FINAL REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: **CHR/ZF/PROTI 100 FS**

Product name(s):

Gamelan 100 FS

Doraltes 100 FS

Chemical active substance:

Prothioconazole, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 07.2021

MS Finalisation date: 05/09/2022

Version history

When	What
October 2021	Dossier sent for evaluation
February 2022	Updates based on feedback from zRMS Poland
June 2022	zRMS evaluation of dRR
September 2022	Final version prepared by zRMS after Commenting period

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

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

Table 8.1-1: Critical use pattern of the formulated product

GAP rev. , date: 2020-09-23

PPP (product name/code)	CHR/ZF/PROTI	Formulation type:	FS
Active substance 1:	prothioconazole	Conc. of as 1:	100,0 g/l
Active substance 2:	n/a	Conc. of as 2:	n/a
Active substance….:	n/a	Conc. of as ….:	n/a
Safener:	-	Conc. of safener:	conc. (c)
Synergist:	-	Conc. of synergist:	conc. (c)
Applicant:	Innvigo	Professional use:	☒
Zone(s):	central	Non professional use:	☐
Verified by MS:	yes~~/no~~		

Field of use: Seed treatment

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. (e)	**Member state(s)**	**Crop and/ or situation** **(crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate per treatment**			**PHI** (days)	**Remarks:** e.g. g safener/synergist per ha (f)
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
~~1~~													
~~2~~													
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)													
~~3~~ 1	PL	Winter wheat (TRZAW)	F	*Tilletia caries, Fusarium sp., Microdochium majus, Ustilago tritici*	winter seed treat-ment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.018-0.025 kg a.s/ha b) 0.018-0.025	max. 0.7 L/100 kg seed	n/a	Sowing rate: 180-250 kg/ha

										kg a.s/ha			
~~4~~ 2	PL	Winter triticale (TTLWI)	F	*Fusarium sp., Microdochium majus*	winter seed treatment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.015-0.025 kg a.s/ha b) 0.015-0.025 kg a.s/ha	max. 0.7 L/100 kg seed	n/a	Sowing rate: 150-250 kg/ha
~~5~~ 3	PL	Winter rye (SECCW)	F	*Fusarium sp., Microdochium majus, Urocystis occulta*	winter seed treatment	n/a	a)1 b)1	n/a	a) Max. 1.0 l /t seed b) Max. 1.0 l /t seed	a) 0.0095-0.025 kg a.s/ha b) 0.0095-0.025 kg a.s/ha	max. 0.7 L/100 kg seed	n/a	Sowing rate: 95-250 kg/ha
Minor uses according to Article 51 (zonal uses)													
6													
7													
Minor uses according to Article 51 (interzonal uses)													
8													
9													

Remarks table heading:

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

Remarks columns:

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

Table 8.1-2: Assessed (critical) uses during approval of Prothioconazole concerning the Section Environmental Fate

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
wheat, rye, triticale	EU North South	Proline	F	Rusts, Eyespot, Fusarium spp., Powd. Mildew, Rhynchospor., Septoria,	EC	250 g/L	overall spray	start 26-29 up to BBCH69 (interval 14 - 21 d)#	1 – 3 #	ref. to growth stage		200 - 400	0.2	35	# timing , no. of applic. depends on national conditions

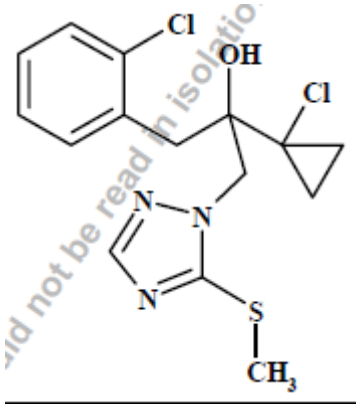
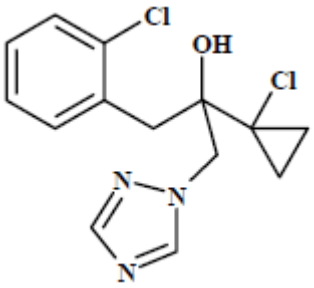
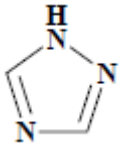
Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hl min max	water l/ha min max	kg as/ha min max		
barley, oat	EU North South	Proline	F	Rusts, Eyespot, Pyren. teres, Powd. Mildew, Fusarium spp., Rhynchospor.	EC	250 g/L	overall spray	start 30 up to BBCH 61 (interval 14 - 21 d)#	1 – 2 #	ref. to growth stage		200 - 400	0.2	35	# timing , no. of applic. depends on national conditions
rape	EU North	Proline	F	Sclerotinia, Botrytis, Alternaria, Leptosphaeria	EC	250 g/L	overall spray	start BBCH 53 (interval 14 - 28 d)#	1 – 2 #	ref. to growth stage		200 - 400	0.175	56	# timing , no. of applic. depends on national conditions

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

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

8.2 Metabolites considered in the assessment

Table 8.2-1: Metabolites of Prothioconazole potentially relevant for exposure assessment

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
Prothioconazole-S-methyl (M01)	358.38		Soil: 14.6%	PECgw PECsoil
Prothioconazole-desthio (M04)	312.2		Soil: 57.1% Water: 32.32% Sediment: 26.9%	PECgw PECsoil PECsw
1, 2, 4-triazole (M13)	69.065		Water/Sediment: ~~32.7~~ 37.2%	PECsw

8.3 Rate of degradation in soil (KCP 9.1.1)

Studies on degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

Studies on aerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion and renewal. All relevant data are presented in :

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

8.3.1.1 Prothioconazole and its metabolites

Mineralization after 100 days ‡	Values are given for day 120: range: 3.0 to 10.7% AR median: 4.8% AR (n=4) (phenyl-label) range: 0.3 to 2.0% AR; median: 1.2% AR (n=2) (triazole-label)
Non-extractable residues after 100 days ‡	Values are given for day 120: range: 35.6 to 46.2% AR; median: 41.0% AR (n = 4) (phenyl-label) range: 42.6 to 48.3% AR; median: 45.5% AR (n = 2) (triazole-label)
Relevant metabolites - name and/or code, % of applied ‡ (range and maximum) at 20°C after 100 days	Prothioconazole-S-methyl *(M01)*: range at day 120: 1.5 to 10.8% AR (n = 6) (both labels) max.: 13.7% AR (phenyl-label, day 7) 14.6% AR (triazole-label, day 7) Prothioconazole-desthio *(M04)*: range at day 120: 15.1 to 42.3% (n = 6) (both labels) max.: 46.5% AR (phenyl-label, day 7) 49.4% AR (triazole-label, day 7)

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anerobic degradation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in:

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

Anaerobic degradation ‡	Not applicable (A case was presented that due to the proposed use patterns as a foliar fungicide prothioconazole will not, in general, be exposed to anaerobic conditions. However, due to the fact that a seed treatment formulation is also being considered, an anaerobic aquatic metabolism study was submitted. The anaerobic study indicated relatively rapid breakdown of parent to prothioconazole-S-methyl (M01), which seems to accumulate. This might indicate that if prothioconazole was applied to an anaerobic soil there would be significant formation of M01. However, the only major period of anaerobic conditions is likely to be in the winter, i.e. following autumn seed treatment. Drilling will only take place in relatively good aerobic conditions under which there will be relatively rapid degradation of the parent compound. Therefore, it is unlikely that there would be significant formation of M01 under field conditions.)

8.4 Field studies (KCP 9.1.1.2)

Field studies ‡ (state location, range or median with n value)	Location: southern (two sites) and northern (four sites) Europe, 1st order calculation prothioconazole $DT_{50}f$: range: 1.3 to 2.8 days, median: 1.6 days, (n = 8), r^2: range: 0.999 – 1.00. Maximum 2.8 day value used for PECsoil calculations. prothioconazole-desthio *(M04)* $DT_{50}f$: range: 16.3 to 72.3 days, median: 42.2 days (n = 8), r2: range: 0.91 – 0.98. (Maximum 72.3 days value and 57.1% conversion rate used for PECsoil calculations).
Field studies ‡ (state location, range or median with n value)	prothioconazole: $DT_{90}f$: range: 4.4 to 9.3 days, median: 5.5 days, (n = 8), r^2: range: 0.999 – 1.00 prothioconazole-desthio *(M04)*: $DT_{90}f$: range: 54.1 to 240 days, median: 140 days (n = 8), r2: range: 0.91 – 0.98 prothioconazole (normalised for 20°C; not normalised for moisture content): DT_{50} @20°C: range: 0.6 to 1.6 days, median: 1.3 days (n = 8), r2: range: 0.995 to 1.000. Geometric mean: 1.2 days, used for PELMOgw modelling. prothioconazole-desthio *(M04)* (normalised for 20°C; not normalised for moisture content): DT_{50} @20°C: range: 10.3 to 61.9 days, median: 22.05 days (n = 8), r2: range: 0.859 to 0.996. Geometric mean: 22.7 days, used for PELMOgw modelling. (57.1% conversion rate used for PELMOgw calculations

8.4.1 Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1)

Studies on dissipation in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in:

- **Prothioconazole -** EFSA Scientific Report (2007) 106, 1-98

8.4.1.1 Prothioconazole and its metabolites

The data presented below concern the laboratory data field data, not field data (removed).

Method of calculation	®ModelMaker, Version 1.1, 1st order kinetics
Laboratory studies ‡ (range or median, with n value, with r^2 value)	DT_{50}lab (20°C, aerobic, soil): prothioconazole (1st order and FOMC): range: 0.07 to 1.27 days, median: 0.5 days, r^2: range: 0.981 to 1.000 (n = 4) prothioconazole-S-methyl *(M01)* (1st order) range: 5.9 to 46.0 days; median: 17.7 days, r2: range: 0.955 to 0.970 (n=4). Mean value of 15.7 days used for PELMOgw modelling. prothioconazole-desthio *(M04)* (1st order) range: 7.0 to 34.0 days; median: 24.1 days r2: range: 0.820 to 0.987 (n=4) minor metabolite 1,2,4-triazole *(M13)* (1st order)[17] range: 5.0 to 9.9 days (at 20°C and pF2/10kPa); geometric mean: 7.4 days r2: range: 0.75 to 0.95 (n=3)
	DT_{90}lab (20°C, aerobic, soil): prothioconazole (1st order and FOMC): range: 0.99 to 78.2 days, median: 4.76 days, r^2: range: 0.981 to 1.000 (n = 4)" prothioconazole-S-methyl *(M01)* (1st order) range: 19.6 to 153.0; median: 58.7 days, r2: range: 0.955 to 0.970 (n=4) prothioconazole-desthio *(M04)* (1st order) range: 23.2 to 113.0; median: 80.1 days r2: range: 0.820 to 0.987 (n=4)DT_{50}lab (10°C, aerobic):
	DT_{50}lab (20°C, anaerobic): (soil, aerobic, 10°C, calculated from 20°C using Arrhenius equation): prothioconazole (1st order): range: 0.20 to 2.8 days; median: 1.1 days prothioconazole-S-methyl *(M01)* (1st order) range: 12.9 to 100.9; median: 38.8 days prothioconazole-desthio *(M04)* (1st order) range: 15.3 to 74.5; median: 52.9 days
	DT_{50}/DT_{90} (soil anaerobic): Not applicable (See case under 'Route of degradation in soil - Supplemental studies')
	Degradation in the saturated zone ‡: No information submitted, none required

zRMS Comments:	The mentioned data/tables in point 8.4.1.1 should concern the field data, not laboratory data. Field data are presented in point 8.4. Above presented tables were removed by evaluator.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation and plateau concentration ‡	Not applicable (Soil accumulation testing is not necessary since DT_{90}f values of prothioconazole and prothioconazole-desthio (M04) are less than one year.)

8.5 Mobility in soil (KCP 9.1.2)

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Studies on mobility in soil with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- **Prothioconazole -** EFSA Scientific Report (2007) 106, 1-98

8.5.1 Prothioconazole and its metabolites

Active substance:

K_f /K_{oc} ‡	K_d and K_{oc} values of prothioconazole determined in aged column leaching studies due to the instability of the compound in standard batch equilibrium studies.
K_{oc} ‡	K_{oc}: 1765 mL/g (aged leaching study, only one soil tested, value used for PELMOgw modelling; 1/n set to 0.90)
K_d ‡	K_d: 15.2 mL/g (aged leaching study)
pH dependence ‡ (yes / no) (if yes type of dependence)	No information

Prothioconazole-S-methyl *(M01)*

K_{oc} K_d pH dependence (yes / no) (if yes type of dependence)	K_{foc}: Adsorption: 1974 – 2995 mL/g (n = 4), mean = 2556.3. Mean value used for PELMOgw modelling. Desorption: 2532 – 3359 mL/g (n = 4), mean = 2985.3 K_d: Adsorption: 15.6 – 64.1 mL/g (n = 4) Desorption: 20.0 – 71.9 mL/g (n = 4) 1/n: Adsorption: 0.85 – 0.91 (n=4), mean = 0.88. Mean value used for PELMOgw modelling. Desorption: 0.85 – 0.91 (n=4), mean = 0.88 No pH dependence

Prothioconazole-desthio *(M04)*

K_{oc} K_d pH dependence (yes / no) (if yes type of dependence)	K_{foc}: Adsorption: 523 – 625 mL/g (n = 4), mean = 575.4. Mean value used for PELMOgw modelling. Desorption: 562 – 876 mL/g (n = 4), mean = 687.2 K_d: Adsorption: 4.1 – 13.4 mL/g (n = 4) Desorption: 6.9 – 14.8 mL/g (n = 4) 1/n: Adsorption: 0.79 – 0.83 (n=4), mean = 0.81. Mean value used for PELMOgw modelling. Desorption: 0.77 – 0.84 mL/g (n=4), mean = 0.82 No pH dependence

1,2,4-triazole (*M13*) (<2% AR in aerobic soil degradation studies)[18]

K_{foc} pH dependence (yes / no) (if yes type of dependence)	K_{foc}: Adsorption: 43 – 202 mL/g (n = 4), mean = 89 mL/g. 1/n: Adsorption: 0.827 – 1.016 (n=4), mean = 0.9155 mL/g. No pH dependence

8.5.2 Column leaching (KCP 9.1.2.1)

Studies on column leaching the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

Column leaching ‡	Guideline: SETAC (1995), BBA Part IV, 6-2 (1986) Precipitation: 200mm Time period: 2days Leachate: <1% AR; fractions not investigated

8.5.3 Lysimeter studies (KCP 9.1.2.2)

Studies on lysimeter formulation were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in :

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

Aged residues leaching ‡	Guideline: US EPA 163-1 (1982) Aged for: 30 hours Precipitation: 1000 mL The total radioactivity in the leachate accounted for only 1.1% of the AR, and no individual leachate fraction resulted in a radioactivity content >0.2% of the AR. Therefore the leachate fractions were not analysed for parent compound or metabolites.

8.5.4 Field leaching studies (KCP 9.1.2.3)

Lysimeter/ field leaching studies ‡	No data submitted, none required.

8.6 Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)

Studies on degradation in water/sediment systems with the formulation were not performed, since it is possible to extrapolate from data obtained with the active substance.

Studies on degradation in water/sediment systems were not performed, since it is possible to extrapolate from data obtained with the active substance. EU approved endpoints were evaluated during Annex I inclusion. All relevant data are presented in:

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

8.6.1 Prothioconazole and its metabolites

Hydrolysis of active substance and relevant metabolites (DT_{50}) ‡ (state pH and temperature)	prothioconazole: DT_{50} at 50°C: pH 9 and 7: > 1 year pH 4: 120 days DT_{50} at 25°C: pH 9, 7 and 4: > 1 year

Photolytic degradation of active substance and relevant metabolites ‡	**Aqueous photolysis study** (25°C, pH7): prothioconazole: phenyl label - DT_{50} = 44.3 hrs (R^2 = 0.999) triazole label - DT_{50} = 51.4 hrs (R^2 = 0.999) mean = 47.7 hours (n=2) predicted environmental half-life under solar summer conditions (June) of Phoenix, AZ, USA of 7.1 days and 11 days at Athens mineralisation at study end (18 days) = 3.0% AR (phenyl label), 0.5% AR (triazole label) Dark controls: prothioconazole was stable in the dark control samples, confirming that photolysis was the main process of degradation. %AR at 18 days was 108.7% for the phenyl label and 107.1% for the triazole label. prothioconazole-desthio (M04): max 55.7% AR 11 d prothioconazole-thiazocine (M12): max 14.1% AR, 5d 1,2,4-triazole (M13): max 11.9% AR, 18d **Quantum yield studies** prothioconazole: Quantum yields Φ of 0.0638 (pH 4) and 0.0047 (pH 9) were calculated. Environmental direct photolysis half-lives were in the range 50 to >200 days at pH 4 and 7 to 20 days at pH 9 for the periods of main use. prothioconazole-desthio *(M04)*: A quantum yield of Φ of 0.00449 was calculated. The resulting quantum yield and the UV absorption were used to estimate the environmental half-life of prothioconazole-desthio *(M04)* concerning direct photodegradation in water by two different simulation models (GC-SOLAR, half-life at 50^0 latitude and 0-1cm depth in the summer season: 269 days and Frank & Klöpffer, half-life at 50^0 latitude and 0-1cm depth > 1 year). 1,2,4-triazole *(M13)*: The UV-absorption data in the environmentally relevant pH range showed that 1,2,4-triazole *(M13)* dissolved in aqueous solution does not absorb any light at wavelengths above 290 nm.

Degradation in water/sediment - DT_{50} water ‡	Aerobic lab sediment/water at 20°C DT_{50} water - 0.8 and 1.0 days, 1st Order (1.0 day value used for PECsw calculation) (1st Order, r^2 = 0.947 and 0.999, respectively, n = 2)
- DT_{90} water ‡	DT_{90} water - 2.7 and 3.4 days (1st Order, r^2 = 0.947 and 0.999, respectively, n = 2)
- DT_{50} whole system ‡	DT_{50} whole system - 2.8 and 1.6 days ('hockey stick', r^2 = 0.953 and 0.998, respectively, n = 2)
- DT_{90} whole system ‡	DT_{90} whole system - 76.4 and 23.6 days ('hockey stick', r^2 = 0.953 and 0.998, respectively, n = 2)
Mineralization	Hönniger Weiher: 14.7% AR at study end (121 days, phenyl-label). 1.9% AR at study end (121 days, triazole-label). Angler Weiher: 29.0% AR at study end (121 days, phenyl-label). 1.9% AR at study end (121 days, triazole-label).
Non-extractable residues	Hönniger Weiher: 50.8% AR at study end (121 days, phenyl-label). 52.5% AR at study end (121 days, triazole-label). Angler Weiher: 31.3% AR at study end (121 days, phenyl-label). 18.9% AR at study end (121 days, triazole-label).
Distribution in water / sediment systems (active substance) ‡	Sediment: phenyl-label: max 21.0 – 23.4 %AR, 1d (n=2) triazole-label: max 18.3 – 22.6 %AR, 1d (n=2)
Distribution in water / sediment systems (metabolites) ‡ Prothioconazole-desthio (M04)	Water layer: phenyl-label: max 13.9 – 32.3 %AR, 0- 7 d (n=2) triazole-label: max 9.2 – 31.9 %AR, 1 - d (n=2) Sediment: phenyl-label: max 21.9 – 26.9 %AR, 14 – 59 d (n=2) triazole-label: max 17.7 – 26.9 %AR, 14 – 59 d (n=2)
1,2,4-triazole (M13)	Water layer: triazole-label: max 0.8 – 37.2 %AR, 59 – 121 d (n=2)

8.7 Predicted Environmental Concentrations in soil (PEC_{soil}) (KCP 9.1.3)

Evaluator's Comments:

The submitted calculations were not accepted. In accordance with EFSA *Scientific Report* (2007) 106, 1-98 the DT_{50} (field) = 2.8 days should be used.
The PECs for active substance and its metabolites were recalculated by evaluator. The application rate: of 25 g a.s./ha and crop interception of 0% were taken into consideration.

The following PECs values for active substance were obtained:

	PECs mg/kg	**PEC_{twa} mg/kg**
initial	0.0333	
1 d	0.0260	0.0297
2 d	0.0203	0.0264
4 d	0.0124	0.0213
7 d	0.0059	0.0159
14 d	0.0010	0.0094

	21 d	0.0002	0.0064
	28 d	<0.0001	0.0048
	42 d	<0.0001	0.0032
	50 d	<0.0001	0.0027
	100 d	<0.0001	0.0014

For metabolites only PECs ini is presented.

The PECs values for active substance, its metabolites and formulation are presented in the table below:

Crop	**Cereals**
	PECs mg/kg soil
Prothioconazole	0.0333
M01	0.0043
M04	0.0152
Formulation	0.3627

There is no necessity to calculate $PEC_{accumulation,}$ because DT_{90} < 1 year.

The PECs values will be used in further risk assessment.

8.7.1 Justification for new endpoints

All endpoints used for PECsoil calculations are EU approved and were evaluated on EU level and presented in:

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

8.7.2 Active substance(s) and relevant metabolite(s)

Table 8.7-1: Input parameters related to application for PEC_{soil} calculations

Use No.	
Crop	**Cereals**
Application rate (g as/ha)	Prothioconazole: 25
Number of applications/interval	1/ -
Crop interception (%)	0%
Depth of soil layer (relevant for plateau concentration) (cm)	5 cm (no tillage)
Use No.	1-3

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	**Molecular weight (g/mol)**	**Max. occurrence (%)**	**DT50 (days)**	**Value in accordance to EU endpoint y/n/ Reference**
Prothioconazole	344.3	-	~~46.6~~ 2.8	***EFSA Scientific Report* (2007)**

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT50 (days)	Value in accordance to EU endpoint y/n/ Reference
				106, 1-98
Prothioconazole-desthio	312.2	57.1	72.3	***EFSA Scientific Report* (2007) 106, 1-98**
Prothioconazole-S-methyl	358.3	14.6	46	***EFSA Scientific Report* (2007) 106, 1-98**

8.7.2.1 Prothioconazole and its metabolites

~~Table 8.7-3: PEC$_{soil}$ for prothioconazole on cereals~~

~~PEC$_{soil}$ (mg/kg)~~		~~winter cereals~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.0333~~	-
~~Short term~~	~~24h~~	~~0.0328~~	~~0.0331~~
	~~2d~~	~~0.0324~~	~~0.0328~~
	~~4d~~	~~0.0314~~	~~0.0324~~
~~Long term~~	~~7d~~	~~0.0300~~	~~0.0317~~
	~~14d~~	~~0.0271~~	~~0.0301~~
	~~21d~~	~~0.0244~~	~~0.0286~~
	~~28d~~	~~0.0220~~	~~0.0273~~
	~~50d~~	~~0.0158~~	~~0.0235~~
	~~100d~~	~~0.0075~~	~~0.0173~~
~~Plateau concentration (5 cm) after year 10~~		~~< 0.0001~~	-
~~PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)~~		-	-

~~PEC$_{soil}$ of metabolites~~

~~Table 8.7-4: PEC$_{soil}$ for Prothioconazole-desthio on cereals~~

~~PEC$_{soil}$ (mg/kg)~~		~~winter cereals~~	
		~~Single application~~	
		~~Actual~~	~~TWA~~
~~Initial~~		~~0.0078~~	-
~~Short term~~	~~24h~~	~~0.0078~~	~~0.0078~~
	~~2d~~	~~0.0078~~	~~0.0078~~
	~~4d~~	~~0.0078~~	~~0.0078~~
~~Long term~~	~~7d~~	~~0.0078~~	~~0.0078~~

	14d	0.0077	0.0078
	21d	0.0076	0.0078
	28d	0.0075	0.0078
	50d	0.0069	0.0077
	100d	0.0052	0.0074
Plateau concentration (5 cm) after year 10		< 0.0001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.7-54: PEC_{soil} for Prothioconazole-S-methyl on cereals

PEC_{soil} (mg/kg)		winter cereals	
		Single application	
		Actual	TWA
Initial		0.0019	-
Short term	24h	0.0019	0.0019
	2d	0.0019	0.0019
	4d	0.0019	0.0019
Long term	7d	0.0019	0.0019
	14d	0.0018	0.0019
	21d	0.0018	0.0019
	28d	0.0017	0.0019
	50d	0.0015	0.0018
	100d	0.0010	0.0017
Plateau concentration (5 cm) after year 10		< 0.0001	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		-	-

Table 8.7-6: PEC_{soil} for CHR/ZF/PROTI 100 FS on cereals

Active substance/ reparation	Application rate (g/ha)	PEC_{act} (mg/kg)	PEC_{twa} 21 d (mg/kg)	Tillage depth (cm)	$PEC_{soil,plateau}$ (mg/kg)	PEC_{accu} = PEC_{act} + $PEC_{soil,plateau}$ (mg/kg)
CHR/ZF/PROTI	272	0.3627	0.3115 0.296	5 cm	-	-

8.8 Predicted Environmental Concentrations in groundwater (PEC_{gw}) (KCP 9.2.4)

Evaluator's Comments:	Presented calculations PECgw for the active substance and its metabolites were accepted. Calculations of PEC_{GW} for active substance were provided in with PUF = 0.0. Modelling was conducted using PEARL and PELMO models for a single maximum application rate for wheat in all relevant scenarios.

	All used endpoints were agreed at the EU level. The maximum PEC_{GW} values for active substance and its metabolites are below the trigger value of 0.1 µg/L.

8.8.1 Justification for new endpoints

All endpoints used for PECgw calculations are EU approved and were evaluated on EU level and presented in:

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

8.8.2 Active substance(s) and relevant metabolite(s) (KCP 9.2.4.1)

Risk envelope use in calculation:

Winter Cereals and surrogate scenarios for winter cereals – GAP – defined use:

Use	Active substance	Application rate (g a.s /ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Winter wheat	Prothioconazole	25	Seed treatment	1	-	BBCH 0
Winter triticale	Prothioconazole	25	Seed treatment	1	-	BBCH 0
Winter rye	Prothioconazole	25	Seed treatment	1	-	BBCH 0

Identifies representative use (risk envelope):

Use	Active substance	Application rate (g a.s /ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Winter Cereals	Prothioconazole	25	Seed treatment	1	-	BBCH 0

Table 8.8-1: Input parameters related to application for PEC_{gw} calculations

Use No.	
Crop	**Winter cereals**
Application rate (g as/ha)	Prothioconazole: 25
Number of applications/interval	1/ -
Relative application date	20 days before emergence
Crop interception (%)	0%
Frequency of application	annual
Use No.	1-3
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.3

8.8.2.1 Prothioconazole and its metabolites

Table 8.8-2: Input parameters related to active substance Prothioconazole and metabolite(s) for PEC_{gw} calculations

Compound	Prothioconazole	Prothioconazole-desthio	Prothioconazole-S-methyl	Value in accordance with EU endpoint y/n/ Reference*
Molecular weight (g/mol)	344.3~~26~~	~~358.38~~ 312.2	~~312.2~~ 358.3	EFSA Scientific Report (2007) 106, 1-98
Water solubility (mg/L):	300	300	300	EFSA Scientific Report (2007) 106, 1-98
Saturated vapour pressure (Pa):	4 x 10^{-7}	0	0	EFSA Scientific Report (2007) 106, 1-98
DT_{50} in soil (d)	1.2	~~15.7~~ 22.7	~~22.7~~ 15.7	EFSA Scientific Report (2007) 106, 1-98
Transformation rate	0.08086722 to Prothioconazole desthio 0.292277238 to Prothioconazole S-methyl 0.204478542 to CO2	0.4415 to CO2	0.030535 to CO2	Calculation based on EFSA Scientific Report (2007) 106, 1-98
K_{foc} (mL/g)/K_{fom}	1765	~~2556.3~~ 575.4	~~575.4~~ 2556.3	EFSA Scientific Report (2007) 106, 1-98
1/n	0.9	~~0.88~~ 0.81	~~0.81~~ 0.88	EFSA Scientific Report (2007) 106, 1-98
Plant uptake factor	0	0	0	EFSA Scientific Report (2007) 106, 1-98
Formation fraction	-	~~0.14~~ 0.57	~~0.57~~ 0.14	EFSA Scientific Report (2007) 106, 1-98

* Delete row in case of no pH dependency

Table 8.8-3: PEC_{gw} for Prothioconazole and its metabolites on winter cereals (with FOCUS PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Prothioconazole	Prothioconazole-desthio	Prothioconazole-S-methyl
Winter cereals	Châteaudun	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Hamburg	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001

	Jokioinen	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Kremsmünster	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Okehampton	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Piacenza	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Porto	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Sevilla	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Thiva	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001

Table 8.8-4: PEC_{gw} for Prothioconazole and its metabolites on winter cereals (with FOCUS PEARL 4.4.4)

Crop	Scenario	80th Percentile PEC_{gw} at 1 m Soil Depth (µg/L)		
		Prothioconazole	**Prothioconazole-desthio**	**Prothioconazole-S-methyl**
Winter cereals	Châteaudun	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Hamburg	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Jokioinen	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Kremsmünster	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Okehampton	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Piacenza	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Porto	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Sevilla	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001
	Thiva	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001	~~<0.00001~~ <0.001

8.9 Predicted Environmental Concentrations in surface water (PEC_{sw}) (KCP 9.2.5)

Evaluator's Comments:

The submitted PEC_{SW} and PEC_{SED} calculations were accepted.
All used endpoints for active substance and its metabolites were agreed at the EU level.

The recommended FOCUS models were used: FOCUS Step 1 & 2, Step 3.

Prothioconazole and its metabolite. The max PEC_{SW} are presented in the table below:

Crop	Prothioconazole	1,2,4-triazole	Prothioconazole-desthio
Winter cereals 25.0 g a.s./ha	Step 2	Step 2	Step 3
	Max PEC_{SW} (µg/L)		
	0.46	0.10	0.1265 D6 ditch

PECsw for the formulation CHR/ZF/PROTI 100 FS for 272 g prod./ha in winter cereals is 1.7475 µg/L.

The relevant mitigation measure will be recommended in ecotoxicological section.

Risk envelope use in calculation:

Winter Cereals and surrogate scenarios for winter cereals – GAP – defined use:

Use	Active substance	Application rate (g a.s /ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Winter wheat	Prothioconazole	25	Seed treatment	1	-	BBCH 0
Winter triticale	Prothioconazole	25	Seed treatment	1	-	BBCH 0
Winter rye	Prothioconazole	25	Seed treatment	1	-	BBCH 0

Identifies representative use (risk envelope):

Use	Active substance	Application rate (g a.s /ha)	Application method	Number of applications	Minimum application interval (days)	Application timing
Winter Cereals	Prothioconazole	25	Seed treatment	1	-	BBCH 0

8.9.1 Justification for new endpoints

All endpoints used for PECsw calculations are EU approved and were evaluated on EU level and presented in:

- Prothioconazole - EFSA Scientific Report (2007) 106, 1-98

8.9.2 Active substance(s), relevant metabolite(s) and the formulation (KCP 9.2.5)

Table 8.9-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Use No.	1-3
Crop	Winter cereals
Application rate (g as/ha)	Prothioconazole: 25
Number of applications/interval	1/ -
Application window	~~October - February~~ September-December
Application method	Seeder
Models used for calculation	FOCUS SWASH v3.1, FOCUS PRZM v3.3.1, FOCUS MACRO v5.5.3, FOCUS TOXWA v3.3.1

Table 8.9-2: FOCUS Step 3 Scenario related input parameters for $PEC_{sw/sed}$ calculations for the application of CHR/ZF/PROTI

Crop	Scenario	Application window used in modelling
Winter cereals,	D3	11 November – 11 December
	D4	12 September – 12 October
	D5	31 October – 30 November
	D6	20 November – 20 December
	R1	2 November – 2 December
	R3	21 November – 21 December

Crop	Scenario	Application window used in modelling
	R4	31 October – 30 November

8.9.2.1 Prothioconazole and its metabolites

Table 8.9-3: Input parameters related to active substance Prothioconazole and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2 and 3(/4) (if necessary)

Compound	Prothioconazole	Prothioconazole-desthio	1,2,4-triazole	Value in accordance to EU endpoint y/n/ Reference
Molecular weight (g/mol)	344.3	312.2	69.065	EFSA Scientific Report (2007) 106, 1-98
Saturated vapour pressure (Pa)	4×10^{-7}	0	0	EFSA Scientific Report (2007) 106, 1-98
Water solubility (mg/L)	300	300	730000	EFSA Scientific Report (2007) 106, 1-98
Diffusion coefficient in water (m^2/d)	not required for Step 1+2/ 4.3×10^{-5}	not required for Step 1+2/ 4.3×10^{-5}	not required for Step 1+2/ 4.3×10^{-5}	default
Diffusion coefficient in air (m^2/d)	not required for Step 1+2/0.43	not required for Step 1+2/0.43	not required for Step 1+2/0.43	default
K_{foc} (mL/g)	1765	575.4	89	EFSA Scientific Report (2007) 106, 1-98
Freundlich Exponent 1/n	0.9	0.81	0.9155	EFSA Scientific Report (2007) 106, 1-98
Plant Uptake	0	0	0	EFSA Scientific Report (2007) 106, 1-98
Wash-Off factor from Crop (1/mm)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2/ 0.05 (MACRO) 0.50 (PRZM)	EFSA Scientific Report (2007) 106, 1-98
$DT_{50,soil}$ (d)	2.8	72.3	60.5	EFSA Scientific Report (2007) 106, 1-98
$DT_{50,water}$ (d)	1	1000	1000	EFSA Scientific Report (2007) 106, 1-98
$DT_{50,sed}$ (d)	2.8	1000	1000	EFSA Scientific Report (2007) 106, 1-98
$DT_{50,whole\ system}$ (d)	2.8	1000	1000	EFSA Scientific Report (2007) 106, 1-98

Compound	Prothioconazole	Prothioconazole-desthio	1,2,4-triazole	Value in accordance to EU endpoint y/n/ Reference
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 57.1 Water: 32.3 Sediment: 26.9	Soil: 0.00001 Water: 37.2	EFSA Scientific Report (2007) 106, 1-98
Formation fraction in soil:	-			

$PEC_{sw/sed}$

Table 8.9-4: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for Prothioconazole following ~~multiple~~ single application of CHR/ZF/PROTI to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	2.49	drainage/run off	0.48	43.86
Step 2		0.46	drainage/run off	0.05	8.15
Northern Europe	October – February	0.46	drainage/run off	0.05	8.15

* single applications should be marked.
** twa-time as required by ecotox

Metabolite(s) of prothioconazole

Table 8.9-5: FOCUS Step 1,2 and 3 PEC_{sw} and PEC_{sed} for Prothioconazole-desthio following ~~multiple~~ single application~~(s)~~ of CHR/ZF/PROTI to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
Step 1	---	**3.82**	drainage/run off	3.80	22.00
Step 2		**1.43**	drainage/run off	1.42	8.24
Northern Europe	October – February	**1.43**	drainage/run off	1.42	8.24
Step 3					
D3	ditch	0.0037	drainage	0.0002	0.0071
D4	pond	0.0036	drainage	0.0029	0.0378
D4	stream	0.0152	drainage	0.0011	0.0144
D5	pond	0.0013	drainage	0.0011	0.0221
D5	stream	0.0082	drainage	0.0002	0.0043
D6	ditch	0.1265	drainage	0.0084	0.0842
R1	pond	0.0057	run off	0.0053	0.0919
R1	stream	0.0329	run off	0.0021	0.0525

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)	Max PEC_{sed} (µg/kg)
R3	stream	0.0427	run off	0.0048	1.4510
R4	stream	0.0939	run off	0.0041	0.0697

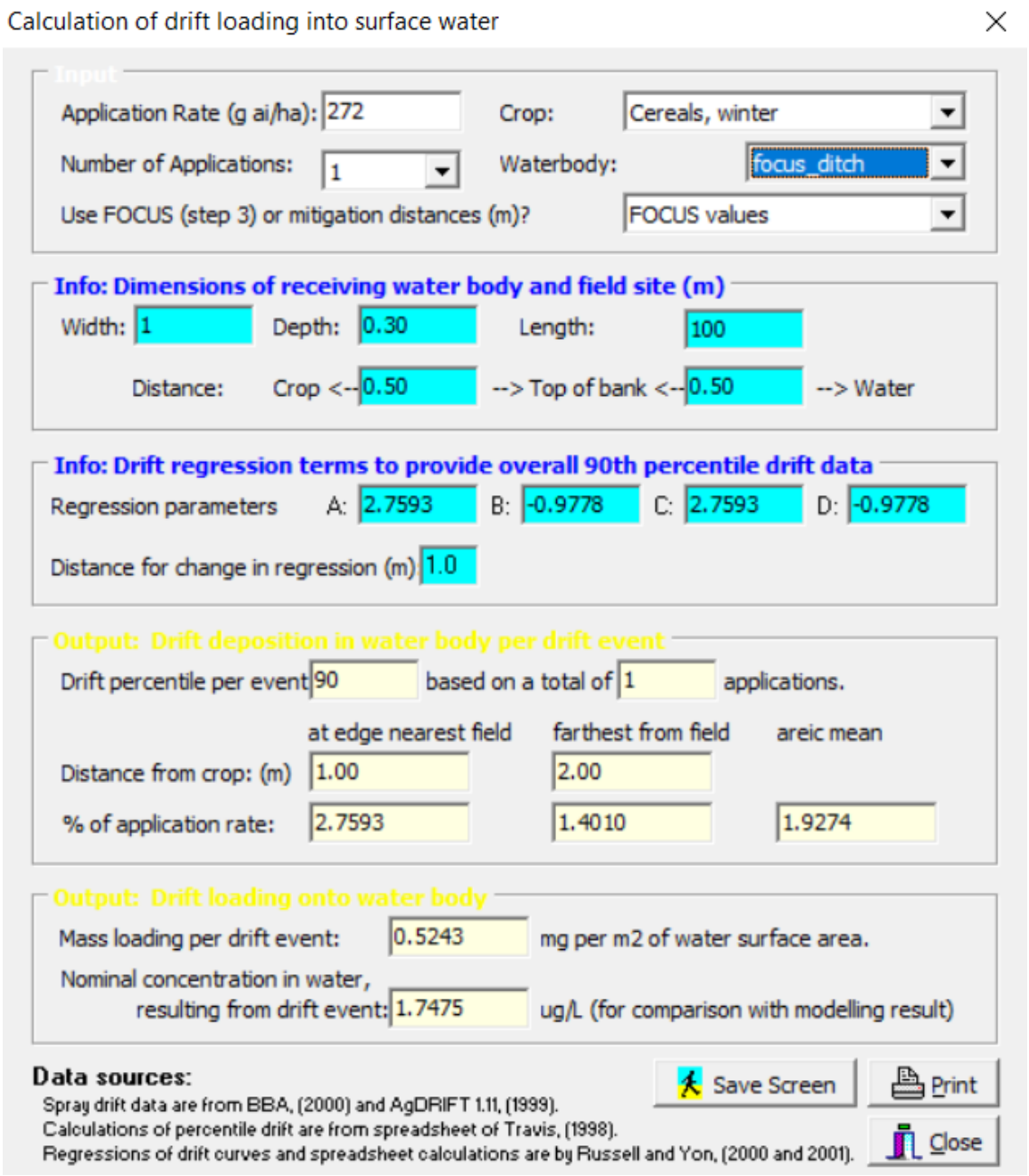
Table 8.9-5: FOCUS Step 1,2 PEC_{sw} and PEC_{sed} for 1,2,4-triazole following multiple application(s) of CHR/ZF/PROTI to winter cereals

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	21 d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	0.56	drainage/run off	0.55	0.49
Step 2		0.10	drainage/run off	0.10	0.09
Northern Europe	October – February	0.10	drainage/run off	0.10	0.09

* single applications should be marked.
** twa-time as required by ecotox

$PEC_{sw/sed}$ of CHR/ZF/PROTI 100 FS

Method of calculation	Drift calculator in SWASH tool calculating instantaneous PECsw at a single drift event 1 m from the field
Application rate winter cereals	1 x 272 g [prod]/ha equivalent to 1 x 25 g a.s/ha
Resulting PECsw winter cereals	1.7475 µg[prod]/L



8.10 Fate and behaviour in air (KCP 9.3, KCP 9.3.1)

Table 8.10-1 Summary of atmospheric degradation and behaviour

Direct photolysis in air ‡	Not studied – no data requested
Quantum yield of direct phototransformation	Not measured – no data requested
Photochemical oxidative degradation in air ‡	Prothioconazole: Half-life: 1.1 hours Chemical lifetime: 1.6 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm^3) prothioconazole-desthio *(M04)*: Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5×10^6 OH radicals/cm^3)
Volatilization ‡	Laboratory route and rate soil studies indicated that volatilisation of prothioconazole and prothioconazole-desthio (*M04*) is unlikely to take place because no volatiles were detected at levels above 0.1% AR.

The vapour pressure at 20 °C of the active substance Prothioconazole is $< 10^{-5}$ Pa. Hence the active substance Prothioconazole is regarded as non-volatile. Therefore exposure of adjacent surface waters and terrestrial ecosystems by the active substance Prothioconazole due to volatilization with subsequent deposition should be considered.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.3	A. Adamczak	2021	*CHR/ZF/PROTI 100 FS Efate Calculations* PUH Chemirol Sp. z o.o. Study code: CHR/ZF/PROTI-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.4	A. Adamczak	2021	*CHR/ZF/PROTI 100 FS Efate Calculations* PUH Chemirol Sp. z o.o. Study code: CHR/ZF/PROTI-B8 Non GLP Unpublished	N	Chemirol
KCP 9.2.5	A. Adamczak	2021	*CHR/ZF/PROTI 100 FS Efate Calculations* PUH Chemirol Sp. z o.o. Study code: CHR/ZF/PROTI-B8 Non GLP Unpublished	N	Chemirol

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 9.1.1/01	Gilges, M.	2000	Aerobic degradation of JAU6476 in two soils Report No. MR-549/99 Bayer AG GLP Unpublished	N	BAY
KCP 9.1.1/02	Hellpointner, E.	2001	Degradation and metabolism of JAU6476 in aerobic soils Report No. MR-104/01 Bayer AG GLP Unpublished	N	BAY
KCP 9.1.1/03	Gilges, M.	2001	Degradation of JAU6476-S-methyl (WAK7861) in four soils under aerobic conditions Report No. MR-340/00 Bayer AG GLP Unpublished	N	BAY
KCP 6.1.1/04	Gilges, M.	2001	Degradation of JAU6476-desthio (SXX0665) in four soils under aerobic conditions Report No. MR-327/00 Bayer AG GLP Unpublished	N	BAY
KCP 9.1.2/01	Gilges, M.	2001	Photolysis of JAU6476 on soil surface Report No. MR-242/00 Bayer AG GLP Unpublished	N	BAY
KCP 9.1.2/02	Schramel, O.	2001	Dissipation of JAU6476 (250EC) in soil under field conditions (France, Germany, Great Britain, Italy) Report No. RA-2152/98 Report includes study nos.: R812587, R812595, R712609, R812617, R812625, R812633, R815667,	N	BAY

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
			R815675		
KCP 9.1.2/03	Schramel, O.	2001	Determination of the sorage stability of JAU6476 and the metabolites JAU6476-desthio and JAU6476-S-methyl in soil Report No. MR-644/99 Bayer AG GLP Unpublished	N	BAY
KCP 9.1.2/04	Hein, W.	1999	Adsorption/desorption of S-methyl-JAU 6476 on four different soils Report No. FM774 Generated by SLFA Neustadt Bayer AG GLP Unpublished	N	BAY
KCP 9.1.2/05	Fent, G.	1998	Adsorption/desorption of [phenyl-UL-14C]SXX 0665 on four different soils Report No. FM768 Generated by SLFA Neustadt Bayer AG GLP Unpublished	N	BAY
KCP 9.1.2/06	Riegner, K.	1999	Leaching behaviour of JAU6476 formulated as 250 EC in soil (parent leaching) Report No.: MR-098/99 Bayer AG GLP Unpublished	N	BAY
KCP 9.1.2/07	Babczinski, P.	2001	Aged soil column leaching of JAU6476 Report No.: MR-364/00 Bayer AG GLP Unpublished	N	BAY

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 9.1.1/05	Schad, T.	2001	Calculation of degradation rates of JAU6476 based on aerobic soil degradation studies Report No.: MR-383/01 Bayer AG non GLP Unpublished	N	BAY
KCP 9.1.1/06	Schad, T.	2001	Calculation of temperature referenced first order DT50 of JAU6476 and its metabolite JAU6476-desthio based on field dissipation studies conducted in Europte Report No.: MR-468/01 Bayer AG non GLP Unpublished	N	BAY
KCP 9.2/01	Schad, T.	2001	Predicted environmental concentrations of JAU6476 and its metabolites JAU6476-desthio and JAU6476-S-methyl in groundwater recharge based on calculation with FOCUS-PELMO Report No.: MR-380/01 Bayer AG non GLP Unbpulished	N	BAY
KCP 9.2/02	Riegner, K.	1998	Hydrolysis of [phenyl-UL-14C]JAU6476 in sterile aqueous buffer solution Report No. MR-623/98 Bayer AG GLP Unpublished	N	BAY
KCP 9.2/03	Hellpointner, E.	2001	Determination of the quantum yield and assessment on the environmental half-life of the direct photodegradation in water of JAU6476 Report No. MR-101/01 Bayer AG GLP Unpublished	N	BAY
KCP 9.2/04	Gilges, M. Bornatsch, W.	2001	Photolysis of JAU 6476 in sterile aqueous buffer Report No. MR-213/01	N	BAY

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
			Bayer AG GLP Unpublished		
KCP 9.2/05	Hellpointner, E.	1993	Determination of the quantum yield and sessment of the environmental half-life of the direct photodegradation of SXX 0665 in water Report No. PF3852 Bayer AG GLP Unpublished	N	BAY
KCP 9.2/06	Schafer, H.	2001	Calculation of DT-50 values of JAU6476 metabolite thiazocine generated by photolysis in aqueous solution Report No. MR-591/01 Bayer AG non GLP Unpublished	N	BAY
KCP 9.2/07	Schafer, H.	2001	Prediction of maximum amounts of JAU6476-thiazocine in surface water under natural conditions Report No. MR-597/01 Bayer AG non GLP Unpublished	N	BAY
KCP 9.2/08	Brumhard, B. Oi, M.	2001	Aerobic degradation and metabolism of the active ingredient JAU6476 in the water/sediment system Report No. MR-395/01 Bayer AG GLP Unpublished	N	BAY
KCP 9.2/09	Scholz, K.	2001	Anaerobic aquatic metabolism of JAU6476 Report No.: MR-275/01 Bayer AG GLP Unpublished	N	BAY

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 9.3/01	Hellpointner, E.	1999	Calculation of the chemical lifetime of JAU6476 in the troposphere Report No. MR-093/99 Bayer AG non GLP Unpublished	N	BAY
KCP 9.3/02	Hellpointner, E.	2000	Calculation of the chemical lifetime of JAU 6476-DESTHI in the troposphere Report No. MR-323/00 Bayer AG non GLP Unpublished	N	BAY

Appendix 2 Detailed evaluation of the new Annex II studies

Appendix 3 Additional information provided by the applicant (e.g. detailed modelling data)