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
S-Europe Oct-Feb	4.6033	0.0694	13.7823	0.0460	0.4603	0.0837	25.6085	0.1280
S-Europe Mar-May	4.6033	0.0694	13.7823	0.0460	0.4603	0.0837	25.6085	0.1280
S-Europe Jun-Sep	3.5898	0.0541	10.7479	0.0359	0.3590	0.0653	19.8714	0.0994
Step 3								
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
D2/ditch	0.3317	0.0050	0.9931	0.0033	0.0332	0.0060	0.4269	0.0021
D2/stream	0.2088	0.0031	0.6251	0.0021	0.0209	0.0038	0.2312	0.0012
D3/ditch	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0374	0.0002
D4/pond	0.0056	0.0001	0.0168	0.0001	0.0006	0.0001	0.0819	0.0004
D4/stream	0.0357	0.0005	0.1069	0.0004	0.0036	0.0006	0.0248	0.0001
D5/pond	0.0022	0.0000	0.0066	0.0000	0.0002	0.0000	0.0676	0.0003
D5/stream	0.0175	0.0003	0.0524	0.0002	0.0018	0.0003	0.0092	0.0000
R1/pond	0.0202	0.0003	0.0605	0.0002	0.0020	0.0004	0.2836	0.0014
R1/stream	0.1932	0.0029	0.5784	0.0019	0.0193	0.0035	0.1241	0.0006
R3/stream	0.4153	0.0063	1.2434	0.0042	0.0415	0.0076	0.3559	0.0018
BBCH 21 (no applications in autumn)								
D2/ditch	0.0258	0.0004	0.0772	0.0003	0.0026	0.0005	0.1750	0.0009
D2/stream	0.0168	0.0003	0.0503	0.0002	0.0017	0.0003	0.0736	0.0004
D3/ditch	0.0001	0.0000	0.0003	0.0000	0.0000	0.0000	0.0308	0.0002
D4/pond	0.0018	0.0000	0.0054	0.0000	0.0002	0.0000	0.1002	0.0005
D4/stream	0.0040	0.0001	0.0120	0.0000	0.0004	0.0001	0.0036	0.0000
D5/pond	0.0021	0.0000	0.0063	0.0000	0.0002	0.0000	0.1152	0.0006
D5/stream	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0008	0.0000
R1/pond	0.0417	0.0006	0.1249	0.0004	0.0042	0.0008	0.3778	0.0019
R1/stream	0.4222	0.0064	1.2641	0.0042	0.0422	0.0077	0.3947	0.0020
R3/stream	0.1627	0.0025	0.4871	0.0016	0.0163	0.0030	0.1312	0.0007
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.0269	0.0004	0.0805	0.0003	0.0027	0.0005	0.2533	0.0013
D2/stream	0.0176	0.0003	0.0527	0.0002	0.0018	0.0003	0.1229	0.0006
D3/ditch	0.0002	0.0000	0.0006	0.0000	0.0000	0.0000	0.0468	0.0002
D4/pond	0.0021	0.0000	0.0063	0.0000	0.0002	0.0000	0.1142	0.0006
D4/stream	0.0036	0.0001	0.0108	0.0000	0.0004	0.0001	0.0045	0.0000
D5/pond	0.0024	0.0000	0.0072	0.0000	0.0002	0.0000	0.1264	0.0006
D5/stream	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0076	0.0000
R1/pond	0.0415	0.0006	0.1243	0.0004	0.0042	0.0008	0.3998	0.0020
R1/stream	0.4106	0.0062	1.2293	0.0041	0.0411	0.0075	0.4041	0.0020
R3/stream	0.1413	0.0021	0.4231	0.0014	0.0141	0.0026	0.1180	0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-37: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	38.9059	0.5868	116.4847	0.3891	3.8906	0.7074	274.1978	1.3710
Step 2								
N-Europe Mar-May	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
N-Europe Jun-Sep	2.5763	0.0389	7.7135	0.0258	0.2576	0.0468	14.1344	0.0707
S-Europe Mar-May	4.6033	0.0694	13.7823	0.0460	0.4603	0.0837	25.6085	0.1280
S-Europe Jun-Sep	3.5898	0.0541	10.7479	0.0359	0.3590	0.0653	19.8714	0.0994
Step 3								
BBCH 14 (early application)								
D1/ditch	0.0372	0.0006	0.1114	0.0004	0.0037	0.0007	1.2600	0.0063
D1/stream	0.0061	0.0001	0.0183	0.0001	0.0006	0.0001	0.0490	0.0002
D3/ditch	0.0002	0.0000	0.0006	0.0000	0.0000	0.0000	0.0492	0.0002
D4/pond	0.0023	0.0000	0.0069	0.0000	0.0002	0.0000	0.1120	0.0006
D4/stream	0.0047	0.0001	0.0141	0.0000	0.0005	0.0001	0.0067	0.0000
D5/pond	0.0023	0.0000	0.0069	0.0000	0.0002	0.0000	0.1239	0.0006
D5/stream	0.0004	0.0000	0.0012	0.0000	0.0000	0.0000	0.0021	0.0000
R1/pond	0.0466	0.0007	0.1395	0.0005	0.0047	0.0008	0.3689	0.0018
R1/stream	0.3543	0.0053	1.0608	0.0035	0.0354	0.0064	0.5617	0.0028
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	0.0284	0.0004	0.0850	0.0003	0.0028	0.0005	0.9589	0.0048
D1/stream	0.0093	0.0001	0.0278	0.0001	0.0009	0.0002	0.0826	0.0004
D3/ditch	0.0005	0.0000	0.0015	0.0000	0.0001	0.0000	0.0912	0.0005
D4/pond	0.0053	0.0001	0.0159	0.0001	0.0005	0.0001	0.1218	0.0006

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D4/stream	0.0189	0.0003	0.0566	0.0002	0.0019	0.0003	0.0239	0.0001
D5/pond	0.0024	0.0000	0.0072	0.0000	0.0002	0.0000	0.1286	0.0006
D5/stream	0.0012	0.0000	0.0036	0.0000	0.0001	0.0000	0.0155	0.0001
R1/pond	0.0440	0.0007	0.1317	0.0004	0.0044	0.0008	0.4354	0.0022
R1/stream	0.2663	0.0040	0.7973	0.0027	0.0266	0.0048	0.7292	0.0036

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-38: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter cereals (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Oct-Feb	8.9950	0.1357	26.9311	0.0900	0.8995	0.1635	50.5791	0.2529
N-Europe Mar-May	3.9276	0.0592	11.7593	0.0393	0.3928	0.0714	21.7838	0.1089
N-Europe Jun-Sep	3.9276	0.0592	11.7593	0.0393	0.3928	0.0714	21.7838	0.1089
S-Europe Oct-Feb	7.3059	0.1102	21.8740	0.0731	0.7306	0.1328	40.9073	0.2045
S-Europe Mar-May	7.3059	0.1102	21.8740	0.0731	0.7306	0.1328	40.9073	0.2045
S-Europe Jun-Sep	5.6167	0.0847	16.8165	0.0562	0.5617	0.1021	31.3456	0.1567
Step 3								
BBCH 25								
D1/ditch	0.0032	0.0000	0.0096	0.0000	0.0003	0.0001	0.2479	0.0012

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D1/stream	0.0014	0.0000	0.0042	0.0000	0.0001	0.0000	0.0192	0.0001
D2/ditch	0.0435	0.0007	0.1302	0.0004	0.0044	0.0008	0.2116	0.0011
D2/stream	0.0281	0.0004	0.0841	0.0003	0.0028	0.0005	0.1071	0.0005
D3/ditch	0.0002	0.0000	0.0006	0.0000	0.0000	0.0000	0.0421	0.0002
D4/pond	0.0019	0.0000	0.0057	0.0000	0.0002	0.0000	0.1049	0.0005
D4/stream	0.0037	0.0001	0.0111	0.0000	0.0004	0.0001	0.0036	0.0000
D5/pond	0.0024	0.0000	0.0072	0.0000	0.0002	0.0000	0.1258	0.0006
D5/stream	0.0004	0.0000	0.0012	0.0000	0.0000	0.0000	0.0027	0.0000
D6/ditch	0.5053	0.0076	1.5129	0.0051	0.0505	0.0092	0.2077	0.0010
R1/pond	0.0444	0.0007	0.1329	0.0004	0.0044	0.0008	0.3563	0.0018
R1/stream	0.3197	0.0048	0.9572	0.0032	0.0320	0.0058	0.5926	0.0030
R3/stream	0.3386	0.0051	1.0138	0.0034	0.0339	0.0062	0.3690	0.0018
R4/stream	0.6905	0.0104	2.0674	0.0069	0.0691	0.0126	0.4042	0.0020
BBCH69								
D1 ditch	0.037	0.001	0.111	0.000	0.004	0.001	1.265	0.001
D1 stream	0.005	0.000	0.015	0.000	0.001	0.000	0.053	0.000
D2 ditch	0.047	0.001	0.141	0.000	0.005	0.001	1.013	0.001
D2 stream	0.029	0.000	0.087	0.000	0.003	0.001	0.59	0.001
D3 ditch	0	0.000	0.000	0.000	0.000	0.000	0.07	0.000
D4 pond	0.003	0.000	0.009	0.000	0.000	0.000	0.115	0.000
D4 stream	0.007	0.000	0.021	0.000	0.001	0.000	0.011	0.000
D5 pond	0.002	0.000	0.006	0.000	0.000	0.000	0.127	0.000
D5 stream	0.001	0.000	0.003	0.000	0.000	0.000	0.008	0.000
D6 ditch	0.001	0.000	0.003	0.000	0.000	0.000	0.125	0.000
R1 pond	0.089	0.001	0.266	0.001	0.009	0.002	0.606	0.001
R1 stream	0.638	0.010	1.910	0.006	0.064	0.012	1.317	0.001
R3 stream	0.709	0.011	2.123	0.007	0.071	0.013	0.788	0.001
R4 stream	0.797	0.012	2.386	0.008	0.080	0.014	0.973	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-39: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-deshtio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	ErC ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Mar-May	3.9276	0.0592	11.7593	0.0393	0.3928	0.0714	21.7838	0.1089
N-Europe Jun-Sep	3.9276	0.0592	11.7593	0.0393	0.3928	0.0714	21.7838	0.1089
S-Europe Mar-May	7.3059	0.1102	21.8740	0.0731	0.7306	0.1328	40.9073	0.2045
S-Europe Jun-Sep	5.6167	0.0847	16.8165	0.0562	0.5617	0.1021	31.3456	0.1567
Step 3								
BBCH 25								
D1/ditch	0.0371	0.0006	0.1111	0.0004	0.0037	0.0007	1.2570	0.0063
D1/stream	0.0047	0.0001	0.0141	0.0000	0.0005	0.0001	0.0426	0.0002
D3/ditch	0.0002	0.0000	0.0006	0.0000	0.0000	0.0000	0.0457	0.0002
D4/pond	0.0023	0.0000	0.0069	0.0000	0.0002	0.0000	0.1095	0.0005
D4/stream	0.0050	0.0001	0.0150	0.0001	0.0005	0.0001	0.0071	0.0000
D5/pond	0.0023	0.0000	0.0069	0.0000	0.0002	0.0000	0.1238	0.0006
D5/stream	0.0004	0.0000	0.0012	0.0000	0.0000	0.0000	0.0021	0.0000
R4/stream	0.5588	0.0084	1.6731	0.0056	0.0559	0.0102	0.7205	0.0036
BBCH69								
D1/ditch	0.037	0.001	0.111	0.000	0.004	0.001	1.259	0.001
D1/stream	0.007	0.000	0.021	0.000	0.001	0.000	0.057	0.000
D3/ditch	0	0.000	0.000	0.000	0.000	0.000	0.058	0.000
D4/pond	0.003	0.000	0.009	0.000	0.000	0.000	0.112	0.000
D4/stream	0.009	0.000	0.027	0.000	0.001	0.000	0.012	0.000
D5/pond	0.002	0.000	0.006	0.000	0.000	0.000	0.125	0.000
D5/stream	0.001	0.000	0.003	0.000	0.000	0.000	0.002	0.000
R4/stream	0.798	0.012	2.389	0.008	0.080	0.015	0.974	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Single applications

Table 9.5-40: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Oct-Feb	3.7675	0.0568	11.2799	0.0377	0.3768	0.0685	21.0356	0.1052
N-Europe Mar-May	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
N-Europe Jun-Sep	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
S-Europe Oct-Feb	3.0852	0.0465	9.2371	0.0309	0.3085	0.0561	17.1731	0.0859
S-Europe Mar-May	3.0852	0.0465	9.2371	0.0309	0.3085	0.0561	17.1731	0.0859
S-Europe Jun-Sep	2.4029	0.0362	7.1943	0.0240	0.2403	0.0437	13.3107	0.0666
Step 3								
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								
D2/ditch	0.0067	0.0001	0.0201	0.0001	0.0007	0.0001	0.1560	0.0008
D2/stream	0.0045	0.0001	0.0135	0.0000	0.0005	0.0001	0.0973	0.0005
D3/ditch	0.0001	0.0000	0.0003	0.0000	0.0000	0.0000	0.0152	0.0001
D4/pond	0.0009	0.0000	0.0027	0.0000	0.0001	0.0000	0.0616	0.0003
D4/stream	0.0017	0.0000	0.0051	0.0000	0.0002	0.0000	0.0016	0.0000
D5/pond	0.0011	0.0000	0.0033	0.0000	0.0001	0.0000	0.0673	0.0003
D5/stream	0.0002	0.0000	0.0006	0.0000	0.0000	0.0000	0.0002	0.0000
R1/pond	0.0108	0.0002	0.0323	0.0001	0.0011	0.0002	0.1135	0.0006
R1/stream	0.1363	0.0021	0.4081	0.0014	0.0136	0.0025	0.0826	0.0004
R3/stream	0.1340	0.0020	0.4012	0.0013	0.0134	0.0024	0.0529	0.0003

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell. prolonged
BBCH 21 (no applications in autumn)								
D2/ditch	0.0072	0.0001	0.0216	0.0001	0.0007	0.0001	0.1167	0.0006
D2/stream	0.0045	0.0001	0.0135	0.0000	0.0005	0.0001	0.0782	0.0004
D3/ditch	0.0001	0.0000	0.0003	0.0000	0.0000	0.0000	0.0152	0.0001
D4/pond	0.0009	0.0000	0.0027	0.0000	0.0001	0.0000	0.0616	0.0003
D4/stream	0.0017	0.0000	0.0051	0.0000	0.0002	0.0000	0.0016	0.0000
D5/pond	0.0011	0.0000	0.0033	0.0000	0.0001	0.0000	0.0673	0.0003
D5/stream	0.0002	0.0000	0.0006	0.0000	0.0000	0.0000	0.0002	0.0000
R1/pond	0.0190	0.0003	0.0569	0.0002	0.0019	0.0003	0.1927	0.0010
R1/stream	0.1850	0.0028	0.5539	0.0019	0.0185	0.0034	0.2147	0.0011
R3/stream	0.0997	0.0015	0.2985	0.0010	0.0100	0.0018	0.0657	0.0003
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D2/ditch	0.0050	0.0001	0.0150	0.0001	0.0005	0.0001	0.1983	0.0010
D2/stream	0.0032	0.0000	0.0096	0.0000	0.0003	0.0001	0.1349	0.0007
D3/ditch	0.0002	0.0000	0.0006	0.0000	0.0000	0.0000	0.0321	0.0002
D4/pond	0.0011	0.0000	0.0033	0.0000	0.0001	0.0000	0.0708	0.0004
D4/stream	0.0011	0.0000	0.0033	0.0000	0.0001	0.0000	0.0031	0.0000
D5/pond	0.0014	0.0000	0.0042	0.0000	0.0001	0.0000	0.0782	0.0004
D5/stream	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0012	0.0000
R1/pond	0.0190	0.0003	0.0569	0.0002	0.0019	0.0003	0.1927	0.0010
R1/stream	0.1850	0.0028	0.5539	0.0019	0.0185	0.0034	0.2147	0.0011
R3/stream	0.2265	0.0034	0.6781	0.0023	0.0227	0.0041	0.3098	0.0015

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-41: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	ErC ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
FOCUS Sce- nario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710
Step 2								
N-Europe Oct-Feb	6.0419	0.0911	18.0895	0.0604	0.6042	0.1099	33.9985	0.1700
N-Europe Mar-May	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
N-Europe Jun-Sep	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
S-Europe Oct-Feb	4.9047	0.0740	14.6847	0.0490	0.4905	0.0892	27.4730	0.1374
S-Europe Mar-May	4.9047	0.0740	14.6847	0.0490	0.4905	0.0892	27.4730	0.1374
S-Europe Jun-Sep	3.7675	0.0568	11.2799	0.0377	0.3768	0.0685	21.0356	0.1052
Step 3								
BBCH 25								
D1/ditch	0.0004	0.0000	0.0012	0.0000	0.0000	0.0000	0.0391	0.0002
D1/stream	0.0006	0.0000	0.0018	0.0000	0.0001	0.0000	0.0044	0.0000
D2/ditch	0.0075	0.0001	0.0225	0.0001	0.0008	0.0001	0.0766	0.0004
D2/stream	0.0048	0.0001	0.0144	0.0000	0.0005	0.0001	0.0055	0.0000
D3/ditch	0.0001	0.0000	0.0003	0.0000	0.0000	0.0000	0.0206	0.0001
D4/pond	0.0009	0.0000	0.0027	0.0000	0.0001	0.0000	0.0615	0.0003
D4/stream	0.0015	0.0000	0.0045	0.0000	0.0002	0.0000	0.0014	0.0000
D5/pond	0.0013	0.0000	0.0039	0.0000	0.0001	0.0000	0.0762	0.0004
D5/stream	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0007	0.0000
D6/ditch	0.5048	0.0076	1.5114	0.0050	0.0505	0.0092	0.2166	0.0011
R1/pond	0.0194	0.0003	0.0581	0.0002	0.0019	0.0004	0.1945	0.0010
R1/stream	0.2009	0.0030	0.6015	0.0020	0.0201	0.0037	0.2241	0.0011
R3/stream	0.2429	0.0037	0.7272	0.0024	0.0243	0.0044	0.3368	0.0017
R4/stream	0.3173	0.0048	0.9500	0.0032	0.0317	0.0058	0.2098	0.0010
BBCH69								
D1/ditch	0.02	0.000	0.060	0.000	0.002	0.000	0.753	0.001
D1/stream	0.001	0.000	0.003	0.000	0.000	0.000	0.024	0.000
D2/ditch	0.037	0.001	0.111	0.000	0.004	0.001	0.941	0.001
D2/stream	0.019	0.000	0.057	0.000	0.002	0.000	0.668	0.001

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D3/ditch	0	0.000	0.000	0.000	0.000	0.000	0.042	0.000
D4/pond	0.002	0.000	0.006	0.000	0.000	0.000	0.068	0.000
D4/stream	0.004	0.000	0.012	0.000	0.000	0.000	0.007	0.000
D5/pond	0.001	0.000	0.003	0.000	0.000	0.000	0.08	0.000
D5/stream	0	0.000	0.000	0.000	0.000	0.000	0.009	0.000
D6/ditch	0.001	0.000	0.003	0.000	0.000	0.000	0.093	0.000
R1/pond	0.043	0.001	0.129	0.000	0.004	0.001	0.301	0.000
R1/stream	0.444	0.007	1.329	0.004	0.044	0.008	0.935	0.001
R3/stream	0.33	0.005	0.988	0.003	0.033	0.006	0.195	0.000
R4/stream	0.797	0.012	2.386	0.008	0.080	0.014	0.974	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-42: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	E _r C ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	38.9059	0.5868	116.4847	0.3891	3.8906	0.7074	274.1978	1.3710
Step 2								
N-Europe Mar-May	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
N-Europe Jun-Sep	1.7206	0.0260	5.1515	0.0172	0.1721	0.0313	9.4482	0.0472
S-Europe Mar-May	3.0852	0.0465	9.2371	0.0309	0.3085	0.0561	17.1731	0.0859
S-Europe Jun-Sep	2.4029	0.0362	7.1943	0.0240	0.2403	0.0437	13.3107	0.0666
Step 3								
BBCH 14 (early application)								
D1/ditch	0.0201	0.0003	0.0602	0.0002	0.0020	0.0004	0.7547	0.0038

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
D1/stream	0.0013	0.0000	0.0039	0.0000	0.0001	0.0000	0.0258	0.0001
D3/ditch	0.0001	0.0000	0.0003	0.0000	0.0000	0.0000	0.0253	0.0001
D4/pond	0.0012	0.0000	0.0036	0.0000	0.0001	0.0000	0.0697	0.0003
D4/stream	0.0019	0.0000	0.0057	0.0000	0.0002	0.0000	0.0024	0.0000
D5/pond	0.0013	0.0000	0.0039	0.0000	0.0001	0.0000	0.0745	0.0004
D5/stream	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0006	0.0000
R1/pond	0.0234	0.0004	0.0701	0.0002	0.0023	0.0004	0.2210	0.0011
R1/stream	0.2776	0.0042	0.8311	0.0028	0.0278	0.0050	0.2469	0.0012
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)								
D1/ditch	0.0178	0.0003	0.0533	0.0002	0.0018	0.0003	0.6306	0.0032
D1/stream	0.0010	0.0000	0.0030	0.0000	0.0001	0.0000	0.0208	0.0001
D3/ditch	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0457	0.0002
D4/pond	0.0015	0.0000	0.0045	0.0000	0.0002	0.0000	0.0675	0.0003
D4/stream	0.0036	0.0001	0.0108	0.0000	0.0004	0.0001	0.0073	0.0000
D5/pond	0.0014	0.0000	0.0042	0.0000	0.0001	0.0000	0.0805	0.0004
D5/stream	0.0009	0.0000	0.0027	0.0000	0.0001	0.0000	0.0089	0.0000
R1/pond	0.0382	0.0006	0.1144	0.0004	0.0038	0.0007	0.3440	0.0017
R1/stream	0.1709	0.0026	0.5117	0.0017	0.0171	0.0031	0.6116	0.0031

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-43: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 6630	NOEC 3.34	EC ₅₀ 10,000	NOEC 100	ErC ₅₀ 550		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		66.30	0.334	100	10	55		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	48.9059	0.7376	146.4249	0.4891	4.8906	0.8892	274.1978	1.3710

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Step 2								
N-Europe Mar-May	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
N-Europe Jun-Sep	2.6303	0.0397	7.8751	0.0263	0.2630	0.0478	14.5982	0.0730
S-Europe Mar-May	4.9047	0.0740	14.6847	0.0490	0.4905	0.0892	27.4730	0.1374
S-Europe Jun-Sep	3.7675	0.0568	11.2799	0.0377	0.3768	0.0685	21.0356	0.1052
Step 3								
BBCH 25								
D1/ditch	0.0200	0.0003	0.0599	0.0002	0.0020	0.0004	0.7533	0.0038
D1/stream	0.0011	0.0000	0.0033	0.0000	0.0001	0.0000	0.0246	0.0001
D3/ditch	0.0001	0.0000	0.0003	0.0000	0.0000	0.0000	0.0238	0.0001
D4/pond	0.0012	0.0000	0.0036	0.0000	0.0001	0.0000	0.0681	0.0003
D4/stream	0.0020	0.0000	0.0060	0.0000	0.0002	0.0000	0.0026	0.0000
D5/pond	0.0013	0.0000	0.0039	0.0000	0.0001	0.0000	0.0744	0.0004
D5/stream	0.0003	0.0000	0.0009	0.0000	0.0000	0.0000	0.0006	0.0000
R4/stream	0.3464	0.0052	1.0371	0.0035	0.0346	0.0063	0.5583	0.0028
BBCH69								
D1/ditch	0.021	0.000	0.063	0.000	0.002	0.000	0.749	0.001
D1/stream	0.001	0.000	0.003	0.000	0.000	0.000	0.025	0.000
D3/ditch	0	0.000	0.000	0.000	0.000	0.000	0.034	0.000
D4/pond	0.002	0.000	0.006	0.000	0.000	0.000	0.066	0.000
D4/stream	0.004	0.000	0.012	0.000	0.000	0.000	0.008	0.000
D5/pond	0.001	0.000	0.003	0.000	0.000	0.000	0.079	0.000
D5/stream	0	0.000	0.000	0.000	0.000	0.000	0.002	0.000
R4/stream	0.797	0.012	2.386	0.008	0.080	0.014	0.985	0.001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

9.5.2.6 Prothioconazole: S-methyl and 1,2,4-triazole

Prothioconazole-S-methyl (M01) Multiple applications

Table 9.5-44: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter oilseed rape (2 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	E _r C ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	2.8215 2.9009	0.1568 0.1612	0.1008 0.1036	0.0006 0.0006
Step 2				
N-Europe Oct-Feb	0.4948 0.5087	0.0275	0.0177	0.0001
N-Europe Mar-May	0.1979 0.2035	0.0110	0.0071	0.0000
N-Europe Jun-Sep	0.1979 0.2035	0.0110	0.0071	0.0000
S-Europe Oct-Feb	0.3958 0.4070	0.0220	0.0141	0.0001
S-Europe Mar-May	0.3958 0.4070	0.0220	0.0141	0.0001
S-Europe Jun-Sep	0.2969 0.3052	0.0165	0.0106	0.0001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-45: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter cereals (2 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	E _r C ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				

Group		Fish acute	Inverteb. acute	Algae
	~~2.8215~~ ~~2.9009~~	~~0.1568~~ ~~0.1612~~	~~0.1008~~ ~~0.1036~~	~~0.0006~~ ~~0.0006~~
Step 2				
N-Europe Oct-Feb	~~0.8245~~ ~~0.8478~~	~~0.0458~~	~~0.0294~~	~~0.0002~~
N-Europe Mar-May	~~0.3299~~ ~~0.3389~~	~~0.0183~~	~~0.0118~~	~~0.0001~~
N-Europe Jun-Sep	~~0.3299~~ ~~0.3389~~	~~0.0183~~	~~0.0118~~	~~0.0001~~
S-Europe Oct-Feb	~~0.6596~~ ~~0.6782~~	~~0.0366~~	~~0.0236~~	~~0.0001~~
S-Europe Mar-May	~~0.6596~~ ~~0.6782~~	~~0.0366~~	~~0.0236~~	~~0.0001~~
S-Europe Jun-Sep	~~0.4948~~ ~~0.5087~~	~~0.0275~~	~~0.0177~~	~~0.0001~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-46: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	ErC ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	~~2.8215~~ ~~2.9009~~	~~0.1568~~ ~~0.1612~~	~~0.1008~~ ~~0.1036~~	~~0.0006~~ ~~0.0006~~
Step 2				
N-Europe Mar-May	~~0.3299~~	~~0.0183~~	~~0.0118~~	~~0.0001~~
N-Europe Jun-Sep	~~0.3299~~	~~0.0183~~	~~0.0118~~	~~0.0001~~
S-Europe Mar-May	~~0.6596~~	~~0.0366~~	~~0.0236~~	~~0.0001~~
S-Europe Jun-Sep	~~0.4948~~	~~0.0275~~	~~0.0177~~	~~0.0001~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-47 1: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	E _r C ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	2.9009	0.1612	0.1036	0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Single applications

Table 9.5-48: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	E _r C ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	~~2.8215~~ 2.9009	~~0.1568~~ 0.1612	~~0.1008~~ 0.1036	~~0.0006~~ 0.0006
Step 2				
N Europe Oct-Feb	0.5908	0.0328	0.0211	0.0001
N Europe Mar-May	0.2363	0.0131	0.0084	0.0000
N Europe Jun-Sep	0.2363	0.0131	0.0084	0.0000
S Europe Oct-Feb	0.4726	0.0263	0.0169	0.0001
S Europe Mar-May	0.4726	0.0263	0.0169	0.0001
S Europe Jun-Sep	0.3545	0.0197	0.0127	0.0001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-49: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	E _r C ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	2.8215 2.9009	0.1568 0.1612	0.1008 0.1036	0.0006 0.0006
Step 2				
N Europe Mar-May	0.2363	0.0131	0.0084	0.0000
N Europe Jun-Sep	0.2363	0.0131	0.0084	0.0000
S Europe Mar-May	0.4726	0.0263	0.0169	0.0001
S Europe Jun-Sep	0.3545	0.0197	0.0127	0.0001

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-50: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter oilseed rape (1 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	E _r C ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	2.8215 2.9009	0.1568 0.1612	0.1008 0.1036	0.0006 0.0006
Step 2				
N Europe Oct-Feb	0.3545	0.0197	0.0127	0.0001
N Europe Mar-May	0.1418	0.0079	0.0051	0.0000
N Europe Jun-Sep	0.1418	0.0079	0.0051	0.0000
S Europe Oct-Feb	0.2836	0.0158	0.0101	0.0001

Group		Fish acute	Inverteb. acute	Algae
S-Europe Mar-May	0.2836	0.0158	0.0101	0.0001
S-Europe Jun-Sep	0.2127	0.0118	0.0076	0.0000

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-51: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-S-methyl for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring oilseed rape (1 x 125 g/ha)

Group		Fish acute	Inverteb. acute	Algae
Test species		<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Pseudokirchn. subcapitata</i>
Endpoint (µg/L)		LC ₅₀ 1800	EC ₅₀ 2800	ErC ₅₀ 47400
AF		100	100	10
RAC (µg/L)		18	28	4740
FOCUS Scenario	PEC _{gl-max} (µg/L)			
Step 1				
	2.8215 2.9009	0.1568 0.1612	0.1008 0.1036	0.0006 0.0006
Step 2				
N-Europe Oct-Feb	0.1418	0.0079	0.0051	0.0000
N-Europe Mar-May	0.1418	0.0079	0.0051	0.0000
N-Europe Jun-Sep	0.2836	0.0158	0.0101	0.0001
S-Europe Oct-Feb	0.2127	0.0118	0.0076	0.0000

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

1,2,4-triazole (M13) Multiple applications

Table 9.5-52: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter cereals (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 498000	NOEC 3200	EC ₅₀ 30000 900000*	NOEC* 100	ErC ₅₀ 22500		NOEC* 2000

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
AF		100	10	100	10	10		10
RAC (µg/L)		4980	320	3000 9000	10	2250		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.3660	0.0268
Step 2								
N-Europe Oct-Feb	0.1723	0.0000	0.0005	0.0000	0.0172	0.0001	0.1405	0.0007
N-Europe Mar-May	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
N-Europe Jun-Sep	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
S-Europe Oct-Feb	0.1558	0.0000	0.0005	0.0000	0.0156	0.0001	0.1267	0.0006
S-Europe Mar-May	0.2236	0.0000	0.0007	0.0000	0.0224	0.0001	0.1811	0.0009
S-Europe Jun-Sep	0.1392	0.0000	0.0004	0.0000	0.0139	0.0001	0.1130	0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Appendix 1 – list of endpoints

Table 9.5-53: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudokirchneriella subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 498000	NOEC 3200	EC ₅₀ 30000* 900000	NOEC 100	ErC ₅₀ 22500		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		4980	320	3000* 9000	10	2250		200

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.3660	0.0268
Step 2								
N-Europe Mar-May	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
N-Europe Jun-Sep	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
S-Europe Mar-May	0.2236	0.0000	0.0007	0.0000	0.0224	0.0001	0.1811	0.0009
S-Europe Jun-Sep	0.1392	0.0000	0.0004	0.0000	0.0139	0.0001	0.1130	0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Appendix 1 – list of endpoints

Table 9.5-54: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in winter oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 498000	NOEC 3200	EC ₅₀ 30000	NOEC 100	E _r C ₅₀ 22500		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		4980	320	3000	10	2250		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.2256	0.0261
Step 2								
N-Europe Oct-Feb	0.2070	0.0000	0.0006	0.0000	0.0207	0.0001	0.1673	0.0008
N-Europe Mar-May	0.1771	0.0000	0.0006	0.0000	0.0177	0.0001	0.1425	0.0007
N-Europe Jun-Sep	0.1771	0.0000	0.0006	0.0000	0.0177	0.0001	0.1425	0.0007

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
S-Europe Oct-Feb	0.1970	0.0000	0.0006	0.0000	0.0197	0.0001	0.1591	0.0008
S-Europe Mar-May	0.1970	0.0000	0.0006	0.0000	0.0197	0.0001	0.1591	0.0008
S-Europe Jun-Sep	0.1870	0.0000	0.0006	0.0000	0.0187	0.0001	0.1508	0.0008

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Appendix 1 – list of endpoints

Table 9.5-55: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀ 498000	NOEC 3200	EC ₅₀ 30000* 900000	NOEC 100	E _r C ₅₀ 22500		NOEC 2000
AF		100	10	100	10	10		10
RAC (µg/L)		4980	320	3000* 9000	10	2250		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.3660	0.0268
Step 2								
N-Europe Mar-May	0.1771	0.0000	0.0006	0.0000	0.0177	0.0001	0.1425	0.0007
N-Europe Jun-Sep	0.1771	0.0000	0.0006	0.0000	0.0177	0.0001	0.1425	0.0007
S-Europe Mar-May	0.1970	0.0000	0.0006	0.0000	0.0197	0.0001	0.1591	0.0008
S-Europe Jun-Sep	0.1870	0.0000	0.0006	0.0000	0.0187	0.0001	0.1508	0.0008

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Appendix 1 – list of endpoints

Single application

Table 9.5-56: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀		NOEC
(µg/L)		498000	3200	30000* 900000	100	22500		2000
AF		100	10	100	10	10		10
RAC (µg/L)		4980	320	3000 9000	10	2250		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.2256	0.0261
Step 2								
N-Europe Oct-Feb	0.1392	0.0000	0.0004	0.0000	0.0139	0.0001	0.1130	0.0006
N-Europe Mar-May	0.1094	0.0000	0.0003	0.0000	0.0109	0.0000	0.0883	0.0004
N-Europe Jun-Sep	0.1094	0.0000	0.0003	0.0000	0.0109	0.0000	0.0883	0.0004
S-Europe Oct-Feb	0.1293	0.0000	0.0004	0.0000	0.0129	0.0001	0.1048	0.0005
S-Europe Mar-May	0.1293	0.0000	0.0004	0.0000	0.0129	0.0001	0.1048	0.0005
S-Europe Jun-Sep	0.1194	0.0000	0.0004	0.0000	0.0119	0.0001	0.0965	0.0005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Appendix 1 – list of endpoints

Table 9.5-57: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring oilseed rape (1 x 125 g/ha)

Group		Fish acute	Fish pro-longed	Inverteb. acute	Inverteb. pro-longed	Algae		Sed. dwell. prolonged
Test species		<i>On-corhynchus mykiss</i>	<i>On-corhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀		NOEC

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. pro- longed	Algae		Sed. dwell, prolonged
(µg/L)		498000	3200	30000* 900000	100	22500		2000
AF		100	10	100	10	10		10
RAC (µg/L)		4980	320	3000 9000	10	2250		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.3660	0.0268
Step 2								
N-Europe Mar-May	0.1094	0.0000	0.0003	0.0000	0.0109	0.0000	0.0883	0.0004
N-Europe Jun-Sep	0.1094	0.0000	0.0003	0.0000	0.0109	0.0000	0.0883	0.0004
S-Europe Mar-May	0.1293	0.0000	0.0004	0.0000	0.0129	0.0001	0.1048	0.0005
S-Europe Jun-Sep	0.1194	0.0000	0.0004	0.0000	0.0119	0.0001	0.0965	0.0005

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole

Appendix 1 – list of endpoints

Table 9.5-58: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

Group		Fish acute	Fish pro- longed	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhyn- chus mykiss</i>	<i>Oncorhyn- chus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo- kirchn. subcapi- tata</i>		<i>Chironomus riparius</i>
Endpoint		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀		NOEC
(µg/L)		498000	3200	30000* 90000	100	22500		2000
AF		100	10	100	10	10		10
RAC (µg/L)	4980	320	3000 9000	10	2250	200		
FOCUS Sce- nario	PEC _{gl- max} (µg/L)						PEC _{gl- max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.3660	0.0268
Step 2								

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
N-Europe Oct-Feb	0.1723	0.0000	0.0005	0.0000	0.0172	0.0001	0.1405	0.0007
N-Europe Mar-May	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
N-Europe Jun-Sep	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
S-Europe Oct-Feb	0.1558	0.0000	0.0005	0.0000	0.0156	0.0001	0.1267	0.0006
S-Europe Mar-May	0.1558	0.0000	0.0005	0.0000	0.0156	0.0001	0.1267	0.0006
S-Europe Jun-Sep	0.1392	0.0000	0.0004	0.0000	0.0139	0.0001	0.1130	0.0006

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Appendix 1 – list of endpoints

Table 9.5-59: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for Prothioconazole-1,2,4-triazole for each organism group based on FOCUS Steps 1, 2 and 3 calculations for single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
Test species		<i>Oncorhynchus mykiss</i>	<i>Oncorhynchus mykiss</i>	<i>Daphnia magna</i>	<i>Daphnia magna</i>	<i>Pseudo-kirchn. subcapitata</i>		<i>Chironomus riparius</i>
Endpoint (µg/L)		LC ₅₀	NOEC	EC ₅₀	NOEC	E _r C ₅₀		NOEC
AF		498000	3200	30000* 900000	100	22500		2000
RAC (µg/L)		100	10	100	10	10		10
		4980	320	3000 9000	10	2250		200
FOCUS Scenario	PEC _{gl-max} (µg/L)						PEC _{gl-max} (µg/kg)	
Step 1								
	6.4888	0.0013	0.0203	0.0007	0.6489	0.0029	5.3660	0.0268
Step 2								
N-Europe Mar-May	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
N-Europe Jun-Sep	0.1227	0.0000	0.0004	0.0000	0.0123	0.0001	0.0993	0.0005
S-Europe Mar-May	0.1558	0.0000	0.0005	0.0000	0.0156	0.0001	0.1267	0.0006

Group		Fish acute	Fish prolonged	Inverteb. acute	Inverteb. prolonged	Algae		Sed. dwell. prolonged
S-Europe Jun-Sep	0.1392	0.0000	0.0004	0.0000	~~0.0139~~	0.0001	~~0.1130~~	~~0.0006~~

AF: Assessment factor; PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

*according to EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of prothioconazole
Appendix 1 – list of endpoints

9.5.2.7 Step 4: Prothioconazole-desthio

For the intended uses on winter and spring oilseed rape and winter cereals, calculated PEC/RAC ratios did not indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for fish as characterised by an NOEC of 3.34 for species *Oncorhynchus mykiss* in connection with an assessment factor of 10) in several FOCUS Steps 1-3 scenarios. Therefore, further PEC/RAC ratios were calculated based on FOCUS Step 4 PEC_{sw} considering reduced exposure of surface water bodies.

Serie 1 (whole system DT50 to the water compartment)

Multiple applications

Table 9.5-60: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in winter oilseed rape (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)					
None	R3 stream	-	0.2198	0.1896	0.0993
75%		0.4159	-	0.1896	-
90%		0.4159	-	0.1896	-
BBCH 21 (no applications in autumn)					
None	R1 stream	-	0.2090	0.1917	0.1004
75%		0.4226	-	0.1917	-
90%		0.4226	-	0.1917	-
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)					
None	R1 stream	-	0.2090	0.1864	0.0976
75%		0.4109	-	0.1864	-
90%		0.4109	-	0.1864	-
RAC (µg/L) 0.334		PEC/RAC ratio			
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)					
None	R3 stream	-	0.6581	0.5677	0.2974
75%		1.2452	-	0.5677	-
90%		1.2452	-	0.5677	-
BBCH 21 (no applications in autumn)					
None	R1 stream	-	0.6257	0.5740	0.3006
75%		1.2653	-	0.5740	-

90%		1.2653	-	0.5740	-
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)					
None	R1 stream	-	0.6257	0.5581	0.2922
75%		1.2302	-	0.5581	-
90%		1.2302	-	0.5581	-

Table 9.5-61: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	<u>Step 4: Prothioconazole-desthio</u>			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 14 (early application)					
None	R1 stream	-	0.2090	0.1613	0.0845
75%		0.3549	-	0.1613	-
90%		0.3549	-	0.1613	-
RAC (µg/L) 0.334		<u>PEC/RAC ratio</u>			
BBCH 14 (early application)					
None	R1 stream	-	0.6257	0.4829	0.2530
75%		1.0626	-	0.4829	-
90%		1.0626	-	0.4829	-

Table 9.5-62: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in winter cereals (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 25					
None	D6 ditch	-	-	-	-
75%		0.5052	-	-	-
90%		0.5052	-	-	-
None	R3 stream	-	0.2198	0.1525	0.07956
75%		0.3393	-	0.1525	-
90%		0.3393	-	0.1525	-
None	R4 stream	-	0.4507	0.3141	0.1645
75%		0.6908	-	0.3141	-
90%		0.6908	-	0.3141	-
				0.405	
90%		0.8905	-	0.3141	-
BBCH69					
None	R1 stream	-	0.4167	0.2903	-
75%		-	-	0.2903	-
90%		-	-	0.2903	-
RAC (µg/L) 0.334		PEC/RAC ratio			

BBCH 25					
None	D6 ditch	-	0.0000	0.0000	0.0000
75%		1.5126	-	0.0000	-
90%		1.5126	-	0.0000	-
None	R3 stream	-	0.6581	0.4566	0.2382
75%		1.0159	-	0.4566	-
90%		1.0159	-	0.4566	-
None	R4 stream	-	1.3494	0.9404	0.4925
75%		2.0683	-	0.9404	-
90%		2.0683	-	0.9404	-
BBCH69					
None	R1 stream	-	1.248	0.869	-
75%		-	-	0.869	-
90%		-	-	0.869	-

Table 9.5-63: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	<u>Step 4: Prothioconazole-desthio</u>			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
None	R4 stream	-	0.3717	0.2580	0.1345
75%		0.5743	-	0.2580	-
90%		0.5743	-	0.2580	-
RAC (µg/L) 0.334		<u>PEC/RAC ratio</u>			
None	R4 stream	-	1.1129	0.7725	0.4027
75%		1.7195	-	0.7725	-
90%		1.7195	-	0.7725	-

Single application

Table 9.5-64: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for a single application of GLOB2021dF in winter oilseed rape (1 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 14 (early application)					
None	R3 stream	-	0.0940	0.0649	0.0336
75%		0.1469	-	0.0649	-
90%		0.1469	-	0.0649	-
RAC (µg/L) 0.334		PEC/RAC ratio			
BBCH 14 (early application)					
None	R3 stream	-	0.2815	0.1942	0.1006
75%		0.4398	-	0.1942	-

90%		0.4398	-	0.1942	-
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Table 9.5-65: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for a single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 25					
None	D6 ditch	-	-	-	-
75%		0.5047	-	-	-
90%		0.5047	-	-	-
BBCH 69					
None	R1 stream	-	0.2895	0.2018	-
75%		-	-	0.2018	-
90%		-	-	0.2018	-
RAC (µg/L) 0.334		PEC/RAC ratio			
BBCH 25					
None	D6 ditch	-	0.0000	0.0000	0.0000
75%		1.5111	-	0.0000	-
90%		1.5111	-	0.0000	-
BBCH 69					
None	R1 stream	-	0.867	0.604	-
75%		-	-	0.604	-
90%		-	-	0.604	-

Table 9.5-66: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for a single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	<u>Step 4: Prothioconazole-desthio</u>			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
None	R4 stream	-	0.2282	0.1590	0.0833
75%		0.3497	-	0.1590	-
90%		0.3497	-	0.1590	-
RAC (µg/L) 0.334		<u>PEC/RAC ratio</u>			
None	R4 stream	-	0.6832	0.4760	0.2494
75%		1.0470	-	0.4760	-
90%		1.0470	-	0.4760	-

Serie 2 (whole system DT50 to the sediment compartment)

Multiple applications

Table 9.5-67: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in winter oilseed rape (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	<u>Step 4: Prothioconazole-desthio</u>			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)					
None	R3 stream	-	0.2713	0.1893	0.0992
75%		0.4153	-	0.1893	-
90%		0.4153	-	0.1893	-
BBCH 21 (no applications in autumn)					
None	R1 stream	-	0.2750	0.1915	0.1003
75%		0.4222	-	0.1915	-
90%		0.4222	-	0.1915	-
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)					
None	R1 stream	-	0.2674	0.1862	0.0975
75%		0.4106	-	0.1862	-
90%		0.4106	-	0.1862	-
RAC (µg/L) 0.334		<u>PEC/RAC ratio</u>			
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)					
None	R3 stream	-	0.8123	0.5668	0.2970
75%		1.2434	-	0.5668	-
90%		1.2434	-	0.5668	-
BBCH 21 (no applications in autumn)					
None	R1 stream	-	0.8234	0.5734	0.3003
75%		1.2641	-	0.5734	-
90%		1.2641	-	0.5734	-
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)					
None	R1 stream	-	0.8006	0.5575	0.2920
75%		1.2293	-	0.5575	-
90%		1.2293	-	0.5575	-

Table 9.5-68: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in spring oilseed rape (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 14 (early application)					
None	R1 stream	-	0.2310	0.1610	0.0844
75%		0.3543	-	0.1610	-
90%		0.3543	-	0.1610	-
RAC (µg/L) 0.334		PEC/RAC ratio			
BBCH 61 (against <i>Alternaria</i> and <i>Sclerotinia</i>)					
None	R1 stream	-	0.6916	0.4820	0.2526

75%		1.0608	-	0.4820	-
90%		1.0608	-	0.4820	-

PEC: Predicted environmental concentration; RAC: Regulatory acceptable concentration; PEC/RAC ratios above the relevant trigger of 1 are shown in bold

Table 9.5-69: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in winter cereals (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 25					
None	D6 ditch	-	0.5053	0.5053	0.5053
75%		0.5053	-	0.5053	-
90%		0.5053	-	0.5053	-
None	R3 stream	-	0.2194	0.1523	0.0794
75%		0.3386	-	0.1523	-
90%		0.3386	-	0.1523	-
None	R4 stream	-	0.4505	0.3140	0.1645
75%		0.6905	-	0.3140	-
90%		0.6905	-	0.3140	-
BBCH69					
None	R1 stream	-	0.4166	0.2902	-
75%		-	-	0.2902	-
90%		-	-	0.2902	-
RAC (µg/L) 0.334		PEC/RAC ratio			
BBCH 25					
None	D6 ditch	-	1.5129	1.5129	1.5129
75%		1.5129	-	1.5129	-
90%		1.5129	-	1.5129	-
None	R3 stream	-	0.6569	0.4560	0.2378
75%		1.0138	-	0.4560	-
90%		1.0138	-	0.4560	-
None	R4 stream	-	1.3488	0.9401	0.4925
75%		2.0674	-	0.9401	-
90%		2.0674	-	0.9401	-
BBCH69					
None	R1 stream	-	1.247	0.869	-
75%		-	-	0.869	-
90%		-	-	0.869	-

Table 9.5-70: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for multiple applications of GLOB2021dF in spring cereals (2 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20

reduction	No spray buffer (m)	1	5	10	20
None	R4 stream	-	0.3616	0.2510	0.1309
75%		0.5588	-	0.2510	-
90%		0.5588	-	0.2510	-
RAC (µg/L) 0.334		PEC/RAC ratio			
None	R4 stream	-	1.0826	0.7515	0.3919
75%		1.6731	-	0.7515	-
90%		1.6731	-	0.7515	-

Single application

Table 9.5-71: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for a single application of GLOB2021dF in winter cereals (1 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
BBCH 25					
None	D6 ditch	-	0.5048	0.5048	0.5048
75%		0.5048	-	0.5048	-
90%		0.5048	-	0.5048	-
BBCH 69					
None	R1 stream	-	0.4166	0.2902	-
75%		-	-	0.2902	-
90%		-	-	0.2902	-
RAC (µg/L) 0.334		PEC/RAC ratio			
BBCH 25					
None	D6 ditch	-	1.5114	1.5114	1.5114
75%		1.5114	-	1.5114	-
90%		1.5114	-	1.5114	-
BBCH 69					
None	R1 stream	-	1.247	0.869	-
75%		-	-	0.869	-
90%		-	-	0.869	-

Table 9.5-72: Aquatic organisms: PEC calculation and acceptability of risk (PEC/RAC < 1) for Prothioconazole-desthio based on FOCUS Step 4 calculations and toxicity data for Fish with mitigation of spray drift and run-off for a single application of GLOB2021dF in spring cereals (1 x 125 g/ha)

PEC _{sw} (µg/L)	Scenario	Step 4: Prothioconazole-desthio			
Nozzle	Vegetative strip (m)	None	5	10	20
reduction	No spray buffer (m)	1	5	10	20
None	R4 stream	-	0.2261	0.1575	0.0825

75%		0.3464	-	0.1575	-
90%		0.3464	-	0.1575	-
RAC (µg/L) 0.334		PEC/RAC ratio			
None	R4 stream	-	0.6769	0.4716	0.2471
75%		1.0371	-	0.4716	-
90%		1.0371	-	0.4716	-

9.5.2.8 Combination toxicity assessment

Since GLOB2021dF contains two active ingredients the formulation toxicity should also be considered. The results from the tests using the formulation indicate that the toxicity of the formulation reflects the toxicity of the constituents. However, to confirm this, the LD₅₀ of the formulated product was compared to the predicted mixture toxicity assuming dose additivity. The following formula (Finney, D.J., 1948 and 1971) is used to derive a surrogate LD₅₀ for the mixture of active substances with known toxicity assuming additivity:

$$\sum_i \frac{X(a.s._i)}{LD_{50}(a.s._i)} = \frac{1}{LD_{50}(mix)}$$

With:

$X(a.s._i)$ = fraction of active substance [i] in the mixture (here: formulation)

$LD_{50}(a.s._i)$ = acute toxicity value for active substance [i]

$LD_{50}(mix)$ = measured acute toxicity value for the mixture (here: formulation)

When the formulation is more toxic than that predicted from the toxicity of the individual compounds, the use of the LD₅₀ of the formulation is recommended for the first-tier assessment because it cannot be excluded that such effects would also occur after exposure of the aquatic organism to residues in the environment.

The calculation is given in table 9.5-74 which shows the toxicity of GLOB2021dF.

Table 9.5-73: Comparison of the toxicity of GLOB2021dF to the predicted one based on the active ingredients

Aquatic organisms	Boscalid concentration (%)	Prothioconazole concentration (%)	Boscalid LC50 / EC50 (mg/L)	Prothioconazole LC50 / EC50 (mg/L)	Predicted LC50 / EC50 of GLOB2021dF based on the a.s. toxicity (mg/L)	LC50 / EC50 of GLOB2021dF from the studies (mg/L)	Comparison toxicity of the formulation and the predicted one
Fish	15.6	15.6	2.7	1.83	6.99	30.04	0.21
Daphnia			5.33	1.3	6.70	5.352	1.27
Algae			1.34	2.18	5.32	8.262	0.64

* For both algal endpoints the same EC50 endpoint was taken into account, i.e. E_bC₅₀.

The comparison between the formulation toxicity and the calculated mixture toxicity can be done by the formula ($MDR = EC_{mix-ca}/EC_{xppp}$). If MDR is between 0.2 and 5, the observed and calculates toxicities are considered in agreement. If MDR is > 5 , the observed toxicity of mixture is higher than that calculated assuming dose additivity. If MDR is < 0.2 , the mixture is less toxic than expected.

The MDR for all aquatic organisms is between 0.2 and 5. Therefore, no synergistic or antagonist effect is expected and the observed and calculated mixture toxicities are in agreement. As a result, the risk be assessed based on the measured mixture toxicity.

Following the step approach found in the Aquatic guidance document, the check of a single drive for the toxicity was also done and is presented below. The check is made with the calculation which is done according to the following formula^[1]:

$$\sum_{i=1}^n TU_i = \sum_{i=1}^n \frac{c_i}{ECx_i}$$

in which TU is the ratio between the concentration (i.e. c_i) of a mixture component and its toxicological acute (e.g. EC_{50}) or chronic (e.g. long-term NOEC) endpoint.

The other calculations are:

Toxicity of the sum of active ingredients ($TOX_{sum(ai)} = 1/(TU(ai1) + TU(ai2))$)

Contribution to toxicity = $TOX_{sum(ai)} * TU(ai) * 100$

Table 9.5-74: Contribution to toxicity of GLOB2021dF by Boscaldi and Prothioconazole

Organism	Active substance	EC ₅₀ (mg/L)	Fraction in mixture	Toxic unit	Tox of the sum ai	Contribution to toxicity (%)
Fish	Boscalid	2.7	0.156	0.06	6.99	40.40
	Prothioconazole	1.83	0.156	0.09		59.60
Daphnia	Boscalid	5.33	0.156	0.03	6.70	19.61
	Prothioconazole	1.3	0.156	0.12		80.39
Algae	Boscalid	1.34	0.156	0.12	5.32	61.93
	Prothioconazole	2.18	0.156	0.07		38.07

The toxicity is not clearly driven by only one of the active substances for all groups of aquatic organisms. Therefore, in accordance with the EFSA guidance document^[1] the risk assessment for aquatic organisms is based on combined-substance toxicity data. Therefore, an acute risk assessment for the formulation needs to be performed. The PEC_{sw} of the formulation GLOB2021dF were calculated further to drift events using the SWASH Calculator tool in ditch, pond and stream surface waters. These PEC_{sw} were used for comparison with the endpoints from the acute toxicity studies with GLOB2021dF.

Table 9.5-75: Aquatic organisms: acceptability of risk ($PEC/RAC < 1$) for GLOB2021dF for each organism group based on Drift Swash Calculator for all intended uses

[1] Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290)

	Group		Fish	Inverteb. acute	Algae
	Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
	Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
	(µg/L)		30040	5352	8262
	AF		100	100	10
	RAC (µg/L)		300.4	53.52	826.2
Cropping scenario	FOCUS scenario	FOCUS values			
		Max. PEC _{sw} (µg/L)	PEC/RAC		
Oilseed rape, winter	Ditch	4.8998	0.0161	0.0916	0.0059
		5.0120	0.0167	0.0935	0.0061
	Pond	0.1565		0.0029	
		0.1600	0.0005	0.0030	0.0002
	Stream	3.5996	0.0118	0.0673	0.0044
		3.6821	0.0123	0.0688	0.0045
Oilseed rape, spring	Ditch	4.8998	0.0161	0.0916	0.0059
		5.0120	0.0167	0.0916	0.0061
	Pond	0.1565		0.0029	
		0.1600	0.0005	0.0030	0.0002
	Stream	3.5996	0.0118	0.0673	0.0044
		3.6821	0.0123	0.0688	0.0045
Cereals, winter	Ditch	4.8998	0.0161	0.0916	0.0059
		5.0120	0.0167	0.0935	0.0061
	Pond	0.1565		0.0029	
		0.1600	0.0005	0.0030	0.0002
	Stream	3.5996	0.0118	0.0673	0.0044
		3.6821	0.0123	0.0688	0.0045
Cereals, spring	Ditch	4.8998	0.0161	0.0916	0.0059
		5.0120	0.0167	0.0935	0.0061
	Pond	0.1565		0.0029	
		0.1600	0.0005	0.0030	0.0002
	Stream	3.5996	0.0118	0.0673	0.0044
		3.6821	0.0123	0.0688	0.0045
	Stream	4.3195	0.0142	0.0807	0.0052
		4.4185	0.0147	0.0826	0.0053

zRMS comments:

On the DE request, provided during the commenting period, the comparison of PEC_{sw} for formulation, calculated using the SWASH Calculator tool, with sum of active substance toxicity was provided below.

Table 9.5-75: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for GLOB2021dF for each organism group based on Drift Swash Calculator for all intended uses and sum of toxicity of active substance

	Group		Fish	Inverteb. acute	Algae
	Test species		<i>O. mykiss</i>	<i>D. magna</i>	<i>P. subcapitata</i>
	Endpoint		LC ₅₀	EC ₅₀	E _r C ₅₀
	(µg/L)		1833	6630	3520
	AF		100	100	10
	RAC (µg/L)		18.33	66.30	35.20
Cropping scenario	FOCUS scenario	FOCUS values			
		Max. PEC _{sw} (µg/L)	PEC/RAC		
Oilseed rape, winter	Ditch	5.0120	0.273	0.076	0.142
	Pond	0.1600	0.009	0.002	0.005
	Stream	3.6821	0.201	0.056	0.105
		4.4185	0.241	0.067	0.125
Oilseed rape, spring	Ditch	5.0120	0.272	0.076	0.142
	Pond	0.1600	0.009	0.002	0.005
	Stream	3.6821	0.201	0.056	0.105
		4.4185	0.241	0.067	0.125
Cereals, winter	Ditch	5.0120	0.273	0.076	0.142
	Pond	0.1600	0.009	0.002	0.005
	Stream	3.6821	0.201	0.056	0.105
		4.4185	0.241	0.067	0.125
Cereals, spring	Ditch	5.0120	0.273	0.076	0.142
	Pond	0.1600	0.009	0.002	0.005
	Stream	3.6821	0.201	0.056	0.105
		4.4185	0.241	0.067	0.125

For the intended use in oilseed rape (winter and spring) and cereals (winter and spring), calculated PEC/RAC ratios for the formulation GLOB2021dF did indicate an acceptable risk for the most sensitive group of aquatic organisms (risk for daphnids as characterised by an LC₅₀ for *Daphnia magna* of 5352 µg/L in connection with an assessment factor of 100). Therefore, no further assessment is necessary.

Since GLOB2021dF contains two active ingredients the formulation toxicity should also be considered. As an alternative approach the accumulated risk for the formulation is calculated by summing up the PEC/RAC ratio's.

Table 9.5-76: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for multiple applications of GLOB2021dF for each organism group based on FOCUS Steps 3 calculations for the use on winter oilseed rape

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	304	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
<u>Step 3</u>	<u>Prothio- conazole Set 1</u>				<u>Prothio- conazole Set 2</u>			
BBCH 14 (only one application in autumn = first application in autumn, second application not in autumn)								
D2/ditch	6.2213	0.0205	0.1162	0.0075	6.2213	0.0205	0.1162	0.0075
D2/stream	4.0587	0.0134	0.0758	0.0049	4.0587	0.0134	0.0758	0.0049
D3/ditch	1.3899	0.0046	0.0260	0.0017	1.3875	0.0046	0.0259	0.0017
D4/pond	0.4483	0.0015	0.0084	0.0005	0.4389	0.0014	0.0082	0.0005
D4/stream	1.4146	0.0047	0.0264	0.0017	1.4146	0.0047	0.0264	0.0017
D5/pond	0.3574	0.0012	0.0067	0.0004	0.3470	0.0011	0.0065	0.0004
D5/stream	1.2760	0.0042	0.0238	0.0015	1.2759	0.0042	0.0238	0.0015
R1/pond	0.1862	0.0006	0.0035	0.0002	0.2099	0.0007	0.0039	0.0003
R1/stream	1.8528	0.0061	0.0346	0.0022	2.1021	0.0069	0.0393	0.0025
R3/stream	1.8107	0.0060	0.0338	0.0022	1.8158	0.0060	0.0339	0.0022
BBCH 21 (no applications in autumn)								
D2/ditch	7.0182	0.0231	0.1311	0.0085	7.0179	0.0231	0.1311	0.0085
D2/stream	4.5577	0.0150	0.0852	0.0055	4.5577	0.0150	0.0852	0.0055
D3/ditch	1.3811	0.0045	0.0258	0.0017	1.3810	0.0045	0.0258	0.0017
D4/pond	0.6946	0.0023	0.0130	0.0008	0.6956	0.0023	0.0130	0.0008
D4/stream	1.6127	0.0053	0.0301	0.0020	1.6127	0.0053	0.0301	0.0020
D5/pond	0.5042	0.0017	0.0094	0.0006	0.5052	0.0017	0.0094	0.0006
D5/stream	1.2252	0.0040	0.0229	0.0015	1.2252	0.0040	0.0229	0.0015
R1/pond	0.2891	0.0010	0.0054	0.0003	0.2904	0.0010	0.0054	0.0004
R1/stream	2.2442	0.0074	0.0419	0.0027	2.2442	0.0074	0.0419	0.0027
R3/stream	2.2348	0.0074	0.0418	0.0027	2.2348	0.0074	0.0418	0.0027
BBCH 59								
D2/ditch	5.7121	0.0188	0.1067	0.0069	5.7113	0.0188	0.1067	0.0069
D2/stream	3.7417	0.0123	0.0699	0.0045	3.7417	0.0123	0.0699	0.0045
D3/ditch	1.3835	0.0046	0.0259	0.0017	1.3835	0.0046	0.0259	0.0017
D4/pond	0.4571	0.0015	0.0085	0.0006	0.4592	0.0015	0.0086	0.0006
D4/stream	1.3108	0.0043	0.0245	0.0016	1.3108	0.0043	0.0245	0.0016
D5/pond	0.4793	0.0016	0.0090	0.0006	0.4806	0.0016	0.0090	0.0006
D5/stream	1.2451	0.0041	0.0233	0.0015	1.2451	0.0041	0.0233	0.0015
R1/pond	0.3354	0.0011	0.0063	0.0004	0.3370	0.0011	0.0063	0.0004
R1/stream	2.6172	0.0086	0.0489	0.0032	2.6172	0.0086	0.0489	0.0032

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	304	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
R3/stream	2.5065	0.0082	0.0468	0.0030	2.5065	0.0082	0.0468	0.0030
BBHCH 60								
D2/ditch	5.4850	0.0180	0.1025	0.0066	5.5210	0.0182	0.1032	0.0067
D2/stream	3.6810	0.0121	0.0688	0.0045	3.7123	0.0122	0.0694	0.0045
D3/ditch	1.3891	0.0046	0.0260	0.0017	1.3889	0.0046	0.0260	0.0017
D5/pond	0.5484	0.0018	0.0102	0.0007	0.5505	0.0018	0.0103	0.0007
D5/stream	1.3598	0.0045	0.0254	0.0016	1.3598	0.0045	0.0254	0.0016
R1/pond	0.2363	0.0008	0.0044	0.0003	0.2391	0.0008	0.0045	0.0003
R1/stream	2.4550	0.0081	0.0459	0.0030	2.4550	0.0081	0.0459	0.0030
R3/stream	2.8341	0.0093	0.0530	0.0034	2.8341	0.0093	0.0530	0.0034

Table 9.5-77: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for multiple applications of GLOB2021dF for each organism group based on FOCUS Steps 3 calculations for the use on spring oilseed rape

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	300.4	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
<u>Step 3</u>	<u>Prothio-conazole Set 1</u>				<u>Prothio-conazole Set 2</u>			
BBCH 21 (no applications in autumn)								
D1/ditch	5.3190	0.0175	0.0994	0.0064	5.3490	0.0176	0.0999	0.0065
D1/stream	3.4420	0.0113	0.0643	0.0042	3.4420	0.0113	0.0643	0.0042
D3/ditch	1.3847	0.0046	0.0259	0.0017	1.3846	0.0046	0.0259	0.0017
D4/pond	0.5916	0.0019	0.0111	0.0007	0.5938	0.0020	0.0111	0.0007
D4/stream	1.4224	0.0047	0.0266	0.0017	1.4224	0.0047	0.0266	0.0017
D5/pond	0.5640	0.0019	0.0105	0.0007	0.5652	0.0019	0.0106	0.0007
D5/stream	1.2577	0.0041	0.0235	0.0015	1.2577	0.0041	0.0235	0.0015
R1/pond	0.2943	0.0010	0.0055	0.0004	0.2959	0.0010	0.0055	0.0004
R1/stream	2.6040	0.0086	0.0487	0.0032	2.6040	0.0086	0.0487	0.0032
BBCH 59								
D1/ditch	5.6230	0.0185	0.1051	0.0068	5.6530	0.0186	0.1056	0.0068
D1/stream	3.6610	0.0120	0.0684	0.0044	3.6610	0.0120	0.0684	0.0044
D3/ditch	1.3847	0.0046	0.0259	0.0017	1.3846	0.0046	0.0259	0.0017
D4/pond	0.6649	0.0022	0.0124	0.0008	0.6671	0.0022	0.0125	0.0008

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	300.4	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
D4/stream	1.5158	0.0050	0.0283	0.0018	1.5158	0.0050	0.0283	0.0018
D5/pond	0.5512	0.0018	0.0103	0.0007	0.5524	0.0018	0.0103	0.0007
D5/stream	1.2379	0.0041	0.0231	0.0015	1.2379	0.0041	0.0231	0.0015
R1/pond	0.2938	0.0010	0.0055	0.0004	0.2955	0.0010	0.0055	0.0004
R1/stream	2.6030	0.0086	0.0486	0.0032	2.6030	0.0086	0.0486	0.0032
BBHCH 60								
D1/ditch	4.1692	0.0138	0.0779	0.0050	4.2080	0.0138	0.0786	0.0051
D1/stream	2.6100	0.0086	0.0488	0.0032	2.6099	0.0086	0.0488	0.0032
D3/ditch	1.3908	0.0046	0.0260	0.0017	1.3905	0.0046	0.0260	0.0017
D4/pond	0.4748	0.0016	0.0089	0.0006	0.4774	0.0016	0.0089	0.0006
D4/stream	1.4670	0.0048	0.0274	0.0018	1.4670	0.0048	0.0274	0.0018
D5/pond	0.4385	0.0014	0.0082	0.0005	0.4407	0.0014	0.0082	0.0005
D5/stream	1.2760	0.0042	0.0238	0.0015	1.2760	0.0042	0.0238	0.0015
R1/pond	0.4772	0.0016	0.0089	0.0006	0.4800	0.0016	0.0090	0.0006

Table 9.5-78: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for multiple applications of GLOB2021dF for each organism group based on FOCUS Steps 3 calculations for the use on winter cereals

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	300.4	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
Step 3	<u>Prothio- conazole Set 1</u>				<u>Prothio- conazole Set 2</u>			
BBCH 25								
D1/ditch	5.3110	0.0175	0.0992	0.0064	6.0100	0.0198	0.1123	0.0073
D1/stream	4.0962	0.0135	0.0765	0.0050	3.9859	0.0131	0.0745	0.0048
D2/ditch	7.7999	0.0257	0.1457	0.0094	7.9139	0.0260	0.1479	0.0096
D2/stream	5.1933	0.0171	0.0970	0.0063	5.1012	0.0168	0.0953	0.0062
D3/ditch	1.3034	0.0043	0.0244	0.0016	1.3836	0.0046	0.0259	0.0017
D4/pond	1.3977	0.0046	0.0261	0.0017	0.7411	0.0024	0.0138	0.0009
D4/stream	1.1388	0.0037	0.0213	0.0014	1.6270	0.0054	0.0304	0.0020
D5/pond	1.0357	0.0034	0.0194	0.0013	0.5524	0.0018	0.0103	0.0007
D5/stream	0.7870	0.0026	0.0147	0.0010	1.3514	0.0044	0.0253	0.0016

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	300.4	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
D6/ditch	2.3199	0.0076	0.0433	0.0028	2.4124	0.0079	0.0451	0.0029
R1/pond	0.9809	0.0032	0.0183	0.0012	0.3237	0.0011	0.0060	0.0004
R1/stream	2.2127	0.0073	0.0413	0.0027	2.6269	0.0086	0.0491	0.0032
R3/stream	2.9319	0.0096	0.0548	0.0035	3.1179	0.0103	0.0583	0.0038
R4/stream	4.0729	0.0134	0.0761	0.0049	3.8889	0.0128	0.0727	0.0047
BBCH 60								
D1/ditch	3.3910	0.0112	0.0634	0.0041	4.4450	0.0146	0.0831	0.0054
D1/stream	3.1570	0.0104	0.0590	0.0038	2.7380	0.0090	0.0512	0.0033
D2/ditch	4.8380	0.0159	0.0904	0.0059	5.1148	0.0168	0.0956	0.0062
D2/stream	3.5058	0.0115	0.0655	0.0042	3.2894	0.0108	0.0615	0.0040
D3/ditch	1.3460	0.0044	0.0251	0.0016	1.3868	0.0046	0.0259	0.0017
D4/pond	1.1131	0.0037	0.0208	0.0013	0.4555	0.0015	0.0085	0.0006
D4/stream	0.7545	0.0025	0.0141	0.0009	1.3131	0.0043	0.0245	0.0016
D5/pond	1.0507	0.0035	0.0196	0.0013	0.4981	0.0016	0.0093	0.0006
D5/stream	0.6836	0.0022	0.0128	0.0008	1.2847	0.0042	0.0240	0.0016
D6/ditch	1.7435	0.0057	0.0326	0.0021	1.8005	0.0059	0.0336	0.0022
R1/pond	0.9665	0.0032	0.0181	0.0012	0.3127	0.0010	0.0058	0.0004
R1/stream	1.7201	0.0057	0.0321	0.0021	2.1292	0.0070	0.0398	0.0026

Table 9.5-79: Aquatic organisms: acceptability of risk (PEC/RAC < 1) for multiple applications of GLOB2021dF for each organism group based on FOCUS Steps 3 calculations for the use on spring cereals

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	300.4	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
<u>Step 3</u>	<u>Prothio- conazole Set 1</u>				<u>Prothio- conazole Set 2</u>			
BBCH 25								
D1/ditch	5.0770	0.0167	0.0949	0.0061	5.1070	0.0168	0.0954	0.0062
D1/stream	3.1610	0.0104	0.0591	0.0038	3.1610	0.0104	0.0591	0.0038
D3/ditch	1.3845	0.0046	0.0259	0.0017	1.3844	0.0046	0.0259	0.0017
D4/pond	0.6885	0.0023	0.0129	0.0008	0.6906	0.0023	0.0129	0.0008
D4/stream	1.5028	0.0049	0.0281	0.0018	1.5028	0.0049	0.0281	0.0018
D5/pond	0.4873	0.0016	0.0091	0.0006	0.4894	0.0016	0.0091	0.0006

<u>Group</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>		<u>Fish</u>	<u>Inverteb. acute</u>	<u>Algae</u>
	<u>RAC</u>	300.4	53.52	826	<u>RAC</u>	300.4	53.52	826
	<u>PEC_{sw sum}</u>				<u>PEC_{sw sum}</u>			
D5/stream	1.2147	0.0040	0.0227	0.0015	1.2147	0.0040	0.0227	0.0015
R4/stream	3.4660	0.0114	0.0648	0.0042	3.4660	0.0114	0.0648	0.0042
BBHCH 60								
D1/ditch	7.8240	0.0257	0.1462	0.0095	7.8540	0.0258	0.1467	0.0095
D1/stream	6.1600	0.0203	0.1151	0.0075	6.1600	0.0203	0.1151	0.0075
D3/ditch	1.4094	0.0046	0.0263	0.0017	1.4093	0.0046	0.0263	0.0017
D4/pond	0.9792	0.0032	0.0183	0.0012	0.9824	0.0032	0.0184	0.0012
D4/stream	2.0939	0.0069	0.0391	0.0025	2.0939	0.0069	0.0391	0.0025
D5/pond	0.5862	0.0019	0.0110	0.0007	0.5881	0.0019	0.0110	0.0007
D5/stream	1.3843	0.0046	0.0259	0.0017	1.3843	0.0046	0.0259	0.0017
R4/stream	2.7079	0.0089	0.0506	0.0033	2.7079	0.0089	0.0506	0.0033

Combined toxicity based on boscalid and prothioconazole – winter oilseed rape

Mixture composition in the formulation versus mixture composition at PEC_{mix} (step 3)

The following results were obtained from the screening step 1 (from the AGD_Aquamix_v1.15).

Screening 1

Fish	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	rothioconazo				
Step 1	0.008	0.015		yes		
Step 2						
N-Europe	0.004	0.001		no	0.005	yes
S-Europe	0.003	0.001		no	0.005	yes
Step 3						
D1 Ditch						
D1 Stream						
D2 Ditch	0.002	0.000		no	0.005	yes
D2 Stream	0.001	0.000		no	0.005	yes
D3 Ditch	0.000	0.000		no	0.005	yes
D4 Pond	0.000	0.000		no	0.005	yes
D4 Stream	0.000	0.000		no	0.005	yes
D5 Pond	0.000	0.000		no	0.005	yes
D5 Stream	0.000	0.000		no	0.005	yes
D6 Ditch						
R1 Pond	0.000	0.000		no	0.005	yes
R1 Stream	0.001	0.000		no	0.005	yes
R2 Stream						
R3 Stream	0.001	0.000		no	0.005	yes
R4 Stream						

Invertebrates	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n
	Boscalid	rothioconazo				
Step 1	0.004	0.021		yes		
Step 2						
N-Europe	0.002	0.001		no	0.005	yes
S-Europe	0.002	0.001		no	0.005	yes
Step 3						
D1 Ditch						
D1 Stream						
D2 Ditch	0.001	0.001		no	0.005	yes
D2 Stream	0.001	0.000		no	0.005	yes
D3 Ditch	0.000	0.001		no	0.005	yes
D4 Pond	0.000	0.000		no	0.005	yes
D4 Stream	0.000	0.000		no	0.005	yes
D5 Pond	0.000	0.000		no	0.005	yes
D5 Stream	0.000	0.000		no	0.005	yes
D6 Ditch						
R1 Pond	0.000	0.000		no	0.005	yes
R1 Stream	0.000	0.000		no	0.005	yes
R2 Stream						
R3 Stream	0.000	0.000		no	0.005	yes
R4 Stream						

Algae	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	rothioconazo				
Step 1	0.016	0.025		no	0.05	yes
Step 2						
N-Europe	0.008	0.001		no	0.05	yes
S-Europe	0.007	0.001		no	0.05	yes
Step 3						
D1 Ditch						
D1 Stream						
D2 Ditch	0.005	0.001		no	0.05	yes
D2 Stream	0.003	0.001		no	0.05	yes
D3 Ditch	0.001	0.001		no	0.05	yes
D4 Pond	0.000	0.000		no	0.05	yes
D4 Stream	0.001	0.001		no	0.05	yes
D5 Pond	0.000	0.000		no	0.05	yes
D5 Stream	0.000	0.001		no	0.05	yes
D6 Ditch						
R1 Pond	0.000	0.000		no	0.05	yes
R1 Stream	0.001	0.000		no	0.05	yes
R2 Stream						
R3 Stream	0.001	0.001		no	0.05	yes
R4 Stream						

Macrophytes	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n
	Boscalid	rothioconazo				
Step 1						
Step 2						
N-Europe						
S-Europe						
Step 3						
D1 Ditch						
D1 Stream						
D2 Ditch						
D2 Stream						
D3 Ditch						
D4 Pond						
D4 Stream						
D5 Pond						
D5 Stream						
D6 Ditch						
R1 Pond						
R1 Stream						
R2 Stream						
R3 Stream						
R4 Stream						

Combined toxicity based on boscalid and prothioconazole – spring oilseed rape

Mixture composition in the formulation versus mixture composition at PECmix (step 3)

The following results were obtained from the screening step 1 (from the AGD_Aquamix_v1.15).

Fish	ETR		Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazole			
Step 1	0.008	0.015	yes		
Step 2					
N-Europe	0.004	0.001	no	0.005	yes
S-Europe	0.003	0.001	no	0.005	yes
Step 3					
D1 Ditch	0.002	0.001	no	0.005	yes
D1 Stream	0.001	0.000	no	0.005	yes
D2 Ditch					
D2 Stream					
D3 Ditch	0.000	0.000	no	0.005	yes
D4 Pond	0.000	0.000	no	0.005	yes
D4 Stream	0.000	0.000	no	0.005	yes
D5 Pond	0.000	0.000	no	0.005	yes
D5 Stream	0.000	0.000	no	0.005	yes
D6 Ditch					
R1 Pond	0.000	0.000	no	0.005	yes
R1 Stream	0.001	0.000	no	0.005	yes
R2 Stream					
R3 Stream					
R4 Stream					

Algae	ETR		Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazole			
Step 1	0.016	0.025	no	0.05	yes
Step 2					
N-Europe	0.008	0.001	no	0.05	yes
S-Europe	0.007	0.001	no	0.05	yes
Step 3					
D1 Ditch	0.003	0.001	no	0.05	yes
D1 Stream	0.002	0.001	no	0.05	yes
D2 Ditch					
D2 Stream					
D3 Ditch	0.001	0.001	no	0.05	yes
D4 Pond	0.000	0.000	no	0.05	yes
D4 Stream	0.001	0.001	no	0.05	yes
D5 Pond	0.000	0.000	no	0.05	yes
D5 Stream	0.000	0.001	no	0.05	yes
D6 Ditch					
R1 Pond	0.000	0.000	no	0.05	yes
R1 Stream	0.001	0.000	no	0.05	yes
R2 Stream					
R3 Stream					
R4 Stream					

Invertebrates	ETR		Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazole			
Step 1	0.004	0.021	yes		
Step 2					
N-Europe	0.002	0.001	no	0.005	yes
S-Europe	0.002	0.001	no	0.005	yes
Step 3					
D1 Ditch	0.001	0.001	no	0.005	yes
D1 Stream	0.001	0.000	no	0.005	yes
D2 Ditch					
D2 Stream					
D3 Ditch	0.000	0.001	no	0.005	yes
D4 Pond	0.000	0.000	no	0.005	yes
D4 Stream	0.000	0.000	no	0.005	yes
D5 Pond	0.000	0.000	no	0.005	yes
D5 Stream	0.000	0.000	no	0.005	yes
D6 Ditch					
R1 Pond	0.000	0.000	no	0.005	yes
R1 Stream	0.000	0.000	no	0.005	yes
R2 Stream					
R3 Stream					
R4 Stream					

Macrophytes	ETR		Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazole			
Step 1					
Step 2					
N-Europe					
S-Europe					
Step 3					
D1 Ditch					
D1 Stream					
D2 Ditch					
D2 Stream					
D3 Ditch					
D4 Pond					
D4 Stream					
D5 Pond					
D5 Stream					
D6 Ditch					
R1 Pond					
R1 Stream					
R2 Stream					
R3 Stream					
R4 Stream					

Combined toxicity based on boscalid and prothioconazole – winter cereals

Mixture composition in the formulation versus mixture composition at PECmix (step 3)

The following results were obtained from the screening step 1 (from the AGD_Aquamix_v1.15).

Fish	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazo				
Step 1	0.008	0.015		yes		
Step 2						
N-Europe	0.004	0.001		no	0.005	yes
S-Europe	0.003	0.001		no	0.005	yes
Step 3						
D1 Ditch	0.002	0.000		no	0.005	yes
D1 Stream	0.001	0.000		no	0.005	yes
D2 Ditch	0.003	0.000		no	0.005	yes
D2 Stream	0.002	0.000		no	0.005	yes
D3 Ditch	0.000	0.000		no	0.005	yes
D4 Pond	0.000	0.000		no	0.005	yes
D4 Stream	0.000	0.000		no	0.005	yes
D5 Pond	0.000	0.000		no	0.005	yes
D5 Stream	0.000	0.000		no	0.005	yes
D6 Ditch	0.001	0.000		no	0.005	yes
R1 Pond	0.000	0.000		no	0.005	yes
R1 Stream	0.001	0.000		no	0.005	yes
R2 Stream						
R3 Stream	0.001	0.000		no	0.005	yes
R4 Stream	0.001	0.000		no	0.005	yes

Algae	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazo				
Step 1	0.016	0.025		no	0.05	yes
Step 2						
N-Europe	0.008	0.001		no	0.05	yes
S-Europe	0.007	0.001		no	0.05	yes
Step 3						
D1 Ditch	0.004	0.001		no	0.05	yes
D1 Stream	0.002	0.001		no	0.05	yes
D2 Ditch	0.005	0.001		no	0.05	yes
D2 Stream	0.003	0.001		no	0.05	yes
D3 Ditch	0.001	0.001		no	0.05	yes
D4 Pond	0.000	0.000		no	0.05	yes
D4 Stream	0.001	0.001		no	0.05	yes
D5 Pond	0.000	0.000		no	0.05	yes
D5 Stream	0.001	0.001		no	0.05	yes
D6 Ditch	0.001	0.001		no	0.05	yes
R1 Pond	0.000	0.000		no	0.05	yes
R1 Stream	0.001	0.000		no	0.05	yes
R2 Stream						
R3 Stream	0.001	0.001		no	0.05	yes
R4 Stream	0.002	0.000		no	0.05	yes

Invertebrates	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n
	Boscalid	prothioconazo				
Step 1	0.004	0.021		yes		
Step 2						
N-Europe	0.002	0.001		no	0.005	yes
S-Europe	0.002	0.001		no	0.005	yes
Step 3						
D1 Ditch	0.001	0.001		no	0.005	yes
D1 Stream	0.001	0.000		no	0.005	yes
D2 Ditch	0.001	0.001		no	0.005	yes
D2 Stream	0.001	0.001		no	0.005	yes
D3 Ditch	0.000	0.001		no	0.005	yes
D4 Pond	0.000	0.000		no	0.005	yes
D4 Stream	0.000	0.000		no	0.005	yes
D5 Pond	0.000	0.000		no	0.005	yes
D5 Stream	0.000	0.000		no	0.005	yes
D6 Ditch	0.000	0.001		no	0.005	yes
R1 Pond	0.000	0.000		no	0.005	yes
R1 Stream	0.000	0.000		no	0.005	yes
R2 Stream						
R3 Stream	0.000	0.001		no	0.005	yes
R4 Stream	0.001	0.000		no	0.005	yes

Macrophytes	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n
	Boscalid	prothioconazo				
Step 1						
Step 2						
N-Europe						
S-Europe						
Step 3						
D1 Ditch						
D1 Stream						
D2 Ditch						
D2 Stream						
D3 Ditch						
D4 Pond						
D4 Stream						
D5 Pond						
D5 Stream						
D6 Ditch						
R1 Pond						
R1 Stream						
R2 Stream						
R3 Stream						
R4 Stream						

Combined toxicity based on boscalid and prothioconazole – spring cereals

Mixture composition in the formulation versus mixture composition at PECmix (step 3)

The following results were obtained from the screening step 1 (from the AGD_Aquamix_v1.15).

Fish	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazo				
Step 1	0.008	0.015		yes		
Step 2						
N-Europe	0.004	0.001		no	0.005	yes
S-Europe	0.003	0.001		no	0.005	yes
Step 3						
D1 Ditch	0.001	0.001		no	0.005	yes
D1 Stream	0.001	0.000		no	0.005	yes
D2 Ditch						
D2 Stream						
D3 Ditch	0.000	0.000		no	0.005	yes
D4 Pond	0.000	0.000		no	0.005	yes
D4 Stream	0.000	0.000		no	0.005	yes
D5 Pond	0.000	0.000		no	0.005	yes
D5 Stream	0.000	0.000		no	0.005	yes
D6 Ditch						
R1 Pond						
R1 Stream						
R2 Stream						
R3 Stream						
R4 Stream	0.001	0.000		no	0.005	yes

Algae	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n?
	Boscalid	prothioconazo				
Step 1	0.016	0.025		no	0.05	yes
Step 2						
N-Europe	0.008	0.001		no	0.05	yes
S-Europe	0.007	0.001		no	0.05	yes
Step 3						
D1 Ditch	0.003	0.001		no	0.05	yes
D1 Stream	0.002	0.001		no	0.05	yes
D2 Ditch						
D2 Stream						
D3 Ditch	0.001	0.001		no	0.05	yes
D4 Pond	0.001	0.000		no	0.05	yes
D4 Stream	0.001	0.001		no	0.05	yes
D5 Pond	0.000	0.000		no	0.05	yes
D5 Stream	0.000	0.001		no	0.05	yes
D6 Ditch						
R1 Pond						
R1 Stream						
R2 Stream						
R3 Stream						
R4 Stream	0.002	0.000		no	0.05	yes

Invertebrates	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n
	Boscalid	prothioconazo				
Step 1	0.004	0.021		yes		
Step 2						
N-Europe	0.002	0.001		no	0.005	yes
S-Europe	0.002	0.001		no	0.005	yes
Step 3						
D1 Ditch	0.001	0.001		no	0.005	yes
D1 Stream	0.000	0.000		no	0.005	yes
D2 Ditch						
D2 Stream						
D3 Ditch	0.000	0.001		no	0.005	yes
D4 Pond	0.000	0.000		no	0.005	yes
D4 Stream	0.000	0.000		no	0.005	yes
D5 Pond	0.000	0.000		no	0.005	yes
D5 Stream	0.000	0.000		no	0.005	yes
D6 Ditch						
R1 Pond						
R1 Stream						
R2 Stream						
R3 Stream						
R4 Stream	0.001	0.000		no	0.005	yes

Macrophytes	ETR			Any a.s. above	ETRtrigger/n (if needed)	All ETRI ≤ ETRtrigger/n
	Boscalid	prothioconazo				
Step 1						
Step 2						
N-Europe						
S-Europe						
Step 3						
D1 Ditch						
D1 Stream						
D2 Ditch						
D2 Stream						
D3 Ditch						
D4 Pond						
D4 Stream						
D5 Pond						
D5 Stream						
D6 Ditch						
R1 Pond						
R1 Stream						
R2 Stream						
R3 Stream						
R4 Stream						

Combined toxicity based on boscalid and prothioconazole-desthio – winter oilseed rape

Mixture composition in the formulation versus mixture composition at PECmix (step 3)

The aim of this step is to check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual active substances is similar to the mixture composition at the PECmix (proportion of each active in the environment (part of the PEC)).

The same equation (equation 13) as for step 2 is used, with the difference that here the p_i is PEC_i/PEC_{mix} . PEC_{mix} is simply the sum the each PEC_i .

Using the same ECxm_{mix}-CA (a.s. in PPP) as the one used in step 2 for MDR, the new ECxm_{mix}-CA (a.s. in PECmix) (representing the mixture as it is in the environment) is calculated.

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Fish	
ECxm _{mix} -CA (a.s. in PPP)/ ECxm _{mix} -CA (a.s. in PECmix)	
Step 1	1.45
Step 2	
N-Europe	0.71

Invertebrates	
ECxm _{mix} -CA (a.s. in PPP)/ ECxm _{mix} -CA (a.s. in PECmix)	
Step 1	0.87
Step 2	
N-Europe	1.08

Algae	
ECxm _{mix} -CA (a.s. in PPP)/ ECxm _{mix} -CA (a.s. in PECmix)	
Step 1	1.18
Step 2	
N-Europe	0.88

The ECxm_{mix}-CA (a.s. in PPP)/ECxm_{mix}-CA (a.s. in PECmix) is not between 0.8 and 1.2 (mixture not similar) for all species. Therefore, as a next step a check for driver of toxicity is performed (**see below**).

Driver of toxicity (step 5)

Following the EFSA Aquatic guidance document^[1], the check of a single drive for the toxicity was made according to the following formula^[1]:

$$\sum_{i=1}^n TU_i = \sum_{i=1}^n \frac{c_i}{ECx_i}$$

in which TU is the ratio between the concentration (i.e. c_i) of a mixture component and its toxicological acute (e.g. EC50) or chronic (e.g. long-term NOEC) endpoint.

Contribution to toxicity = $TU(a_i) * 100 / TU_{sum}(a_i)$

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Next Step for:	Fish				Conclusion	
FOCUS	Boscalid	thioconazole				
Step 1		Driver			Go to Step 6	
Step 2						
N-Europe		Driver			Go to Step 6	

[1] Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290)

Next Step for: Invertebrates					
FOCUS	Boscalid	thioconazole-			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8

Next Step for: Algae					
FOCUS	Boscalid	thioconazole-			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8

There is no driver of toxicity identified for any of the aquatic organisms. Therefore, in the next step, a mixture risk assessment is conducted based on the calculated mixture toxicity (ETR_{mix-CA}).

Calculated mixture toxicity (Step 8)

Fish	
ETR _{mix-CA}	
Step 1	14.65
Step 2	
N-Europe	1.69
S-Europe	1.38
Step 3	
D1 Ditch	
D1 Stream	
D2 Ditch	0.10
D2 Stream	0.06
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.01
D5 Pond	0.00
D5 Stream	0.01
D6 Ditch	
R1 Pond	0.01
R1 Stream	0.13
R2 Stream	
R3 Stream	0.13
R4 Stream	

Invertebrates	
ETR _{mix-CA}	
Step 1	Go to Step 4
Step 2	
N-Europe	Go to Step 4
S-Europe	Go to Step 4
Step 3	
D1 Ditch	
D1 Stream	
D2 Ditch	0.00
D2 Stream	0.00
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	
R1 Pond	Go to Step 4
R1 Stream	Go to Step 4
R2 Stream	
R3 Stream	Go to Step 4
R4 Stream	

Algae	
ETR _{mix-CA}	
Step 1	Go to Step 4
Step 2	
N-Europe	Go to Step 4
S-Europe	Go to Step 4
Step 3	
D1 Ditch	
D1 Stream	
D2 Ditch	0.01
D2 Stream	0.00
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	
R1 Pond	0.00
R1 Stream	0.00
R2 Stream	
R3 Stream	0.00
R4 Stream	

Risk assessment for identified driver (Step 6)

See table 9.5.28, 9.5.36, 9.5.51 and 9.5.58.

Measured risk assessment (Step 4)

Fish		Invertebrates		Algae	
ETRmix-PPP		ETRmix-PPP		ETRmix-PPP	
Step 1	Go to Step 5/8	Step 1	0.01	Step 1	0.20
Step 2		Step 2		Step 2	
N-Europe	Go to Step 5/8	N-Europe	0.00	N-Europe	0.05
S-Europe	Go to Step 5/8	S-Europe	0.00	S-Europe	0.04
Step 3		Step 3		Step 3	
D1 Ditch		D1 Ditch		D1 Ditch	
D1 Stream		D1 Stream		D1 Stream	
D2 Ditch	Go to Step 5/8	D2 Ditch	Go to Step 5/8	D2 Ditch	Go to Step 5/8
D2 Stream	Go to Step 5/8	D2 Stream	Go to Step 5/8	D2 Stream	Go to Step 5/8
D3 Ditch	0.00	D3 Ditch	0.00	D3 Ditch	0.00
D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8
D4 Stream	Go to Step 5/8	D4 Stream	0.00	D4 Stream	0.00
D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8
D5 Stream	0.00	D5 Stream	0.00	D5 Stream	0.00
D6 Ditch		D6 Ditch		D6 Ditch	
R1 Pond	Go to Step 5/8	R1 Pond	0.00	R1 Pond	Go to Step 5/8
R1 Stream	Go to Step 5/8	R1 Stream	0.00	R1 Stream	Go to Step 5/8
R2 Stream		R2 Stream		R2 Stream	
R3 Stream	Go to Step 5/8	R3 Stream	0.00	R3 Stream	0.01
R4 Stream		R4 Stream		R4 Stream	

The risk is acceptable for all aquatic organisms at Step 4. Risk mitigation measures are needed.

Combined toxicity based on boscalid and prothioconazole-desthio – spring oilseed rape

Mixture composition in the formulation versus mixture composition at PECmix (step 3)

The aim of this step is to check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual active substances is similar to the mixture composition at the PECmix (proportion of each active in the environment (part of the PEC)).

The same equation (equation 13) as for step 2 is used, with the difference that here the pi is PECi/PECMix. PECmix is simply the sum the each PECi.

Using the same ECxmixture-CA (a.s. in PPP) as the one used in step 2 for MDR, the new ECxmixture-CA (a.s. in PECmix) (representing the mixture as it is in the environment) is calculated.

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Fish		Invertebrates		Algae	
ECxmixture-CA (a.s. in PPP)/ ECxmixture-CA (a.s. in PECmix)		ECxmixture-CA (a.s. in PPP)/ ECxmixture-CA (a.s. in PECmix)		ECxmixture-CA (a.s. in PPP)/ ECxmixture-CA (a.s. in PECmix)	
Step 1	1.34	Step 1	0.90	Step 1	1.14
Step 2		Step 2		Step 2	
N-Europe	0.40	N-Europe	1.17	N-Europe	0.75

The ECxmixture-CA (a.s. in PPP)/ECxmixture-CA (a.s. in PECmix) is not between 0.8 and 1.2 (mixture not similar) for all species. Therefore, as a next step a check for driver of toxicity is performed (**see below**).

Driver of toxicity (step 5)

Following the EFSA Aquatic guidance document^[1], the check of a single drive for the toxicity was made according to the following formula^[1]:

[1] Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290)

$$\sum_{i=1}^n TU_i = \sum_{i=1}^n \frac{c_i}{ECx_i}$$

in which TU is the ratio between the concentration (i.e. c_i) of a mixture component and its toxicological acute (e.g. EC50) or chronic (e.g. long-term NOEC) endpoint.

Contribution to toxicity = $TU(ai) * 100 / TU_{sum}(ai)$

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Next Step for: Fish					
FOCUS	Boscalid	rothioconazo			Conclusion
Step 1		Driver			Go to Step 6
Step 2					
N-Europe		Driver			Go to Step 6
Next Step for: Invertebrates					
FOCUS	Boscalid	rothioconazo			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8
Next Step for: Algae					
FOCUS	Boscalid	rothioconazo			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8

There is no driver of toxicity identified for any of the aquatic organisms. Therefore, in the next step, a mixture risk assessment is conducted based on the calculated mixture toxicity (ETR_{mix-CA}).

Calculated mixture toxicity (Step 8)

Fish		Invertebrates		Algae	
ETRmix-CA		ETRmix-CA		ETRmix-CA	
Step 1	11.66	Step 1	Go to Step 4	Step 1	Go to Step 4
Step 2		Step 2		Step 2	
N-Europe	0.78	N-Europe	Go to Step 4	N-Europe	0.01
S-Europe	1.38	S-Europe	Go to Step 4	S-Europe	Go to Step 4
Step 3		Step 3		Step 3	
D1 Ditch	0.03	D1 Ditch	0.00	D1 Ditch	0.00
D1 Stream	0.00	D1 Stream	0.00	D1 Stream	0.00
D2 Ditch		D2 Ditch		D2 Ditch	
D2 Stream		D2 Stream		D2 Stream	
D3 Ditch	0.00	D3 Ditch	0.00	D3 Ditch	0.00
D4 Pond	0.00	D4 Pond	0.00	D4 Pond	0.00
D4 Stream	0.01	D4 Stream	0.00	D4 Stream	0.00
D5 Pond	0.00	D5 Pond	0.00	D5 Pond	0.00
D5 Stream	0.00	D5 Stream	0.00	D5 Stream	0.00
D6 Ditch		D6 Ditch		D6 Ditch	
R1 Pond	0.01	R1 Pond	Go to Step 4	R1 Pond	0.00
R1 Stream	0.11	R1 Stream	Go to Step 4	R1 Stream	0.00
R2 Stream		R2 Stream		R2 Stream	
R3 Stream		R3 Stream		R3 Stream	
R4 Stream		R4 Stream		R4 Stream	

Risk assessment for identified driver (Step 6)

See table 9.5.29, 9.5.37, 9.5.52 and 9.5.59.

Measured risk assessment (Step 4)

Fish		Invertebrates		Algae	
ETRmix-PPP		ETRmix-PPP		ETRmix-PPP	
Step 1	Go to Step 5/8	Step 1	0.01	Step 1	0.17
Step 2		Step 2		Step 2	
N-Europe	Go to Step 5/8	N-Europe	0.00	N-Europe	Go to Step 5/8
S-Europe	Go to Step 5/8	S-Europe	0.00	S-Europe	0.04
Step 3		Step 3		Step 3	
D1 Ditch	Go to Step 5/8	D1 Ditch	0.00	D1 Ditch	Go to Step 5/8
D1 Stream	Go to Step 5/8	D1 Stream	0.00	D1 Stream	Go to Step 5/8
D2 Ditch		D2 Ditch		D2 Ditch	
D2 Stream		D2 Stream		D2 Stream	
D3 Ditch	0.00	D3 Ditch	0.00	D3 Ditch	0.00
D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8
D4 Stream	0.00	D4 Stream	0.00	D4 Stream	0.00
D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8
D5 Stream	0.00	D5 Stream	0.00	D5 Stream	0.00
D6 Ditch		D6 Ditch		D6 Ditch	
R1 Pond	Go to Step 5/8	R1 Pond	0.00	R1 Pond	Go to Step 5/8
R1 Stream	Go to Step 5/8	R1 Stream	0.00	R1 Stream	Go to Step 5/8
R2 Stream		R2 Stream		R2 Stream	
R3 Stream		R3 Stream		R3 Stream	
R4 Stream		R4 Stream		R4 Stream	

The risk is acceptable for all aquatic organisms at Step 4. Risk mitigation measures are needed.

Combined toxicity based on boscalid and prothioconazole-desithio – winter cereals

Mixture composition in the formulation versus mixture composition at PECmix (step 3)

The aim of this step is to check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual active substances is

similar to the mixture composition at the PECmix (proportion of each active in the environment (part of the PEC)).

The same equation (equation 13) as for step 2 is used, with the difference that here the pi is PECi/PECMix. PECmix is simply the sum the each PECi.

Using the same ECxmixture-CA (a.s. in PPP) as the one used in step 2 for MDR, the new ECxmixture-CA (a.s. in PECmix) (representing the mixture as it is in the environment) is calculated.

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Fish		Invertebrates		Algae	
ECxmixture-CA (a.s. in PPP)/ ECxmixture-CA (a.s. in PECmix)		ECxmixture-CA (a.s. in PPP)/ ECxmixture-CA (a.s. in PECmix)		ECxmixture-CA (a.s. in PPP)/ ECxmixture-CA (a.s. in PECmix)	
Step 1	1.30	Step 1	0.91	Step 1	1.12
Step 2		Step 2		Step 2	
N-Europe	0.76	N-Europe	1.07	N-Europe	0.90

The ECxmixture-CA (a.s. in PPP)/ECxmixture-CA (a.s. in PECmix) is not between 0.8 and 1.2 (mixture not similar) for all species. Therefore, as a next step a check for driver of toxicity is performed (see below).

Driver of toxicity (step 5)

Following the EFSA Aquatic guidance document^[1], the check of a single drive for the toxicity was made according to the following formula^[1]:

$$\sum_{i=1}^n TU_i = \sum_{i=1}^n \frac{c_i}{ECx_i}$$

in which TU is the ratio between the concentration (i.e. ci) of a mixture component and its toxicological acute (e.g. EC50) or chronic (e.g. long-term NOEC) endpoint.

Contribution to toxicity = TU(ai) * 100/ TUsum(ai)

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Next Step for:		Fish			
FOCUS	Boscalid	Desthio			Conclusion
Step 1		Driver			Go to Step 6
Step 2					
N-Europe		Driver			Go to Step 6

Next Step for:		Invertebrates			
FOCUS	Boscalid	Desthio			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8

^[1] Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290)

Next Step for:	Algae					
FOCUS	Boscalid	Desthio			Conclusion	
Step 1						Go to Step 8
Step 2						
N-Europe						Go to Step 8

There is no driver of toxicity identified for any of the aquatic organisms. Therefore, in the next step, a mixture risk assessment is conducted based on the calculated mixture toxicity (ETR_{mix-CA}).

Calculated mixture toxicity (Step 8)

Fish	
ETR _{mix-CA}	
Step 1	10.78
Step 2	
N-Europe	1.90
S-Europe	1.55
Step 3	
D1 Ditch	0.01
D1 Stream	0.00
D2 Ditch	0.02
D2 Stream	0.01
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	0.15
R1 Pond	0.01
R1 Stream	0.10
R2 Stream	#VALUE!
R3 Stream	0.10
R4 Stream	0.21

Invertebrates	
ETR _{mix-CA}	
Step 1	Go to Step 4
Step 2	
N-Europe	Go to Step 4
S-Europe	Go to Step 4
Step 3	
D1 Ditch	0.00
D1 Stream	0.00
D2 Ditch	0.00
D2 Stream	0.00
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	Go to Step 4
R1 Pond	Go to Step 4
R1 Stream	Go to Step 4
R2 Stream	#VALUE!
R3 Stream	Go to Step 4
R4 Stream	Go to Step 4

Algae	
ETR _{mix-CA}	
Step 1	Go to Step 4
Step 2	
N-Europe	Go to Step 4
S-Europe	Go to Step 4
Step 3	
D1 Ditch	0.00
D1 Stream	0.00
D2 Ditch	0.01
D2 Stream	0.00
D3 Ditch	0.00
D4 Pond	0.00
D4 Stream	0.00
D5 Pond	0.00
D5 Stream	0.00
D6 Ditch	0.00
R1 Pond	0.00
R1 Stream	0.00
R2 Stream	#VALUE!
R3 Stream	0.00
R4 Stream	0.00

Risk assessment for identified driver (Step 6)

See table 9.5.30, 9.5.38, 9.5.53 and 9.5.60.

Measured risk assessment (Step 4)

Fish		Invertebrates		Algae	
ETRmix-PPP		ETRmix-PPP		ETRmix-PPP	
Step 1	Go to Step 5/8	Step 1	0.01	Step 1	0.16
Step 2		Step 2		Step 2	
N-Europe	Go to Step 5/8	N-Europe	0.00	N-Europe	0.05
S-Europe	Go to Step 5/8	S-Europe	0.00	S-Europe	0.04
Step 3		Step 3		Step 3	
D1 Ditch	Go to Step 5/8	D1 Ditch	Go to Step 5/8	D1 Ditch	Go to Step 5/8
D1 Stream	Go to Step 5/8	D1 Stream	0.00	D1 Stream	Go to Step 5/8
D2 Ditch	Go to Step 5/8	D2 Ditch	Go to Step 5/8	D2 Ditch	Go to Step 5/8
D2 Stream	Go to Step 5/8	D2 Stream	Go to Step 5/8	D2 Stream	Go to Step 5/8
D3 Ditch	0.00	D3 Ditch	0.00	D3 Ditch	0.00
D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8
D4 Stream	Go to Step 5/8	D4 Stream	0.00	D4 Stream	0.00
D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8
D5 Stream	0.00	D5 Stream	0.00	D5 Stream	0.00
D6 Ditch	Go to Step 5/8	D6 Ditch	0.00	D6 Ditch	0.01
R1 Pond	Go to Step 5/8	R1 Pond	Go to Step 5/8	R1 Pond	Go to Step 5/8
R1 Stream	Go to Step 5/8	R1 Stream	0.00	R1 Stream	Go to Step 5/8
R2 Stream		R2 Stream		R2 Stream	
R3 Stream	Go to Step 5/8	R3 Stream	0.00	R3 Stream	0.01
R4 Stream	Go to Step 5/8	R4 Stream	Go to Step 5/8	R4 Stream	Go to Step 5/8

The risk is acceptable for all aquatic organisms at Step 3. No risk mitigation measures are needed.

Combined toxicity based on boscalid and prothioconazole-desthio – spring cereals

Mixture composition in the formulation versus mixture composition at PECmix (step 3)

The aim of this step is to check whether the mixture composition in the formulation study giving the measured mixture toxicity (ECxPPP) in terms of the relative proportions of the individual active substances is similar to the mixture composition at the PECmix (proportion of each active in the environment (part of the PEC)).

The same equation (equation 13) as for step 2 is used, with the difference that here the pi is PECi/PECMix. PECmix is simply the sum the each PECi.

Using the same ECxmix-CA (a.s. in PPP) as the one used in step 2 for MDR, the new ECxmix-CA (a.s. in PECmix) (representing the mixture as it is in the environment) is calculated.

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Fish		Invertebrates		Algae	
ECxmix-CA (a.s. in PPP)/ ECxmix-CA (a.s. in PECmix)		ECxmix-CA (a.s. in PPP)/ ECxmix-CA (a.s. in PECmix)		ECxmix-CA (a.s. in PPP)/ ECxmix-CA (a.s. in PECmix)	
Step 1	0.82	Step 1	0.87	Step 1	1.18
Step 2		Step 2		Step 2	
N-Europe	1.09	N-Europe	1.07	N-Europe	0.90
S-Europe	1.09	S-Europe	1.07	S-Europe	0.90

The ECxmix-CA (a.s. in PPP)/ECxmix-CA (a.s. in PECmix) is not between 0.8 and 1.2 (mixture not similar) for all species. Therefore, as a next step a check for driver of toxicity is performed (see below).

Driver of toxicity (step 5)

Following the EFSA Aquatic guidance document^[1], the check of a single drive for the toxicity was made according to the following formula^[1]:

^[1] Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters (EFSA Journal 2013;11(7):3290)

$$\sum_{i=1}^n TU_i = \sum_{i=1}^n \frac{c_i}{ECx_i}$$

in which TU is the ratio between the concentration (i.e. c_i) of a mixture component and its toxicological acute (e.g. EC50) or chronic (e.g. long-term NOEC) endpoint.

Contribution to toxicity = $TU(ai) * 100 / TU_{sum}(ai)$

The following results were obtained for Step 1 and 2 (from the AGD_Aquamix_v1.15).

Next Step for: Fish					
FOCUS	Boscalid	rothioconazo			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8
Next Step for: Invertebrates					
FOCUS	Boscalid	rothioconazo			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8
Next Step for: Algae					
FOCUS	Boscalid	rothioconazo			Conclusion
Step 1					Go to Step 8
Step 2					
N-Europe					Go to Step 8

There is no driver of toxicity identified for any of the aquatic organisms. Therefore, in the next step, a mixture risk assessment is conducted based on the calculated mixture toxicity (ETR_{mix-CA}).

Calculated mixture toxicity (Step 8)

Fish		Invertebrates		Algae	
ETRmix-CA		ETRmix-CA		ETRmix-CA	
Step 1	Go to Step 4	Step 1	Go to Step 4	Step 1	Go to Step 4
Step 2		Step 2		Step 2	
N-Europe	Go to Step 4	N-Europe	Go to Step 4	N-Europe	Go to Step 4
S-Europe	Go to Step 4	S-Europe	Go to Step 4	S-Europe	Go to Step 4
Step 3		Step 3		Step 3	
D1 Ditch	0.00	D1 Ditch	0.00	D1 Ditch	0.00
D1 Stream	0.00	D1 Stream	0.00	D1 Stream	0.00
D2 Ditch		D2 Ditch		D2 Ditch	
D2 Stream		D2 Stream		D2 Stream	
D3 Ditch	0.00	D3 Ditch	0.00	D3 Ditch	0.00
D4 Pond	0.00	D4 Pond	0.00	D4 Pond	0.00
D4 Stream	0.00	D4 Stream	0.00	D4 Stream	0.00
D5 Pond	0.00	D5 Pond	0.00	D5 Pond	0.00
D5 Stream	0.00	D5 Stream	0.00	D5 Stream	0.00
D6 Ditch		D6 Ditch		D6 Ditch	
R1 Pond		R1 Pond		R1 Pond	
R1 Stream		R1 Stream		R1 Stream	
R2 Stream		R2 Stream		R2 Stream	
R3 Stream		R3 Stream		R3 Stream	
R4 Stream	0.00	R4 Stream	Go to Step 4	R4 Stream	0.00

Risk assessment for identified driver (Step 6)

See table 9.5.31, 9.5.39, 9.5.54 and 9.5.61.

Measured risk assessment (Step 4)

Fish		Invertebrates		Algae	
ETRmix-PPP		ETRmix-PPP		ETRmix-PPP	
Step 1	0.01	Step 1	0.05	Step 1	0.07
Step 2		Step 2		Step 2	
N-Europe	0.00	N-Europe	0.01	N-Europe	0.02
S-Europe	0.00	S-Europe	0.01	S-Europe	0.01
Step 3		Step 3		Step 3	
D1 Ditch	0.00	D1 Ditch	0.00	D1 Ditch	0.01
D1 Stream	Go to Step 5/8	D1 Stream	0.00	D1 Stream	Go to Step 5/8
D2 Ditch		D2 Ditch		D2 Ditch	
D2 Stream		D2 Stream		D2 Stream	
D3 Ditch	0.00	D3 Ditch	0.00	D3 Ditch	0.00
D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8	D4 Pond	Go to Step 5/8
D4 Stream	0.00	D4 Stream	0.00	D4 Stream	0.00
D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8	D5 Pond	Go to Step 5/8
D5 Stream	0.00	D5 Stream	0.00	D5 Stream	0.00
D6 Ditch		D6 Ditch		D6 Ditch	
R1 Pond		R1 Pond		R1 Pond	
R1 Stream		R1 Stream		R1 Stream	
R2 Stream		R2 Stream		R2 Stream	
R3 Stream		R3 Stream		R3 Stream	
R4 Stream	Go to Step 5/8	R4 Stream	0.00	R4 Stream	Go to Step 5/8

The risk is acceptable for all aquatic organisms at Step 3. No risk mitigation measures are needed.

9.5.3 Summary of mitigation measures

In the table below an overall summary is given for the mitigation measures needed for each relevant FOCUS

scenario (D3, D4, R1) in order to have an acceptable risk (PEC/RAC < 1).

Intended Crop	Focus Scenario	Mitigation measure for acceptable risk to aquatic organisms (except sediment dwellers)	Mitigation measure for acceptable risk to sediment dwellers	Overall mitigation measures when D3, D4, R1 relevant
Multiple applications				
Winter oilseed rape 2 x 125g boscalid + 125g Prothioconazole	D2 ditch	/	-	5m VFS
	D2 stream	/	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	D5 stream	-	-	
	R1 pond	-	-	
	R1 stream	5m VFS	-	
	R3 stream	5m VFS	-	
Spring oilseed rape 2 x 125g boscalid + 125g Prothioconazole	D1 ditch	/	-	5m VFS
	D1 stream	/	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	D5 stream	-	-	
	R1 pond	-	-	
	R1 stream	5m VFS	-	
Winter cereals 2 x 125g boscalid + 125g Prothioconazole	D1 ditch	/	-	5-10m VFS
	D1 stream	/	-	
	D2 ditch	/	-	
	D2 stream	/	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	D5 stream	-	-	
	D6 ditch	/	-	
	R1 pond	-	-	
	R1 stream	5-10m VFS	-	
	R3 stream	5m VFS	-	
	R4 stream	10m VFS	-	
Spring cereals 2 x 125g boscalid + 125g Prothioconazole	D1 ditch	/	-	-10m VFS
	D1 stream	/	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	R4 stream	10m VFS	-	
	R1 stream	5m VFS	-	
Single application				
Winter oilseed rape 1 x 125g boscalid + 125g Prothioconazole	D2 ditch	-	-	-
	D2 stream	-	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	D5 stream	-	-	
	R1 pond	-	-	

	R1 stream	-	-	
	R3 stream	-	-	
Spring oilseed rape 1 x 125g boscalid + 125g Prothioconazole	D1 ditch	-	-	-
	D1 stream	-	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	D5 stream	-	-	
	R1 pond	-	-	
	R1 stream	-	-	
Winter cereals 1 x 125g boscalid + 125g Prothioconazole	D1 ditch	-	-	-
	D1 stream	-	-	
	D2 ditch	-	-	
	D2 stream	-	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	D5 stream	-	-	
	D6 ditch	/	-	
	R1 pond	-	-	
	R1 stream	5 m VFS	-	
	R3 stream	-	-	
	R4 stream	-	-	
Spring cereals 1 x 125g boscalid + 125g Prothioconazole	D1 ditch	-	-	-
	D1 stream	-	-	
	D3 ditch	-	-	
	D4 pond	-	-	
	D4 stream	-	-	
	D5 pond	-	-	
	R4 stream	5m VFS	-	

NSB= No-spray buffer, VFS= vegetated filter strip

9.5.4 Overall conclusions

The TERA and TERIt for GLOB2021dF, the active substances and the metabolites are above the Annex VI trigger values, indicating that GLOB2021dF poses low acute and chronic risk to aquatic organisms when the following risk mitigation measures are taken into account:

Winter oilseed rape 2 x 125g boscalid and 125g prothioconazole/ ha:

- 5m vegetated filter strip

Spring oilseed rape 2 x 125g boscalid and 125g prothioconazole/ ha:

- 5m vegetated filter strip

Winter cereals 2 x 125g boscalid and 125g prothioconazole/ ha:

- 5m vegetated filter strip

Spring cereals 2 x 125g boscalid and 125g prothioconazole/ ha:

- /

zRMS comments:

The endpoints for active substances and their metabolites, provided by the applicant, are considered valid.

Boscalid

For the assessment of risk for Boscalid, FOCUS Step 3 PEC_{sw} values, accepted in Section 8, were used. All acute and chronic PEC/RAC ratios, for all intended ususes are below trigger value of 1.

Prothioconazole and its metabolites

For the assessment of risk for Prothioconazole and its metabolites FOCUS Step 1-3 PEC_{sw} values, accepted in Section 8, were used.

All acute and chronic PEC/RAC ratios for prothioconazole are below trigger value of 1 with PEC_{sw} values at Step 2.

For the assessment of risk for prothioconazole-S-methyl and prothioconazole-1,2,4-triazole, FOCUS Step 1-2 PEC_{sw} values, accepted in Section 8, were used.

For metabolites prothioconazole-S-methyl and prothioconazole-1,2,4-triazole all acute and chronic PEC/RAC ratios are below trigger value of 1 with PEC_{sw} values at Step 1-2.

For the assessment of risk for prothioconazole- desithio FOCUS Step 1-3 PEC_{sw} values, accepted in Section 8, were used.

With FOCUS Step 3 PEC_{sw} values the risk is not accepted for scenarios:

Multiple application:

- winter oilseed rape –R3 stream (BBCH 14), R1 stream (BBCH21) and R1 stream (BBCH61)
- spring oilseed rape –R1 stream (BBCH 14)
- winter cereals – D6 ditch (BBCH 25), R3 stream (BBCH 25), R4 stream (BBCH 25), R1 stream (BBCH 69), R3 stream (BBCH 69) and R4 stream (BBCH 69)
- spring cereals – R4 stream (BBCH 25 I 69)

Single application

- winter oilseed rape –none
- spring oilseed rape –none
- winter cereals – D6 ditch (BBCH 25), R1 stream (BBCH 69) and R4 stream (BBCH 69)
- spring cereals – R4 stream (BBCH 25 and 69)

For the refinement of risk the FOCUS Step 4 PEC_{sw} values were used.

With FOCUS Step 4 PEC_{sw} values the risk is accepted for scenarios:

Multiple application:

- winter oilseed rape –R3 stream (BBCH 14), R1 stream (BBCH21) and R1 stream (BBCH) with 5 m buffer zone and 5 m vegetated buffer strip
- spring oilseed rape –R1 stream (BBCH 14) with 5 m buffer zone and 5 m vegetated buffer strip
- winter cereals –R3 stream (BBCH 25) with 5 m buffer zone and 5 m vegetated buffer strip and R4 stream (BBCH 25) with 10 m buffer zone and 10 m vegetated buffer strip, R1 stream (BBCH 69) with 10 m buffer zone and 10 m vegetated buffer strip. For R3 stream and R4 stream (BBCH 69) risk is unresolved.
- spring cereals – R4 stream with 10 m buffer zone and 10 m vegetated buffer strip and taking into account the surrogate crops (spring oilseed rape) for R1 stream 5 m buffer zone and 5 m vegetated buffer strip

Single application

- winter oilseed rape – acceptable at step 3
- spring oilseed rape – acceptable at step 3
- winter cereals – D6 (BBCH 25) -unresolved, R1 stream (BBCH 69) - with 5 m buffer zone and 5 m vegetated buffer strip, R4 stream (BBCH 69) unresolved.
- spring cereals – R4 stream with 5 m buffer zone and 5 m vegetated buffer strip and taking into account the surrogate crops (spring oilseed rape) for R1 stream no buffer zone is required.

Formulation

For GLOB2021dF, tests on fish *Oncorhynchus mykiss*, invertebrates *Daphnia magna*, algae *Raphidocelis subcapitata* (*Pseudokirchneriella subcapitata*) were provided by Applicant. The risk to aquatic organisms is acceptable without risk mitigation measures for the intended uses.

Conclusion:

According to the performed risk assessment there is no potential of risk for aquatic organisms resulting from acute and long-term exposure to active substances and metabolites following use of GLOB2021dF in compliance with proposed GAP with appropriate risk mitigation measures except for the following scenarios in the following uses for the metabolite prothioconazole-desthio:

Multiple application:

- winter cereals for R3 stream and R4 stream (BBCH 69)
- spring cereals for R4 stream (BBCH 69)

Single application:

- winter cereals for R4 stream (BBCH 69)
- spring cereals for R4 stream (BBCH 69)

Further refinement for winter and spring cereals for the metabolite prothioconazole-desthio for these scenarios (BBCH 69) and tThe risk mitigation measures should be considered at national level. If it is necessary, Member states will need to further consider the risk to aquatic organisms based on national requirements.

The GAP change for oilseed rape from BBCH 61 to 69 is already covered by the existing risk assessment for aquatic organisms.

9.6 Effects on bees (KCP 10.3.1)

The evaluation of the risk for bees 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). Additionally the risk assessment for honey bees according to the EFSA 2013 guidance, using the EFSA Bee Calculator Tool v3 was conducted and presented in this section of the dossier.

According to the requirements of SANCO/10329/2002 (final, 2002), the risk for bees was evaluated on the basis of the highest rate of a single application of the plant protection product for which authorization is sought. GLOB2021dF is intended to be used by spray application at a maximum rate of 0.8 L per hectare, equivalent to 125 g boscalid and 125 g prothioconazole/ha.

9.6.1 Toxicity data

Studies on the toxicity to bees have been carried out with boscalid and prothioconazole. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on bees of GLOB2021F were not evaluated as part of the EU assessment of boscalid and prothioconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.6-1: Endpoints and effect values relevant for the risk assessment for bees

Species	Substance	Exposure System	Results	Reference
<i>Apis mellifera</i>	Boscalid	Oral	LD ₅₀ = 166 µg a.s./bee	EFSA 2008
<i>Apis mellifera</i>	Boscalid	Contact	LD ₅₀ = 200 µg a.s./bee	EFSA 2008
<i>Apis mellifera</i>	Prothioconazole	Oral	LD ₅₀ > 71 µg/bee	EFSA, 2007
<i>Apis mellifera</i>	Prothioconazole	Contact	LD ₅₀ > 200 µg/bee	EFSA, 2007
<i>Apis mellifera</i>	GLOB2021dF	Oral, 48 h	LD ₅₀ ⇒ 100 µg/bee (nominal) LD ₅₀ > 87.4 µg/bee	Orosz I., 2023a
<i>Apis mellifera</i>	GLOB2021dF	Contact, 48 h	LD ₅₀ = > 100 µg/bee	Orosz I., 2023a
<i>Apis mellifera</i>	GLOB2021dF	Chronic oral, 10 d	LDD ₅₀ ⇒ 79.1 µg/bee/day NOEC = 1000 mg/kg feeding solution NOEDD = 79.1 µg/bee/day	Orosz I., 2023b
<i>Apis mellifera</i>	GLOB2021dF	Larval, 22 d	NOED = >100 µg/larva LDC ₅₀ > 100 µg/larva	Wozniak A., 2023c
<i>Bombus terrestris</i>	GLOB2021dF	Oral, 48 h	LD ₅₀ > 100 µg f.p./bumblebee (nominal) LD ₅₀ > 96 µg/bee	Orosz I., 2023c
<i>Bombus terrestris</i>	GLOB2021dF	Contact, 48 h	LD ₅₀ > 100 µg f.p./bumblebee	Orosz I., 2023c
Higher-tier studies (tunnel test, field studies)				

Species	Substance	Exposure System	Results	Reference

9.6.1.1 Justification for new endpoints

As the formulation is a mixture of two active ingredients, toxicity to honeybees from the formulation was tested and used in the risk assessment.

9.6.2 Acute Risk assessment

9.6.2.1 Hazard quotients for bees

Table 9.6-2: First-tier assessment of the risk for bees due to the use of GLOB2021dF in oilseed rape and cereals

Intended use		Oilseed rape and cereals	
Active substance		Boscalid	
Application rate (g/ha)		2 x 125	
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	166	125	0.75
Contact toxicity	200		0.63
Product		Prothioconazole	
Application rate (g/ha)		2 x 125	
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	≥71	125	≤ 1.76
Contact toxicity	≥200		≤ 0.63
Product		GLOB2021dF	
Application rate (g/ha)		2 × 893*	
Test design	LD ₅₀ (lab.) (µg/bee)	Single application rate (g/ha)	Q _{HO} , Q _{HC} criterion: Q _H ≤ 50
Oral toxicity	100 >87.4	893	8.93 <10.2
Contact toxicity	⇒100		≤ 8.93

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger.

*based on an application rate of 0.8 L/ha and a density of 1.1168 g/mL

9.6.2.2 Acute risk assessment (KCP 10.3.1.1) according to EFSA 2013

Contact & Oral route of exposure (pollen and nectar)
--

	"calculation factor" (linked with dust)	HQ	Trigger	Risk indicator
HB – acute: contact	1	8.9	42	OK
	"calculation factor" (Ef x SV)	ETR	Trigger	Risk indicator
HB – acute: oral	7.6	0.07	0.2	OK

No unacceptable acute risk is present for honey bees.

9.6.2.3 Higher-tier risk assessment for bees (tunnel test, field studies)

Not relevant.

9.6.3 Chronic Risk Assessment

9.6.3.1 Chronic risk assessment (KCP 10.3.1.1) according to EPPO 2010

Larval chronic risk assessment

A chronic larval study is available and the potential acceptable risk can be further demonstrated by carrying out a worst-case risk assessment through the calculation of a TER value as set out in the modified EPPO 2010 approach and according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028).

A worst-case of potential exposure via residues in pollen and nectar can be estimated based on the default worst-case residue of 1 mg a.s./kg plant material as proposed in the EPPO 2010 scheme (see Note 6 therein), based on a database of measured values from aerial plant parts, as a surrogate for nectar and pollen.

The default residues can then be combined with a measure of consumption in order to estimate the exposure. Worst-case data from Rortais et al., 2005¹, as proposed in the EPPO scheme, have been used to estimate the consumption by bee larvae:

Worker larvae consuming 59.4 mg sugar in 5 days. Assuming 30% sugar content of nectar, the worst-case consumption for worker larvae is:

$$59.4/0.30 = 198 \text{ mg nectar in 5 days.}$$

In addition worker larvae are considered to consume 2 mg pollen during their development phase (EFSA 2013).

Thus considering the mean RUD values for nectar and pollen in EFSA 2013, exposure can be estimated for the whole development period. With an application rate of 156g boscalid/ha and 156g prothioconazole/ha (corresponding with 893 g GLOB2021dF/ha) this results into an exposure of nectar and pollen as follows:

Boscalid

¹ Agnès RORTAIS, Gérard ARNOLD, Marie-Pierre HALM, Frédérique TOUFFET-BRIENS (2005). Modes of honeybees exposure to systemic insecticides: estimated amounts of contaminated pollen and nectar consumed by different categories of bees. Apidologie 36 (2005) 71–83

Nectar dose: $0.125 \times 2.9 \times 198/1000 = 0.0718 \mu\text{g as/larva}$
Pollen dose: $0.125 \times 6.1 \times 2/1000 = 0.00153 \mu\text{g as/larva}$

Prothioconazole

Nectar dose: $0.125 \times 2.9 \times 198/1000 = 0.0718 \mu\text{g as/larva}$
Pollen dose: $0.125 \times 6.1 \times 2/1000 = 0.00153 \mu\text{g as/larva}$

GLOB2021dF

Nectar dose: $0.893 \times 2.9 \times 198/1000 = 0.5128 \mu\text{g as/larva}$
Pollen dose: $0.893 \times 6.1 \times 2/1000 = 0.0109 \mu\text{g as/larva}$

Total exposure ETE = $0.0733 \mu\text{g boscalid and prothioconazole /larvae}$ and $0.5237 \mu\text{g GLOB2021dF}$ (as a default worst-case residue at $0.125 \text{ kg boscalid and prothioconazole/ha}$ and $0.893 \text{ kg GLOB2021dF/ha}$)

This can be compared to the larval NOED of $>15.6 \mu\text{g boscalid/larva}$, $15.6 \mu\text{g prothioconazole/larva}$ and $100 \mu\text{g GLOB2021dFF/larva}$.

Boscalid

~~TER = NOEDD ($\mu\text{g/larva}$) / ETE ($\mu\text{g/larva}$) = $15.6/0.0733 = 212.82$~~

Prothioconazole

~~TER = NOEDD ($\mu\text{g/larva}$) / ETE ($\mu\text{g/larva}$) = $15.6/0.0733 = 212.82$~~

GLOB2021dF

TER = NOEDD ($\mu\text{g/larva}$) / ETE ($\mu\text{g/larva}$) = $100/0.5237 = 190.95$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the chronic risk to honey bees. It is clear that with a TER value of 212.82 (Boscalid and prothioconazole) and of 190.95 (GLOB2021dF), the proposed uses of GLOB2021dFF pose an acceptable risk to bee larval development.

Adult chronic risk assessment

The adult chronic risk assessment is performed using the modified EPPO 2010 approach according to the ECPA proposal of 9 June 2017 (POS/17/LO/28028).

This is based upon the method of EPPO 2010 risk assessment for systemic substances which is cited in the regulation as a current risk assessment scheme. It uses NOEDD values for the endpoint so avoids the issues associated with the generation of LDD₅₀ values for substances of low toxicity, and calculates exposure in a similar way to EFSA 2013. The approach is also in line with other chronic risk assessments (e.g. birds and mammals). EPPO 2010 recommended the calculation of a TER using the following equation:

TER = NOEDD/daily dose

Where daily dose (DD) is based on the worst case a sugar need of 128 mg/bee/day (Rortais *et al.*, 2005) of a bee feeding exclusively from nectar containing 30% sugar using the following equation:

Boscalid

Daily dose ($\mu\text{g a.i./bee}$) = A.R. $\times [128 \text{ mg}/(1000 \times 0.3)] \times \text{RUD} = 0.125 \times [128/(1000 \times 0.3)] \times 2.9 = 0.155 \mu\text{g/bee}$

A.R. = application rate in kg a.i./ha

RUD = residue per unit dose from the EFSA bee guidance. Mean RUDnectar = 2.9 mg a.i./kg (foliar sprays).

$$TER = NOEDD / \text{daily dose} = 12.34 / 0.155 = 79.61$$

Prothioconazole

Daily dose (µg a.i./bee) = A.R. x [128 mg/(1000 x 0.3)] x RUD = 0.125 x [128/(1000x0.3)] x 2.9 = 0.155 µg/bee

A.R. = application rate in kg a.i./ha

RUD = residue per unit dose from the EFSA bee guidance. Mean RUDnectar = 2.9 mg a.i./kg (foliar sprays).

$$TER = NOEDD / \text{daily dose} = 12.34 / 0.155 = 79.61$$

GLOB2021dF

Daily dose (µg a.i./bee) = A.R. x [128 mg/(1000 x 0.3)] x RUD = 0.893 x [128/(1000x0.3)] x 2.9 = 1.105 µg/bee

A.R. = application rate in kg a.i./ha

RUD = residue per unit dose from the EFSA bee guidance. Mean RUDnectar = 2.9 mg a.i./kg (foliar sprays).

$$TER = NOEDD / \text{daily dose} = 79.1 / 1.105 = 71.58$$

The EPPO 2010 scheme proposes a trigger of 1 for assessment of the chronic risk to honey bees. It is clear that with a TER value of 79.61 for Boscalid and prothioconazole and 71.58 for GLOB2021dF, the proposed uses of GLOB2021dF pose an acceptable chronic risk to adult bees.

9.6.3.2 Chronic risk assessment (KCP 10.3.1.1) according to EFSA 2013

Oral route of exposure (pollen and nectar)				
	"calculation factor" (Ef x SV)			
		ETR	Trigger	Risk indicator
HB - chronic	7.6	0.086	0.03	!
HB - larvae	4.4	0.04	0.2	OK

Crop Category	Application	BBCH	scenario	Ef	SV HB	TWA HB	ETR HB	trigger	Risk indicator
Oilseed rape (rapeseed)	spray DW	10 - 29	treated crop	1	5,8	0,72	0,047	0,03	!
Oilseed rape (rapeseed)	spray DW	30 - 39	treated crop	1	5,8	0,72	0,047	0,03	!
Oilseed rape (rapeseed)	spray DW	40 - 69	treated crop	1	5,8	0,72	0,047	0,03	!
Oilseed rape (rapeseed)	spray DW	10 - 29	weeds	1	2,9	0,72	0,024	0,03	OK
Oilseed rape (rapeseed)	spray DW	30 - 39	weeds	0,3	2,9	0,72	0,007	0,03	OK
Oilseed rape (rapeseed)	spray DW	40 - 69	weeds	0,25	2,9	0,72	0,006	0,03	OK
Oilseed rape (rapeseed)	spray DW	10 - 29	field margin	0,0092	2,9	0,72	0,000	0,03	OK
Oilseed rape (rapeseed)	spray DW	30 - 39	field margin	0,0092	2,9	0,72	0,000	0,03	OK
Oilseed rape (rapeseed)	spray DW	40 - 69	field margin	0,0092	2,9	0,72	0,000	0,03	OK

Oilseed rape (rapeseed)	spray DW	10 - 29	adjacent crop	0,0033	5,8	0,72	0,000	0,03	OK
Oilseed rape (rapeseed)	spray DW	30 - 39	adjacent crop	0,0033	5,8	0,72	0,000	0,03	OK
Oilseed rape (rapeseed)	spray DW	40 - 69	adjacent crop	0,0033	5,8	0,72	0,000	0,03	OK
Oilseed rape (rapeseed)	spray DW	10 - 29	next crop	1	0,54	0,72	0,004	0,03	OK
Oilseed rape (rapeseed)	spray DW	30 - 39	next crop	1	0,54	0,72	0,004	0,03	OK
Oilseed rape (rapeseed)	spray DW	40 - 69	next crop	1	0,54	0,72	0,004	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	10 - 29	treated crop	1	0,92	0,72	0,007	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	30 - 39	treated crop	1	0,92	0,72	0,007	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	40 - 69	treated crop	1	0,92	0,72	0,007	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	10 - 29	weeds	1	2,9	0,72	0,024	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	30 - 39	weeds	0,5	2,9	0,72	0,012	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	40 - 69	weeds	0,3	2,9	0,72	0,007	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	10 - 29	field margin	0,0092	2,9	0,72	0,000	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	30 - 39	field margin	0,0092	2,9	0,72	0,000	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	40 - 69	field margin	0,0092	2,9	0,72	0,000	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	10 - 29	adjacent crop	0,0033	5,8	0,72	0,000	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	30 - 39	adjacent crop	0,0033	5,8	0,72	0,000	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	40 - 69	adjacent crop	0,0033	5,8	0,72	0,000	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	10 - 29	next crop	1	0,54	0,72	0,004	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	30 - 39	next crop	1	0,54	0,72	0,004	0,03	OK
Cereals: Barley, Oats, Rice (paddy), Rye, Triticale, Wheat	spray DW	40 - 69	next crop	1	0,54	0,72	0,004	0,03	OK

An unacceptable chronic risk is observed for honey bee adults. This risk is allocated to the uses on oilseed rape for the treated crop scenario's (BBCH 10-29, 30-39, 40-69). Therefore a higher tier risk assessment is necessary for the treated crop scenario, and this is presented here below. Based on the 1st tier oral risk assessment, a potential risk could not be excluded regarding chronically exposed honey bee adults, although crop and life stage specific assumptions have been considered. This is primarily driven by very conservative default Shortcut values (SVs) for the oral exposure that are based on sugar content, food consumption and default Residue per Unit Dose (RUD) values which are proposed by the EFSA Bee GD (EFSA 2013).

However, the EFSA Bee GD (2013) offers several options to refine the risk for bees via the refinement of the exposure estimates, which lead to re-calculated SVs via the Monte-Carlo simulations. Following this, re-calculations were performed using EFSA's SHVAL tool (EFSA 2014) considering option a) the use of a refined nectar sugar content in the treated crop and option b) refined default residue levels of the active substance in adult food (nectar) via its degradation (DT_{50}) in this matrix and c) the combination of both approaches.

Approach a) Refined shortcut value based on a refined nectar sugar content

The current SVs used for the 1st tier oral risk assessment are based on a sugar concentration of 15% for the treated crop, which was considered by the EFSA Working Group as the worst-case value (i.e. nectar with the lowest sugar content from the ranges which maybe foraged by honey bees). According to the revised EFSA bee GD (2023), the SVs can be refined based on a refined sugar category for the relevant crop. For oilseed rape, a sugar content of 20% is assumed, which correlates to sugar category 2 (see Table 17, p 38; revised EFSA bee GD 2023).

The SVs were therefore refined based on a nectar sugar content of 20% using EFSA's SHVAL tool, version 1.1 (EFSA 2014). Input parameters (RUDs, consumption rates) for downward (DW) spray applications were taken from Table J4 of the EFSA Bee GD (2013). An overview of the input parameters and the results of the SV refinement are presented below.

Refined SV for the chronic oral exposure of honey bee larvae in the 'treated crop' scenario, applying EFSA's tool 'SHVAL' (EFSA 2014) using a refined sugar content

Exposed life stage	Exposure scenario	Default SV parameters						Refined SV parameters	
		Pollen consumption [mg/bee]	Sugar consumption [mg/bee]	RUDs pollen [mg/kg]	RUDs nectar [mg/kg]	Sugar content [%]	Default SV	Sugar content [%]	Refined SV
HB, adult, repeated	Treated crop, down ward spray	0	32-128	13.02 ± 1.386	2.478 ± 1.153	15	5.8	20	4.35

HB: Honey bee; SV: Shortcut value

Approach b) Refined shortcut value based on a refined DT_{50} in nectar

The default SVs, calculated with the Monte-Carlo simulations using the SHVAL tool (EFSA 2014) and used in the EFSA bee calculator tool (Bee-Tool v.3) consider that no degradation of the active substance occurs during the exposure. However, EFSA suggests that in principle field exposure studies can also be used for refining the default DT_{50} of 10 days with the SHVAL tool (which is currently not used for SV calculations). A current analysis of the EFSA publication 'Collection and analysis of pesticide residue data for pollen and nectar' (EFSA 2017) shows that reliable DT_{50} values, calculated for several active substances in pollen and nectar under natural conditions, were less than 2 days in 21 out of 24 studies (in many studies even ≤ 1 day) and approximately 4 days in single cases (3 out of 24 studies). Consequently, the publication concluded that "these values are much lower than the default value of 10 days that is used according to the EFSA GD". The latter refers to the EFSA Bee GD (EFSA 2013).

This outcome was also taken up in the revised EFSA bee GD (EFSA 2023), where a DT_{50} of 3 days for pollen and 2 days for nectar (see page 41 of the document) was concluded. Thus, a DT_{50} of 2 days for nectar was used here, to refine the SV for the chronic exposure of adult honey bees.

The resulting refined SVs for the repeated oral exposure of adult honey bees is presented in the following table and figure.

Refined SV for the repeated oral exposure of honey bee adults in the 'treated crop' scenario, applying EFSA's tool 'SHVAL' (EFSA 2014) using a refined DT_{50}

Exposed life stage	Exposure scenario	Default SV parameters						Refined SV parameters	
		Pollen consumption [mg/bee]	Sugar consumption [mg/bee]	RUDs pollen [mg/kg]	RUDs nectar [mg/kg]	Sugar content [%]	De-fault SV	DT ₅₀	Refined SV
HB, adult, repeated	Treated crop, downward spray	0	32-128	13.02 ± 1.386	2.478 ± 1.153	15	5.8	Nectar: 2 Pollen: 3	1.62

HB: Honey bee; SV: Shortcut value

Approach c) Combination of Approach a and b

Both the refined sugar content and the DT₅₀ in pollen and nectar were taken into account.

Refined SV for the repeated oral exposure of honey bee adults in the 'treated crop' scenario, applying EFSA's tool 'SHVAL' (EFSA 2014) using a refined sugar content and refined DT₅₀

Exposed life stage	Exposure scenario	Default SV parameters						Refined SV parameters		
		Pollen consumption [mg/bee]	Sugar consumption [mg/bee]	RUDs pollen [mg/kg]	RUDs nectar [mg/kg]	Sugar content [%]	De-fault SV	DT ₅₀	Sugar content (%)	Refined SV
HB, adult, repeated	Treated crop, downward spray	0	32-128	13.02 ± 1.386	2.478 ± 1.153	15	5.8	Nectar: 2 Pollen: 3	20	1.21

HB: Honey bee; SV: Shortcut value

2nd Tier oral risk assessment

The above refined SVs were used to refine the risk assessment which is presented below.

2nd tier risk assessment for the repeated oral exposure of honey bee adults based on the a refined sugar content and a DT₅₀ refinement in nectar/pollen

Crop (Crop group according to EFSA tool)	Exposure scenario	Application rate [kg product/ha]*	BBCH range according to GAP	ETR oral exposure scenario			Trigger
				1 st tier ETR based on default SV value (ratio)	2 nd tier ETR (refined SV)		
Oilseed rape	Treated crop, DW	0.893	10-29	0.047 (1.5)	a, SV 4.35	0.035	0.03
					b, SV 1.62	0.018	
					c, SV 1.21	0.014	
			30-39	0.047 (1.5)	a, SV 4.35	0.035	0.03
					b, SV 1.62	0.018	
					c, SV 1.21	0.014	
			40-69	0.047 (1.5)	a, SV 4.35	0.035	0.03
					b, SV 1.62	0.018	
					c, SV 1.21	0.014	

ETR values in bold breach the relevant trigger. DW: downwards spraying

* based on the product density of 1.1168 g/mL and an application rate of 0.8L/ha.

Based on a refined SV considering a refinement of the nectar sugar content (option a) the 2nd tier oral risk assessment determined an ETR of 0.035 a chronic risk to honey bee adults cannot be excluded for the intended use in oilseed rape considering a refinement with option a).

Considering a refined SV based on a degradation time of 2 days for nectar and 3 days for pollen (option b) results in an ETR of 0.018, demonstrating acceptable risk for the relevant uses oilseed rape according to the proposed use pattern. Taking the refined sugar content into account further reduces the chronic risk to honey bees.

9.6.4 Effects on bumblebees

9.6.4.1 Hazard quotients for bumblebees

Table 9.6-3: First-tier assessment of the risk for bumble bees due to the use of GLOB2021dF

Intended use	Group 1		
Active substance	GLOB2021dF		
Application rate (g/ha)	2 × 893 g/ha		
Test design	LD₅₀ (lab.) (µg/bee)	Single application rate (g/ha)*	Q_{HO}, Q_{HC} criterion: Q_H ≤ 50
Oral toxicity	> 100 > 96	893	< 8.93 < 9.3
Contact toxicity	> 100		< 8.93

Q_{HO}, Q_{HC}: Hazard quotients for oral and contact exposure. Q_H values shown in bold breach the relevant trigger. *Two applications of this rate without degradation were used as representative of all intended uses of GLOB2021dF.

All the hazard quotients are below 50, indicating that the application of GLOB2021dF poses a low acute risk to bumble bees.

9.6.4.1 Acute risk assessment (KCP 10.3.1.1) to bumblebees according to EFSA 2013

Contact & Oral route of exposure (pollen and nectar)				
	"calculation factor" (linked with dust)	HQ	Trigger	Risk indicator
BB – acute: contact	1	8.9	7	!
	"calculation factor" (Ef x SV)	ETR	Trigger	Risk indicator
BB – acute: oral	11.2	0.10	0.036	!

An unacceptable acute risk is observed for bumblebees. This risk is allocated to the uses on oilseed rape for the treated crop scenario's (BBCH 10-29, 30-39, 40-69), oilseed rape and cereals for the weeds scenario (BBCH 10-29). Therefore a higher tier risk assessment is necessary for the treated crop scenario, and this is presented here below. Based on the 1st tier oral risk assessment, a potential risk could not be excluded regarding chronically exposed honey bee adults, although crop and life stage specific assumptions have been considered. This is primarily driven by very conservative default Shortcut values (SVs)

for the oral exposure that are based on sugar content, food consumption and default Residue per Unit Dose (RUD) values which are proposed by the EFSA Bee GD (EFSA 2013). However, the EFSA Bee GD (2013) offers several options to refine the risk for bees via the refinement of the exposure estimates, which lead to re-calculated SVs via the Monte-Carlo simulations. Following this, re-calculations were performed using EFSA's SHVAL tool (EFSA 2014) considering option a) the use of a refined nectar sugar content in the treated crop and option b) refined default residue levels of the active substance in adult food (nectar) via its degradation (DT_{50}) in this matrix and c) the combination of both approaches.

Approach a) Refined shortcut value based on a refined nectar sugar content

The current SVs used for the 1st tier oral risk assessment are based on a sugar concentration of 15% for the treated crop, which was considered by the EFSA Working Group as the worst-case value. According to the revised EFSA bee GD (2023), the SVs can be refined based on a refined sugar category for the relevant crop. For oilseed rape, a sugar content of 20% is assumed, which correlates to sugar category 2 (see Table 17, p 38; revised EFSA bee GD 2023).

The SVs were therefore refined based on a nectar sugar content of 20% using EFSA's SHVAL tool, version 1.1 (EFSA 2014). Input parameters (RUDs, consumption rates) for downward (DW) spray applications were taken from Table J4 of the EFSA Bee GD (2013). An overview of the input parameters and the results of the SV refinement are presented below.

Refined SV for the acute exposure of bumblebees, applying EFSA's tool 'SHVAL' (EFSA 2014) using a refined sugar content

Exposed life stage	Exposure scenario	Default SV parameters						Refined SV parameters	
		Pollen consumption [mg/bee]	Sugar consumption [mg/bee]	RUDs pollen [mg/kg]	RUDs nectar [mg/kg]	Sugar content [%]	Default SV	Sugar content [%]	Refined SV
BB, adult, acute	Treated crop, downward spray	0	111-149	13.02 ± 1.386	2.478 ± 1.153	15	11.2	20	8.91

BB: Bumblebee; SV: Shortcut value

Approach b) Refined shortcut value based on a refined DT_{50} in nectar

The default SVs, calculated with the Monte-Carlo simulations using the SHVAL tool (EFSA 2014) and used in the EFSA bee calculator tool (Bee-Tool v.3) consider that no degradation of the active substance occurs during the exposure. However, EFSA suggests that in principle field exposure studies can also be used for refining the default DT_{50} of 10 days with the SHVAL tool (which is currently not used for SV calculations). A current analysis of the EFSA publication 'Collection and analysis of pesticide residue data for pollen and nectar' (EFSA 2017) shows that reliable DT_{50} values, calculated for several active substances in pollen and nectar under natural conditions, were less than 2 days in 21 out of 24 studies (in many studies even ≤ 1 day) and approximately 4 days in single cases (3 out of 24 studies). Consequently, the publication concluded that "these values are much lower than the default value of 10 days that is used according to the EFSA GD". The latter refers to the EFSA Bee GD (EFSA 2013). This outcome was also taken up in the revised EFSA bee GD (EFSA 2023), where a DT_{50} of 3 days for pollen and 2 days for nectar (see page 41 of the document) was concluded. Thus, a DT_{50} of 2 days for nectar was used here, to refine the SV for the chronic exposure of adult honey bees. The resulting refined SVs for the repeated oral exposure of adult honey bees is presented in the following table and figure.

Refined SV for the acute exposure of bumblebees, applying EFSA's tool 'SHVAL' (EFSA 2014) using a refined DT_{50}

Exposed life stage	Exposure scenario	Default SV parameters						Refined SV parameters	
		Pollen consumption [mg/bee]	Sugar consumption [mg/bee]	RUDs pollen [mg/kg]	RUDs nectar [mg/kg]	Sugar content [%]	De-fault SV	DT ₅₀	Refined SV
BB, adult, acute	Treated crop, downward spray	0	111-149	13.02 ± 1.386	2.478 ± 1.153	15	11.2	Nectar: 2 Pollen: 3	3.36

BB: Bumblebee; SV: Shortcut value

Approach c) Combination of Approach a and b

Both the refined sugar content and the DT₅₀ in pollen and nectar were taken into account. This approach is also considered for the weed scenario's as the default SV for weeds is already based on a refined sugar content.

Refined SV for acute exposure of bumblebees, applying EFSA's tool 'SHVAL' (EFSA 2014) using a refined sugar content and refined DT₅₀

Exposed life stage	Exposure scenario	Default SV parameters						Refined SV parameters		
		Pollen consumption [mg/bee]	Sugar consumption [mg/bee]	RUDs pollen [mg/kg]	RUDs nectar [mg/kg]	Sugar content [%]	De-fault SV	DT ₅₀	Sugar content (%)	Refined SV
BB, adult, acute	Treated crop, downward spray	0	111-149	13.02 ± 1.386	2.478 ± 1.153	15	11.2	Nectar: 2 Pollen: 3	20	2.73
BB, adult, acute	Weeds, downward spray	0	111-149	13.02 ± 1.386	2.478 ± 1.153	30	11.2	Nectar: 2 Pollen: 3	30	2.09

BB: Bumblebee; SV: Shortcut value

2nd Tier oral risk assessment

The above refined SVs were used to refine the risk assessment which is presented below.

2nd tier risk assessment for the repeated oral exposure of bumblebees based on a refined sugar content and a DT₅₀ refinement in nectar/pollen

Crop (Crop group according to EFSA tool)	Exposure scenario	Application rate [kg product/ha]*	BBCH range according to GAP	ETR oral exposure scenario		Trigger
				1 st tier ETR based on default SV value (ratio)	2 nd tier ETR (refined SV)	
Oilseed rape	Treated crop, DW	0.893	10-29	0.1 (2.8)	a, SV 8.91	0.080
					b, SV 3.36	0.030
					c, SV 2.73	0.024
			30-39	0.1 (2.8)	a, SV 8.91	0.080
					b, SV 3.36	0.030

					c, SV 2.73	0.024	
			40-69	0.1 (2.8)	a, SV 8.91	0.080	
					b, SV 3.36	0.030	0.036
					c, SV 2.73	0.024	
	Weeds, DW	0.893	10-29	0.0580 (1.6)	c, SV 2.09	0.019	0.036
Cereals	Weeds, DW	0.893	10-29	0.0580 (1.6)	c, SV 2.09	0.019	0.036

ETR values in bold breach the relevant trigger. DW: downwards spraying

* based on the product density of 1.1168 g/mL and an application rate of 0.8L/ha.

Based on a refined SV considering a refinement of the nectar sugar content (option a) the 2nd tier oral risk assessment determined an ETR of 0.080, an acute risk to bumblebees cannot be excluded for the intended use in oilseed rape considering a refinement with option a).

Considering a refined SV based on a degradation time of 2 days for nectar and 3 days for pollen (option b) results in an ETR of 0.030, demonstrating acceptable risk for the relevant uses oilseed rape according to the proposed use pattern. Taking the refined sugar content into account further reduces the chronic risk to bumblebees. The weeds scenario's also show an acceptable risk with approach c in both oilseed rape and in cereals.

9.6.5 Effects on solitary bees

No data/information available.

9.6.6 Overall conclusions

HQ values for oral and dermal exposure are below the relevant trigger. Therefore, it can be assumed that the intended uses of GLOB2021dF represent low acute risk exposure to honeybees and bumblebee.

The chronic TERs for honey bee adults and larvae are higher than the trigger of 1, indicating that the proposed uses according to the intended GAP of GLOB2021dF poses an acceptable chronic risk to honey bee larvae and adults.

Based on the EFSA 2013 guidance for the risk assessments on bees, the use of the proposed refinements results in an acceptable risk towards bees.

zRMS comments:

The evaluation of the risk for bees was performed in accordance with the recommendations of the "Guidance The submitted risk assessment is based on the recommendations of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2) and new EU guidance (2013).

The EU agreed endpoints for active substance were used in risk assessment. The acute toxicity data for boscalid and prothioconazole are in line with EU agreed endpoints reported in EFSA Scientific Report (2008) and EFSA Scientific Report (2007).

In addition to that, the Applicant submitted studies on chronic toxicity of formulation Pirlanko (GLOB2021dF) to adult bees and larvae. New studies were accepted. Therefore, the requirements set out in Regulation 284/2013 are considered fulfilled.

The acute risk assessment performed in accordance with the SANCO guidance presented by the Applicant was accepted.

There is currently no EU agreed chronic risk assessment scheme for bees. However, as agreed in the Central Zone a risk assessment based on the EFSA bee GD is presented below for illustrative purposes. It should be noted that according to conclusions of the Central Zone Harmonization Meeting in Warsaw in 2023, the chronic risk assessment according to recommendations of EFSA (2013) for adult and larvae bees should be presented for the zonal evaluations.

zRMS is aware that the new EFSA bee GD is not yet noted by the MSs, nonetheless several MS (partially) use it. This is in line with PRAS 133 (2015) and CZ guidance, stating that it is recommended to perform the first tier of the honeybee risk assessment following the EFSA (2013) Bee GD with available data.

Therefore, the screening and first Tier of EFSA risk assessment according to the guidance document (2013) was included by the Applicant and evaluated by zRMS.

Based on the results above acceptable chronic oral risks to adult honey bees for uses in cereals, for all relevant scenarios and BBCH growth stages was demonstrated.
For uses in oilseed rape an acceptable risk was demonstrated for all relevant scenarios and BBCH growth stages, **except** for all growth stages of the scenario “**treated crop**”.

Risk assessment based on EFSA (2013) is provided above for informative purposes only and is not the basis for derivation of conclusion regarding the risk to bees at the zonal level. Further refinement of risk assessment based on indications of EFSA (2013) must be performed at the national level by cMS that do require such evaluation. Proposed further refinement (2nd Tier) has not been evaluated by zRMS. Therefore, further refinement is required at MSs level depend on their own requirements.

Final decision should be taken into account at MSs level.

In case of Poland, the chronic risk is not required until relevant EFSA Bee GD will implemented.

An acceptable risk to bees of the formulation Pirlanko (GLOB2021dF) can be concluded, based on the risk assessment scheme of the Guidance Document on Terrestrial Ecotoxicology (SANCO/10329/2002 rev 2).

The GAP change for oilseed rape from BBCH 61 to 69 does not impact the risk assessment for bees.

9.7 Effects on arthropods other than bees (KCP 10.3.2)

9.7.1 Toxicity data

Studies on the toxicity to non-target arthropods have been carried out with boscalid and prothioconazole. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target arthropods of GLOB2021dF were not evaluated as part of the EU assessment of boscalid and prothioconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The risk assessment is performed for both the use in oilseed rape and in cereals as this represents the worst case use due to the highest dose rate of 2 x 0.8 L GLOB2021dF/ha.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.7-1: Endpoints and effect values relevant for the risk assessment for non-target arthropods

Species	Substance	Exposure System	Results	Reference
<i>Typhlodromus pyri</i>	BAS 510 01 F (Boscalid 50%)	Laboratory test Glass plates (2D) 14 d	LR ₅₀ > 1800 g a.s./ha	EFSA 2008
<i>Aphidius rhopalosiphi</i>	BAS 510 01 F (Boscalid 50%)	Laboratory test Glass plates (2D) 48 h	LR ₅₀ > 1800 g a.s./ha	EFSA 2008
<i>Typhlodromus pyri</i>	BAS 510 01 F (Boscalid 50%)	Extended laboratory test Glass plates (2D) 14 d	Mortality (after 1 week): 0% at 1800 g a.s./ha Fertility (after 4 weeks): 3% at 1800 g a.s./ha	EFSA 2008
<i>Aphidius rhopalosiphi</i>	BAS 510 01 F (Boscalid 50%)	Extended laboratory test Glass plates (2D) 48 h	Mortality (after 1 week): 11% at 1800 g a.s./ha Fertility (after 4 weeks): 34% at 1800 g a.s./ha	EFSA 2008
<i>Typhlodromus pyri</i> (larvae/adults)	EC 250	Laboratory test, coffin cells, 14 d	LR ₅₀ = 18.7 g/ha	EFSA 2007
<i>Typhlodromus pyri</i> (larvae/adults)	EC 250	Ext. lab., lean leaves, 14 d	LR ₅₀ = 445.5 g/ha	EFSA 2007
<i>Typhlodromus pyri</i> (larvae/adults)	EC 250	Ext., lab., aged residues, bean leaves, 300 g a.s./ha, exposure 14 d (each test) Test started 1 day after appl Test started 15 days after appl.	Mortality Repro 14.5% 7.5% 6.4% -28.8%	EFSA 2007
<i>Aphidius rhopalosiphi</i> (adults)	EC 250	Lab., glass plates, 14 d	LR ₅₀ = 139.9 g/ha	EFSA 2007
<i>Aphidius rhopalosiphi</i> (adults)	EC 250	Ext. lab., wheat plants	48 h mortality <5% in any of test concentrations.	EFSA 2007
<i>Typhlodromus pyri</i>	GLOB2021dF	Extended lab.	LR ₅₀ = 800 mL/ha LR ₅₀ > 1200 mL/ha ER ₅₀ = 900 mL/ha	Orovecz B., 2023a
<i>Aphidius rhopalosiphi</i>	GLOB2021dF	Extended lab. (3 D)	LR ₅₀ mortality => 1200 mL/ha ER ₅₀ repro => 1200 mL/ha	Orovecz B., 2023b
<i>Chrysoperla carnea</i>	GLOB2021dF	Extended lab., 49 d	LR ₅₀ = 2180.1mL/ha	Kubisiak K., 2023b

Species	Substance	Exposure System	Results	Reference
<i>Coccinella septempunctata</i>	GLOB2021dF	Extended lab., 21 d	LR ₅₀ = 594.64 mL/ha	Domagala J., 2023a
<i>Coccinella septempunctata</i>	GLOB2021dF	Aged residue, 28 d	Rate with ≤ 50 % effect (g/ha) at 28 DALT: 1400 mL/ha (1563.5 g/ha)	Domagala J., 2023b
Field or semi-field tests				

9.7.1.1 Justification for new endpoints

As the formulation is a mixture of two active ingredients, toxicity to non-target arthropods from the formulation was tested and used in the risk assessment.

9.7.2 Risk assessment

The evaluation of the risk for non-target arthropods 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), and in consideration of the recommendations of the guidance document ESCORT 2.

9.7.2.1 Risk assessment for in-field exposure

Non-target arthropods living in the crop can be exposed to residues from GLOB2021dF by direct contact either as a result of overspray or through contact with residues on plants and soil or in food items. GLOB2021dF is applied at a maximum rate of 2 x 0.8 L formulation/ha with a 15 day interval in oilseed rape and cereals.

The in-field exposure (predicted environmental residue, PER) is calculated according to ESCORT 2 using the following equation:

$$PER_{in-field} = Application\ rate\ (L\ fp/ha) \times MAF$$

The MAF is a generic multiple application factor, which is used to take into account the potential build-up of applied substances between applications based on the application interval, DT₅₀ value and number of applications. Default foliar and soil MAF values following two applications are given in the ESCORT 2 Guidance Document. This leads to a MAF of 1.7 and 1.9 soil for leaf-dwelling and soil-dwelling arthropods respectively for 2 applications every 15 days in oilseed rape and cereals.

The potential risk of GLOB2021dF to in-field non-target arthropods was assessed by calculation of the hazard quotient (HQ = exposure/toxicity) with the predicted environmental rate (PER) and the lowest lethal rate (LR₅₀) values according to the following formula:

$$\text{In field HQ} = \frac{\text{In-field PER}}{LR_{50}}$$

Table 9.7-2: First- and higher-tier assessment of the in-field risk for non-target arthropods due to the use of GLOB2021dF in oilseed rape

Intended use	Oilseed rape and cereals		
Active substance/product	Boscalid and prothioconazole / GLOB2021dF		
Application rate (g/ha)	2 × 0.8		
MAF	1.7 for 2 applications (default value) for leaf-dwelling arthropods		
Test species Tier II	LR₅₀ (lab.) (L/ha)	PER_{in-field} (L/ha)	HQ_{in-field} criterion: HQ ≤ 21
<i>Typhlodromus pyri</i>	0.8	1.36	1.7
<i>Aphidius rhopalosiphi</i>	1.2	1.36	1.13
<i>Coccinella septempunctata</i>	0.594	1.36	2.29
<i>Chrysoperla carnea</i>	2.180	1.36	0.62
Test species Higher-tier	Rate with ≤ 50 % effect* (L/ha)	PER_{in-field} (Lg/ha)	PER_{in-field} below rate with ≤ 50 % effect?
<i>Coccinella septempunctata</i>	1.4	1.36	yes

MAF: Multiple application factor; PER: Predicted environmental rate; HQ: Hazard quotient; DALT: Days after last treatment. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.2 Risk assessment for off-field exposure

Risk assessment of areas immediately surrounding the crop is considered important since these areas represent a natural reservoir for immigration, emigration and reproduction of arthropod populations and provide increased species diversity. Exposure of non-target arthropods living in off-field areas to GLOB2021dF will mainly be due to spray drift from field applications. Off-field areas are assumed to be densely vegetated and thus spray drift is unlikely to reach bare ground. Therefore, evaluation of exposure via soil residues in off-field areas was not considered. Off-field foliar PER values were calculated from in-field foliar PERs in conjunction with drift values published by the BBA (2000)² as shown in the following equation:

$$\text{Off- field foliar PER} = \frac{\text{Maximum in-field foliar PER} \times (\% \text{ drift}/100)}{\text{vegetation distribution factor}}$$

Vegetation distribution factor: The model used to estimate spray drift was developed for drift onto a two-dimensional water surface and, as such, does not account for interception and dilution by three-dimensional vegetation in off-crop areas. Therefore, a vegetation distribution or dilution factor is incorporated into the equation when calculating PERs to be used in conjunction with toxicity endpoints derived from two-dimensional (glass plate or leaf disc) studies. A dilution factor of 10 is recommended by ESCORT 2. For 3-dimensional studies, i.e. where spray treatment is applied onto whole plants, the dilution factor of 10 is not used, as any dilution over the 3-dimensional vegetation surface is accounted for in the study design.

² 90th percentile drift according to BBA (2000): Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden

The drift value at 1 m distance in field crops such as oilseed rape and cereals is 2.77% of the application rate (90th percentile drift). The drift factor (% drift/100) is therefore 0.0277 (2.77/100).

In order to assess the potential risk of GLOB2021dF to off-field non-target arthropods, the predicted environmental rate (Table 9.7-2) is compared with the toxicity endpoints according to the following formula:

$$\text{Off-field HQ} = \frac{PER_{\text{off-field}} \text{ (g/ha)}}{LR_{50} \text{ (g/ha)}} \times \text{Correction factor}$$

Correction factor: ESCORT 2 recommends that a correction factor of 5 be used when assessing Tier II data, or 10 for Tier I data, to account for extrapolation from testing just 2 representative species, to the species diversity expected in off-crop areas.

Table 9.7-3: First- and higher-tier assessment of the off-field risk for non-target arthropods due to the use of GLOB2021dF in oilseed rape and cereals

Intended use		Oilseed rape and cereals			
Active substance/product		Boscalid and prothioconazole / GLOB2021dF			
Application rate (g/ha)		2 × 0.8 L/ha every 15 days			
MAF		1.7 for 2 applications (default value) for leaf-dwelling arthropods			
vdf		105 (2D) / 1 (3D)			
Test species Tier II	LR₅₀ (lab.) (L/ha)	Drift rate	PER_{off-field} (Lg/ha)	CF	HQ_{off-field} criterion: HQ ≤ 21
<i>Typhlodromus pyri</i>	0.8	0.0277 0.0238	0.0377 0.00377 0.006474	5	0.24 0.024 0.04
<i>Aphidius rhopalosiphi</i>	1.2		0.0377 0.006474		0.16 0.016 0.0065
<i>Coccinella septempunctata</i>	0.594		0.0377 0.00377 0.006474		0.32 0.032 0.015
<i>Chrysoperla carnea</i>	2.180				0.09 0.009 0.015
Test species Higher-tier	Rate with ≤ 50 % effect* (L/ha)	Drift rate	PER_{off-field} (Lg/ha)	CF	PER_{in-field} below rate with ≤ 50 % effect?
<i>Coccinella septempunctata</i>	1.4	0.0277 0.0238	0.0377 0.00377 0.006474	5	yes

MAF: Multiple application factor; vdf: Vegetation distribution factor; (corr.) PER: (corrected) Predicted environmental rate; CF: Correction factor; HQ: Hazard quotient. Criteria values shown in bold breach the relevant trigger.

* If an LR₅₀ or ER₅₀ from a relevant extended laboratory test is available, it should be considered in place of the rate with ≤ 50 % effect.

9.7.2.3 Additional higher-tier risk assessment

Not relevant.

9.7.2.4 Risk mitigation measures

No risk mitigation needed.

9.7.3 Overall conclusions

The risk assessment indicates that the risk for non-target arthropods is acceptable for the intended use of GLOB2021dF.

zRMS Comments:	The submitted risk assessment based on the “Guidance Document on Terrestrial Ecotoxicology” (2002) was accepted. The laboratory studies 2D and 3D for <i>Aphidius rhopalosiphi</i>, <i>Typhlodromus pyri</i>, <i>Coccinella septempunctata</i> and <i>Chrysoperla carnea</i> are submitted and accepted for risk assessment. In field risk The hazard quotients are below the trigger value ($HQ \leq 1$) for <i>Aphidius rhopalosiphi</i>, <i>Typhlodromus pyri</i> and <i>Chrysoperla carnea</i>. For <i>Aphidius rhopalosiphi</i>, <i>Typhlodromus pyri</i> and <i>Coccinella septempunctata</i> the $HQ > 1$ therefore the higher tier assessment was required. Effects at the highest application rate x MAF are below 50% since the resulting HQ value would be < 2 for <i>Coccinella septempunctata</i>, therefore low risk to in-field habitat has been demonstrated. Off-field risk The hazard quotients are below the trigger value ($HQ \leq 1$) for all species indicating that the formulation GLOB2021dF poses an acceptable risk to arthropods other than bees. The hazard quotients for in-field and off-field risk to terrestrial arthropods other than bees are below the trigger value, indicating that the formulation poses an acceptable risk.
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The GAP change for oilseed rape from BBCH 61 to 69 does not impact the risk assessment for non-target arthropods.

9.8 Effects on non-target soil meso- and macrofauna (KCP 10.4)

9.8.1 Toxicity data

Studies on the toxicity to earthworms and other non-target soil organisms (meso- and macrofauna) have been carried out with Boscalid and prothioconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on earthworms and other non-target soil organisms (meso- and macrofauna) of GLOB2021dF were

not evaluated as part of the EU assessment of boscalid or prothioconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

Table 9.8-1: Endpoints and effect values relevant for the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna)

Species	Substance	Exposure System	Results	Reference
<i>Eisenia fetida</i>	Boscalid	14 d, acute	LC ₅₀ > 1000 mg a.s./kg dw LC_{50,corr} > 500 mg a.s./kg dw*	SANCO/3919 /2007- rev. 5
<i>Eisenia fetida</i>	BAS 510 01 F (Boscalid 500 g/kg)	14 d, acute	LC ₅₀ > 1000 mg prod./kg dw LC _{50, corr} > 500 mg prod./kg dw*	SANCO/3919 /2007- rev. 5
<i>Eisenia fetida</i>	BAS 510 01 F (Boscalid 500 g/kg)	56 d, chronic	NOEC = 3.6 kg prod./ha NOEC _{corr} = 1.8 kg prod./ha* NOEC_{corr} = 1.197 mg a.s./kg dw*	SANCO/3919 /2007- rev. 5
<i>Folsomia candida</i>	BAS 510 01 F (Boscalid 500 g/kg)	28 d, chronic	NOEC (reproduction) >1000 mg BAS 510 01 F /kg soil (>500 mg a.s./kg soil) NOEC_{corr} >500 mg BAS 510 01 F /kg soil* (>250 mg a.s./kg soil*)	Monograph Boscalid, 2002
<i>Eisenia fetida</i>	Prothioconazole	14 d, acute	LC ₅₀ >1000 mg as/kg dw LC _{50corr} >500 mg as/kg dw*	EFSA (2007)
<i>Eisenia fetida</i>	Prothioconazole-desthio	14 d, acute	LC ₅₀ > 1000 mg met/kg soil LC _{50corr} > 500 mg met/kg soil*	EFSA (2007)
<i>Eisenia fetida</i>	Prothioconazole-S-methyl	14 d, acute	LC ₅₀ > 1000 mg met/kg soil LC _{50corr} > 500 mg met/kg soil*	EFSA (2007)
<i>Eisenia fetida</i>	Prothioconazole**	56 d, chronic (artificial substrate)	NOEC = 1.33 mg/kg soil NOEC _{corr} = 0.67 mg/kg soil*	EFSA (2007)
<i>Eisenia fetida</i>	Prothioconazole-desthio	56 d, chronic (artificial substrate)	NOEC = 1 mg/kg soil NOEC _{corr} = 0.50 mg/kg soil*	EFSA (2007)
<i>Eisenia fetida</i>	Prothioconazole-S-methyl	56 d, chronic (artificial substrate)	NOEC = 100 mg/kg soil	EFSA (2007)

Species	Substance	Exposure System	Results	Reference
			NOEC _{corr} = 50 mg/kg soil*	
<i>Folsomia candida</i>	Prothioconazole	Mixed into substrate chronic	NOEC = 64mg as/kg dw NOEC _{corr} = 32 mg/kg dw*	EFSA (2007)
<i>Folsomia candida</i>	Prothioconazole-desthio	Mixed into substrate chronic	NOEC = 62.5 mg met/kg dw NOEC _{corr} = 31.25 mg met/kg dw*	EFSA (2007)
<i>Folsomia candida</i>	Prothioconazole-S-methyl	Mixed into substrate chronic	NOEC = 31.6 mg met/kg dw NOEC _{corr} = 15.8 mg met/kg dw*	EFSA (2007)
<i>Hypoaspis aculeifer</i>	Prothioconazole	Mixed into substrate chronic	NOEC = 100 mg as/kg dw NOEC _{corr} = 50 mg/kg dw*	EFSA (2007)
<i>Eisenia fetida</i>	GLOB2021dF	Mortality	NOEC = 1000 mg fp/kg dw	Orosz I., 2023d
<i>Eisenia fetida</i>	GLOB2021dF	56 d, chronic (reproduction)	NOEC = 125 mg fp/kg dw EC ₁₀ = 47 mg test item/kg soil dry weight	Orosz I., 2023d
<i>Folsomia candida</i>	GLOB2021dF	28 d, chronic (reproduction)	NOEC = 309 mg fp/kg dw	Orosz I., 2023e
<i>Hypoaspis aculeifer</i>	GLOB2021dF	Mortality	LC ₅₀ >1000 mg/kg soil dry weight NOEC ≥ 1000 mg/kg soil dry weight	Orosz I., 2023f
<i>Hypoaspis aculeifer</i>	GLOB2021dF	16 d, chronic (reproduction)	EC ₅₀ >1000 mg/kg soil dry weight NOEC ≥ 1000 mg/kg soil dry weight	Orosz I., 2023f
Field studies				
- <i>Lumbricius terrestris</i> , <i>L. rubellus</i> , <i>L. castanea</i> , <i>Aporrectodea caliginosa</i> , <i>A. terrestris longa</i>	EC 250	field study (grassland site)	3 × 200 g a.s./ha 5 different species identified and assessed. 46% reduction in the number of <i>A. caliginosa</i> juveniles 7 weeks after first	EFSA Scientific Report (2007) 106, 1-98

Species	Substance	Exposure System	Results	Reference
			application (2 weeks after final application). No adverse effect 5 month after first application. (Maximum measured soil PEC 0.052 mg prothioconazole/kg based on soil sampling depth of 10 cm which is equivalent to a soil PEC of 0.104 mg prothioconazole/kg over the standard 5 cm depth)	
Litter bag test				
Not required				

* Corrected value derived by dividing the endpoint by a factor of 2 in accordance with the EPPO earthworm scheme 2002.

9.8.1.1 Justification for new endpoints

As the formulation is a mixture of two active ingredients, toxicity to non-target soil meso- and macrofauna from the formulation was tested and used in the risk assessment.

9.8.2 Risk assessment

The evaluation of the risk for earthworms and other non-target soil organisms (meso- and macrofauna) 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).

9.8.2.1 First-tier risk assessment

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 – 8.7-11. According to the assessment of environmental-fate data, multi-annual accumulation in soil is considered for boscalid but not for prothioconazole.

Table 9.8-2: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of GLOB2021dF in oilseed rape

Intended use	Oilseed rape multiple application		
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _a (criterion TER ≥ 10)
Boscalid	> 500	0.1844 0.1405*	>2711.49 >3559*

Prothioconazole	> 500	0.2000 0.0340* 0.100***	>2500 14706 5000
Prothioconazole-desthio	> 500	0.0712 0.0608*	7022.47 8224
Prothioconazole-S-methyl	> 500	0.0203 0.0163*	24630.54 30675
GLOB2021dF	1000 500corr	0.7148 1.4295* 0.953***	1398 350 545
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Boscalid	1.197	0.1844 0.1405*	6.49 8.52
Prothioconazole	0.67	0.0667 0.0340* 0.1000***	10.04 19.71 6.7
Prothioconazole-desthio	0.5	0.0712 0.0608*	7.02 8.22
Prothioconazole-S-methyl	50	0.0203 0.0163*	2463.05 3067
GLOB2021dF	125(based on NOEC) 62.5corr 47 (based on EC ₁₀) 23.5corr	0.7148 1.4295* 0.953***	174.87 44 66 25
Chronic effects on other soil macro- and mesofauna			
Collembola			
Product/active substance	NOEC (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Boscalid	>250	0.1844 0.1405*	1355.75 1779
Prothioconazole	65 64 32corr	0.2000 0.0340* 0.1000***	325 941 320
Prothioconazole-desthio	62.5 31.25corr	0.0712 0.0608*	877.81 514
Prothioconazole-S-methyl	> 31.6 15.8corr	0.0203 0.0163*	1556.65 969
GLOB2021dF	309 154.5corr	0.7148 1.4295* 0.953***	432.29 108 162
<i>Hypoaspis aculeifer</i>			
Product/active substance	NOEC (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)

Boscalid	-	0.1844 0.1405*	-
Prothioconazole	> 100 50corr	0.2000 0.0340* 0.1000***	> 500 >1471 >500
Prothioconazole-desthio	> 100 10**	0.0712 0.0608*	>1404.50 >164
Prothioconazole-S-methyl	> 100 10**	0.0203 0.0163*	>4926.11 >613
GLOB2021dF	1000 500corr	0.7148 1.4295* 0.953***	1398 350 52

TER values shown in bold fall below the relevant trigger.

*correct value according to Part B8

**The EU agreed endpoint not available therefore are considered 10 time more toxic then the parent

*** correct value according to Part B8 after commenting period

Table 9.8-3: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of GLOB2021dF in oilseed rape

Intended use	Oilseed rape, single application		
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _a (criterion TER ≥ 10)
Boscalid	> 500	0.1435 0.1109*	>348 >4509
Prothioconazole	> 500	0.0667 0.1000*	7496.25 >5000
Prothioconazole-desthio	> 500	0.0534 0.0524*	>9363.30 >9542
Prothioconazole-S-methyl	> 500	0.0153 0.0152*	>32679.74 >32895
GLOB2021dF	1000 500corr	0.7148 1.4295* 0.7148***	1398 350 699
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Boscalid	1.197	0.1435 0.1109*	8.34 10.79
Prothioconazole	0.67	0.0667 0.1000*	10.04 6.7
Prothioconazole-desthio	0.5	0.0534 0.0524*	9.36 9.54
Prothioconazole-S-methyl	50	0.0153 0.0152*	3267.97 3289

GLOB2021dF	125(based on NOEC) 62.5corr 47 (based on EC ₁₀) 23.5corr	0.7148	174.87 87.44 32.18
Chronic effects on other soil macro- and mesofauna			
Collembola			
Product/active substance	NOEC (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Boscalid	>250	0.1435 0.1109*	1742.16 >2254
Prothioconazole	> 65 32corr	0.2000 0.1000*	325.00 320
Prothioconazole-desthio	62.5 31.25corr	0.0534 0.0524*	1170.41 2056
Prothioconazole-S-methyl	> 31.6 >15.8corr	0.0153 0.0152*	2065.36 >1039
GLOB2021dF	309 154.5corr	0.7148	432.29 216
<i>Hypoaspis aculeifer</i>			
Product/active substance	NOEC (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Boscalid	-	0.1435 0.1109*	-
Prothioconazole	> 100 >50corr	0.2000 0.1000*	> 500
Prothioconazole-desthio	>100 10**	0.0534 0.0524*	>1872.66 191
Prothioconazole-S-methyl	>100 10**	0.0153 0.0152*	>6535.95 658
GLOB2021dF	1000 500corr	0.7148	1398 699

TER values shown in bold fall below the relevant trigger.

*correct value according to Part B8

**The EU agreed endpoint not available therefore are considered 10 time more toxic then the parent

*** correct value according to Part B8 after commenting period

Table 9.8-4: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of GLOB2021dF in cereals

Intended use	cereals multiple application		
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _a (criterion TER ≥ 10)

Boscalid	> 500	0.0934 0.2320* 0.1752***	5353.32 2155 3289
Prothioconazole	> 500	0.0667 0.0340* 0.1333***	7496.25 14706 3751
Prothioconazole-desthio	> 500	0.0356 0.0752*	14044.94 6649
Prothioconazole-S-methyl	> 500	0.0102 0.0203*	49019.61 24631
GLOB2021dF	1000 500corr	0.2383 0.4765* 1.191***	4196.39 1049 420
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Boscalid	1.197	0.1844 0.2320* 0.1752***	12.82 5.2 6.8
Prothioconazole	0.67	0.0667 0.0340* 0.1333***	10.04 19.7 5.03
Prothioconazole-desthio	0.5	0.0712 0.0752*	14.04 6.6
Prothioconazole-S-methyl	50	0.0203	4901.96 2463
GLOB2021dF	125(based on NOEC) 62.5corr 47 (based on EC ₁₀) 23.5corr	0.7148 0.4765* 1.191***	524.55 131 52 20
Chronic effects on other soil macro- and mesofauna			
Collembola			
Product/active substance	NOEC (mg/kg dw)	PEC_{soil} (mg/kg dw)	TER_{lt} (criterion TER ≥ 5)
Boscalid	>250	0.1844 0.2320* 0.1752***	2676.66 1078 1427
Prothioconazole	> 65 32corr	0.2000 0.0340* 0.1333***	974.51 941 240
Prothioconazole-desthio	62.5 31.25corr	0.0712 0.0752*	1755.62 416
Prothioconazole-S-methyl	> 31.6 15.8corr	0.0203	3098.04 778
GLOB2021dF	309 154.5corr	0.7148 0.4765* 1.191***	1296.68 324 130

<i>Hypoaspis aculeifer</i>			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Boscalid	-	0.1844 0.2320* 0.1752**	-
Prothioconazole	> 100 >50corr	0.2000 0.0340* 0.1333***	1499.25 1470 375
Prothioconazole-desthio	> 100 10**	0.0712 0.0752*	2808.99 133
Prothioconazole-S-methyl	> 100 10**	0.0203	9803.92 493
GLOB2021dF	1000 500corr	0.7148 0.4765* 1.191***	1398 1049 420

TER values shown in bold fall below the relevant trigger.

*correct value according to Part B8

**The EU agreed endpoint not available therefore are considered 10 time more toxic then the parent

*** correct value according to Part B8 after commenting period

Table 9.8-5: First-tier assessment of the acute and chronic risk for earthworms and other non-target soil organisms (meso- and macrofauna) due to the use of GLOB2021dF in cereals

Intended use	cereals single application		
Acute effects on earthworms			
Product/active substance	LC ₅₀ (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _a (criterion TER ≥ 10)
Boscalid	> 500	0.0478 0.1478*	10460.25 3383
Prothioconazole	> 500	0.0667 0.1333*	7496.25 3751
Prothioconazole-desthio	> 500	0.0178 0.0698*	28089.89 7163
Prothioconazole-S-methyl	> 500	0.0051 0.0203*	98039.22 24631
GLOB2021dF	1000 500corr	0.2383 0.953***	4196.39 2098 525
Chronic effects on earthworms			
Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Boscalid	1.197	0.0478 0.1478*	25.04 8.10
Prothioconazole	0.67	0.0667 0.1333*	10.04 5.03

Prothioconazole-desthio	0.5	0.0178 0.0698*	28.09 7.16
Prothioconazole-S-methyl	50	0.0051 0.0203*	9803.92 2463
GLOB2021dF	125(based on NOEC) 62.5corr 47 (based on EC ₁₀) 23.5corr	0.2383 0.953***	524.55 262 66 25

Chronic effects on other soil macro- and mesofauna

Collembola

Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Boscalid	>250	0.0478 0.1478*	5230.13 1691
Prothioconazole	> 65 32corr	0.0667 0.1333*	974.51 240
Prothioconazole-desthio	62.5 31.25corr	0.0178 0.0698*	3511.24 448
Prothioconazole-S-methyl	> 31.6 15.8corr	0.0051 0.0203*	6196.08 778
GLOB2021dF	309 154.5corr	0.2383 0.953***	1296.68 648 162

Hypoaspis aculeifer

Product/active substance	NOEC (mg/kg dw)	PEC _{soil} (mg/kg dw)	TER _{lt} (criterion TER ≥ 5)
Boscalid	-	0.0478 0.1478*	-
Prothioconazole	> 100 >50corr	0.0667 0.1333*	1499.25 375
Prothioconazole-desthio	> 100 10**	0.0178 0.0698*	5617.98 143
Prothioconazole-S-methyl	> 100 10**	0.0051 0.0203*	19607.84 493
GLOB2021dF	1000 500corr	0.2383 0.953***	4196.39 2098 525

TER values shown in bold fall below the relevant trigger.

*correct value according to Part B8

**The EU agreed endpoint not available therefore are considered 10 time more toxic then the parent

*** correct value according to Part B8 after commenting period

9.8.2.2 Higher-tier risk assessment

Not relevant

9.8.3 Overall conclusions

The TER values together indicate an acceptable risk for earthworms and other non-target soil organisms for the intended use of GLOB2021dF.

zRMS conclusion:

PECsoil values were calculated considering GAP of GLOB2021dF. The highest predicted environmental concentrations (PECsoil) of the active substances, metabolites and formulation were taken into account for the risk assessment.

Boscalid

The risk assessment for boscalid was performed based on the EU agreed endpoints.

The acute risk assessment is no longer required, however the TER_A values for active substance are above the trigger value of 10.

All TER_{LT} values are above trigger value of 5.

Prothioconazole and its metabolites

The risk assessment for prothioconazole and its metabolites was performed based on the EU agreed endpoints. Considering that for prothioconazole, the toxicity study on *H. aculeifer* was performed using a natural soil Lufa 2.1 (soil, ca. 0.9 % organic carbon), the correction factor is not necessary to be applied and the risk assessment could therefore be conducted using the NOEC_{repro} = 100 mg a.s./kg soil, what is in line with EFSA Scientific Report (2007) 106, 1-98, Conclusion on the peer review of Prothioconazole. However for consistency reasons, the worse-case approach using corrected value is presented in the tables above. Additionally, for completeness the risk assessment for the metabolites of prothioconazole on *H. aculeifer* is presented above considering them as 10 times more toxic than the parent.

The acute risk assessment is no longer required, however the TER_A values for active substance are above the trigger value of 10.

All TER_{LT} values are above trigger value of 5.

GLOB2021dF

The risk assessment for GLOB2021dF was performed based on the results of studies performed with formulation and summarised in Appendix 2.

The acute risk assessment is no longer required, however the TER_A values for formulation are above the trigger value of 10.

All TER_{LT} values are above trigger value of 5.

Conclusion:

According to the performed risk assessment there is low chronic risk to earthworms and other non-target organisms resulting from long-term exposure to active substances following application of GLOB2021dF in compliance with proposed GAP.

The GAP change for oilseed rape from BBCH 61 was already covered by the existing risk assessment for soil organism.

9.9 Effects on soil microbial activity (KCP 10.5)

9.9.1 Toxicity data

Studies on effects soil microorganisms have been carried out with boscalid, prothioconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on soil microorganisms of GLOB2021dF were not evaluated as part of the EU assessment of boscalid and prothioconazole. New data submitted with this application are listed in Appendix 1 and summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process. Justifications are provided below.

Table 9.9-1: Endpoints and effect values relevant for the risk assessment for soil microorganisms

Endpoint	Substance	Exposure System	Results	Reference
N-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy sand	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg a.s./kg soil	EFSA 2008
C-mineralisation	BAS 510 01 F (Boscalid 500 g/kg)	28 d, aerobic Loamy silt	No effect up to 12 kg prod./ha Equivalent to 6 kg a.s./ha or 8 mg a.s./kg soil	EFSA 2008
N-mineralisation	Prothioconazole	28 d, aerobic	No effects $\geq 25\%$ at ≥ 2.71 mg as/kg dws, equivalent to ≥ 2.03 kg as/ha.	EFSA, 2007
C-mineralisation	Prothioconazole	28 d, aerobic	No effects $\geq 25\%$ at 200 mg parent/ha	EFSA, 2007
N-mineralisation	Prothioconazole-S-methyl	28 d, aerobic	No effects $\geq 25\%$ at ≥ 2.69 mg metab./kg dws, equivalent to ≥ 2.02 kg metab./ha.	EFSA, 2007
C-mineralisation	Prothioconazole-S-methyl	28 d, aerobic	No effects $\geq 25\%$ at 200 mg parent/ha	EFSA, 2007
N-mineralisation	Prothioconazole-desthio	42d, aerobic	No effects $\geq 25\%$ at ≥ 0.27 mg metab./kg dws, equivalent to ≥ 0.205 kg metab./ha.	EFSA, 2007
N-mineralisation	Prothioconazole-desthio	28d, aerobic	No effects $\geq 25\%$ at ≥ 1.37 mg metab./kg dws, equivalent to ≥ 1.03 kg metab./ha.	EFSA, 2007
N-mineralisation	GLOB2021dF	28d, aerobic	No effects $\geq 25\%$ at ≥ 3 mg/kg dws	Adamcsik B.T., 2023

9.9.1.1 Justification for new endpoints

As the formulation is a mixture of two active ingredients, toxicity to soil micro-organisms from the formulation was tested and used in the risk assessment.

9.9.2 Risk assessment

The evaluation of the risk 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).

The relevant PEC_{soil} for risk assessments covering the proposed use pattern are taken from Section 8 (Environmental Fate), Chapter 8.7.2, Table 8.7-3 – 8.7-11 and were already used in the risk assessment for earthworms and other non-target soil organisms (meso- and macrofauna) (see 9.8).

Table 9.9-2: Assessment of the risk for effects on soil micro-organisms due to the use of GLOB2021dF in Oilseed rape

Intended use	Oilseed rape (multiple application)		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	0.1844 0.1405	Yes
Prothioconazole	2.71	0.0667 0.0340 0.1000*	Yes
Prothioconazole-desthio	2.69 1.37	0.0712 0.0608	Yes
Prothioconazole-S-methyl	0.27 2.69	0.0203 0.0163	Yes
GLOB2021dF	3	0.7148 1.4295 0.953*	Yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	0.1844	Yes
Prothioconazole	20	0.0.667	Yes
Prothioconazole-S-methyl	2	0.0203	Yes

*correct value according to Part B8 after commenting period

Table 9.9-3: Assessment of the risk for effects on soil micro-organisms due to the use of GLOB2021dF in Oilseed rape

Intended use	Oilseed rape (single application)
N-mineralisation	

Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	~~0.1435~~ 0.1109	Yes
Prothioconazole	2.71	~~0.0667~~ 0.1000	Yes
Prothioconazole-desthio	~~2.69~~ 1.37	~~0.0534~~ 0.0524	Yes
Prothioconazole-S-methyl	~~0.27~~ 2.69	~~0.0153~~ 0.0152	Yes
GLOB2021dF	3	0.7148	Yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	0.1435	Yes
Prothioconazole	20	0.0667	Yes
Prothioconazole-S-methyl	2	0.0153	Yes

Table 9.9-4: Assessment of the risk for effects on soil micro-organisms due to the use of GLOB2021dF in cereals

Intended use	Cereals (multiple application)		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	0.0934 0.2320 0.1752*	Yes
Prothioconazole	2.71	0.0667 0.0340 0.1333*	Yes
Prothioconazole-desthio	2.69 1.37	0.0356 0.0752	Yes
Prothioconazole-S-methyl	0.27 2.69	0.0102 0.0203	Yes
GLOB2021dF	3	0.7148 0.4765 1.191*	Yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	0.0934	Yes
Prothioconazole	20	0.0667	Yes
Prothioconazole-S-methyl	2	0.0102	Yes

*correct value according to Part B8 after commenting period

Table 9.9-5: Assessment of the risk for effects on soil micro-organisms due to the use of GLOB2021dF in cereals

Intended use	Cereals (single application)		
N-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	~~0.0478~~ 0.1478	Yes
Prothioconazole	2.71	~~0.0667~~ 0.1333	Yes
Prothioconazole-desthio	~~2.69~~ 1.37	~~0.0178~~ 0.0698	Yes
Prothioconazole-S-methyl	~~0.27~~ 2.69	~~0.0051~~ 0.0203	Yes
GLOB2021dF	3	~~0.2383~~ 0.953*	Yes
C-mineralisation			
Product/active substance	Max. conc. with effects ≤ 25 % (mg/kg dw)	PEC _{soil} (mg/kg dw)	Risk acceptable?
Boscalid	8	0.0478	Yes
Prothioconazole	20	0.0667	Yes
Prothioconazole-S-methyl	2	0.0051	Yes

*correct value according to Part B8 after commenting period

9.9.3 Overall conclusions

The EU review for Boscalid and prothioconazole and the test on the formulation show that there are no effects on soil microbial activity at dose rates far higher than the corresponding PEC_{soil} of the intended use. Therefore it is concluded that there is no unacceptable risk on soil microbial activity for GLOB2021dF.

zRMS comments:

C-mineralisation is no longer required.

The risk assessment was performed by comparison of PECs values with concentrations of the test items at which effects were ≤ 25%.

PEC_{soil} values were calculated considering GAP of GLOB2021dF. The highest predicted environmental concentrations (PEC_{soil}) of the active substances, metabolites and formulation were taken into account for the risk assessment.

Conclusion:

Since no effects (> 25%) were seen at application rates far higher than the values of PEC_{soil} for active substances, metabolites and formulation it can be concluded that application of GLOB2021dF, according to the GAP, will not cause any detrimental effect to soil micro-organisms.

The GAP change for oilseed rape from BBCH 61 was already covered by the existing risk assessment for soil micro-organisms.

9.10 Effects on non-target terrestrial plants (KCP 10.6)

9.10.1 Toxicity data

Studies on the toxicity to non-target terrestrial plants have been carried out with boscalid and prothioconazole and its relevant metabolites. Full details of these studies are provided in the respective EU DAR and related documents.

Effects on non-target terrestrial plants of GLOB2021dF were not evaluated as part of the EU assessment of Boscalid and prothioconazole. New data submitted with this application are listed in Appendix 1 summarised in Appendix 2.

The selection of studies and endpoints for the risk assessment is in line with the results of the EU review process.

Table 9.10-1: Endpoints and effect values relevant for the risk assessment for non-target terrestrial plants

Species	Substance	Exposure System	Results	Reference
Avena sativa (Oat) _m Allium cepa (Onion) _m Daucus carota (Carrot) _d Brassica oleracea cv capitata (Cabbage) _d Pisum sativum (Pea) _d Zea mays (Maize) _m	GLOB2021dF	21 d Seedling emergence	NOEC emergence > 800 mL/ha NOEC plant weight > 800 mL/ha NOEC visual effects of phytotoxicity > 800 mL/ha	Varga-László E., 2023a
Avena sativa (Oat) _m Allium cepa (Onion) _m Daucus carota (Carrot) _d Brassica oleracea cv capitata (Cabbage) _d Pisum sativum (Pea) _d Zea mays (Maize) _m	GLOB2021dF	21 d Vegetative vigour	NOEC mortality > 800 mL/ha NOEC dry shoot weight > 800 mL/ha NOEC visual effects of phytotoxicity > 800 mL/ha	Varga-László E., 2023b

m: monocotyledonous; d: dicotyledonous

9.10.1.1 Justification for new endpoints

As the formulation is a mixture of two active ingredients, toxicity to soil micro-organisms from the formulation was tested and used in the risk assessment.

9.10.2 Risk assessment

9.10.2.1 Tier-1 risk assessment (based screening data)

Not relevant.

9.10.2.2 Tier-2 risk assessment (based on dose-response data)

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 situations, as non-target plants are non-crop plants located outside the treated area.

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to spray drift. The amount of spray drift reaching off-crop habitats is derived by the *BBA (2000)*³ from the spray-drift predictions of *Ganzelmeier & Rautmann (2000)*⁴ as recommended by the “Guidance Document on Terrestrial Ecotoxicology under Council Directive 91/414/EEC, SANCO/10329/2002.

Consequently, the initial exposure assessment was based on air deposition following the application of GLOB2021dF to areas adjacent to the field without and (if appropriate) with consideration of drift mitigation measures. Predicted exposure rates were calculated with the following formula:

$$PER_{\text{off-field}} = (\text{Appl. rate} \times \text{Spray drift})$$

where PER = Predicted Environmental Rate (kg/ha or L/ha)

Appl. rate = rate of a single application expressed in the same units as the PER

Spray drift = % of the applied rate deposited to the off-field area by spray drift

Table 9.10-2: Assessment of the risk for non-target plants due to the use of GLOB2021dF in oilseed rape and cereals

Intended use	Oilseed rape and cereals				
Active substance/product	boscalid and prothioconazole/ GLOB2021dF				
Application rate (g/ha)	0.8 L/ha				
MAF*	1.7*				
Test species	ER₅₀ (mL/ha)	Drift rate	PER_{off-field} (mL/ha)	TER criterion: TER ≥ 5	
Avena sativa (Oat) _m	>800	2.77 %	22.16	36.10	
Allium cepa (Onion) _m			37.67*	21.24*	
Daucus carota (Carrot) _d					
Brassica oleracea cv capitata (Cabbage) _d					
Pisum sativum (Pea) _d					
Zea mays (Maize) _m					

PER: Predicted environmental rate; TER: toxicity to exposure ratio. TER values shown in bold fall below the relevant trigger.
m: monocotyledonous; d: dicotyledonous

*Additional calculation if MAF for multiple applications is required

9.10.2.3 Higher-tier risk assessment

Not relevant.

³ BBA (2000) Bundesanzeiger Jg. 52 (Official Gazette), Nr 100, S. 9879-9880 (25.05.2000) Bekanntmachung über die Abtrifteckwerte, die bei der Prüfung und Zulassung von Pflanzenschutzmitteln herangezogen werden. Public domain.

⁴ Ganzelmeier H., Rautmann D. (2000) Drift, drift-reducing sprayers and sprayer testing. Aspects of Applied Biology 57, 2000, Pesticide Application. Public domain.

9.10.2.4 Risk mitigation measures

No risk mitigation needed.

9.10.3 Overall conclusions

Tier-2 risk assessment indicates that there is no unacceptable risk from GLOB2021dF for non-target plants when applied according to the proposed use rates.

zRMS comments:

GLOB2021dF is a fungicide and therefore is not expected to have any significant herbicidal effect. The risk assessment was performed based on the results of studies with formulation.

As noted in the Working document on Risk Assessment of Plant Protection Products in the Central Zone Ecotoxicology Version 2.0, August 2023, most, but not all, countries have agreed to use MAF in risk assessment. Therefore, the calculation with MAF was added.

For active substances the EU agreed endpoints were established, therefore the risk assessment using these endpoints was added below for completeness.

EU agreed endpoints

Species	Substance	Exposure System	Results	Reference
<i>Daucus carota</i> _d ¹⁾ <i>Brassica oleracea</i> _d ²⁾ <i>Pisum sativum</i> _d ³⁾ <i>Zea mays</i> _m ⁴⁾ <i>Avena sativa</i> _m ⁵⁾ <i>Allium cepa</i> _m ⁶⁾	BAS 510 01 F (Boscalid 500 g/kg)	14 d Vegetative vigour 1.2 kg a.s./ha	¹⁾ 2.5 ²⁾ 0 ³⁾ 0 ⁴⁾ 0 ⁵⁾ 0 ⁶⁾ 0 Mean phytotoxicity (% control)	Monograph Boscalid, 2002
<i>Daucus carota</i> _d ¹⁾ <i>Brassica oleracea</i> _d ²⁾ <i>Pisum sativum</i> _d ³⁾ <i>Zea mays</i> _m ⁴⁾ <i>Avena sativa</i> _m ⁵⁾ <i>Allium cepa</i> _m ⁶⁾	BAS 510 01 F (Boscalid 500 g/kg)	14 d Vegetative vigour 3.6 kg a.s./ha	¹⁾ 5 ²⁾ 0 ³⁾ 0 ⁴⁾ 0 ⁵⁾ 0 ⁶⁾ 0 Mean phytotoxicity (% control)	Monograph Boscalid, 2002
<i>Daucus carota</i> _d ¹⁾ <i>Brassica oleracea</i> _d ²⁾ <i>Pisum sativum</i> _d ³⁾ <i>Zea mays</i> _m ⁴⁾ <i>Avena sativa</i> _m ⁵⁾ <i>Allium cepa</i> _m ⁶⁾	BAS 510 01 F (Boscalid 500 g/kg)	14 d Vegetative vigour 1.2 kg a.s./ha	¹⁾ 109.4 ²⁾ 100.2 ³⁾ 91.2 ⁴⁾ 101.9 ⁵⁾ 105.7 ⁶⁾ 108.2 Mean fresh weight (% control)	Monograph Boscalid, 2002

<i>Daucus carota</i> ^{d 1)} <i>Brassica oleracea</i> ^{d 2)} <i>Pisum sativum</i> ^{d 3)} <i>Zea mays</i> ^{m 4)} <i>Avena sativa</i> ^{m 5)} <i>Allium cepa</i> ^{m 6)}	BAS 510 01 F (Boscalid 500 g/kg)	14 d Vegetative vigour 3.6 kg a.s./ha	¹⁾ 110.6 ²⁾ 98.9 ³⁾ 97.5 ⁴⁾ 103.5 ⁵⁾ 99.5 ⁶⁾ 113.6 Mean fresh weight (% control)	Monograph Boscalid, 2002
<i>Amaranthus retroflexus</i>	Prothioconazole	21 d Pre-emergence	Max phytotoxic effect: 5% at 200 g a.s./ha	EFSA Scientific Re- port (2007) 106, 1- 98
<i>Amaranthus retroflexus</i> , <i>Beta vulgaris</i>	Prothioconazole	21 d Post-emergence	Max phytotoxic effect: 10% at 250 g a.s./ha	EFSA Scientific Re- port (2007) 106, 1- 98
<i>Amaranthus retroflexus</i>	EC 250 (Prothioconazole)	21 d Pre-emergence	Max phytotoxic effect: 5% at 200 g a.s./ha	EFSA Scientific Re- port (2007) 106, 1- 98

TER calculations

Intended use		Winter wheat		
Active substance/product		Boscalid		
Application rate (g/ha)		2 x 125		
MAF		1		
MAF*		1.7*		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Daucus carota</i> <i>Brassica oleracea</i> <i>Pisum sativum</i> <i>Zea mays</i> <i>Avena sativa</i> <i>Allium cepa</i>	>3600	0.0277	3.463 6.028*	>1040 >597*
Active substance/product		Prothioconazole		
Application rate (g/ha)		2 x 250		
MAF		1		
MAF		1.7*		
Test species	ER₅₀ (g/ha)	Drift rate	PER_{off-field} (g/ha)	TER criterion: TER ≥ 5
<i>Amaranthus retroflexus</i> , <i>Beta vulgaris</i>	>250	0.0277	6.925 11.773*	>36 >21*

*Additional calculation if MAF for multiple applications is required

All TER values are above the trigger value of 5 set by Commission Regulation (EU) No. 546/2011.

Conclusion

No unacceptable risk to non-target terrestrial plants is expected following the application of GLOB2021dF according to the proposed use pattern.

The GAP change for oilseed rape from BBCH 61 does not impact the risk assessment for non-target plants.

9.11 Effects on other terrestrial organisms (flora and fauna) (KCP 10.7)

Tests on other non-target species are not required.

9.12 Monitoring data (KCP 10.8)

Not relevant

9.13 Classification and Labelling

Implications for labelling resulting from ecotoxicological assessment (justification is provided in section C):

The ecotoxicological classification of GLOB2021dF was based on theoretical calculations according to Regulation 1272/2008 or based on own available data on the formulation. Reference is made to part C of this dossier. As GLOB2021dF contains boscalid and co-formulants in a concentration above the threshold, it **should be classified as Aquatic Chronic 2, H411**.

The following classification is than proposed from an ecotoxicological point of view.

Pictogram: GHS09
Signal word: Warning

H-statements

H411 Toxic to aquatic life with long lasting effects.

P-statements

P273 Avoid release to the environment.

P391 Collect spillage.

P501 Dispose of contents/container to ... in accordance with local/regional/national/international regulations (to be specified).

Other safety/precautionary phrases:

SP1: Do not contaminate water with the product or its container.

EUH401: To avoid risks to human health and the environment, comply with the instructions for use.

SPe3: To protect aquatic organisms, the applicant proposes different mitigation measures:

Appropriate risk mitigation measures are given in section 9.5.

~~Winter oilseed rape 2 x 125g boscalid and 125g prothioconazole/ ha:
— 5m vegetated filter strip~~

~~Spring oilseed rape 2 x 125g boscalid and 125g prothioconazole/ ha:
— 5m vegetated filter strip~~

~~Winter cereals 2 x 125g boscalid and 125g prothioconazole/ ha:
— 5m vegetated filter strip~~

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

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

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 10.2		2024	Acute Toxicity Study of GLOB2021 dF in Fish (<i>Oncorhynchus mykiss</i>) according to OECD GD 201 guideline GLP Unpublished	Y	Globachem N.V.
KCP 10.2	Kubisiak K.	2023a	<i>Daphnia magna</i> acute immobilization test of the test item GLOB2021dF according to OECD GD 202 guideline 00664/0031/E Sorbolab Research Laboratory LLC GLP Unpublished	N	Globachem N.V.
KCP 10.2	Zaworska K.	2023	Freshwater algae (<i>Raphidocelis subcapitata</i>) growth inhibition test of the test item GLOB2021dF according to OECD GD 201 guideline 00664/0030/E Sorbolab Research Laboratory LLC GLP Unpublished	N	Globachem N.V.
KCP 10.3.1	Orosz I.	2023a	A GLP acute contact and oral toxicity study with GLOB2021dF on honey bees (<i>Apis mellifera</i>) 22/136-116MT	N	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			Charles River Laboratories Hungary Kft. GLP Unpublished		
KCP 10.3.1	Orosz I.	2023b	A GLP 10-day chronic oral toxicity study with GLOB2021dF on honey bees (<i>Apis mellifera</i>) 22/136-134MT Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.3.1	Wozniak A.	2023	Honey bee larval toxicity test following repeated exposure of the test item GLOB2021dF according to OECD GD 239 ENV/JM/MONO(2016)34 00664/0032/E Sorbolab Research Laboratory LLC GLP Unpublished	N	Globachem N.V.
KCP 10.3.1	Orosz I.	2023c	A GLP acute contact and oral toxicity study with GLOB2021dF on bumblebees (<i>Bombus terrestris</i>) 22/136-116MTB Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.3.2	Orovecz B.	2023a	Effect of GLOB2021dF on the predatory mite (<i>Typhlodromus pyri</i>) in an extended laboratory trial 22/136-351RA Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.3.2	Kubisiak, K.	2023b	Extended laboratory test to determine the effects of the test item GLOB2021dF on the green lacewing (<i>Chrysoperla carnea</i>) 00664/0034/E Sorbolab Research Laboratory LLC	N	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.3.2	Domagala J.	2023a	Extended laboratory test to determine the effects of the test item GLOB2021dF on the ladybird beetle (<i>Coccinella septempunctata</i>) 00664/0033/E Sorbolab Research Laboratory LLC GLP Unpublished	N	Globachem N.V.
KCP 10.3.2	Domagala J.	2023a	Aged-residue extended laboratory test to determine the effects of the test item GLOB2021dF on the ladybird beetle (<i>Coccinella septempunctata</i>) according to IOBC, BART and EPPO Joint initiative. M.P. Candolfi, et. Al. (2000) 00664/0042/E Sorbolab Research Laboratory LLC GLP Unpublished	N	Globachem N.V.
KCP 10.3.2	Orovecz B.	2023b	Effect of GLOB2021dF on the parasitic wasp (<i>Aphidius rhopalosiphi</i>) in an extended laboratory trial 22/136-351FD Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.4	Orosz I.	2023d	A GLP reproduction study of GLOB2021dF on earthworms (<i>Eisenia fetida</i>) 22/136-211G Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.4	Orosz I.	2023e	A GLP reproduction test of GLOB2021dF in soil with Collembolan (<i>Folsomia candida</i>) 22/136-130CO Charles River Laboratories Hungary Kft.	N	Globachem N.V.

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
			GLP Unpublished		
KCP 10.4	Orosz I.	2023f	A GLP Reproduction Test of GLOB2021dF in Soil with Predatory mite (<i>Hypoaspis (Geolaelaps) aculeifer</i>) 22/136-389TLA Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.5	Adamcsik B.T.	2023	A GLP Soil Microorganisms Nitrogen Transformation Study of GLOB2021dF 22/136-055AN Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.6	Varga-László E.	2023a	GLOB2021dF: A GLP Seedlings Emergence and Seedling Growth Test 22/136-126PL Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.
KCP 10.6	Varga-László E.	2023b	GLOB2021dF: A GLP Vegetative Vigour Test 22/136-136PL Charles River Laboratories Hungary Kft. GLP Unpublished	N	Globachem N.V.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report N Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Detailed evaluation of the new studies

A 2.1 KCP 10.2 Effects on aquatic organisms

A 2.1.1.1 Study 1

Comments of zRMS:	The study was performed according to OECD TG 203 and principles of GLP. The validity criteria are met: - the mortality in the control was 0%, - the dissolved oxygen concentration was greater than 60% of the air saturation value throughout the test. No deviation was observed during the study. The study is considered acceptable and suitable for the risk assessment. 96h LC50 30.04 mg/L mg PPP/L
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Reference:	KCP 10.2
Report	Acute Toxicity Study of GLOB2021 dF in Fish (<i>Oncorhynchus mykiss</i>) according to OECD GD 203 guideline
Guideline(s):	Yes, OECD 203
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	Yes

The objective of the study was to conduct acute toxicity study of GLOB2021 dF in Freshwater Fish (*Oncorhynchus mykiss*) as per OECD guideline for the testing of chemicals, number 203. The test item was formulated with RO water. Test aquarium was filled with appropriate volume of RO water containing different test concentrations of the test item. Concurrent control group was also maintained. Ten fishes were maintained for the control and each treatment groups. The duration of the study was 96 hours.

Prior to the exposure, length and body weight (wet) of ten fishes were recorded. The fishes were observed daily during the acclimatization period and were found to be normal.

Initially, range finding test was conducted with 5 different concentrations such as 0.1, 1, 10, 50 and 100 mg/L. In the range finding experiment, 0% mortality was observed in fish exposed with

control, 0.1, 1 and 10 mg/L and 100 % mortality observed in 50 and 100 mg/L concentrations respectively. Based on the results of the range finding test, the definitive test was conducted with the concentrations of 9.88, 14.81, 22.22, 33.33 and 50 mg/L along with control. After test item exposure, fishes were maintained in the temperature between 12.4 to 12.5°C and light Intensity was 732 to 829 during the test period of 96 hours. Physico-chemical parameters such as pH, dissolved oxygen, temperature, water hardness and conductivity were within the range during acclimatization and definitive Test.

Observation for mortality and abnormal behaviours was made on day 0 at 2.5 and 6 hours, then on 24, 30, 48, 54, 72, 78 and 96 hrs (± 10 minutes) after exposure.

At the end of 96 hours of the Definitive test showed no mortality and abnormal response in control and fishes exposed with 9.88 and 14.81 mg/L and 20%, 50% and 100% mortality observed in 22.22, 33.33 and 50 mg/L concentrations respectively.

CONCLUSION

Based on the above results, The LC50 of GLOB2021 dF was observed as 30.04 mg/L with 95% confidence limits between 23.64 and 36.44 mg/L for the period of 96 hours in fish (*Oncorhynchus mykiss*). The NOEC was 14.81 mg/L and LOEC was 22.22 mg/L.

A 2.1.1.1.2 Study 2

Comments of zRMS:	The study was performed according to OECD TG 202 and principles of GLP. The validity criteria are met: - in the control, the number of immobilized daphnia at the end of the test was 0%, (required: not exceed 10%) - the control daphnids showed no immobilization or other signs of disease or stress, for example, discoloration or unusual behavior such as trapping at surface water (required: not more than 10 %) - the lowest dissolved oxygen concentration at the end of the test was 9.87 mg/L, (required ≥ 3 mg/L) in control and test concentrations. All results refer to nominal concentrations since the measured concentrations were within 80 to 120% of nominal. The study is considered acceptable and suitable for the risk assessment. 48h-EC50 of 5.352 mg PPP/L
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Reference: KCP 10.2

Report *Daphnia magna* acute immobilization test of the test item GLOB2021dF according to OECD GD 202 guideline
00664/0031/E
Kubisiak K., 2023a,

	Sorbolab Research Laboratory LLC
Guideline(s):	Yes, OECD 202
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The aim of the study was the evaluation of the test item GLOB2021dF effect on the invertebrate *Daphnia magna* immobilization. The study was conducted in accordance with OECD guideline 202. The impact of the test item was compared to the control group. Based on the results obtained, EC₁₀, EC₂₀, EC₅₀, EC₉₅ NOEC and LOEC values were estimated.

The definitive test: Test design	tested concentrations and control in four repetitions – 5 daphnids in one replicate
Type of exposure	static test
Test vessels	glass beakers of 100 mL volume; volume of solution 80 mL
Medium	M7
Time of exposure	48 h
Tested concentrations	☐ control (0 mg of the test item/L of medium) ☐ 0.50 mg of the test item/L of medium ☐ 1.10 mg of the test item/L of medium ☐ 2.42 mg of the test item/L of medium ☐ 5.32 mg of the test item/L of medium ☐ 11.72 mg of the test item/L of medium
Test conditions	average temperature of medium: 20.5°C (min. temperature 20.0°C, max. temperature 20.9°C) photoperiod 16 h day/8 h night with an average light intensity of 1267 lux

Conclusion

In the course of the test, it was shown that the test item had statistically significant effect on immobilization of daphnia in the range of concentrations 1.10 mg of test item/L of medium – 11.72 mg of the test item/L of medium.

Based on the obtained results values NOEC was determined to be 0.50 mg of the test item/L of medium and LOEC to be 1.10 mg of the test item/L of medium (after 48 h of exposure).

Results of the study presented Table 1.

Table 1. Final results of the study

Final results calculated using ToxRat Professional	
Parameter	Exposure time
24 h	48 h
EC ₁₀	2.694 1.025

[mg/L]	(0.443 – 5.836)*	(0.414 – 1.646)*
EC20	6.921	1.807
[mg/L]	(3.269 – 50.845)*	(0.972 – 2.666)*
EC50	>11.72**	5.352
[mg/L]		(3.678 – 9.073)*
EC95	>11.72**	>11.72**
[mg/L]		
LOEC	2.420	1.100
[mg/L]		
NOEC	1.100	0.500
[mg/L]		

EC₁₀ effective concentration of test item for 10% reduction

EC₂₀ effective concentration of test item for 20% reduction

EC₅₀ effective concentration of test item for 50% reduction

EC₉₅ effective concentration of test item for 95% reduction

LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control

NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control

* the lower and upper 95% confidence limits are given in brackets

** due to the lack of a concentration, the endpoints were defined as higher than the highest concentration tested >11.72 mg of the test item/L of medium

A 2.1.1.1.3 Study 3

Comments of zRMS:	The study was performed according to OECD TG 201 and principles of GLP. The validity criteria are met. - yield in control during 72 hours of test increased exponentially 123.1 times (requirements according to OECD 201: ≥ 16) - the coefficient of variance for the average specific growth rate for all repetitions of the control culture over the entire time of the test was 0.20% (requirements according to OECD 201: $< 7\%$) - the average coefficient of variance for a specific growth rate day after day (0-24 h, 24-48 h, 48-72 h) for the control culture was 17.66% (requirements according to OECD 201: $< 35\%$). All results refer to nominal concentrations since the measured concentrations were within 80 to 120% of nominal. The study is considered acceptable and suitable for the risk assessment. 72h-ErC50 = 8.262 mg PPP/L 72h-EbC50 = 3.914 mg PPP/L
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Reference: KCP 10.2

Report Freshwater algae (*Raphidocelis subcapitata*) growth inhibition test of the test item GLOB2021dF according to OECD GD 201 guideline 00664/0030/E
Zaworska., 2023,
Sorbolab Research Laboratory LLC

Guideline(s): Yes, OECD 201

Deviations: No

GLP: Yes

Acceptability: Yes/No/Supplementary

Duplication No
(if vertebrate study)

Materials and methods

The assessment test of the test item GLOB2021dF effect on the freshwater algae *Raphidocelis subcapitata* growth expressed in yield, average specific growth rate, sectional specific growth rate was conducted in accordance with the OECD guideline 201. Based on the algae cell count measurements EC₁₀, EC₂₀, EC₅₀, NOEC and LOEC values were estimated after 24, 48 and 72 hours of exposure to the test item. Test design

Test vessels

Type of exposure

Time of exposure

Shaking

Medium

Tested concentrations of the test item

Test conditions

stability test:

tested concentration and control in 2 replicates (one replicate with test item solutions and one with test item solutions inoculated with algae)

range-finding:

tested concentrations in 2 replicates and control in 4 replicates

definitive test:

tested concentration in 3 replicates and control in 6 replicates

stability test, range-finding, definitive test:

250 mL conical glass flasks covered with sterile stoppers ensuring gas exchange, volume solution 100 mL

static test

72 h

continuous on orbital shakers with a frequency of 90 rpm

AAP

stability test: control (0 mg of the test item/L of AAP medium)

1.00 mg of the test item/L of AAP medium

13.03 mg of the test item/L of AAP medium

range finding test: control (0 mg of the test item/L of AAP medium) 0.1 mg of the test item/L of AAP medium 1 mg of the test item/L of AAP medium 10 mg of the test item/L of AAP medium

definitive test:

control (0 mg of the test item/L of AAP medium)

1.00 mg of the test item/L of AAP medium

1.90 mg of the test item/L of AAP medium

3.61 mg of the test item/L of AAP medium

6.86 mg of the test item/L of AAP medium

13.03 mg of the test item/L of AAP medium

stability test:

average medium temperature 22.6°C (min 22.4°C, max 22.8°C)¹

continuous fluorescent lightening: 100.83-109.81 µE·m⁻²s⁻¹

range-finding test:

average medium temperature 22.5°C (min 22.2°C, max 22.6°C)¹

continuous fluorescent lightening: 101.01-109.24 µE·m⁻²s⁻¹

definitive test:
average medium temperature 22.0°C (min 21.5°C, max 23.4°C)
continuous fluorescent lightening: 100.97-109.52 $\mu\text{E}\cdot\text{m}^{-2}\text{s}^{-1}$

Conclusion

In course of the experiment, the test item GLOB2021dF shown effect on the freshwater algae *Raphi-docelis subcapitata* in yield and average specific growth rate in all tested doses and did not shown effect on sectional specific growth rate in all tested doses.

The final results of the experiment are presented in Table 1.

Table 1. Final results of the study

Parameter	Yield	Average specific growth rate	Sectional growth rate
EC10 - 72 h	1.893	3.518	8.595
[mg/L]	(1.783 – 2.010)*	(3.371 – 3.671)*	(6.187 – 11.941)*
EC20 - 72 h	2.429	4.716	10.334
[mg/L]	(2.296 – 2.570)*	(4.529 – 4.912)*	(7.419 – 14.406)*
EC50 - 72 h	3.914	8.262	14.699
[mg/L]	(3.654 – 4.190)*	(7.853 – 8.679)*	(8.992 – 23.450)*
LOEC - 72 h	≤1.000	≤1.000	>13.030
[mg/L]			
NOEC - 72 h	<1.000	<1.000	≥13.030
[mg/L]			

EC₁₀ effective concentration of test item for 10% reduction

EC₂₀ effective concentration of test item for 20% reduction

EC₅₀ effective concentration of test item for 50% reduction

LOEC lowest observe effective concentration cause statistically significant differences in comparison to the control
NOEC highest non observe effective concentration cause no statistically significant differences in comparison to the control

* he lower and upper 95% confidence limits are given in brackets

A 2.2 KCP 10.3 Effects on arthropods

A 2.2.1.1.1 Study 1

Comments of zRMS:	The study was conducted in line with OECD 213 and 214. All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment: The contact LD50 (48 h) >100 μg product /bee The nominal oral LD50 (48 h) $\geq$ 100 μg product /bee In the oral experiment the mean food consumption was 87.4% in the concentration level of 100 μg a.i./bee group. Therefore calculated oral dose is: oral LD50 (48 h) > 87.4 μg product /bee
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Reference:	KCP 10.3.1.1
Report	A GLP acute contact and oral toxicity study with GLOB2021dF on honey bees (<i>Apis mellifera</i>), 22/136-116MT, Orosz I., 2023a, Charles River Laboratories Hungary Kft.
Guideline(s):	Yes, OECD 213 and 214
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

SUMMARY

The objective of the study was to determine the acute oral and acute contact toxicity of the test item in the honey bee according to the OECD Guideline for Testing of Chemicals No. 213 and 214.

Based on the results of the preliminary range finding test, a limit test was performed at only one test dose with bees provided with 100 µg test item/bee.

In the oral experiment the test item was diluted in a 50 % w/v sucrose vehicle solution and was offered to the bees in a volume of 20 µL/bee. In the contact experiment two control groups, deionised water and DMSO were allocated in the experiment. The test item was diluted in acetone and a volume of 1 µL/bee was dropped onto the dorsal side of each bee.

Five replicates of 10 bees were used in the test item group as well as in the vehicle control groups. The duration of the experiments was 48 hours. There was no treatment related mortality during the experiments. There was no test item related clinical symptoms in the test item treated groups in both experiments.

In the oral experiment the mean food consumption was 92% in the control group. In the concentration level of 100 µg a.i./bee, the mean food consumption was 87.4%.

No repellent effect was observed in the other groups.

In the oral reference experiment the mean food consumption was between the range of 40% and 65%.

Conclusion

The acute oral and acute contact toxicity of the test item was tested on honey bees (*Apis mellifera*) under laboratory conditions. Based on the results obtained, the LD50 (48 h) in the oral toxicity test was determined to be 100 µg formulated product/bee. No adverse effects were noticed on behaviour.

In the contact toxicity test, the LD50 (48 h) was determined to be higher than 100 µg formulated product/bee. No adverse effects were noticed on behaviour.

Oral 48 h LD50: 100 µg test item/bee

Contact 48 h LD50: > 100 µg formulated product/bee

A 2.2.1.2 KCP 10.3.1.2. Chronic toxicity to bees

A 2.2.1.2.1 Study 1

Comments of zRMS:	The study was conducted in line with OECD 245.
	Deviations: Due to technician safety reasons, minimal amounts of CO ₂ were used for the rapid and safe collection of bees during allocation of the bees to the group cages.

	These facts were considered by the Study Director to have no impact on the study, the results or integrity of the study. All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment: LDD₅₀ > 79.1 µg/bee/day NOEC = 1000 mg/kg feeding solution NOEDD = 79.1 µg/bee/day
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Reference:	KCP 10.3.1.2
Report	A GLP 10-day chronic oral toxicity study with GLOB2021dF on honey bees (<i>Apis mellifera</i>) 22/136-134MT, Orosz I., 2023b, Charles River Laboratories Hungary Kft.
Guideline(s):	Yes, OECD ~~245213~~ and 214
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Summary

The objective of the study was to determine the chronic oral toxicity of the test item in honey bees (max. 2 days old) according to the OECD Guideline for Testing of Chemicals No. 245. Groups of bees were given test item in sucrose solution and observed for mortality and adverse clinical signs for 10 days.

Based on the results of the preliminary range finding test, five dose levels and two untreated control groups were used in the main test. The following dose levels will be used: 1, 3.1, 9.8, 31.3 and 100 µg test item/bee.

The test item was diluted in a 50 % w/v sucrose vehicle solution and was offered *ad libitum* to the honeybees via two feeders (each vial was a 2.0 mL plastic Eppendorf tube with cap and a feeding hole in the base). Each feeding interval was 24 h. Three replicates of 10 bees were used in the test item groups as well as in the vehicle controls (sucrose solution only) and the reference control. The duration of the experiment was 10 days.

All validity criteria were within acceptable limits and therefore the study can be considered as valid.

The test concentrations were analytically determined at the start of the experiment, and compared with QC samples. During the formulation analysis the content boscalid and prothioconazole was determined. The analyzed concentrations were at 83.8 and 99.6% relative to the nominal dose in case of boscalid and 92.4 and 104% relative to the nominal dose in case of prothioconazole, indicating a fully adequate preparation of the feeding solutions.

There was 15% mortality in the control group and it was between 3 and 18% in the test item treated groups during the experiment.

The average mortality in the reference substance treated group was 80% at the end of the test.

The degree/incidence of behavioural impairments did not indicate an adverse effect of test item during the experiment.

The overall mean group food consumption was 81 mg/bee/day. There were no trends or differences between treated groups and the negative control group.

Based on the measured food consumption per group, the mean calculated doses per group were: 0.8, 2.4, 7.5, 26.6 and 79.1 µg/bee/day.

Conclusion

The chronic oral toxicity of the test item was tested on honey bees (*Apis mellifera*) under laboratory conditions. The limit test was performed at 100 µg test item / 100 mg feeding solution (the expected intake per bee per day). The actual food intake was ~80 mg/bee/day. No test item related mortality occurred and no adverse effects were noticed on behaviour.

LD ₅₀ :	> 1000 mg/kg feeding solution (nominal)
LOEC:	> 1000 mg/kg feeding solution (nominal)
NOEC:	1000 mg/kg feeding solution (nominal)
LDD ₅₀ :	> 100 µg test item/100 mg feeding solution / 79.1 µg test item/bee/day
LOEDD:	> 100 µg test item/100 mg feeding solution / 79.1µg test item/bee/day
NOEDD:	100 µg test item/100 mg feeding solution / 79.1µg test item/bee/day

A 2.2.1.3 KCP 10.3.1.3 Effects on honey bee development and other honey bee life stages

A 2.2.1.3.1 Study 1

Comments of zRMS:	The study was conducted in line with OECD 239. Deviations were found concerning: - changes in temperature and humidity during larval, pre-pupal development during the range-finding and definitive and reference test - temperature during pupal/imago development during definitive and reference tests. These were short-term changes. According to study director the above deviations did not affect the test result. All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment: NOED = >100 µg of test item/larva LD₅₀ > 100 µg of test item/larva
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Reference:	KCP 10.3.1.3
Report	Honey bee larval toxicity test following repeated exposure of the test item GLOB2021dF according to OECD GD 239 ENV/JM/MONO(2016)34 00664/0032/E Wozniak A., 2023, Sorbolab Research Laboratory LLC
Guideline(s):	Yes, OECD 239
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The assessment test of the test item GLOB2021dF toxicity on honey bee larvae (*Apis mellifera* L.) was conducted in accordance with the OECD GD 239 ENV/JM/MONO(2016)34 Guideline.

During the test, the impact on the successive stages of development of the honey bee, resulting from the repeated exposure of the larval stage to the test item, were determined. The aim of the study was to determine the concentration of the test item causing the mortality of 50% of the population in the test (LC₅₀ value) and the dose of the test item causing the mortality of 50% of the population after 22 days (LD₅₀ value). The values of NOEC and NOED, LC₁₀/LD₁₀ and LC₂₀/LD₂₀ were determined for emerged adults (survival) on the 22nd day of the study. Test design
Test cages

stability test:
tested concentrations and control in one replicate
range-finding, definitive test, reference test:
tested concentrations and control in one replicate; 36 larvae per replicate, 12 larvae from 3 different breeding

Exposition time
Duration of the test

stability test:
volumetric flask of 100 mL volume
range-finding, definitive, reference test:
48-well breeding plates with queen-cell cups placed in the dissector and placed in incubator; from day 15 of the test – transparent plastic boxes placed in test room
4 days (from day 3 to day 6)

Tested concentrations (doses)

stability test:
72 hours
range-finding, definitive, reference test:
22 days
stability test:
control (0 g of test item/L of deionized water)
0.05 g of test item/L of deionized water, corresponding to 0.65 mg of test item/kg of diet with deionized water
50 g of test item/L of deionized water, corresponding to 650 mg of test item/kg of diet with deionized water
range-finding test:
control (0 mg of test item/kg of diet with deionized water, corresponding to 0 µg of test item/larva (0 g of test item/L of deionized water)
0.65 mg of test item/kg of diet with deionized water, corresponding to 0.1 µg of test item/larva (0.05 g of test item/L of deionized water)
6.5 mg of test item/kg of diet with deionized water, corresponding to 1 µg of test item /larva (0.50 g of test item/L of deionized water)

65 mg of test item/kg of diet with deionized water, corresponding to 10 µg of test item /larva (5.0 g of test item/L of deionized water)

650 mg of test item/kg of diet with deionized water, corresponding to 100 µg of test item /larva (50.0 g of test item/L of deionized water)

definitive test:

control (0 mg of test item/kg of diet with deionized water, corresponding to 0 µg of test item/larva (0 g of test item/L of deionized water)

8.02 mg of test item/kg of diet with deionized water, corresponding to 1.23 µg of test item/larva (0.62 g of test item/L of deionized water)

24.07 mg of test item/kg of diet with deionized water, corresponding to 3.70 µg of test item/larva (1.85 g of test item/L of deionized water)

72.22 mg of test item/kg of diet with deionized water, corresponding to 11.11 µg of test item/larva (5.56 g of test item/L of deionized water)

216.67 mg of test item/kg of diet with deionized water, corresponding to 33.33 µg of test item/larva (16.67 g of test item/L of deionized water)

650.00 mg of test item/kg of diet with deionized water, corresponding to 100.00 µg of test item/larva (50.0 g of test item/L of deionized water)

reference test:

control - 0 mg of reference item/kg of diet with deionized water

dimethoate: 48 mg of reference item/kg of diet with deionized water i.e. 0.053 µg of reference item/µL, corresponding to 7.39 µg of reference item/larva (0.528 g of reference item/L of deionized water)

Test conditions

stability test:

average temperature 5.5°C (minimum temperature 4.5°C; maximum temperature 6.5°C); darkness*

range-finding test*:

□ for larval stage (day 1-8): average temperature 34.3°C (min 33.9°C, max 34.9°C), average relative humidity 92% (min 89%, max 96%)**

□ for pre-pupal stage (day 8-15): average temperature 34.3°C (min 33.0°C, max 34.8°C), average relative humidity 82% (min 74%, max 95%)**

□ for pupal/imago stage (day 15-22): average temperature 34.4°C (min 34.0°C, max 34.8°C), average relative humidity 73% (min 60%, max 85%)

definitive test:

□ for larval stage (day 1-8): average temperature 34.1°C (min 32.8°C, max 34.5°C), average relative humidity 96.2% (min 76.6%, max 99.9%), darkness**

- for pre-pupal stage (day 8-15): average temperature 34.0°C (min 33.4°C, max 34.3°C), average relative humidity 84.3% (min 70.9%, max 87.8%)**
- for pupal/imago stage (day 15-22): average temperature 34.0°C (min 33.9°C; max 34.1°C); average relative humidity 81.8% (min 79.5%; max 83.1%)**

Conclusion

In course of the experiment, the test item has shown no apitoxic effect in mortality of following developmental stages of bees after 22 days of the test.

At the end of the study, the concentration and the dose causing 10% mortality of the population in the test (LC₁₀ and LD₁₀) was determined. The concentrations causing 20% and 50% mortality of the population in the test (LC₂₀, LC₅₀ and, LD₂₀, LD₅₀ values) were not determined. The NOEC and NOED values were determined at 22nd day.

Final results of the experiment are presented in Table 1.

Parameter	Concentration [mg of test item/kg of food]	Parameter	Dose [µg of test item/larva]
LC ₁₀	157.848	LD ₁₀	24.275
LC ₂₀	>650.00**	LD ₂₀	>100**
LC ₅₀	>650.00**	LD ₅₀	>100**
NOEC	≥650	NOED	≥100
LOEC	>650**	LOED	>100**

LC₁₀ test item concentration causing mortality of 10% population

LC₂₀ test item concentration causing mortality of 20% population

LC₅₀ test item concentration causing mortality of 50% population

NOEC the highest test item concentration not causing statistically significant differences in relations to the control

LOEC the lowest test item concentration causing statistically significant differences in relations to the control

LD₁₀ test item dose causing mortality of 10% population

LD₂₀ test item dose causing mortality of 20% population

LD₅₀ test item dose causing mortality of 50% population

NOED the highest test item dose not causing statistically significant differences in relations to the control

LOED the lowest test item dose causing statistically significant differences in relations to the control

* upper and lower confidence limits (95%) given in the brackets

** values determined based on the analysis of the results

A 2.2.1.4 KCP 10.3.1.5 Acute toxicity to bumblebees

Comments of zRMS:	The study was conducted in line with OECD 246 and 247. Deviations were found concerning relative humidity values (minimum of 33%, maximum of 88%) outside the expected range of 40-80% were recorded occasionally during the study. This fact had no impact on the study on the results or integrity of the study. All the validity criteria were met and the study is considered acceptable with the following endpoints relevant for the risk assessment:
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	Oral 48 h LD50: > 100 µg test item/bumblebee (nominal) Contact 48 h LD50: > 100 µg test item/bumblebee (nominal) In the oral experiment the mean food consumption was 96% in the concentration level of 100 µg/bumblebeegroup. Therefore calculated oral dose is: oral LD50 (48 h) > 96 µg/bumblebee
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Reference:	KCP 10.3.1
Report	A GLP acute contact and oral toxicity study with GLOB2021dF on bumblebees (<i>Bombus terrestris</i>) 22/136-136MTB Orosz I., 2023c, Charles River Laboratories Hungary Kft
Guideline(s):	Yes, OECD 246 and 247
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

Materials and methods

The objective of the study was to determine the acute oral and acute contact toxicity of the test item in the bumblebee according to the OECD Guideline for Testing of Chemicals No. 246 and 247.

Based on the results of the preliminary range finding test, a limit test was performed at only one test dose with bees provided with 100 µg test item/bumblebee.

In the oral experiment the test item was diluted in a 50 % w/v sucrose vehicle solution and was offered to the bumblebees in a volume of 40 µL/bumblebee.

In the contact experiment two control groups, deionised water and DMSO, were allocated in the experiment. The test item was diluted in DMSO and a volume of 2 µL/bumblebee was dropped onto the dorsal side of each bumblebee.

Fifty bumblebees were used in the contact and oral test item groups and in the vehicle control groups. The duration of the experiments was 48 hours.

Samples taken from the test formulation were analyzed. Based on these results, effect parameters were expressed as analytically confirmed nominal doses.

There was no treatment related mortality during the experiments.

There were no test item related clinical symptoms in the test item treated groups in either experiment.

In the oral experiment the mean food consumption was 97% or provided feed in the control group and at the concentration level of 100 µg/bee, the mean food consumption was 96%, hence there was no repellency.

Results and discussions

Table 1: Mortality at the end of the oral definitive test

Nominal dose (µg/bumblebee)	Control (sucrose solution)	100	Reference control (4 µg a.i./bumblebee)
Cumulative mortality	0/50	1/50	29/30
Percentage mortality (%)	0	2	97

Table 2: Mortality at the end of the contact definitive test

Nominal dose (µg/bumblebee)	Control (deionised water)	Control (DMSO)	100	Reference control (10 µg a.i./bumblebee)
Cumulative mortality	1/50	0/50	1/50	17/30
Percentage mortality (%)	2	0	2	57

Conclusion

The acute oral and acute contact toxicity of the test item was tested on bumblebees (*Bombus terrestris*) under laboratory conditions. Based on the results obtained, the LD50 (48 h) in the oral toxicity test was determined to be >100 µg test item/bumblebee (nominal). No adverse effects were noticed on behaviour.

In the contact toxicity test, the LD50 (48 h) was determined to be higher than 100 µg test item/bumblebee (nominal). No adverse effects were noticed on behaviour.

Oral 48 h LD50: > 100 µg test item/bumblebee (nominal)

Contact 48 h LD50: > 100 µg test item/bumblebee (nominal)

A 2.2.1.5 KCP 10.3.2 Effects on arthropods other than bees

A 2.2.1.5.1 Study 1

Comments of zRMS:	The study was conducted according to the method IOBC Blümel et al. (2000). Validity criteria were met: - mortality in the control treatment over the initial 7 days did not exceed 20% (actual: 10%). - mortality in the toxic reference was 50-100 % (96.7 %). - the mean cumulative number of eggs produced between 7 and 14 days exceeded 4.0 per female in the control treatment (actual 4.7 eggs/female) The study is acceptable and suitable for the use in the risk assessment. Deviation occurred in the experimental part of the study; in the definitive test relative humidity values (minimum of 50%) outside the expected range of 60-90% were recorded occasionally during the study. LR50 >1.2 L GLOB2021dF/ha
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	ER50 > 0.9 L GLOB2021dF/ha NOERmortality $\geq$ 0.8 L GLOB2021dF/ha NOERreproduction > 0.8 L GLOB2021dF/ha
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Reference:	KCP 10.3.2
Report	Effect of GLOB2021dF on the predatory mite (<i>Typhlodromus pyri</i>) in an extended laboratory trial 22/136-351RA Orovecz B., 2023a, Charles River Laboratories Hungary Kft
Guideline(s):	Yes, IOBC - Blümel, 2000
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

In an extended laboratory study, *Typhlodromus pyri* (Acarina: Phytoseiidae) were exposed to dried residues of GLOB2021dF on treated leaf discs (bean leaves, *Phaseolus vulgaris*).

The effects on mortality and reproduction were determined. As no significant mortalities or toxic effects were observed throughout the preliminary range-finding test, three application rates at 0.4 L/ha, 0.8 L/ha (Maximum Use Rate) and 1.2 L/ha, were tested in the main experiment. Based on the result of the preliminary range-finding test, a limit test could have been performed, but at the request of the Sponsor two additional concentrations (one higher and one lower than Maximum Use Rate) were used in the main test.

After 7 days, the corrected mortality for the different rates ranged between 0.0 % and 18.5 %. Statistically higher mortality than control was observed at the test item treatment rate of 1.2 L/ha; the LR₅₀ was determined to be higher than 1.2 L GLOB2021dF/ha in 200 L water/ha, the highest tested rate in the study.

The reproductive capacity of the mites was assessed at 0.4, 0.8 and 1.2 L/ha GLOB2021dF, because the corrected mortalities were less than 50 % in all treatment rates. The reproduction rate amounted to 4.7 eggs/female in the control treatment. The 4.5 eggs per female were laid in the test item treatment of 0.4 L/ha, 3.1 eggs per female in the test item group of 0.8 L/ha and 1.0 eggs per female were counted at the highest test rate of 1.2 L/ha. Therefore, effects on reproduction of 4.1 %, 33.7 % and 77.8 % were calculated, respectively. Statistically significant difference on reproduction was observed at the treatment rates of 0.8 and 1.2 L/ha when compared to the control but the of value of 0.8 L/ha was less than the 50% threshold value, hence the only unacceptable result indicating significant effects on reproduction was the highest test rate of 1.2 L/ha.

Under the conditions of the test, the test item LR₅₀ for adult mite mortality was > 1.2 L GLOB2021dF/ha in 200 L water/ha. No unacceptable biologically adverse effect (effects < 50%) was observed on reproduction of mites at 0.8 L GLOB2021dF/ha in 200 L water/ha.

Adult mortality

LR₅₀: >1.2 L GLOB2021dF/ha in 200 L water/ha
(95 % conf. limits: n.d.)

NOER: 0.8 L GLOB2021dF/ha in 200 L water/ha

LOER: 1.2 L GLOB2021dF/ha in 200 L water/ha

Note: n.d.: not determined due to mathematical reasons or inappropriate data.

Reproduction

ER₅₀: 0.9 L GLOB2021dF/ha in 200 L water/ha
(95 % conf. limits: 0.8 – 1.0 L/ha)

NOER: 0.8 L GLOB2021dF/ha in 200 L water/ha

LOER: 1.2 L GLOB2021dF/ha in 200 L water/ha

A 2.2.1.5.2 Study 2

Comments of zRMS:	The study was carried out according to current guidelines. The study is considered acceptable, validity criteria were met. • Pre-imaginal mortality within the control treatment was 3.33% (should not exceed 20.0%, i.e. 8 lacewings from 40). • Corrected pre-imaginal mortality within the toxic-reference treatment was 68.97% (should exceed 50%). • Mean egg production per female per day in the control treatment was 18.03 (should be ≥ 15.0 per female per day). • Mean egg viability in the control treatment was 86.39% (should be $\geq 70\%$). In the experimental part of the study a deviation from the guidelines developed by the IOBC, BART and EPPO Joint initiative (Vogt H. et al., 2000) occurred. Deviation occurred in the experimental part of the study; in the definitive test the temperature lowered to minimum of 19.9°C and increased to maximum of 27.9°C with average temperature of 23.4°C (requirements: 25±2°C) and relative humidity values (minimum of 49.9%) outside the expected range of 60-90% were recorded occasionally during the study. The oviposition stabilization phase lasted for 10 days instead of planned 7 days and time of reproductive performance lasted for 9 days instead of planned minimum 14 days. According to the study director these deviations did not affect the conduction and results of the study. Agreed endpoint: LR50 > 2180 L prod./ha
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Reference: KCP 10.3.2

Report Extended laboratory test to determine the effects of the test item GLOB2021dF on the green lacewing (*Chrysoperla carnea*)
00664/0034/E
Kubisiak, K., 2023c,
Sorbolab Research Laboratory LLC

Guideline(s): Yes, IOBC, BART, EPPO

Deviations: No

GLP: Yes

Acceptability: Yes/No/Supplementary

Duplication No

(if vertebrate study)

Materials and methods

An extended laboratory study of the effect of the test item GLOB2021dF on mortality of larvae and pupae and sub-lethal effect on reproductive performance of the green lacewing (*Chrysoperla carnea*) was carried out in accordance with IOBC, BART, EPPO Joint Initiative and Vogt et al., 2000 and ESCORT 2. Candolfi et al. 2001. The endpoints of the experiment are LR10, LR20 and LR50 values for larval and pupal mortality and quantitative judgement on the reproductive performance – number of eggs laid per female (fecundity) and hatching ability (fertility). The NOER and LOER values were also statistically determined. Reference item treatment was conducted.

Test design

range-finding test:

- tested doses and control in 15 replicates (1 larva per replicate)

definitive and reference test:

- tested doses and control in 30 replicates (1 larva per replicate)

Experimental area

bean leaf with designated experimental area

Duration

range-finding test:

- ☐ 0-26 day after treatment (mortality assessment)

reference item treatment:

- ☐ 0-29 day after treatment (mortality assessment)

definitive test:

- ☐ 0-27 day after treatment (mortality assessment)
- ☐ 40-49 day after treatment (reproduction performance)¹

Test item doses

range-finding test:

- ☐ control (0 mL of the test item/200 L of water/ha)
- ☐ 20 mL of the test item/200 L of water /ha
- ☐ 200 mL of the test item/200 L of water/ha
- ☐ 2000 mL of the test item/200 L of water/ha

definitive test:

- ☐ control (0 mL of the test item/200 L of water/ha)
- ☐ 125 mL of the test item/200 L of water /ha
- ☐ 250 mL of the test item/200 L of water/ha
- ☐ 500 mL of the test item/200 L of water/ha
- ☐ 1000 mL of the test item/200 L of water/ha
- ☐ 2000 mL of the test item/200 L of water/ha

reference item treatment:

- ☐ 15 g of dimethoate/200 L of water/ha

Test conditions

range-finding test:

- ☐ average temperature 25.6°C (min 20.6°C, max 27.9°C)²
- ☐ average relative humidity 61.8% (min 48.4%, max 78.9%)²
- ☐ photoperiod 16 h day/8 h night with a light intensity 1163-1253 lux

definitive test:

- ☐ average temperature 23.4°C (min 19.9°C, max 27.9°C)³
- ☐ average relative humidity 66.8% (min 49.9%, max 81.2%)³

☐ photoperiod 16 h day/8 h night with a light intensity 1133-1277 lux

reference item treatment:

- ☐ average temperature 23.5°C (min 19.9°C, max 27.9°C)4
- ☐ average relative humidity 62.6% (min 49.9%, max 68.8%)4
- ☐ photoperiod 16 h day/8 h night with a light intensity 1120-1279 lux

Results

The test item in an extended laboratory test showed a statistically significant effect on the survival of the larvae, pupae and adults during emergence of the green lacewing in doses of 500 mL of the test item/200 L of water/ha, 1000 mL of the test item/200 L of water/ha and 2000 mL of the test item/200 L of water/ha.

The test item did not affect the reproductive performance of the green lacewing. Average number of laid eggs/female/day (fecundity) for control and all tested doses is ≥ 15 and mean hatching rate (fertility) is $\geq 70\%$, which, in accordance with the adopted method of assessment, means no effect of the test item on reproductive ability. Individuals from the all tested doses were assessed for reproduction. This was due to a mortality of $\leq 50\%$ of the introduced organisms.

Final results of the test are presented in Table 1.

Table 1. Final results

Dose [mL of the test item/200 L of water/ha]	Mortality						
	Mortality [%]	Abbott corected mortality [%]	LR ₁₀	LR ₂₀	LR ₅₀	NOER	LOER
Control	3.33	0.00	[mL of the test item/200 L of water/ha]				
125	6.67	3.45	338.044	710.288	2180.081	250.000	500.000
250	10.00	6.90	[g of active substance/200 L of water/ha]				
500	16.67	13.79	Boscalid 49.919	Boscalid 104.888	Boscalid 321.933	Boscalid 36.918	Boscalid 73.835
1000	33.33	31.03	Prothioco- nazole 52.978	Prothioco- nazole 111.316	Prothioco- nazole 341.662	Prothioco- nazole 39.180	Prothioco- nazole 78.360
2000	46.67	44.83					
Reference item [15 g of dimethoate/ 200 L of water/ha]	70.00	68.97					
Dose [mL of the test item/ 200 L of water/ha]	Impact of the test item on reproductive performance						
	Average number of eggs per female per day [psc.]		Hatching rate [%]		Significance*		
Control	18.03		86.39		not applicable		
125	17.19		87.10		-		
250	17.73		88.66		-		
500	17.58		88.77		-		
1000	16.70		87.03		-		
2000	17.25		82.19		-		

Dose [mL of the test item/200 L of water/ha]		Mortality					
Mortality [%]	Abbott corrected mortality [%]	LR10	LR20	LR50	NOER	LOER	
Control		3.33		0.00			[mL of the test item/200 L of water/ha]
338.044	710.288		2180.081	250.000		500.000	
125			6.67			3.45	
250		10.00		6.90			[g of active sub- stance/200 L of wa- ter/ha]
500	16.67	13.79	Boscalid	Boscalid	Boscalid	Boscalid	Boscalid
			49.919	104.888	321.933	36.918	73.835
			Prothioeco- nazole	Prothioeco- nazole	Prothioeco- nazole	Prothioeco- nazole	Prothioeco- nazole
			52.978	111.316	341.662	39.180	78.360
1000		33.33		31.03			
2000		46.67		44.83			
Reference item		70.00		68.97			
[15 g of dimethoate/ 200 L of water/ha]							
Dose [mL of the test item/ 200 L of water/ha]		Impact of the test item on reproductive perfor- mance					
Average number of eggs per fe- male per day [pse.]	Hatching rate [%]	Significance [±]					
Control	18.03	86.39				not applicable	
125	17.19	87.10				-	
250	17.73	88.66				-	
500	17.58	88.77				-	
1000	16.70	87.03				-	
2000	17.25	82.19				-	

A 2.2.1.5.3 Study 3

Comments of zRMS:	The study was conducted according to the method Schmuck et al., 2000 Validity criteria were met: - Pre-imaginal mortality (this includes dead larvae, pupae and adults dying during emergence from their pupae) in the control treatment should not exceed 30% (actual 10%), - The level of mortality in the toxic reference treatment should be $\geq 50\%$ (actual 92.%). - Mean egg production should be > 2 viable eggs/female/day in the control treatment (4 at 0 DAT and 9.5 at 14 DAT). There were no deviations. The study is acceptable and suitable for the use in the risk assessment.
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Reference: KCP 10.3.2

Report Extended laboratory test to determine the effects of the test item GLOB2021dF on the ladybird beetle (*Coccinella septempunctata*)

	00664/0033/E Domagala J., 2023c, Sorbolab Research Laboratory LLC
Guideline(s):	Yes, IOBC, BART, EPPO
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

An extended laboratory study of the effect of the test item GLOB2111F on larval, pupae mortality and sublethal effect on reproductive performance of the ladybird beetle (*Coccinella septempunctata*) was carried out in accordance with IOBC, BART, EPPO Joint Initiative, Schumck et al. 2000 guideline. The endpoints of the experiment are LR₁₀, LR₂₀, LR₅₀ values for larval and pupal mortality and quantitative judgement on the reproductive performance – number of eggs laid per female (fecundity) and hatching ability (fertility). The NOER and LOER values were also statistically determined.

The definitive test: Test design

Test surface	30 replicates 1 larva per replicate bean leaf with designated test area
Duration	mortality assessment: ☐ 21 days ☐ 6 days (reference item treatment time) reproduction assessment: 29 days in total (including 14 days of eggs laid assessment)
Rates used in the test	☐ control (0 mL of the test item/200 L water/ha) ☐ 87.5 mL of the test item/200 L of water /ha ☐ 175 mL of the test item/200 L of water/ha ☐ 350 mL of the test item/200 L of water/ha ☐ 700 mL of the test item/200 L of water/ha ☐ 1400 mL of the test item/200 L of water/ha ☐ reference item treatment: 3.2 g dimethoate/200 L water/ha
Test conditions	temperature: average 25.5°C (min 20.8°C, max 28.9°C) ₁ relative humidity: average 74.4% (min 51.0%, max 91.7%) ₂ photoperiod 16 h day/8 h night with a light intensity: ☐ 1160-1230 lux (test item treatment) ☐ 1180-1200 lux (reference item treatment)

1,2 A deviations from the Study plan and guidelines were found, concerning temperature and humidity. The deviations are described in point 6.

Results

The test item in the course of study did show a statistically significant effect on the mortality of *Coccinella septempunctata* in rates of 87.5 mL of the test item/200 L water/ha, 175 mL of the test item/200 L water/ha, 350 mL of the test item/200 L water/ha, 700 mL of the test item/200 L water/ha and 1400 mL of the test item/200 L water/ha.

The final results of the study are presented in Table 1.

Comments of zRMS:	The study was conducted according to the method Schmuck et al., 2000 Validity criteria were met: - Pre-imaginal mortality (this includes dead larvae, pupae and adults dying during emergence from their pupae) in the control treatment should not exceed 30% (actual 10%), - The level of mortality in the toxic reference treatment should be $\geq 50\%$ (actual 92.%). - Mean egg production should be > 2 viable eggs/female/day in the control treatment (4 at 0 DAT and 9.5 at 14 DAT). There were no deviations. The study is acceptable and suitable for the use in the risk assessment.
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Reference: KCP 10.3.2

Report Aged-residue extended laboratory test to determine the effects of the test item GLOB2021dF on the ladybird beetle (*Coccinella septempunctata*) according to IOBC, BART and EPPO Joint initiative. M.P. Candolfi, et. Al. (2000) 00664/0042/E
Domagala J., 2023c,
Sorbolab Research Laboratory LLC

Guideline(s): Yes, IOBC, BART and EPPO Joint initiative. M.P. Candolfi, et. Al. (2000)

Deviations: No

GLP: Yes

Acceptability: Yes/No/Supplementary

Duplication (if vertebrate study) No

An aged-residue test of the effect of the test item GLOB2021dF on larval, pupae and adults mortality during emergence and sublethal effect on reproduction of the ladybird beetle (*Coccinella septempunctata*) in accordance with IOBC, BART, EPPO Joint Initiative, Candolfi et al., 2000 using bean leaves (*Phaseolus vulgaris* cv. Piękny Jaś) as a test surface a certain number days after treatment (DAT).

The aim of the experiment was to determine the effects of freshly-dried and field-aged residues of the test item in series of bioassays through assess the mortality and reproductive performance of the test organism until no unacceptable effect due to test item occurred in two consecutive bioassays.

Test design control and test item rate – 40 replicates for each bioassays, 1 larva per replicate
reference item rate – 30 replicates for each bioassays, 1 larva per replicate

Test surface bean leaf with designated test area

Duration

- 0 DAT:

mortality assessment:

- 22 days

- 6 days (reference item treatment time)

reproduction assessment was not performed due to high mortality in the test item rates

- 7 DAT:

mortality assessment:

- 21 days

- 7 days (reference item treatment time)

reproduction assessment was not performed due to high mortality in the test item rates

- 21 DAT:

mortality assessment:

- 21 days

- 6 days (reference item treatment time)

reproduction assessment: 30 days in total (including 14 days of eggs laid assessment)

- 28 DAT:

mortality assessment:

- 20 days

- 6 days (reference item treatment time)

reproduction assessment: 31 days in total (including 14 days of eggs laid assessment)

Rates 0 mL of the test item/200 L water/ha – control

1400 mL of the test item/200 L water/ha

reference item: 3.2 g dimethoate/200 L water/ha*

Laboratory bioassays were carried out using pots with treated seedlings:

☐ 0 DAT – fresh dried residues;

mortality assessment using :

0 mL of the test item/200 L water/ha – control

1400 mL of the test item/200 L water/ha

☐ 7 DAT

mortality assessment using :

0 mL of the test item/200 L water/ha – control

1400 mL of the test item/200 L water/ha

☐ 21 DAT

mortality assessment using :

0 mL of the test item/200 L water/ha – control

1400 mL of the test item/200 L water/ha

reproduction assessment using rates:

0 mL of the test item/200 L water/ha – control

1400 mL of the test item/200 L water/ha

☐ 28 DAT

mortality assessment using :

0 mL of the test item/200 L water/ha – control

1400 mL of the test item/200 L water/ha

reproduction assessment using rates:

0 mL of the test item/200 L water/ha – control

1400 mL of the test item/200 L water/ha

Test conditions Storage outdoor:

temperature: average 20.8°C (min. 12.8°C, max. 31.5°C)

relative humidity: average 63.3% (min. 33.6%, max. 91.9%)

0 DAT

temperature: average 25.4°C (min. 20.8°C, max. 28.9°C)¹

relative air humidity: average 73.6% (min. 51.0%, max. 91.7%)²

lighting: daily cycle, 16 h light/8 h darkness

light intensity:

☐ 1160–1230 lux (definitive test)

☐ 1160–1200 lux (reference item treatment)

7 DAT

temperature: average 25.2°C (min. 20.8°C, max. 28.9°C)³

relative air humidity: average 74.2% (min. 60.0%, max. 88.8%)

lighting: daily cycle, 16 h light/8 h darkness

light intensity:

☐ 1170–1230 lux (definitive test)

☐ 1170–1220 lux (reference item treatment)

21 DAT

temperature: average 25.4°C (min. 22.2°C, max. 27.7°C)⁴

relative air humidity: average 76.4% (min. 63.6%, max. 89.7%)

lighting: daily cycle, 16 h light/8 h darkness

light intensity:

☐ 1160–1230 lux (definitive test)

☐ 1180–1210 lux (reference item treatment)

28 DAT

temperature: average 25.3°C (min. 22.1°C, max. 27.7°C)⁵

relative air humidity: average 77.0% (min. 63.6%, max. 89.7%)

lighting: daily cycle, 16 h light/8 h darkness

light intensity:

☐ 1170–1230 lux (definitive test)

☐ 1170–1210 lux (reference item treatment)

Conclusions:

The impact of the freshly-dried and field-aged residues of the test item on the *Coccinella septempunctata* were evaluated under laboratory test conditions on following bioassays: 0 DAT, 7 DAT, 21 DAT and 28 DAT. The test item achieved <50% mortality and <50% reduction in reproductive performance (relative to the control) in two subsequent bioassays at 21 DAT and 28 DAT for rate 1400 mL of the test item/200 L water/ha.

A 2.2.1.5.4 Study 4

Comments of zRMS:	The study was conducted according to the method Gandolfi (2001), Validity criteria were met: -mortality in the control treatment at 48 h did not exceed 10 % (actual: 0%). -mortality in the toxic reference treatment ≥ 50 % at 48 h (actual: 80 %). - all wasps survived the 24-hour oviposition period,
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	-the mean number of mummies in the control treatment was >5.0 per per female (actual: 9.9) and no more than two females should fail to produce mummies (actual: no zero values). Deviation occurred in the experimental part of the study. Due to technical reasons, relative humidity and temperature values outside the expected range were recorded occasionally during the study. This deviation was considered to have no impact on the outcome of the study and interpretation of the results. The study is acceptable and suitable for the use in the risk assessment. 48h LR50> 1.2 l product/ha ER50> 1.2 l product/ha NOERMortality 1.2 L/ha NOERreproduction 1.2 L/ha
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Reference:	KCP 10.3.2
Report	Effect of GLOB2021dF on the parasitic wasp (<i>Aphidius rhopalosiphi</i>) in an extended laboratory trial 22/136-351FD Orovecz B., 2023b, Charles River Laboratories Hungary Kft
Guideline(s):	Yes, IOBC - Mead-Briggs, 2010
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

In an extended laboratory study, adults of *Aphidius rhopalosiphi* (Hymenoptera, Braconidae) were exposed to dried residues of GLOB2021dF on barley plants.

The effects on mortality and reproduction were determined. As no mortalities or toxic effects were observed throughout the preliminary range-finding test, three application rates at 0.4 L/ha, 0.8 L/ha (Maximum Use Rate) and 1.2 L/ha, were tested in the main experiment. Based on the result of the preliminary range-finding test, a limit test could have been performed, but at the request of the Sponsor two additional concentrations (one higher and one lower than Maximum Use Rate) were used in the main test.

After 48 hours, one wasp (1/30) was dead in the 1.2 L/ha group and no mortality was noted in the 0.4 and 0.8 L/ha test item or control groups. The LR₅₀ was determined to be higher than the highest tested rate of 1.2 L/ha GLOB2021dF in 400 L water/ha.

Reproduction was assessed in the control and test item treatments. The mean number of mummies per female was 9.9 in the control, while it was 11.2, 7.9 and 8.3 in the test item rates of 0.4, 0.8 and 1.2 L/ha. A statistically no significant of reproduction was observed at the all-test item treatment rate when compared to the control.

A toxic reference item (Dimethoate Pestanal at 3.4 g/ha) was included in the test to indicate the relative susceptibility of the test organism and the sensitivity of the test system. The results of toxic reference item were 73.3% (> 50%) mortality at 48 h. No reproduction assessment was performed with the reference item treatment.

Under the conditions of the test, the test item had no effect on the adult mortality or repellency or on reproduction of wasps at 1.2 L GLOB2021dF/ha in 400 L water/ha.

Adult mortality and repellency

LR₅₀: >1.2 L GLOB2021dF/ha in 400 L water/ha
NOER: 1.2 L GLOB2021dF/ha in 400 L water/ha
LOER: ≥1.2 L GLOB2021dF/ha in 400 L water/ha

Reproduction

ER₅₀: >1.2 L GLOB2021dF/ha in 400 L water/ha
(95 % conf. limits: n.d.)
NOER: 1.2 L GLOB2021dF/ha in 400 L water/ha
LOER: ≥1.2 L GLOB2021dF/ha in 400 L water/ha

Note: n.d.: not determined due to mathematical reasons or inappropriate data.

A 2.3 KCP 10.4 Effects on non-target soil meso- and macrofauna

A 2.3.1 KCP 10.4.1 Earthworms

Comments of zRMS:	The study was performed according to OECD TG 222 and principles of GLP. The validity criteria are met. For the control group: - The mean adult mortality in the control: ≤ 10% (0.0%) - Mean reproduction in control: at least 30 juveniles per container (178.6) - Coefficient of variance of reproduction in control: ≤ 30% (14.4%) A deviation from the guideline occurred during the study. According to the relevant guideline (OECD No.222) the test should be carried out under controlled light-dark cycles (preferably 16 hours light and 8 hours dark). Because of technical reasons (the earthworms try to escape from the test vessels in the dark, with illumination the worms remain in the soil) the test was performed under continuous lighting according to the experience of this laboratory. This deviation is considered to be justified on scientific grounds and to have no impact on the outcome of the study or the interpretation of the results (under the soil, the earthworms remain in dark conditions). This deviation was considered to have no impact on the outcome of the study and interpretation of the results. The study is considered acceptable and suitable for the risk assessment. NOEC = 125 mg test item/kg soil dry weight EC₁₀ = 47 mg test item/kg soil dry weight
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Reference: KCP 10.4

Report A GLP reproduction study of GLOB2021dF on earthworms (*Eisenia fetida*) 22/136-211G

Orosz i., 2023d,
Charles River Laboratories Hungary Kft.

Guideline(s): Yes, OECD 222
Deviations: No
GLP: Yes
Acceptability: Yes/No/Supplementary
Duplication (if vertebrate study) No

The objective of the study was to determine the effects of test item on reproduction of earthworms (*Eisenia fetida*).

This test involved keeping adult earthworms in precisely defined test item treated artificial soil. Mortality and growth effects on the adult worms were determined after four weeks exposure. The adults were then removed from the soil and effects on reproduction were assessed after a further four weeks by counting the number of offspring present in the soil.

Different concentrations of the test item were mixed homogeneously into the soil and filled into plastic containers before the earthworms were introduced on top of the soil. Five concentrations (4 replicates each) and an untreated control (8 replicates) were prepared. Each replicate contained 10 worms at the start of the test. The test was performed according to guidelines OECD 222 (2016).

The test concentrations selected for definitive test based on the results of the range finding test were: 62.5, 125, 250, 500 and 1000 mg /kg soil dry weight.

As the results of the control group show, validity criteria were met in the study.

One out of forty animal died at the concentration level of 125 mg/kg soil dry weight during the experiment, this was considered to be due to natural causes rather than a toxic effect as this mortality was 2.5 % in this test group (within the historical control range and no dose response).

No behavioural effects were observed during the experiment in the control group.

No test item related effects were detected in changes in biomass or on food consumption during the study in the treated groups when compared to the controls.

In the control, the average number of offspring was 178.6 juveniles per replicate. The number of juveniles was statistically significantly reduced at the concentration range between 250 and 1000 mg/kg soil dry weight compared to the control, with an apparent dose response.

The biological results of the test are summarised in the following table:

	Control	62.5	125	250	500	1000
The biological results of the test are summarised in the following table: Concentration [mg/kg]						
Mortality [%]- Day 28	0.0 –	0.0 n.d.	2.5 n.s.	0.0 n.d.	0.0 n.d.	0.0 n.d.
Weight change [%]-Day 28	16.0 –	10.1 n.d.	19.4 n.d.	23.5 n.d.	15.1 n.d.	11.3 n.d.

Number of juveniles- 178.6 – 141.8 n.s. 155.0 n.s. 110.3 * 94.8 * 64.8 *
Day 56

Conclusion

The validity criteria of the study were met.

Under the conditions of the test, the test item had no effect on the mortality, clinical signs or weight gain, but there was a treatment related toxic effect on reproduction of earthworms (*Eisenia fetida*) at the concentration levels of 250, 500 and 1000 mg/kg soil dry weight.

Adult mortality

LC50 (28 day): >1000 mg/kg soil dry weight

NOEC: 1000 mg/kg soil dry weight

LOEC: >1000 mg/kg soil dry weight

Reproduction

EC10 (56 day): 47 mg/kg soil dry weight

(95 % conf. limits: 16 – 141 mg/kg soil dry weight)

EC50 (56 day): 547 mg/kg soil dry weight

(95 % conf. limits: 131 – 2147 mg/kg soil dry weight)

NOEC: 125 mg/kg soil dry weight

LOEC: 250 mg/kg soil dry weight

A 2.3.2 KCP 10.4.2 Effects on non-target soil meso- and macrofauna (other than earthworms)

Comments of zRMS:	The study was performed according to OECD TG 232 and principles of GLP. The validity criteria were met. For the control group: -The mortality of the adults in the control at the end of the test: $\leq 20\%$. - The reproduction rate reaches a minimum of 100 juveniles per control vessel. - The coefficient of variation of reproduction in the control: $< 30\%$. There were no deviations to the study plan. The study is considered acceptable and suitable for the risk assessment. NOECrepr. = 309 mg test item/kg soil dry weight
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Reference:	KCP 10.4
Report	A GLP reproduction test of GLOB2021dF in soil with Collembolan (<i>Folsomia candida</i>) 22/136-130CO Orosz i., 2023d, Charles River Laboratories Hungary Kft.
Guideline(s):	Yes, OECD 232
Deviations:	No
GLP:	Yes

Acceptability: Yes/No/Supplementary
Duplication No
(if vertebrate study)

A Collembola (*Folsomia candida*) reproduction study was performed to determine the effect of the test item on the mortality and reproduction of Collembolans by cutaneous and alimentary uptake in a defined artificial soil substrate. The toxic effects of the test item were evaluated according to the OECD No. 232 guideline (2016).

The effects of different concentrations of test item were determined on the reproduction of 11-day old springtails (*Folsomia candida*) in defined artificial soil substrate, as recommended in OECD 232. Four replicates were used per concentration; eight replicates were used for the control each containing 10 springtails. The springtails were incubated in the substrate in glass containers for 28 days (until offspring (F1) emerged from eggs laid by mature adults). The number of offspring and the mortality of adults were determined at the end of the test. The examined concentrations were 16.3, 29.4, 52.9, 95.3, 171, 309, 556, 1000 mg/kg artificial soil dry weight. At the start of the test and after a period of 14 days the adult springtails were fed with about 2 mg of granulated dry yeast per container. The test containers were tightly closed during the test and open briefly twice a week to allow aeration. The test containers were held in a climate chamber under controlled light-dark cycles and the temperature was checked continuously.

There was no statistically significant adult mortality at the tested concentration levels compared to the control. The mean mortality was between 0 and 15% in the test item treated groups. The LC10 value was calculated as 940 mg/kg soil dry weight, however the LC50 value is bigger than the highest tested concentration.

The number of juveniles was statistically significant at the concentration levels of 556 and 1000 mg/kg soil dry weight concentration.

Mean values and coefficient of variations for counted adults and juveniles were calculated for each treatment concentration on the 28th day of the test. The LC50 and EC50 value of the test item were calculated using ToxRatPro statistical software. Differences between controls and the groups were statistically analysed. The No-Observed-Effect-Concentration (NOEC) and the Lowest-Observed-Effect-Concentration (LOEC) were determined.

Conclusion

The test item has adverse effect on the mortality of adults and on reproduction of springtails (*Folsomia candida*).

Adult mortality

LC10 (28 days): 940 mg/kg soil dry weight

LC50 (28 days): >1000 mg/kg soil dry weight

NOEC for mortality: ≥1000 mg/kg soil dry weight

LOEC for mortality: >1000 mg/kg soil dry weight

Comments of zRMS:	The study was performed according to OECD TG 226 and principles of GLP. The validity criteria were met. For the control group: - Mean mortality of adult females: ≤ 20 % - Mean number of juveniles per replicate: ≥ 50 - Coefficient of variation (mean number of juveniles per replicate): ≤ 30 % The deviation were recorded: Due to technical reasons temperature values (minimum of 17.6°C) outside the expected range of 18-22°C were recorded occasionally during the study. Due to technical reasons temperature values (minimum of 34.8°C, maximum of 40.8°C) outside the expected range of 30-40°C or 40-50°C were recorded occasionally during the extraction phase of the preliminary experiment in the extraction equipment no. 1. Due to technical reasons temperature values (minimum of 34.8°C, maximum of
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	39.9°C) outside the expected range of 40-50°C were recorded occasionally during the extraction phase of the preliminary experiment in the extraction equipment no. 3. Due to technical error the extraction equipment no. 1 and no. 3 was switched to 45°C 3 hours later then indicated in the Study Plan during the preliminary experiment. These deviations were considered to have no impact on the outcome of the test and interpretation of the results. The study is considered acceptable and suitable for the risk assessment. NOEC_{repr} > 1000 mg test item/kg soil dry weight
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Reference:	KCP 10.4
Report	A GLP Reproduction Test of GLOB2021dF in Soil with Predatory mite (<i>Hypoaspis (Geolaelaps) aculeifer</i>) 22/136-389TLA Orosz i., 2023f, Charles River Laboratories Hungary Kft.
Guideline(s):	Yes, OECD 226
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

A predatory mite (*Hypoaspis (Geolaelaps) aculeifer*) reproduction study was performed to determine the effect of the test item on the mortality and reproduction of mites by cutaneous and alimentary uptake in a defined artificial soil substrate. The toxic effects of the test item were evaluated according to the OECD No. 226 guideline (2016).

The effects of the Limit concentration of test item were determined on the reproduction of 28-30 days old mites in defined artificial soil substrate, as recommended in OECD 226. Eight replicates were used for the control, for the Limit concentration and for the reference control each containing 10 mites. The mites were incubated in the substrate in glass containers for 14 days. The surviving mites were extracted from the soil via heat/light extraction (25°C for 12 h, 45°C for 36 hours (in total 48 hours)). On Day 16 of the experiment, the number of surviving adults and juveniles were determined.

As no significant toxic response was observed in the Range-finding test at the highest concentration, only this concentration, one control and one reference control sample was tested as a Limit test.

Predatory mites were fed with cheese mites (*Tyrophagus putrescentiae*) *ad libitum*. The test containers were tightly closed during the test and open briefly twice a week to allow aeration. The test containers were held in a climate chamber under controlled light-dark cycles and the temperature was checked continuously.

The mortality was 1.3% in the control group during the study. There was no statistically significant mortality at the Limit dose compared to the control.

The mean number of juveniles was 196 in the control group. There was no statistically significantly reduced reproduction at the Limit dose compared to the control.

The mortality was 100% and statistically significantly reduced reproduction (99.4%) was observed in the reference control group. The observed toxicity in the reference control group demonstrated that the laboratory test conditions were adequate during the study.

Conclusion

The test item has the expected adverse effect on the mortality of adults and on reproduction of predatory mites (*Hypoaspis (Geolaelaps) aculeifer*).

Adult mortality

LC₅₀ (14 days): >1000 mg/kg soil dry weight
NOEC for mortality: ≥1000 mg/kg soil dry weight
LOEC for mortality: >1000 mg/kg soil dry weight

Reproduction

EC₅₀ (14 days): >1000 mg/kg soil dry weight
NOEC for reproduction: ≥1000 mg/kg soil dry weight
LOEC for reproduction: >1000 mg/kg soil dry weight

A 2.4 KCP 10.5 Effects on soil nitrogen transformation

Comments of zRMS:	The study was conducted to OECD guideline 216 and according to the principles of GLP. All the validity criterion were met.
	The study is considered to be reliable and suitable for the risk assessment.

Reference: KCP 10.5
Report A GLP Soil Microorganisms Nitrogen Transformation Study of GLOB2021dF 22/136-055AN Adamcsik B.T., 2023, Charles River Laboratories Hungary Kft.

Guideline(s): Yes, OECD 216
Deviations: No
GLP: Yes
Acceptability: Yes/No/Supplementary
Duplication (if vertebrate study) No

The purpose of this study was to assess the potential long-term adverse effects of the test item, GLOB2021dF, on the nitrogen transformation activity of soil microorganisms after a single exposure, under aerobic conditions. The methods followed the OECD guideline No. 216 for substances considered as agro-chemical and complies the Sponsor requirements.

The samples of standard sandy loam soil were treated at two concentration levels selected by the Sponsor (0.6 and 3.0 mg test item / kg soil dry weight). The treated soil samples were incubated parallel with the untreated (control) samples for 28 days. The nitrate content of the soil samples was monitored at Day 0 (start), Day 7, Day 14 and Day 28. After 28 days, the formed nitrate was calculated in treated and control soil samples.

There was a statistically significant difference between the nitrate formation rate of the tested high concentration level (3.0 mg test item / kg soil dry weight) and the control soil at the end of the 28-day testing period. However, the difference was less than 25%, therefore, the test item is considered to have no clear long-term adverse effect on the nitrogen transformation activity of soil microorganisms.

The relative standard deviation (RSD) of the nitrate content of the control samples on each sampling occasion was less than $\pm 15\%$, therefore, the results are met the validity criterion.

A 2.5 KCP 10.6 Effects on terrestrial non-target higher plants

Comments of zRMS:	The study was conducted to OECD guideline 208 and according to the principles of GLP. All the validity criterion are met. Deviations were recorded: The organic content of the soil was higher than 1.5% (as defined in the Study Plan), this deviation had no impact on the results of the study. The applied soil is certified from a well-known laboratory supplier and widely used in experiments. The relative humidity value was occasionally out from the defined range (99%), but this deviation is considered to have no impact on the study results. Due to unscheduled delay of reporting Final Report was issued later than indicated in the Study Plan Amendment The study is considered to be reliable and suitable for the risk assessment. NOEC = 8000 mL test item/ha
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Reference: KCP 10.6
Report GLOB2021dF: A GLP Seedlings Emergence and Seedling Growth Test 22/136-126PL
Varga-László E., 2023a,
Charles River Laboratories Hungary Kft.

Guideline(s): Yes, OECD 208
Deviations: No
GLP: Yes
Acceptability: Yes/No/Supplementary
Duplication (if vertebrate study) No

The objective of the study was to assess the potential effects on seedling emergence and early growth on selected terrestrial higher plant species, following exposure to GLOB2021dF, deposited on the soil surface after sowing, according to the OECD Guideline for Testing of Chemicals No. 208 and the Sponsor requirements.

Based on the results of the preliminary range finding test, a limit test was performed at only one test dose level with test plant species at 4 mL/L spray concentration (corresponding 0.8 L in 200 L/ha spraying application).

The test item had no effect on the emergence, survival, plant height, seedling fresh weight or seedling dry weight parameters, in any species tested in the limit test.

No biologically relevant test item related differences or adverse effects were recorded between the control and the treated plants regarding visual injury or phytotoxicity at the maximum recommended field application rate.

Conclusion

The NOEC and LOEC for the seedling emergence and early growth for oat, pea, carrot, cabbage, maize and onion species was determined to be above the maximum recommended application rate for GLOB2021dF (0.8 L/ha in 200 L spraying solution).

Comments of zRMS:	The study was conducted to OECD guideline 227 and according to the principles of GLP. All the validity criterion are met. Deviations were recorded: The organic content of the soil was higher than 1.5% (as defined in the Study Plan), this deviation is considered to have no significant impact on the results of the study. The applied soil is certified from a well-known laboratory supplier and widely used in experiments. The relative humidity value was occasionally out from the defined range (99%), but this deviation is considered to have no impact on the study results. The dark/light cycle was deviated from the defined value between 07 and 09 of July 2023. It was concluded that the light failure had adverse effect on the integrity of the study, therefore, the experiment was terminated, and all the plant species were re-planted on 31 July 2023. The study is considered to be reliable and suitable for the risk assessment. NOEC = 8000 mL test item/ha
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Reference:	KCP 10.6
Report	GLOB2021dF: A GLP Vegetative Vigour Test 22/136-139PL Varga-László E., 2023b, Charles River Laboratories Hungary Kft.
Guideline(s):	Yes, OECD 227
Deviations:	No
GLP:	Yes
Acceptability:	Yes/No/Supplementary
Duplication (if vertebrate study)	No

The objective of the study was to assess the potential effects on vegetative vigour on selected terrestrial higher plants, following above ground exposure to GLOB2021dF when reaching 2 to 4 true leaves stage, according to the OECD Guideline for Testing of Chemicals No. 227 and the Sponsor requirements.

Based on the results of the preliminary range finding test in case of oat, onion and pea plant species, a limit test was performed at only one test dose level with test plant species, at 4 mL/L spray concentration (corresponding 0.8 L in 200 L/ha field spraying application).

Based on the results of the preliminary range finding test in case of cabbage and maize plant species, a definitive test was performed at 0.25, 0.5, 1, 2 and 4 mL/L concentrations (corresponding 0.05, 0.1, 0.2, 0.4 and 0.8 L in 200 L/ha field spraying applications).

In the main test:

In the limit testing with oat, onion and pea species, the test item had no biologically relevant effect on the emergence, survival, plant height, seedling fresh weight or seedling dry weight parameters, when tested at 0.8 L test item in 200 L/ha spraying application.

The test item had no biologically relevant effect on-survival, plant height, seedling fresh weight or seedling dry weight parameters of the maize or cabbage plants at the tested concentration range of 0.05, 0.1, 0.2, 0.4 and 0.8 L in 200 L/ha spraying application rates (i.e. no effect at the limit concentration).

No biologically relevant test item related differences or adverse effects were recorded between the control and the treated plants regarding visual injury or phytotoxicity at the maximum recommended field application rate.

Conclusion

The LOEC and NOEC for the vegetative vigour for oat, pea, carrot, cabbage, maize and onion species was determined to be above the maximum recommended application rate for GLOB2021df (0.8 L/ha in 200 L spraying solution).