REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: ADM.03503.F.1.A

Product name(s): see Part A

Chemical active substance(s):

Fluxapyroxad, 75 g/L

Prothioconazole, 150 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Country organisation / representative as specified in Part A

Submission date: April 2022

MS Finalisation date: May 2023 (initial Core Assessment)
November 2023 (final Core Assessment)

Version history

When	What
2022/04	Version 1 Applicant
2023/05	Initial zRMS assessment The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are ~~struck through~~ and shaded for transparency.
2023/11	Final report (Core Assessment updated following the commenting period) Additional information/assessments included by the zRMS in the report in response to comments received from the cMS and the Applicant are highlighted in yellow. Information no longer relevant is ~~struck through~~ and shaded.

DATA PROTECTION CLAIM

In order to present a dossier fully compliant with today’s requirements (Reg. 284/2013), studies have been performed on ADM.03503.F.1.A. Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for the studies conducted with ADM.03503.F.1.A. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A.

STATEMENT FOR OWNERSHIP

The summaries and evaluations contained in this document may be based on unpublished proprietary data submitted for the purpose of the assessment undertaken by the regulatory authority that prepared it. Other registration authorities should not grant, amend, or renew a registration on the basis of the summaries and evaluation of unpublished proprietary data contained in this document unless they have received the data on which the summaries and evaluation are based, either –

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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. 1~~0~~, date: October 2023 ~~May 2023 February 2022~~

PPP (product name/code):	ADM.03503.F.1.A	Formulation type:	EC [a, b]
Active substance 1:	Fluxapyroxad	Conc. of as 1:	75 g/L [c]
Active substance 2:	Prothioconazole	Conc. of as 2:	150 g/L [c]
Applicant:	Country organisation/representative of ADAMA as given in Part A	Professional use:	☒
Zone(s):	Central Zone	Non professional use:	☐
Verified by MS:	Yes ~~no~~		
Field of use:	Fungicide		

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
					Application				**Application rate**					**Conclusion**
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)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max	**PHI** (days)	**Remarks:** e.g. g safener/ synergist per ha	Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
1	Belgium	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici Drechslera tritici-repentis (DTR) Puccinia striiformis Puccinia recondita, Blumeria graminis f. sp. tritici, Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
2	Belgium	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis Pyrenophora teres Ramularia collo-cygni Puccinia hordei Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
3	Belgium	Rye (SECCW)	F	*Rhyncosporium secalis Puccinia recondita Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 /	125-400			A

										187.5				
4	Belgium	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
5	Netherlands	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp. tritici,* *Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
6	Netherlands	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
7	Netherlands	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
8	Netherlands	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
9	Czechia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp. tritici,* *Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
10	Czechia	Winter barley (HORVW) Spring barley	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 /	125-400			A

		(HORVS)		*Puccinia hordei* *Blumeria graminis f. sp. hordei*						187.5				
11	Czechia	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
12	Czechia	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
13	Germany	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp. tritici,* *Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
14	Germany	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
15	Germany	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
16	Germany	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
17	Ireland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp.*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A

				tritici, *Fusarium + microdochium*										
18	Ireland	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
19	Ireland	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
20	Ireland	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400			A
21	Poland	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp. tritici,* *Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
22	Poland	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
23	Poland	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
24	Poland	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A

25	Slovakia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp. tritici,* *Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
26	Slovakia	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
27	Slovakia	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
28	Slovakia	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
29	Hungary	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp. tritici,* *Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
30	Hungary	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
31	Hungary	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A

32	Hungary	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
33	Slovenia	Winter wheat (TRZAW) Spring wheat (TRZAS)	F	*Zymoseptoria tritici* *Drechslera tritici-repentis (DTR)* *Puccinia striiformis* *Puccinia recondita,* *Blumeria graminis f. sp. tritici,* *Fusarium + microdochium*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
34	Slovenia	Winter barley (HORVW) Spring barley (HORVS)	F	*Rhyncosporium secalis* *Pyrenophora teres* *Ramularia collo-cygni* *Puccinia hordei* *Blumeria graminis f. sp. hordei*	foliar, spraying, overall	-/ BBCH 30-65 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
35	Slovenia	Rye (SECCW)	F	*Rhyncosporium secalis* *Puccinia recondita* *Puccinia striiformis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A
36	Slovenia	Triticale (TTLSS)	F	*Zymoseptoria tritici* *Puccinia recondita* *Puccinia striiformis* *Drechslera tritici-repentis (DTR)* *Blumeria graminis*	foliar, spraying, overall	-/ BBCH 30-69 spring	a) 1 (-) b) 1 (-)		a) 1.25 L/ha b) 1.25 L/ha	a) 93.75 / 187.5 b) 93.75 / 187.5	125-400		Range of rates 1.0-1.25L	A

* 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

Explanation for column 15 "Conclusion"

A	Safe use
R	Further refinement and/or risk mitigation measures required
C	To be confirmed by cMS
N	No safe use

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
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)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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	**PHI** (days)	**Remarks:** e.g. g safener / synergist per ha
-	EU	W. Wheat S. Wheat Durum W. Barley S. Barley Triticale Rye Oat	F	*P. herpotrichoides E. graminis Septoria spp. Puccinia spp. P. trticirepentis P. teres R.secalis R. collo-cygni*	Foliar spray	BBCH 25-69	a) 1 b) 2	21	a) 2.0 b) 4.0	a) 0.125 b) 0.250	100 – 300	35	'BAS 700 00F''

Table 8.1-3: Assessed (critical) uses during approval of prothioconazole concerning the Section Environmental Fate

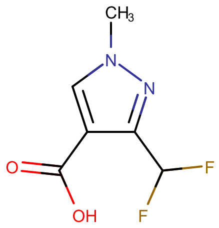
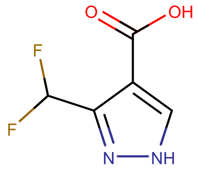
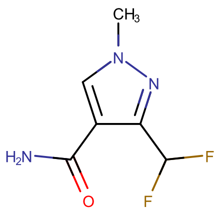
1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
Use-No. *	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg 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	**PHI** (days)	**Remarks:** e.g. g safener / synergist per ha
-	EU North South	wheat, rye, triticale	F	Rusts, Eyespot, *Fusarium spp.*, *Powd. Mildew*, *Rhynchospor.*, *Septoria*	overall spray	start 26-29 up to BBCH69 (interval 14 - 21 d) #	1 – 3 #	ref. to growth stage	0.8	0.2	200 - 400	35	# timing , no. of applic. depends on national conditions
-	EU North South	barley, oat	F	Rusts, Eyespot, *Pyren. teres*, *Powd. Mildew*, *Fusarium spp.*, *Rhynchospor*	overall spray	start 30 up to BBCH 61 (interval 14 - 21 d) #	1 – 2 #	ref. to growth stage	0.8	0.2	200 - 400	35	# timing , no. of applic. depends on national conditions
-	EU North	rape	F	*Sclerotinia*, *Botrytis*, *Alternaria*, *Leptosphaeria*	overall spray	start BBCH 53 (interval 14 - 28 d) #	1 – 2 #	ref. to growth stage	0.7	0.175	200 - 400	56	# timing , no. of applic. depends on national conditions
-	EU North South	wheat, rye, triticale, oat, barley	F	*Fusarium spp.*, *Bunt*, Smut	seed treatment	pre sowing	1	-	0.045 – 0.09	*approx. 9-18 g as/ha (180 kg seed/ha)	200 – 400 mL water/dt	-	*5 – 10 g as/dt seed [1]

* 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

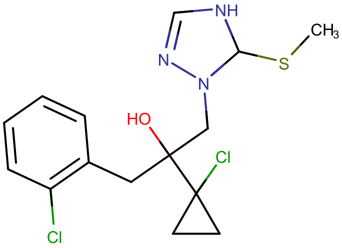
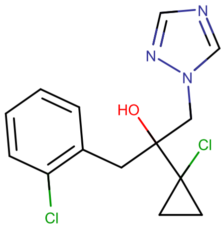
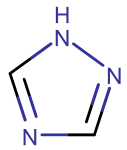
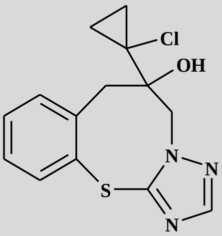
Table 8.2-1: Metabolites of fluxapyroxad potentially relevant for exposure assessment (EFSA, 2012)

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
M700F001 3-(difluoromethyl)-1-methyl-1H-pyrazole-4-carboxylic acid	176.1		Soil: 12.1 % Water: 10.9 % Sediment: < 5 %	PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
M700F002 3-(difluoromethyl)-1H-pyrazole-4-carboxylic acid	162		Soil: 70.5 % Water: < 5 % Sediment: < 5 %	PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
M700F007 3-(difluoromethyl)-1-methyl1H-pyrazole-4-carboxamide	175.1		Soil: < 5 % Water: 17.7 %	$PEC_{SW/SED}$: not covered by EU assessment

zRMS comments:

Information regarding fluxapyroxad metabolites provided in Table 8.2-1 is agreed by the zRMS. It is noted that slightly different occurrence of some metabolites is reported in EFSA Journal 2012;10(1):2522 in points regarding route of degradation studies. However, values presented in Table 8.2-1 are fully in line with maximum occurrence considered in exposure estimation performed at the EU level.

Table 8.2-2: Metabolites of prothioconazole potentially relevant for exposure assessment (EFSA, 2007)

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
JAU 6476-S-methyl (M01) 2-(1-chlorocyclopropyl)-1-(2-chlorophenyl)-3- (4,5-dihydro-5-methylthio-1,2,4-triazolyl-1)-propan-2-ol	358.3		Soil: 14.6 % Sediment: 77 % (anaerob) water/sediment (aerobic): 12.7% (whole system); 3.1% (water); 9.6% (sediment)	PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
JAU 6476-desthio (M04) 2-(1-chlorocyclopropyl)1-(2- chlorophenyl)-3-(1,2,4- triazol-1-yl)-propan-2-ol	312.2		Soil: 57.1 % Water: 32.3 % Sediment: 26.9 %	PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
1,2,4-triazole (M13) 1H-1,2,4-triazole	69.1		Soil: < 5 % Water: 37.2 % Sediment: 4.6 %	$PEC_{SW/SED}$: not covered by EU assessment
JAU 6476-thiazocine (prothioconazole-thiazocine, M12)	307.8		Aqueous photolysis study: 14.1% on day 5	Considered not relevant in EFSA (2007)

zRMS comments:
Information regarding prothioconazole metabolites is in general line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106, with some minor corrections. Information on metabolite JAU 6476-thiazocine has been added by the zRMS, as this metabolite was found at >10% in aqueous photolysis study. However, it was considered not relevant for the exposure assessment during EU review.

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)

8.3.1.1 Fluxapyroxad and its metabolites

The route and rate of degradation of fluxapyroxad (BAS 700 F) was investigated in four soils with pyrazole labelled fluxapyroxad (BAS 700 F), and in one soil with aniline and one with trifluorophenyl labelled fluxapyroxad (BAS 700 F). Fluxapyroxad (BAS 700 F) exhibits medium to very high persistence in these studies. **For modelling endpoints, please refer to field studies**. No metabolites were identified above a concentration of 5 % AR in the aniline and trifluorophenyl labelled studies. Two metabolites, **M700F001** and **M700F002**, were observed in the pyrazole labelled study above 10 % AR. The levels of metabolite M700F002 were still increasing at the end of the study (120 d). Unextracted residues at the end of the studies (120 d) amounted to 54.7 % AR in the aniline labelled test, 29.9 % AR in the trifluorophenyl labelled test and up to 25.9 % AR in the pyrazole labelled ones. Mineralization (as CO_2) was 12.7 % AR in the aniline labelled experiment, 6 % in the trifluorophenyl labelled test and from negligible up to 7.3 % AR in the pyrazole labelled ones (end of studies, 120 d).
The rate of degradation of the metabolites M700F001 and M700F002 was also investigated in separate studies. Metabolite M700F001 may be considered to exhibit low persistence in soil, while metabolite M700F002 may be considered to exhibit high persistence in soil under aerobic conditions in laboratory experiments.

Table 8.3.1.1-1: Summary of aerobic degradation rates for M700F001 - laboratory studies

M700F001, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**St. (χ^2)**	**Kinetic model**	**Evaluated on EU level**
†Bruch West	Sandy loam*	7.1	20	40	**10**	33.1	7.7	25.1	SFO	y EFSA (2012)
*Li10	Loamy sand	6.3	20	40	9.3	30.7	8.9	2.9	SFO	y EFSA (2012)
*LUFA 2.2	Sand	5.9	20	40	6.5	21.5	5.2	1.1	SFO	y EFSA (2012)
*Wisconsin	Loamy sand	5.9	20	40	2.3	9.2	2.1	3.1	FOMC	y EFSA (2012)
**Wisconsin*	*Loamy sand*	*5.9*	*20*	*40*	*2.5*	*8.2*	*2.3*	*4.8*	*SFO*	*y EFSA (2012)*
Geometric mean (n=4)							**5.4****	y EFSA (2012)		
pH-dependency:							n			

* M700F001 applied, † Parent applied study, ** 5.4 d geometric mean is used given in EFSA (2012) -> 5.2 d is correct geomean
Bold value used for modelling
Italic font indicates no best fit kinetics for triggering purposes

Table 8.3.1.1-2: Summary of aerobic degradation rates for M700F002 - laboratory studies

M700F002, Laboratory studies, aerobic conditions (pyrazole label)											
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t.°C**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**f.f.*** k_{dp}/k_f**	**DT50 (d) 20°C pF2/10kPa**	**St. (χ^2)**	**Kinetic model**	**Evaluated on EU level**
Li10*	**Loamy sand**	**6.3**	**20**	**40**	**168**	**557**	**0.90**	**161**	**2.2**	**SFO**	**y EFSA (2012)**
LUFA 2.2*	**Sand**	**5.9**	**20**	**40**	**148/ 490**	**490**	**0.79**	**117**	**2.1**	**SFO**	**y EFSA (2012)**
Wisconsin*	**Loamy sand**	**5.9**	**20**	**40**	**131**	**435**	**0.77**	**118**	**3.4**	**SFO**	**y EFSA (2012)**
Li10**	**Loamy sand**	**6.3**	**20**	**40**	**152 overall; 0.968 DT_{50} fast; 178 DT_{50} slow**	**567**	**-**	**123 overall; 0.786 fast; 145 slow**	**0.4**	**DFOP**	**y EFSA (2012)**
LUFA 2.2**	**Sand**	**5.9**	**20**	**40**	**147**	**>1000**	**-**	**147**	**1.9**	**FOMC**	**y EFSA (2012)**
LUFA 2.2**	Sand	5.9	20	40	120 overall; 4.86 DT_{50} fast; 193 DT_{50} slow	567	-	120 overall; 4.86 fast; 193 slow	2.1	DFOP	y EFSA (2012)
Wisconsin **	**Loamy sand**	**5.9**	**20**	**40**	**76.6**	**>1000**	**-**	**70.4**	**2.2**	**FOMC**	**y EFSA (2012)**
Wisconsin **	Loamy sand	5.9	20	40	83.1 overall; 5.06 DT_{50} fast; 161 DT_{50} slow	454	-	76.3 overall; 4.65 fast; 148 slow	2.5	DFOP	y EFSA (2012)
Bruch West**	**Sandy loam**	**7.4**	**20**	**40**	**197**	**>1000**	**-**	**134**	**2.0**	**FOMC**	**y EFSA (2012)**
Bruch West**	Sandy loam	7.4	20	40	158 overall; 9.94 DT_{50} fast; 204 DT_{50} slow	636	-	108 overall; 6.78 fast; 139 slow	2.2	DFOP	y EFSA (2012)
Geometric mean #					164 slow	-	0.82	143 slow			
pH-dependency:					n						

* M700F001 applied, * M700F002 applied, *** Formation fraction from M700F001

\# Where both best fit and modelling fit kinetics are reported, the geometric mean is calculated from the kinetic fit for modelling. Where more than one test value is available for an individual soil, a geometric mean was taken of those values for use in the overall geometric mean calculation. Calculated geomean values for individual soils were 153 d for Li10; 150 d for LUFA 2.2; and 132 d for Wisconsin. **Bold** font indicates best fit kinetics for triggering purposes.

Soil photolysis

Photolysis in soil was investigated in an experiment under simulated summer sunlight at 49°N (Xenon lamp, filtered for λ < 290 nm) for 15 days of continuous irradiation. Photolysis slightly enhances the degradation of fluxapyroxad (BAS 700 F) in soil, producing minor metabolites not found in the dark control. However, these metabolites appeared at levels < 5 % AR and are not considered to require further assessment.

zRMS comments:
Soil degradation data presented in tables above are in line with EU agreed endpoints presented in EFSA Journal 2012;10(1):2522. Information on DT_{50} values considered for purposes of estimation of exposure in particular environmental compartments is thus given in the respective points of this document.

8.3.1.2 Prothioconazole and its metabolites

A summary of the EU agreed aerobic soil degradation data of prothioconazole is given in Table 8.3.1.2-1.

Table 8.3.1.2-1: Summary of EU agreed aerobic degradation rates for prothioconazole - laboratory studies (according to DAR, 2005)

Prothioconazole, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. °C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Laacher Hof	sandy loam	6.6	20	34.42	0.07	5.3	-	-	FOMC	y/ DAR, 2005; EFSA, 2007
Stanley	silty clay loam	5.9	20	56.25	0.7	78.2	-	-	FOMC	
Höfchen	silt	6.8	20	63.1	0.3	0.99	-	-	SFO	
Byromville	loamy sand	6.1	20	49*	1.27	4.22	-	-	SFO	
Geometric mean/Median (n=4)							0.37/0.5			
pH-dependency: y/n							n			

* % of 1/3 bar moisture

Un-normalised $DegT_{50}$ and $DegT_{90}$ values of prothioconazole in aerobic laboratory soils ranged from 0.07 to 1.27 days and 0.99 to 78.2 days, respectively. **For modelling endpoints, please refer to field studies.**

<u>Metabolites</u>

A summary of the EU agreed aerobic soil degradation data of prothioconazole metabolites is given in Table 8.3.1.2-2 and Table 8.3.1.2-3.

Table 8.3.1.2-2: Summary of EU agreed aerobic degradation rates for prothioconazole-S-methyl (M01) laboratory studies (according to DAR, 2005)

Prothioconazole-S-methyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type (DIN)**	**pH ($CaCl_2$)**	**t. °C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**$DegT_{50}$ (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level**
Höfchen	loamy silt	6.5	20	63.1	5.9	19.6	-	-	1st order SFO	y/ DAR, 2005; EFSA, 2007
Laacher Hof	loamy silt	6.7	20	36.4	27.2	90.2	-	-		
Laacher Hof	sandy loam	6.3	20	34.4	8.2	27.2	-	-		
Stanley	silty clay	5.2	20	43.8	**46.0**1)	153	-	-		
Geometric mean (n = 4)							**15.7**2)			
pH-dependency: y/n							n			

Bold value used for PECsoil1), PEC_{GW}2) and $PEC_{SW/SED}$2) modelling

Un-normalised DT_{50} and DT_{90} values of prothioconazole-S-methyl ranged from 5.9–46.0 days and 19.6–153 days, respectively. This results in a DT_{50} geometric mean of 15.7 days which is the EU agreed endpoint (EFSA, 2007) used for PEC_{GW} and $PEC_{SW/SED}$ calculations. Maximum unnormalized DT_{50} was used for PEC_{soil} assessment.

Table 8.3.1.2-3: Summary of EU agreed aerobic degradation rates for prothioconazole-desthio laboratory studies (according to DAR, 2005)

Prothioconazole-desthio, Laboratory studies, aerobic conditions										
Soil name	**Soil type (DIN)**	**pH ($CaCl_2$)**	**t. °C**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**$DegT_{50}$ (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Höfchen	loamy silt	6.5	20	36.4	34.0	113.0	-	-	1st order SFO	y/ DAR, 2005; EFSA, 2007
Laacher Hof	loamy silt	6.7	20	43.8	29.6	98.3	-	-		
Laacher Hof	sandy loam	6.3	20	43.8	7.0	23.2	-	-		
Stanley	silty clay	5.2	20	43.8	18.6	61.9	-	-		
Geometric mean/Median (n = 4)							19.0/24.1			
pH-dependency: y/n							n			

Un-normalised DT_{50} and DT_{90} values of prothioconazole-desthio ranged from 7.0–34.0 days and 23.2–113.0 days, respectively. **For modelling endpoints, please refer to field studies.**

Soil photolysis

Information on soil photolysis of the parent compound prothioconazole is available from the DAR (2005). It is summarised hereafter.

Table 8.3.1.2-4: Summary of agreed EU photolysis data of prothioconazole in laboratory soils (according to DAR, 2005)

Prothioconazole, Laboratory studies, soil photolysis										
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. °C**	**1/3 bar MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**$DegT_{50}$ (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Byromville	loamy sand	6.1	20	75	4.1 [a)] 14.7 [b)] 22.9 [e)]	13.7 [a)]	-	-	1st order SFO	y/ DAR, 2005

[a)] DT_{50}/DT_{90} experimental

[b)] predicted environmental half-life under solar summer conditions of Phoenix, AZ, USA in June

[c)] predicted environmental half-life under solar summer conditions of Athens, Greece in June

A soil photolysis study is available with phenyl-^{14}C-labelled prothioconazole. Results demonstrated prothioconazole to be degraded rapidly (prothioconazole amounted to 18.6% AR in the irradiated samples after 15 days, end of the study) on soil surface if irradiated by simulated sunlight. However, the fast degradation observed for the dark control (19.0% AR at 15d) revealed photo transformation not to be the dominant process of degradation. M04 (prothioconazole-desthio) appears at relatively high concentrations in both irradiated and dark control samples (maximum observed at day 7: 38.5% A.R. and 29.4% A.R respectively), indicating that photolysis will not significantly contribute to the overall degradation of prothioconazole in soil under environmental conditions. The first order DT_{50} value for the degradation of the active ingredient yielded 4.1 days, equated to 22.9 days under sola summer conditions of Athens (Greece) in June.

Table 8.3.1.2-5: Summary of agreed EU photolysis data of prothioconazole in laboratory soils (EFSA, 2007)

Soil photolysis	
Metabolites that may require further consideration for risk assessment	none

zRMS comments:
Soil degradation data for prothioconazole and its metabolites are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Fluxapyroxad and its metabolites

According to EFSA (2012) the applicant submitted a study to investigate the degradation of fluxapyroxad (BAS 700 F) in soil under anaerobic conditions with the substance labelled only in the aniline and pyrazole rings. A further study with triflurophenyl-U-^{14}C labelled fluxapyroxad (BAS 700 F) would be needed to complete the data requirements for the route and rate of degradation under anaerobic conditions. However, no further data have been requested at EU level since anaerobic conditions are considered to be unlikely to occur for the representative uses evaluated.

zRMS comments:
Information regarding formation on anaerobic metabolites of fluxapyroxad is not full in line with information reported in EFSA Journal 2012;10(1):2522, as under anaerobic conditions metabolite M007F001 was formed at maximum 19.9% of AR. Nevertheless, anaerobic conditions are not expected at the time of application of ADM.03503.F.1.A (cereals at BBCH 30-69).

8.3.2.2 Prothioconazole and its metabolites

Soil degradation under anaerobic conditions was not investigated. EFSA (2007) provides the following information on the anaerobic degradation of **prothioconazole:** Due to the fact that a seed treatment formulation was considered, an anaerobic aquatic metabolism study was submitted.

The anaerobic study indicated relatively rapid breakdown of parent to JAU-S-methyl, which seems to accumulate. This might indicate that if prothioconazole was applied to an anaerobic soil there would be significant formation of JAU-S-methyl. However, the only major period of anaerobic conditions is likely to be in winter. According to the underlying GAP table no seed treatment is envisaged and the application of ADM.03503.F.1.A will only take place in spring. Therefore, it is unlikely that there would be significant formation of JAU-S-methyl under field conditions.

zRMS comments:
It is noted that in line with information provided in EFSA Scientific Report (2007) 106, prothioconazole might be potentially exposed to anaerobic conditions when applied during the winter, following autumn seed treatment. The application pattern of ADM.03503.F.1.A does not include application as a seed treatment, so anaerobic route of exposure is not considered further, in line with EU conclusions.

8.4 Field studies (KCP 9.1.1.2)

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

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

Soil dissipation data on fluxapyroxad and its metabolite is available from the EFSA conclusion of fluxapyroxad, 2012. No additional studies have been performed.
Soil dissipation data on prothioconazole and its metabolite is available from the DAR of prothioconazole, 2005. No additional studies have been performed.

8.4.1.1 Fluxapyroxad and its metabolites

The dissipation of fluxapyroxad (BAS 700 F) under field conditions was investigated in six locations in Europe. In these trials the samples have also been analysed for the soil metabolites M700F001, M700F002 and the potential metabolite M700F003. The very high persistence of fluxapyroxad (BAS 700 F) observed in the laboratory studies was confirmed by these trials. Additionally, four field trials (Denmark, Germany, Italy and Southern France), where metabolite M700F002 was applied as parent, were performed.

Triggering endpoints

Table 8.4.1.1-1: Summary of aerobic degradation rates for fluxapyroxad - field studies: Triggering endpoints

Fluxapyroxad (BAS 700 F) – triggering endpoints, field studies, aerobic conditions								
Location	**Soil type (USDA)**	**pH ($CaCl_2$)**	**Depth (cm)**	**DT50 (d)**	**DT90 (d)**	**St. (χ^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Wilson, UK	Loam – bare soil	6.9	0-30	**370**	>1000	6.8	FOMC*	y EFSA (2012)
Garz, Germany (East)	Loamy sand – bare soil	5.0	0-30	140	>1000	8.5	FOMC	y EFSA (2012)
Goch-Nierswalde, Germany (West)	Silt Loam – bare soil	6.1	0-30	132	>1000	6.4	FOMC	y EFSA (2012)
Meistratzheim, France	Silt Loam – bare soil	7.4	0-20	284	>1000	7	FOMC	y EFSA (2012)
Poggio Renatico, Italy	Silt Loam – bare soil	7.6	0-10	38.9	854	6.7	DFOP	y EFSA (2012)
Alberic, Spain	Silty Clay Loam – bare soil	7.7	0-50	124	882	8.4	FOMC	y EFSA (2012)

Bold value used for PECsoil modelling

* FOMC: alpha = 0.2059; beta = 13.1342 used for PEC soil accumulation calculation

Table 8.4.1.1-2: Summary of aerobic degradation rates for M700F002 - field studies: Triggering endpoints

M700F002 – triggering endpoints, field studies, aerobic conditions								
Location	**Soil type (USDA)**	**pH ($CaCl_2$)**	**Depth (cm)**	**DT50 (d)**	**DT90 (d)**	**St. (χ^2)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Middelfart, Denmark	Loamy sand – bare soil	5.8	0-40	39.2	188	12.0	FOMC*	y EFSA (2012)
Goch-Nierswalde, Germany	Silt Loam – bare soil	6.4	0-40	38.0	155	5.7	FOMC	y EFSA (2012)
Poggio Renatico, Italy	Silt Loam – bare soil	7.7	0-70	37.4	186	7.0	DFOP	y EFSA (2012)
Meauzac. Southern France	Loam – bare soil	5.5	0-60	25.5	84.8	6.9	SFO	y EFSA (2012)

* FOMC: alpha = 2.4056; beta = 117.5 used for PEC soil calculation

Modelling endpoints

Table 8.4.1.1-3: Summary of aerobic degradation rates for fluxapyroxad - field studies: Modelling endpoints

Fluxapyroxad (BAS 700 F) – modelling endpoints, field studies, aerobic conditions							
Location	**Soil type (USDA)**	**pH ($CaCl_2$)**	**Depth (cm)**	**St. (χ^2)**	**DT50 norm (d)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Wilson, UK	Loam – bare soil	6.9	0-30	7.1	26.8 fast; 187 slow	HS	y EFSA (2012)
Garz, Germany (East)	Loamy sand – bare soil	5.0	0-30	7.1	83.9	SFO	y EFSA (2012)
Goch-Nierswalde, Germany (West)	Silt Loam – bare soil	6.1	0-30	4.6	28.5 fast; 193 slow	HS	y EFSA (2012)
Meistratzheim, France	Silt Loam – bare soil	7.4	0-20	7.7	132	SFO	y EFSA (2012)
Poggio Renatico, Italy	Silt Loam – bare soil	7.6	0-10	8.3	40.1 fast; 224 slow	HS	y EFSA (2012)
Alberic, Spain	Silty Clay Loam – bare soil	7.7	0-50	8.0	131	SFO	y EFSA (2012)
Geometric mean (n=6), based on slow HS					59.5 fast; **151** slow		y EFSA (2012)

Bold value used for PEC_{GW} and $PEC_{SW/SED}$ calculation

Table 8.4.1.1-4: Summary of aerobic degradation rates for M700F002 - field studies: Modelling endpoints

M700F002 – modelling endpoints, field studies, aerobic conditions							
Location	**Soil type (USDA)**	**pH ($CaCl_2$)**	**Depth (cm)**	**St. (χ^2)**	**DT50 norm (d)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Middelfart, Denmark	Loamy sand – bare soil	5.8	0-40	13.2	17.9	SFO	y EFSA (2012)
Goch-Nierswalde, Germany	Silt Loam – bare soil	6.4	0-40	10.3	23.1	SFO	y EFSA (2012)
Poggio Renatico, Italy	Silt Loam – bare soil	7.7	0-70	11.9	44.1	SFO	y EFSA (2012)
Meauzac. Southern France	Loam – bare soil	5.5	0-60	9.1	24.6	SFO	y EFSA (2012)
Geometric mean (n=6), based on slow HS					**25.9**		y EFSA (2012)

Bold value used for PEC_{GW} and $PEC_{SW/SED}$ calculation

zRMS comments:

Field degradation data presented in Tables 8.4.1.1-1 to 8.4.1.1-4 above are in with EU agreed endpoints presented in EFSA Journal 2012;10(1):2522. The minor differences are result of rounding.

8.4.1.2 Prothioconazole and its metabolites

Dissipation of prothioconazole and prothioconazole-desthio was examined in eight studies under field conditions at four sites in Northern Europe and two sites in Southern Europe. Application of the test substance was directly onto bare soil. Details on soil type and study location are presented in Table 8.4.1.2-1 and Table 8.4.1.2-2.

<u>Prothioconazole</u>

The $DissT_{50field}$ values of prothioconazole were in the range of 1.3–2.8 days (DT_{90} = 4.4–9.3 days) (see Table 8.4.1.2-1) following 1st order kinetics. The maximum $DissT_{50}$ of 2.8 days is the EU agreed endpoint (EFSA, 2007) considered for PEC_{SOIL} calculations. Normalised field soil dissipation modelling endpoints of prothioconazole range between 0.6 to 1.6 days. For PEC_{GW} and PEC_{SW} modelling of prothioconazole the geometric mean of 1.2 days was used.

Table 8.4.1.2-1: Summary of EU agreed aerobic degradation rates for prothioconazole - field studies: Triggering and Modelling endpoints (according to DAR, 2005)

Prothioconazole, Field studies – Triggering endpoints (actual) and Modelling endpoints (normalised)									
Soil type DIN 19682 / USDA)	**Location**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**DT_{50}, norm 20°C (d)**	**St. (r^2)**	**Method of calculation**	**Evaluated on EU level**
Loamy silt / Silt loam	51399 Burscheid, Trial Station Höfchen Germany	6.25	0-10	1.9	6.4	1.2	1.00		
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	1.6	5.5	0.8	1.00		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	1.3	4.4	1.6	1.00		
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	2.8	9.3	1.4	0.99	1st order	y DAR, 2005; EFSA, 2007
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	1.4	4.5	1.6	1.00		
Sandy loamy silt / Silt loam	13103 St. Etienne du Gres France (South)	7.61	0-10	1.7	5.6	1.1	0.99		
Weak loamy sand / Sandy loam	37060 Pradelle Di Nogarole Rocca (VR) Italy	7.56	0-10	1.6	5.4	1.5	0.99		
Loamy sand / Sandy loam	40789 Monheim Trial Station Laacherhof Germany	6.32	0-10	1.5	5.1	0.6	1.00		
Maximum (n=8)				**2.8***	9.3	-			
Geomean (n=8)				**-**	-	**1.2#**			

Bold values used for *PEC_{SOIL} calculations and #PEC_{GW}, PECsw simulations

Prothioconazole-desthio

The $DissT_{50field}$ of prothioconazole-desthio (see Table 8.4.1.2-2) ranged from 16.3 days to 72.3 days (DT_{90} = 54.1–240 days). The $DissT_{50}$ of 54.7 days was considered as endpoint for PEC_{SOIL} calculations. Normalised field soil dissipation modelling endpoints of prothioconazole-desthio range between 10.3 to 61.9 days. For PEC_{GW} and PEC_{sw} modelling the geometric mean of 22.7 days along with a conversion rate of 57.1 % for prothioconazole-desthio was used.

Table 8.4.1.2-2: Summary of EU agreed aerobic degradation rates for prothioconazole -desthio field studies: Triggering and Modelling endpoints (according to DAR, 2005)

Prothioconazole-desthio, Field studies – Triggering endpoints (actual) & Modelling endpoints (normalised)									
Soil type DIN 19682 / USDA)	**Location**	**pH**	**Depth (cm)**	**$DissT_{50}$ (d) actual**	**DT_{90} (d) actual**	**DT_{50}, norm 20°C (d)**	**St. (r^2)**	**Method of calculation**	**Evaluated on EU level**
Loamy silt / Silt loam	51399 Burscheid, Trial Station Höfchen Germany	6.25	0-10	16.3	54.1	10.3	0.98	1st order	y DAR 2005; EFSA, 2007
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	54.7	182	27.0	0.96		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	47.6	158	27.5	0.94		
Sandy clay loam / Sandy clay loam	IP31 3SH Thurston, Bury St. Edmunds Elm Farm Development Station Great Britain	7.56	0-10	50.2	167	23.4	0.91		
Weak loamy silt / Silt	27700 Fresne l'Archeveque France (North)	6.42	0-10	36.8	122	20.1	0.93		
Sandy loamy silt / Silt loam	13103 St. Etienne du Gres France (South)	7.61	0-10	72.3 ~~a)~~	240	61.9	0.91		
Weak loamy sand / Sandy loam	37060 Pradelle Di Nogarole Rocca (VR) Italy	7.56	0-10	30.5	101	20.7	0.98		
Loamy sand / Sandy loam	40789 Monheim Trial Station Laacherhof Germany	6.32	0-10	27.9 b)	92.6 b)	15.2	0.98		
Maximum (n=8)				**72.3**	240	-			
~~Maximum (n=7)~~				~~**54.7***~~	~~182~~	~~-~~			
Geomean (n=8)				-	-	**22.7#**			

~~a) excluded because this soil located in southern France is not considered relevant for application in the central zone~~

b) without day 0 sample, because maximum concentrations were found at later sampling dates

Bold values used for *PEC_{SOIL} calculations and #PEC_{GW}, PECsw simulations

zRMS comments:
The triggering endpoints for prothioconazole and metabolite JAU 5479-desthio provided in Tables 8.4.1.2-1 and 8.4.1.2-2 above are in line with data reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

The Applicant indicated that the maximum field DT_{50} of 54.7 days is an EU agreed endpoint relevant for PEC_{SOIL} calculations. This is, however, not true, since the maximum DT_{50} of 72.3 days was agreed at the EU level for soil exposure assessment and no differentiation was made between soils in particular climatic zones. Furthermore, the field DT_{50} values calculated for particular test sites within the EU do not seem to be significantly different and therefore should be merged. Taking this into account, exclusion of the degradation data from trials performed in Spain is not justified. To support such an exclusion the Applicant would have to provide detailed analysis demonstrating that DT_{50} in the Southern France soil is significantly different comparing to test sites within the Central Zone, which was not done.

For relevant endpoints considered in exposure assessment, please refer to points 8.7 (soil), 8.8 (groundwater) and 8.9 (surface water) of this document.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

According to EFSA (2012) accumulated PEC soil were calculated by the RMS for fluxapyroxad (BAS 700 F) and its metabolites M700F001 and M700F002 based on worst-case field half-life for fluxapyroxad (BAS 700 F). Plateau is expected to be reached after 13 years.

According to EFSA (2007) no data on soil accumulation was submitted and none is required for **prothioconazole and prothioconazole-desthio**. This is substantiated by field soil dissipation studies resulting in DT_{90} values for prothioconazole and prothioconazole-desthio below the trigger of 1 year in any trial (see Table 8.4.1.2-1 and Table 8.4.1.2-2, Annex point 8.4.1). For prothioconazole-S-methyl no field studies are triggered (DT_{50lab} < 60 days, see Table 8.3.1.2-2).

zRMS comments:

No EU agreed data from soil accumulation studies with fluxapyroxad and prothioconazole are available in EFSA Journal 2012;10(1):2522 and in in EFSA Scientific Report (2007) 106, respectively. Potential for soil accumulation is thus addressed in calculation of soil exposure in point 8.7 of this report.

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.
Data on the mobility in soil are available for fluxapyroxad (EFSA 2012) and prothioconazole (DAR 2005, EFSA, 2007) are summarised in the following.

8.5.1 Fluxapyroxad and its metabolites

The mobility of fluxapyroxad (BAS 700 F) and its metabolites M700F001 and M700F002 was assessed by batch adsorption/desorption studies in eight soils. According to the results of these studies, fluxapyroxad (BAS 700 F) may be considered low to medium mobile in soil, while metabolites M700F001 and M700F002 high to very high mobile.

Table 8.5.1-1: Summary of EU agreed soil adsorption for fluxapyroxad

Fluxapyroxad							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
LUFA 2.1	Sand	0.52	5.2	4.3	818	0.945	y EFSA, 2012
Obihiro	Sandy Loam*	2.74	5.6	15.2*	556*	0.897*	
Li 10	Loamy Sand	0.88	5.9	6.8	777	0.916	
New Jersey	Silt Loam	0.9	6.3	8.6	955	0.921	
Nierswalde	Silt Loam	1.63	6.5	17.9	1101	0.942	
LUFA 2.3	Sandy Loam	1.09	6.9	5.7	527	0.875	
La Gironda	Silty Clay Loam	3.84	7.5	12.3	320	0.902	
California	Sandy Loam	0.41	7.6	2.5	603	0.9	
Arithmetic mean (n = 7)					**728**	**0.914**	
pH-dependency y/n					n		

* Volcanic ash - excluded from mean calculation
Bold values used for #PEC_{GW}, $PEC_{SW/SED}$ simulations

Table 8.5.1-2: Summary of EU agreed soil adsorption for M700F001

M700F001							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
LUFA 2.1	Sand	0.52	5.2	0.02	4.2	0.715	y EFSA, 2012
Obihiro	Sandy Loam*	2.74	5.6	1.8*	65.8*	0.981*	
Li 10	Loamy Sand	0.88	5.9	0.03	3.6	1.047	
New Jersey	Silt Loam	0.9	6.3	0.03	3.4	0.914	
Nierswalde	Silt Loam	1.63	6.5	0.11	6.7	1.002	
LUFA 2.3	Sandy Loam	1.09	6.9	0	0	0.9**	
La Gironda	Silty Clay Loam	3.84	7.5	0	0	0.9**	
California	Sandy Loam	0.41	7.6	0	0	0.9**	
Arithmetic mean (n = 7)					**2.6**	**0.911**	
pH-dependency y/n					n		

* Volcanic ash - excluded from mean calculation; ** FOCUS default
Bold values used for #PEC_{GW}, $PEC_{SW/SED}$ simulations

Table 8.5.1-3: Summary of EU agreed soil adsorption for M700F002

M700F002							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH ($CaCl_2$)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level**
LUFA 2.1	Sand	0.52	5.2	0.07	13.1	0.969	y EFSA, 2012
Obihiro	Sandy Loam*	2.74	5.6	2.74*	99.9*	0.963*	
Li 10	Loamy Sand	0.88	5.9	0.04	4.8	0.842	
New Jersey	Silt Loam	0.9	6.3	0.13	14.1	1.165	
Nierswalde	Silt Loam	1.63	6.5	0.15	9.0	0.937	
LUFA 2.3	Sandy Loam	1.09	6.9	0.06	5.6	1.078	
La Gironda	Silty Clay Loam	3.84	7.5	0.04	1.0	0.990	
California	Sandy Loam	0.41	7.6	0.02	5.6	0.764	
Arithmetic mean (n = 7)					**7.6**	**0.964**	
pH-dependency y/n					n		

* Volcanic ash - excluded from mean calculation
Bold values used for #PEC_{GW}, $PEC_{SW/SED}$ simulations

zRMS comments:
Soil sorption data for fluxapyroxad and its metabolites presented in Tables 8.5.1-1 to 8.5.1-3 above are in line with information presented in EFSA Journal 2012;10(1):2522.

8.5.2 Prothioconazole and its metabolites

Prothioconazole

During the EU review adsorption coefficient for prothioconazole could not be determined via standard batch equilibrium studies due to the instability of the compound in these systems. Therefore, K_d and K_{oc} values of prothioconazole were estimated from aged column leaching studies.

Phenyl- UL-^{14}C radiolabelled prothioconazole was applied on a loamy sand soil and incubated at 20 ºC under aerobic conditions for 30 hours. The resulting values for prothioconazole were K_d = 15.2 and K_{oc} = 1765 mL/g (slightly mobile compound). At the end of the study, the extracted radioactivity was composed of 22.7% unchanged parent compound, the known metabolites from the soil metabolism study M04 (31.8% AR), M01 (8.1% AR) and prothioconazole-sulfonic acid (M02) (1.5%). The total radioactivity in the leachate accounted for only 1.1% AR of the applied radioactivity, and in the leachate fraction a radioactivity content of < 0.2% of the applied radioactivity was measured. The leaching behaviour of phenyl-UL-^{14}C radiolabelled prothioconazole was further investigated in a non-aged soil column leaching study on four soils. The level of radioactivity detected in the leachates was < 1% AR in all samples. Therefore, the leachate fractions were not analysed. The majority of the residue of the active substance was detected in the top 6 cm layer (14.6-40.7% AR in 0-6 cm layer, not detected in the 6-12 cm layer), this also being the case for the metabolites prothioconazole-S-methyl (5.5-11.2% AR in the 0-6 cm layer, not detected in the 6-12 cm layer) and prothioconazole-desthio (15.4-28.0% AR in the 0-6 cm layer, not detected in the 6-12 cm layer).
The sole K_{oc} value of 1765 mL/g along with a default 1/n (0.9) has been considered for the use in FOCUS PEC groundwater and PEC surface water/sediment modelling.

Metabolites

Adsorption/desorption data from four different soils are available for the major metabolite prothioconazole-S-methyl as shown in Table 8.5.2-1. K_f^{ads} values range from 15.6–64.1 mL/g. The K_{foc}^{ads} values range from 1973.6–2995.0 mL/g resulting in an arithmetic mean of **2556.3** mL/g, which is the EU agreed endpoint (EFSA, 2007) considered for PEC_{GW} and $PEC_{SW/SED}$ calculations. Freundlich coefficients vary from 0.85–0.91 with an arithmetic mean of **0.88** considered as EU agreed endpoint in PEC_{GW} and $PEC_{SW/SED}$ calculations. No soil pH dependent adsorption was observed.
The second major metabolite prothioconazole-desthio was investigated with the same soils. Results are presented in Table 8.5.2-2. K_f^{ads} values range from 4.1–13.4 mL/g. The K_{foc}^{ads} values range from 523.0–625.3 mL/g resulting in an arithmetic mean of **575.4** mL/g, which is the EU agreed endpoint (EFSA, 2007) considered for PEC_{GW} and $PEC_{SW/SED}$ calculations. Freundlich coefficients vary from 0.79–0.83 with an arithmetic mean of **0.81** considered as EU agreed endpoint in PEC_{GW} and $PEC_{SW/SED}$ calculations. No soil pH dependent adsorption was observed.

Table 8.5.2-1: Summary of EU agreed soil adsorption for prothioconazole-S-methyl (according to DAR, 2005)

Prothioconazole-S-methyl							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher Hof AXXa, Rhineland, Germany	sandy loam	2.02	7.2	56.0	2772.4	0.87	y/ DAR, 2005; EFSA, 2007
Höfchen, Rhineland, Germany	silt	2.14	7.1	64.1	2995.0	0.88	

Prothioconazole-S-methyl							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Stanley, Kansas, USA	silty clay loam	1.66	5.9	41.2	2484.0	0.91	
Byromville, Georgia, USA	loamy sand	0.79	6.8	15.6	1973.6	0.85	
Arithmetic mean (n = 4)					**2556.3**	**0.88**	
Median (n = 4)					2628.2	0.875	
Geometric mean (n=4)					2525.9	0.88	
pH-dependency y/n					n		

Bold values used for #PEC_{GW}, $PEC_{SW/SED}$ simulations

Table 8.5.2-2: Summary of EU agreed soil adsorption for prothioconazole-desthio (according to EFSA, 2007)

Prothioconazole-desthio							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Laacher Hof AXXa, Rhineland, Germany	sandy loam	2.02	7.2	12.46	616.8	0.79	y/ DAR, 2005; EFSA, 2007
Höfchen, Rhineland, Germany	silt	2.14	7.1	13.38	625.3	0.83	
Stanley, Kansas, USA	silty clay loam	1.66	5.9	8.90	536.4	0.83	
Byromville, Georgia, USA	loamy sand	0.79	6.8	4.13	523.0	0.80	
Arithmetic mean (n = 4)					**575.4**	**0.81**	
Median (n = 4)					576.60	0.82	
Geometric mean (n=4)					573.53	0.81	
pH-dependency y/n					n		

Bold values used for #PEC_{GW}, $PEC_{SW/SED}$ simulations

Table 8.5-3: Summary of EU agreed soil adsorption for 1,2,4-triazole (according to EFSA, 2008) of tebuconazole

1,2,4-triazole							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_f^{ads} (mL/g)**	**K_{foc}^{ads} (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n/ Reference**
Alpaugh, USA	Sandy loam	0.70	8.8	0.833	120	0.897	EFSA Scientific Report (2008) 176, 1-109 Conclusion on the peer review of tebuconazole
Hollister, USA	Clay loam	1.74	6.9	0.748	43	0.827	
Lawrenceville, USA	Silty clay loam	0.70	7.0	0.722	104	0.922	
Pachappa, USA	Sandy loam	0.81	6.9	0.720	89 ~~86~~	1.016	
Arithmetic mean (n = 4)					**89**	**0.916**	
pH-dependency y/n					n		

Bold values used for #PEC_{GW}, $PEC_{SW/SED}$ simulations

zRMS comments:
Soil mobility data for prothioconazole and its major soil metabolites are in line with EU agreed endpoints as reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR of 2005.

It is noted that at the EU level no respective soil adsorption-desorption studies were performed with prothioconazole and the Koc of 1765 mL/g has been derived from the aged leaching study. The method used for this calculation is questionable and was not agreed during the recent EU renewal of this active substance. Nevertheless, as the renewal process is still ongoing, the Koc of 1765 mL/g is considered to be an EU agreed endpoint that is relevant for the exposure assessment until new list of endpoints becomes valid.

For metabolites JAU 6476-S-methyl and JAU 6476-desthio the geometric mean Kfoc values were calculated by the Applicant, although in the EFSA conclusion only arithmetic mean values are reported and further used for groundwater and surface water modelling. The geometric mean values calculated by the Applicant were based on the individual Kfoc from the LoEP and are confirmed to be correct. The results of the modelling simulation were validated by the zRMS with consideration of the EU agreed arithmetic mean values.

Information on soil sorption of the metabolite 1,2,4-triazole presented in Table 8.5-3 is in line with EU agreed endpoints as reported in EFSA Scientific Report (2008) 176 for tebuconazole with some minor amendments.

8.5.3 Column leaching (KCP 9.1.2.1)

Leaching behaviour of **prothioconazole** was investigated under laboratory conditions in four soils. The study was carried out according to SETAC Guidelines (1995), BBA Guideline Part IV, 4-2 (1986) and in accordance with the principles of GLP. 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.

zRMS comments:

The column leaching studies were not required during the EU review of fluxapyroxad.
Results of column leaching and aged residues leaching of prothioconazole are reported in EFSA Scientific Report (2007) 106. The leaching potential of fluxapyroxad and prothioconazole or their metabolites following application of ADM.03503.F.1.A is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

According to EU evaluation of fluxapyroxad and prothioconazole no lysimeter data have been submitted. The results of the PEC_{GW} simulations as given under point 8.8 indicate a low leaching risk of fluxapyroxad and metabolites, as well as prothioconazole and metabolites. Therefore, lysimeter studies are not required.

zRMS comments:

The lysimeter studies were not required during the EU review of both active substances. The leaching potential of fluxapyroxad, prothioconazole and their pertinent metabolites following application of ADM.03503.F.1.A is addressed in groundwater modelling presented in point 8.8 of this document.

8.5.5 Field leaching studies (KCP 9.1.2.3)

According to EU evaluation of fluxapyroxad and prothioconazole no field leaching studies have been submitted. Based on the outcome of the PEC_{GW} simulations as provided under point 8.8, the leaching potential of fluxapyroxad and metabolites, as well as prothioconazole and its metabolites is low, which is why field leaching studies are not required.

zRMS comments:

The field leaching studies were not required during the EU review of both active substances.The leaching potential of fluxapyroxad, prothioconazole and their pertinent metabolites following application of ADM.03503.F.1.A is addressed in groundwater modelling presented in point 8.8 of this document.

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.
Data on the degradation of the active substance fluxapyroxad and its metabolites in water/sediment systems are available in the context of the respective EU evaluation process. For details see EFSA (2012).
Data on the degradation of the active substance prothioconazole and its metabolites in water/sediment systems are available in the context of the respective EU evaluation process. For details see EFSA (2007) and the DAR (2005) for prothioconazole.

8.6.1 Fluxapyroxad and its metabolites

Fluxapyroxad (BAS 700 F) was estimated to be stable to hydrolysis in buffer aqueous solutions (25°C, pH 4, 5, 7 and 9; from measurements performed at 50°C). Fluxapyroxad (BAS 700 F) was stable to aqueous photolysis. The water sediment metabolite **M700F007** under irradiated conditions is also stable to hydrolysis (25°C, pH 4, 5, 7 and 9) and aqueous photolysis. Fluxapyroxad (BAS 700 F) is not readily biodegradable according to the available study (OECD 301B). The degradation of fluxapyroxad (BAS 700 F) was investigated under dark and irradiated water/sediment systems. In dark systems the primary dissipation from the water phase occurs by partition to the sediment phase. Only minor degradation occurred in the whole water/sediment system experiments under dark conditions. No metabolites > 5 % AR were observed.
A default DT_{50} whole system = 1000 d has been assumed for the environmental risk assessment. Enhanced degradation was observed in the irradiated systems, resulting in the formation of two metabolites M700F001 (10.9 % AR at day 43) and M700F007 (7.5 % AR at day 57, increasing at the end of the study). The fact that fluxapyroxad (BAS 700 F) has shown to be practically stable in the aqueous photolysis study suggests that the acetone used as a vehicle to apply the product or other substances in the system may have acted as photosensitisers inducing indirect photolysis of fluxapyroxad (BAS 700 F). Also, the fact that the temperature was higher in the irradiated systems may have contributed to the apparent enhanced degradation. Since the degradation was only marginally increased with respect to the dark experiments, the results of the irradiated systems have not been considered further in the environmental risk assessment (EFSA, 2012).

zRMS comments:
Information presented above is in general in line with data presented in EFSA Journal 2012;10(1):2522.

8.6.2 Prothioconazole and its metabolites

Information on the aerobic degradation of prothioconazole in water sediment systems was available for two aquatic systems, Hönniger Weiher and Angler Weiher. From the two systems a geometric mean $DegT_{50}$ of 2.1 days was calculated for the whole system (Table 8.6.2-1), which is considered as endpoint for $PEC_{SW/SED}$ modelling. In addition, the anaerobic degradation of prothioconazole was investigated in an anaerobic water/sediment system (Fuquay, Montezuma, Georgia, USA). The disappearance of prothioconazole from the total water/sediment system had a DT_{50} of 72 days, while the DT_{50} in the supernatant water has calculated to be 2.5 days.

Table 8.6.2-1: Summary of degradation in water/sediment of prothioconazole

DAR, 2005: Prothioconazole distribution (max. sediment 23.4% after 1 days)										
Water / sediment system	**pH water/ sed. (H_2O)**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic, Fit**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic, Fit**	**$DissT_{50}$ sed. (d)**	**Kinet ic, Fit**	**Evaluated on EU level y/n/ Reference**
Hönniger Weiher	7.84 / 6.6	2.8	76.4	'hockey stick', r^2=0.953	0.8	2.7	1st order, r^2=0.947	n.c.	-	y/ DAR, 2005; EFSA, 2007
Angler Weiher	7.45 / 8.5	1.6	23.6	'hockey stick', r^2=0.998	1.0	3.4	1st order, r^2=0.999	n.c.	-	
Geometric mean (n=2)		**2.1**								FOCUS (2006)

n.c.: not calculated; **bold** values used as endpoint for $PEC_{SW/SED}$ calculations

Table 8.6.2-2: Summary of observed metabolites

Metabolites in Water/sediment system	Max occurrence [%]	DT_{50} in sediment/water system [d]	Evaluated on EU level
Prothioconazole-desthio	in water 32.3 % after 7 d in sediment 26.9 % after 14 d in whole system 54.6% (32.3% of day 7 + 22.3% of day 7)	49.9 (whole system value, n=2)	y/ DAR, 2005; EFSA, 2007
Prothioconazole-S-methyl	in sediment 77% after 240 d (anaerob)	40.2 (whole system value, n=2)	
1,2,4-triazole	in water 37.2 % after 121 d in sediment 4.6 % after 121 d in whole system 41.8 % after 121 d	-	

Hydrolysis, phototransformation in water and ready biodegradability

The aqueous **hydrolysis** of prothioconazole was investigated in one study at different pH values at 50 °C. Prothioconazole was found to hydrolyse slowly at pH 7 and 9 (DT_{50} estimated greater than one year). At pH 4 and 25 °C the DT_{50} was estimated to be 120 days.

The aqueous **photolysis** of phenyl- and triazole-labelled prothioconazole was studied following SETAC Guidelines (1995), US EPA Guideline 162-1 (1982) in accordance with the principles of GLP. Test solutions made up in sterile aqueous solution at pH 7 with a concentration of approximately 4 mg/l were continuously exposed to simulated sunlight using a xenon light (290 nm UV filter). Exposure period was equated 65.0 solar summer days in June in Arizona (USA) and 100.7 days in Athens (Greece). Prothioconazole was completely photodegraded within the duration of the experiment. Determined mean experimental half-life was 47.7 h (44.3 h, k = 0.0157 h^{-1}, R^2 = 0.999 for the phenyl-labelled and 51.4 h, k = 0.0135 h^{-1}, R^2 = 0.999 for the triazole-labelled test substance).

In a second study quantum yields and direct photodegradation of prothioconazole was investigated according to ECETOC method (1981, 1984), Test Guideline 'Phototransformation of chemicals in water,

Part A (Berlin, 1992) and in accordance with the principles of GLP. Mean quantum yields of 0.0638 (pH 4) and 0.0047 (pH 9) were calculated for 50° latitude and a 0 – 5 cm water depth. Resulting assessed environmental direct photolysis half-lives were 50 to < 200 days at pH 4 and 7 to 20 days at pH 9 in the periods of main use.
In another study following the same methods and guidelines quantum yield of prothioconazole-desthio was investigated in pure water. Determined quantum yield was 0.00449. Quantum yield was used for the estimation of the environmental half-life using two different simulation models (GC-SLOAR and Frank & Klöpffer). Results indicated an insignificant contribution of direct photodegradation in water to the overall elimination of prothioconazole-desthio in the environment.

In another study the molar extinction coefficient of 1,2,4-triazole was investigated according to Test Guideline ‘Phototransformation of chemicals in water, Part A (Berlin, 1992) and in accordance with principles of GLP. UV-absorption data in the environmentally relevant pH range showed no absorption of light at wavelength above 290 nm by 1,2,4-triazole. Therefore, no contribution of direct photodegradation to the overall elimination of 1,2,4-triazole in the aqueous environment is to be expected.

zRMS comments:

Degradation data for prothioconazole and is metabolites in water/sediment systems provided in tables above are in line with EU agreed endpoints reported in EFSA Scientific Report (2007) 106 and prothioconazole DAR (2005) and are relevant for the surface water exposure assessment.
Information of metabolite 1,2,4-triazole is in line with EU agreed endpoints as reported in EFSA Scientific Report (2008) 176 for tebuconazole.

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

8.7.1 Justification for new endpoints

Unless otherwise stated, EU endpoints refer to those stated in the EU review of fluxapyroxad **(Fluxapyroxad, EFSA Journal 2012;10(1):2522 and DAR 2010;B8)** and of prothioconazole **(Prothioconazole, EFSA Journal 2007;106,1-98 and DAR 2005;B8)**.

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

The following PEC_S calculations for fluxapyroxad, prothioconazole and their respective metabolites have not previously been reviewed and are provided in support of this assessment in Appendix 3 of this document.

Table 8.7.2-1: Input parameters related to application for PEC_{soil} calculations

Use No.	1-36
Crop	Field crops (cereals)
Application rate [g as/ha]	Fluxapyroxad: 93.75 Prothioconazole: 187.5
Number of applications / interval [d]	1 / -
BBCH stage	30
Crop interception (%)	80
Tillage (relevant for $PEC_{S,plateau}$)	20 cm tillage
Models used for calculation	ESCAPE v.2.0

Table 8.7.2-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_{soil} calculation

Compound	Molar mass [g/mol]	Formation fraction [-]	DT_{50} [d]	K_{FOC} [mL/g]	Value in accordance to EU endpoint / Reference
Fluxapyroxad	381.31	-	PECini 370 ~~(SFO)~~ FOMC, worst case, non-normalized, from field studies, n = 6 (α: 2.059, β: 13.1342) PECaccu 378 (DFOP, worst case, non-normalized, from field studies, n = 6 k_1: 0.0321 d^{-1} (21.6 d), k_2: 6.9 x 10^{-4} d^{-1} (i.e. fixed to 1000 days), g: 0.3502) ~~alpha: 0.2059~~ ~~beta: 13.1342 (FOMC)~~	728 (arithmetic mean, n=7)	Yes / EFSA (2012)
M700F001	176.1	1 from parent	10 d (SFO, Maximum, laboratory studies, unnormalised)	2.6 (arithmetic mean, n=7)	Yes / EFSA (2012), DAR (2010)
M700F002*	162	1 from M700F001	39.2 d (Maximum, laboratory studies, unnormalised) alpha: 2.4056 beta: 117.5 (FOMC)	7.6 (arithmetic mean, n=7)	Yes / EFSA (2012), DAR (2010)
Prothioconazole ~~**~~	344.3	-	2.8 d (SFO, Maximum, field studies, unnormalised	1765 (aged soil column leaching, n=1)	Yes / EFSA (2007)
JAU 6476-S-methyl (M01)	358.3	0.146 from parent	46 d (SFO, Maximum, laboratory studies, unnormalised)	2556.3 (arithmetic mean, n=4)	Yes / EFSA (2007)

Compound	Molar mass [g/mol]	Formation fraction [-]	DT_{50} [d]	K_{FOC} [mL/g]	Value in accordance to EU endpoint / Reference
JAU 6476-desthio (M04)	312.2	Parallel: 0.571 from parent Sequence: 1 from M01	72.3 (max. field, non-normalised, n= 3) ~~54.7 d *** (SFO, Maximum, field studies, unnormalised)~~	575.4 (arithmetic mean, n=4)	Yes / EFSA (2007)

* Applied as 'pseudo' parent using FOMC kinetics

~~** Applied as parent with 2 metabolites in parallel and in sequence. M04 PECs were sum up at the end.~~

~~*** One soil located in Southern Europe was excluded from calculations because it is not considered relevant for application in the Central Zone.~~

The ESCAPE model was used to calculate the PECsoil values. The degradation scheme was included in ESCAPE and thus PECsoil for metabolite were calculated using a kinetic approach. Further details are provided in Appendix 3.

zRMS comments:

The application pattern assumed in soil exposure assessment is in line with the critical Central Zone GAP and it is thus agreed. Relevant crop interception of 80% in line with FOCUS groundwater guidance (2021) has been selected.

Endpoints considered in soil exposure calculations for fluxapyroxad and metabolites M700F001 and M700F002 are in general in line with EU agreed parameters as reported in EFSA Journal 2012;10(1):2522. For calculation of accumulation of fluxapyroxad in soil the DT_{50} derived from DFOP kinetic is more relevant than FOMC kinetic according to the LoEP.
The information of longest un-normalised DT_{50} of 39.2 days derived from field dissipation studies has been added to the Table 8.7.2-2.

Degradation data considered for prothioconazole and metabolite JAU 6476-S-methyl (M01) are in line with input parameters reported in EFSA Journal 2011;9(1):1967.

It is noted that for metabolite JAU-Desthio the DT_{50} of 54.7 days were taken into account, as one soil located in Southern Europe was excluded from the calculations as considered not relevant by the Applicant for application in the Central Zone. In opinion of the zRMS DT_{50} of 72.3 days should be used for PEC_{SOIL} calculation as this value is EU agreed endpoints and exclusion of the degradation data from the Southern France soil should be supported by the respective statistical analysis demonstrating that the results in this soil are significantly different comparing to soils at other locations. For more details, please refer to point 8.4.1.1 above.

8.7.2.1 Fluxapyroxad and its metabolites

Table 8.7.2-1: PEC_{soil} for fluxapyroxad and its metabolites on cereals

PECs (mg/kg)		Field crops					
		1 × 93.75 g/ha, 80% interception				1 × 28.08 g/ha*, 80% interception	
		Fluxapyroxad		M700F001		M700F002 as parent	
		Actual	TWA	~~Actual~~	~~TWA~~	Actual	TWA
Initial		0.0250	-	~~0.0003~~	~~-~~	0.0075	-
Short term	24h	0.0250	0.0250	~~0.0003~~	~~0.0003~~	0.0073	0.0074
	2d	0.0249	0.0250	~~0.0003~~	~~0.0003~~	0.0072	0.0073
	4d	0.0248	0.0249	~~0.0003~~	~~0.0003~~	0.0069	0.0072
Long term	7d	0.0247	0.0248	~~0.0003~~	~~0.0003~~	0.0065	0.0070
	14d	0.0244	0.0247	~~0.0003~~	~~0.0003~~	0.0057	0.0065
	21d	0.0240	0.0245	~~0.0003~~	~~0.0003~~	0.0050	0.0062
	28d	0.0237	0.0244	~~0.0003~~	~~0.0003~~	0.0045	0.0058
	42d	0.0231	0.0240	~~0.0003~~	~~0.0003~~	0.0036	0.0052
	50d	0.0228	0.0239	~~0.0003~~	~~0.0003~~	0.0032	0.0049
	100d	0.0207	0.0228	~~0.0002~~	~~0.0003~~	0.0017	0.0036

Plateau concentration (20 cm) with tillage after year 10	0.0132 (DFOP) ~~0.0063 (FOMC)~~	-	~~0.0001~~	~~-~~	~~0.0001~~	-
$PEC_{accumulation}$ (PEC_{act} + $PEC_{soil\ plateau}$)	0.0382 (DFOP) ~~0.0313 (FOMC)~~	-	0.0021* ~~0.0004~~	~~-~~	0.0114* ~~0.0076~~	-

~~* Pseudo-application rate (Parent application rate × molecular weight correction × max. occurrence in soil)~~

* Peak concentration for M700F001 and M700F002, respectively, following accumulation of parent corrected for molecular mass and maximum occurrence of the metabolite

8.7.2.2 Prothioconazole and its metabolites

Table 8.7.2-1: PEC$_S$ for prothioconazole and its metabolites on field crops with an 5cm soil depth

PEC_S (mg/kg)		**Field crops**					
		1 × 187.5 g/ha, 80% interception					
		Prothioconazole		~~**JAU 6476-S-methyl (M01)**~~		~~**JAU 6476-desthio (M04) ***~~	
		Actual	**TWA**	~~**Actual**~~	~~**TWA**~~	~~**Actual**~~	~~**TWA**~~
Initial		0.0500	-	~~0.0064~~	~~-~~	~~0.0249 (0.0222 + 0.0027)~~	~~-~~
Short term	24h	0.0390	0.0445	~~0.0064~~	~~0.0064~~	~~0.0248 (0.0221 + 0.0027)~~	~~0.0249 (0.0222 + 0.0027)~~
	2d	0.0305	0.0396	~~0.0063~~	~~0.0064~~	~~0.0247 (0.022 + 0.0027)~~	~~0.0249 (0.0222 + 0.0027)~~
	4d	0.0186	0.0319	~~0.0063~~	~~0.0064~~	~~0.0244 (0.0217 + 0.0027)~~	~~0.0248 (0.0221 + 0.0027)~~
Long term	7d	0.0088	0.0239	~~0.0060~~	~~0.0063~~	~~0.0238 (0.0211 + 0.0027)~~	~~0.0248 (0.0221 + 0.0027)~~
	14d	0.0016	0.0140	~~0.0055~~	~~0.0062~~	~~0.0221 (0.0195 + 0.0026)~~	~~0.0244 (0.0217 + 0.0027)~~
	21d	0.0003	0.0096	~~0.0050~~	~~0.0060~~	~~0.0204 (0.0178 + 0.0026)~~	~~0.0239 (0.0212 + 0.0027)~~
	28d	<0.0001	0.0072	~~0.0045~~	~~0.0058~~	~~0.0188 (0.0163 + 0.0025)~~	~~0.0232 (0.0206 + 0.0026)~~
	42d	<0.0001	0.0048	~~0.0036~~	~~0.0054~~	~~0.0161 (0.0137 + 0.0024)~~	~~0.0219 (0.0193 + 0.0026)~~
	50d	<0.0001	0.0041	~~0.0032~~	~~0.0052~~	~~0.0147 (0.0124 + 0.0023)~~	~~0.0211 (0.0185 + 0.0026)~~
	100d	<0.0001	0.0020	~~0.0015~~	~~0.0039~~	~~0.0082 (0.0066 + 0.0016)~~	~~0.017 (0.0145 + 0.0025)~~

* Sum of formation from parent and from M01

zRMS comments:

The soil exposure for fluxapyroxad and prothioconazole and their metabolites has been independently validated by the zRMS using FOCUS methods using EU agreed endpoints and the pseudo-application rates of metabolites derived with consideration of the parent rate, molar ratio and peak occurrence in soil.

The calculated PEC_{SOIL} values for fluxapyroxad were recalculated by the zRMS since for calculation of $PEC_{soil,plateau}$ DFOP kinetics is more suitable than FOMC kinetic, (refitting DFOP values by fixing k_1: 0.0321 d^{-1} (21.6 d), k_2: 6.9 x 10^{-4} d^{-1} (i.e. fixed to 1000 days), g: 0.3502) as mentioned in EFSA Journal 2012;10(1):2522. Moreover, according to LoEP the plateau concentration for metabolites M700F001 and M700F002, should be calculated as an accumulation of the parent corrected for molecular mass and maximum occurrence of the metabolite. Thus, respective changes were introduced in Table 8.7.2-1.

The calculated PEC_{SOIL} values for prothioconazole, ~~fluxapyroxad and its metabolite M700F002~~ were similar to those obtained by the Applicant, and therefore results reported in table~~s~~ above may be used for the soil risk assessment purposes.

The new calculation and results for fluxapyroxad metabolite M700F001 and for prothioconazole metabolites JAU 6476-S-methyl and metabolite JAU-Desthio are presented in the table below, as they were higher comparing to Applicants' results. The maximum occurrence of 12.1%, 14.6% and 57.1% for metabolites M700F001, JAU 6476-S-methyl and JAU-Desthio, respectively were used in calculation.
The $PEC_{SOIL,ACCU}$ was not required as DT_{50} of the metabolite is below 100 days. The short- and long-term PEC_{SOIL} values are not reported below as they are not necessary for the risk assessment purposes. Only 21 TWA PEC_{SOIL} is provided as being required for evaluation of the risk of secondary poisoning for birds and mammals.

PEC_S (mg/kg	**M700F001**	**JAU 6476-S-methyl (M01)**	**PEC_{SOIL} JAU-Desthio (mg/kg)**
Initial	0.0014	0.0076	0.0259
21-d TWA	0.0007	0.007	0.023

8.7.2.3 PEC_{soil} of ADM.03503.F.1.A

Table 8.7.2-1: PEC_{soil} for ADM.03503.F.1.A on cereals

Formulation	**Crop**	**Application rate (g/ha) [a]**	**PEC_{act} (mg/kg) (5 cm)**	**Interception (%)**
ADM.03503.F.1.A	Field crops, cereals	1349	0.360	80

[a] The application rate of the formulation was based on a specific density of 1.0792 g/mL with an application rate of 1.25 L/ha.

zRMS comments:

Soil exposure for the formulated product was recalculated by the zRMS and the same PEC_{soil} was obtained. For this reason PEC_{soil} as reported in table above is considered relevant for the soil risk assessment.

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

8.8.1 Justification for new endpoints

Unless otherwise stated, EU endpoints refer to those stated in the EU review of fluxapyroxad **(Fluxapyroxad, EFSA Journal 2012;10(1):2522 and DAR 2010;B8)** and of prothioconazole **(Prothioconazole, EFSA Journal 2007;106,1-98 and DAR 2005;B8)**.

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

The following PEC_{GW} modelling has not previously been reviewed and a summary is provided below. The data used here and relied on is based on the report Brauer and Jarvis, 2022a and Brauer and Jarvis, 2022b.

Table 8.8.2-1: Input parameters related to application for PEC_{GW} calculations

Use No.	1-36
Crop	Winter and Spring wheat / barley
FOCUS Crop	Winter and Spring cereals
Application rate (g as/ha)	Fluxapyroxad: 93.75 Prothioconazole: 187.5
Number of applications / interval (d)	1/-
BBCH growth stage	30
Crop interception (%)	80
Effective rate to soil (g as/ha)	Fluxapyroxad: 18.75 Prothioconazole: 37.5
Frequency of application	annual
Models used for calculation	FOCUS PELMO 6.6.4, FOCUS PEARL 5.5.5, FOCUS MACRO 5.5.4

Table 8.8.2-2: Application dates used for groundwater risk assessment

Use no.	1-48	
Scenario	**Winter cereals BBCH 30**	**Spring cereals BBCH 30**
	1 appl.	1 appl.
Châteaudun	15-Apr (105 *)	16-Apr (106 *)
Hamburg	04-May	28-Apr
Jokioinen	14-May	05-Jun
Kremsmünster	24-Apr	27-Apr
Okehampton	21-Apr	22-Apr
Piacenza	19-Mar	-
Porto	30-Jan	16-Apr
Sevilla	06-Jan	-
Thiva	18-Jan	-

Application dates were selected using AppDate 3.06
* Julian day used in MACRO

zRMS comments:

The application pattern assumed in simulations is in line with the critical Central Zone GAP as presented in Table 8.1-1. The crop interception assumed in calculations is in line with the most recent version of the FOCUS Groundwater Guidance of 2021.
Application dates presented in Table 8.8.2-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable.

8.8.2.1 Fluxapyroxad and its metabolites

Table 8.8.2.1-1: Input parameters related to active substance fluxapyroxad PEC_{GW} calculations

Parameter	Value	Remarks
Molecular weight [g/mol]	381.31	Physico-chemical properties in LoEP (EFSA, 2012)
Water solubility [mg/L]	3.44	pH 7 at 20°C LoEP (EFSA, 2012)
Vapor pressure [Pa]	2.7×10^{-9} Pa	At 20°C, physico-chemical properties in LoEP (EFSA, 2012)
DT_{50} (soil) [d]	151 59.5	Geometric mean, n=6, field, normalized to 20°C, pF2, Q_{10} = 2.58, SFO and slow phase of HS Geometric mean, n=6, filed, normalized to 20°C, pF2, Q_{10} = 2.58, fast phase
K_{FOC} [L/kg]	728	Arithmetic mean, n=7 (EFSA, 2012)
1/n [-]	0.914	Arithmetic mean, n=7 (EFSA, 2012)
Plant uptake factor (PUF/TSCF) [-]	0	Worst-case default
Formation to metabolites	1 to M700F001	DAR (2010); EFSA (2012)

Table 8.8.2.1-2: Input parameters related to metabolite M700F001 PEC_{GW} calculations

Parameter	Value	Remarks
Molecular weight [g/mol]	176.1	-
Water solubility [mg/L]	39990	Value used in modelling in LoEP in EFSA (2012)
Vapor pressure [Pa]	10×10^{-10}	Value used in modelling in DAR (2010)
DT_{50} (soil) [d]	5.4	Geometric mean, n=4, lab DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (DAR, 2010; EFSA, 2012)
K_{FOC} [L/kg]	2.6	Arithmetic mean, n=7 (DAR, 2010; EFSA, 2012)
1/n [-]	0.911	Arithmetic mean, n=7 (DAR, 2010)
Plant uptake factor (PUF/TSCF) [-]	0	Worst-case default
Formation fraction (PELMO)	1 from parent	Worst case assumption

Table 8.8.2.1-3: Input parameters related to metabolite M700F002 PEC_{GW} calculations

Parameter	Value	Remarks
Molecular weight [g/mol]	162	-
Water solubility [mg/L]	31580	Value used in modelling in LoEP in EFSA (2012)
Vapor pressure [Pa]	10×10^{-10}	Value used in modelling in DAR (2010)
DT_{50} (soil) [d]	25.9	Geometric mean, n=4, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2012)
K_{FOC} [L/kg]	7.6	Arithmetic mean, n=7 (DAR, 2010; EFSA, 2012)
1/n [-]	0.964	Arithmetic mean, n=7 (EFSA, 2012)
Plant uptake factor (PUF/TSCF) [-]	0	Worst-case default
Formation fraction (PELMO)	1 from M700F001	Worst case assumption

Table 8.8.2.1-4: PEC$_{GW}$ for Fluxapyroxad, M700F001 and M700F002 at BBCH 30

FOCUS Model	Uses covered	1-48					
	Scenario	PEC$_{GW}$ [µg/L]			PEC$_{GW}$ [µg/L]		
		Fluxapyroxad	**M700F001**	**M700F002**	**Fluxapyroxad**	**M700F001**	**M700F002**
		Winter cereals (BBCH 30) 1×93.75 g/ha, 80% int.			**Spring cereals (BBCH 30) 1×93.75 g/ha, 80% int.**		
PEARL	Châteaudun	< 0.001	0.004	**0.266**	< 0.001	0.004	**0.251**
	Hamburg	< 0.001	0.053	**0.837**	< 0.001	0.060	**1.045**
	Jokioinen	< 0.001	0.081	**1.054**	< 0.001	0.085	**0.904**
	Kremsmünster	< 0.001	0.012	**0.435**	< 0.001	0.014	**0.471**
	Okehampton	< 0.001	0.026	**0.477**	< 0.001	0.026	**0.480**
	Piacenza	< 0.001	0.011	**0.256**	-	-	-
	Porto	< 0.001	0.018	**0.249**	< 0.001	0.024	**0.292**
	Sevilla	< 0.001	0.002	0.086	-	-	-
	Thiva	< 0.001	0.004	**0.161**	-	-	-
PELMO	Châteaudun	< 0.001	0.004	**0.228**	< 0.001	0.005	**0.194**
	Hamburg	< 0.001	0.064	**0.714**	< 0.001	0.069	**0.728**
	Jokioinen	< 0.001	**0.113**	**0.935**	< 0.001	**0.118**	**0.872**
	Kremsmünster	< 0.001	0.020	**0.456**	< 0.001	0.020	**0.465**
	Okehampton	< 0.001	0.037	**0.477**	< 0.001	0.035	**0.459**
	Piacenza	< 0.001	0.025	**0.325**	< 0.001	-	-
	Porto	< 0.001	0.042	**0.302**	< 0.001	0.042	**0.315**
	Sevilla	< 0.001	0.006	**0.101**	< 0.001	-	-
	Thiva	< 0.001	0.006	**0.142**	< 0.001	-	-
MACRO	Châteaudun	< 0.001	0.004	0.097	< 0.001	0.005	0.092

Bold values exceed 0.1 µg/L

zRMS comments:

Input parameters presented in Table 8.8.2.1-1 to 8.8.2.1-3 are in general in line with EU agreed endpoints. It is noted that for fluxapyroxad HS slow phase DT_{50} of 151 days is only reported, however according to EFSA Journal 2012;10(1):2522 fast phase DT_{50} of 59.5 days is reported to provide more precautionary assessment for metabolites.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2021).

The groundwater modelling was independently validated by the zRMS in additional modelling with FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4 using the EU agreed input parameters and application dates as suggested by AppDate 3.06.

Obtained results were in good agreement with these derived by the Applicant for fluxapyroxad and its metabolites presented in Table 8.8.2.1-4. Additional modelling was performed by the zRMS with consideration for the fluxapyroxad HS fast phase DT_{50} of 59.5 days. Obtained results for fluxapyroxad metabolites were lower from these presented by the Applicant when consider fluxapyroxad HS slow phase with DT_{50} of 151 days.

Overall, groundwater modelling provided by the Applicant is agreed by the zRMS. Performed simulations indicate that no unacceptable leaching of fluxapyroxad is expected following application of ADM.03503.F.1.A according to the intended Central Zone use pattern given in Table 8.1-1. However, potential leaching of metabolites M700F001 and M700F002 cannot be excluded on the basis of the available data. According to EFSA Journal 2012;10(1):2522, both metabolites are toxicologically not relevant.

The PEC$_{GW}$ value for metabolite M700F001 is > 0.1 µg/L only in Jokioinen scenario for application in winter and spring cereals. Since Jokioinen scenario is not relevant for the Central Zone no further assessment was necessary.

The PEC$_{GW}$ values for metabolite M700F002 are above 0.1 µg/L in almost all scenarios following application in spring and winter cereals exceeded the threshold of 0.75 µg/L for non-relevant metabolites and the consumer risk assessment was required. Details of the evaluation of the toxicological relevance and consumer risk assessment may be found the Core Assessment, Part B, Section 10.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.8.2.2 Prothioconazole and its metabolites

Table 8.8.2.2-1: Input parameters related to active substance prothioconazole PEC_{GW} calculations

Parameter	Value	Remarks
Molecular weight [g/mol]	344.26	EFSA (2007)
Water solubility [mg/L]	300	20°C, pH 8 (EFSA, 2007)
Vapor pressure [Pa]	4.0×10^{-7}	20°C (EFSA, 2007)
DT_{50} (soil) [d]	1.2	Geometric mean, n=8, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2007)
K_{FOC} [L/kg]	1765	Single value from aged soil column leaching study (EFSA, 2007)
1/n [-]	0.9	Old default value used in EFSA (2007)
Plant uptake factor (PUF/TSCF) [-]	0	Worst-case default
Formation to JAU 6476-S-methyl (M01)	0.146	(EFSA, 2007)
Formation to JAU 6476-desthio (M04)	0.571	(EFSA, 2007)

Table 8.8.2.2-2: Input parameters related to metabolite JAU 6476-S-methyl (M01) PEC_{GW} calculations

Parameter	Value	Remarks
Molecular weight [g/mol]	358.3	(EFSA, 2007)
Water solubility [mg/L]	300	Parent value, 20°C, pH 8 (EFSA, 2007)
Vapor pressure [Pa]	4.0×10^{-7}	Parent value, 20°C, pH 8 (EFSA, 2007)
DT_{50} (soil) [d]	15.7	Geometric mean, n=4, laboratory DT_{50} non-normalized (EFSA, 2007)
K_{FOC} [L/kg]	2556.3	Arithmetic mean, n=4 (EFSA, 2007)
1/n [-]	0.88	Arithmetic mean, n=4 (EFSA, 2007)
Plant uptake factor (PUF/TSCF) [-]	0	Worst-case default
Formation to JAU 6476-desthio (M04)	1	Worst-case default (EFSA, 2007)

Table 8.8.2.2-3: Input parameters related to metabolite JAU 6476-desthio (M04) PEC_{GW} calculations

Parameter	Value	Remarks
Molecular weight [g/mol]	312.2	-
Water solubility [mg/L]	300	Parent value, 20°C, pH 8 (EFSA, 2007)
Vapor pressure [Pa]	4.0×10^{-7}	Parent value, 20°C, pH 8 (EFSA, 2007)
DT_{50} (soil) [d]	22.7	Geometric mean, n=8, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2007)
K_{FOC} [L/kg]	575.4	Arithmetic mean, n=4 (EFSA, 2007)
1/n [-]	0.81	Arithmetic mean, n=4 (EFSA, 2007)
Plant uptake factor (PUF/TSCF) [-]	0	Worst-case default

Table 8.8.2.2-4: PEC$_{GW}$ for Prothioconazole, M01 and M04 at BBCH 30

FOCUS Model	Uses covered	1-48					
	Scenario	PEC$_{GW}$ [µg/L]			PEC$_{GW}$ [µg/L]		
		Prothioconazole	**JAU 6476-S-methyl (M01)**	**JAU 6476-desthio (M04)**	**Prothioconazole**	**JAU 6476-S-methyl (M01)**	**JAU 6476-desthio (M04)**
		Winter cereals (BBCH 30) 1×187.5 g/ha, 80% int.			**Spring cereals (BBCH 30) 1×187.5 g/ha, 80% int.**		
PEARL	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	-	-	-
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	-	-	-
	Thiva	< 0.001	< 0.001	< 0.001	-	-	-
PELMO	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Okehampton	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Piacenza	< 0.001	< 0.001	< 0.001	< 0.001	-	-
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	-	-
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	-	-
MACRO	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001	< 0.001

Bold values exceed 0.1 µg/L

zRMS comments:

Input parameters presented in Tables 8.8.2.2-1 to 8.8.2.2-3 and used in the modelling are in line with the EU agreed endpoints reported in EFSA Scientific Report (2007) 106.

In simulations PUF value of 0 was assumed for all compounds, which is in line with recommendations of the most recent version of the FOCUS Groundwater Guidance (2014 and 2021).

The performed calculations were independently validated by the zRMS in additional modelling and resulted with the same PEC$_{GW}$ values as these obtained by the Applicant. Overall, no unacceptable leaching of prothioconazole and its metabolites is expected following application of ADM.03503.F.1.A according to the intended use pattern.

Please note that additional groundwater modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

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

8.9.1 Justification for new endpoints

Unless otherwise stated, EU endpoints refer to those stated in the EU review of fluxapyroxad **(Fluxapyroxad, EFSA Journal 2012;10(1):2522 and DAR 2010;B8)** and of prothioconazole **(Prothioconazole, EFSA Journal 2007;106,1-98 and DAR 2005;B8)**. Additionally, newer EU endpoints for the prothioconazole metabolite 1,2,4-triazole were taken from the EU review of tebuconazole **(Tebuconazole, EFSA Journal 2014;12(1):3485)**.

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

The following PEC_{SW} modelling has not previously been reviewed. The data used here and relied on is based on the report Brauer et al., 2022c,d and Weber et al., 2022a and b.

Table 8.9.2-1: Input parameters related to application for $PEC_{SW/SED}$ calculations

Plant protection product	ADM.03503.F.1.A
Use No.	1-36
Crop	Winter and Spring wheat / barley
FOCUS Crop	Winter and Spring cereals
Application rate (g as/ha)	Fluxapyroxad: 93.75 Prothioconazole: 187.5
Number of applications/interval (d)	1/-
Application window	**Step 1-2** North Europe: Mar-May / Jun-Sep *, South Europe: Mar-May / Jun-Sep **Step 3-4** Start window from BBCH 30 using AppDate 3.06
Application method	Foliar spray
CAM (Chemical application method)	2
Soil depth (cm)	5
Models used for calculation	SWASH 5.3, FOCUS MACRO 5.5.4, FOCUS PRZM 4.3.1, FOCUS TOXSWA 5.5.3, SWAN v5.0.0

* Season Mar-May has identical properties and results as Jun-Sep in NEU

Table 8.9.2-2: FOCUS Step 3 Scenario related input parameters for $PEC_{SW/SED}$ calculations for the application of ADM.03503.F.1.A

Scenario	Crop	Appl. window	Days of Year	Appl. date chosen by PAT
D1	Cereals, winter	25-Mar-24-Apr	84-114	29-03-1982
D1	Cereals, winter	25-Mar-24-Apr	84-114	29-03-1982
D2	Cereals, winter	4-Apr-4-May	94-124	04-04-1986
D3	Cereals, winter	16-Apr-16-May	106-136	20-04-1992
D4	Cereals, winter	18-Mar-17-Apr	77-107	19-03-1985
D5	Cereals, winter	15-Mar-14-Apr	74-104	08-04-1978
D6	Cereals, winter	16-Feb-18-Mar	47-77	27-02-1986
R1	Cereals, winter	24-Apr-24-May	114-144	26-04-1984
R3	Cereals, winter	19-Mar-18-Apr	78-108	28-03-1980
R4	Cereals, winter	24-Jan-23-Feb	24-54	04-02-1980
D1	Cereals, spring	27-May-26-Jun	147-177	17-06-1982
D1	Cereals, spring	27-May-26-Jun	147-177	17-06-1982
D3	Cereals, spring	28-Apr-28-May	118-148	04-05-1992
D4	Cereals, spring	18-May-17-Jun	138-168	30-05-1985
D5	Cereals, spring	9-Apr-9-May	99-129	14-04-1978
R4	Cereals, spring	9-Apr-9-May	99-129	04-05-1984

zRMS comments:

Application dates presented in Table 8.9.2-2 were checked by the zRMS using AppDate ver. 3.06 tool and are considered acceptable. The application pattern assumed in simulations is in line with central Zone GAP as presented in Table 8.1-1.

8.9.2.1 Fluxapyroxad and its metabolites

Table 8.9.2.1-1: Summary of input data for FOCUS Step 1-2 calculations – fluxapyroxad

Parameter	Value	Remarks
Molecular weight [g/mol]	381.31	Physico-chemical properties in LoEP (EFSA, 2012)
Water solubility [mg/L]	3.44	pH 7 at 20°C LoEP (EFSA, 2012)
DT_{50} (soil) [d]	151	Geometric mean, n=6, field, normalized to 20°C, pF2, Q_{10} = 2.58, SFO and slow phase of HS
K_{FOC} [L/kg]	728	Arithmetic mean, n=7 (EFSA, 2012)
DT_{50} total aquatic system [d] (Step 1)	1000	Worst-case default
DT_{50} water [d]	1000	Worst-case default
DT_{50} sediment [d]	1000	Worst-case default

Table 8.9.2.1-2: Summary of input data for FOCUS Step 3-4 calculations – fluxapyroxad

Parameter	Value	Remarks
Molecular weight [g/mol]	381.31	Physico-chemical properties in LoEP (EFSA, 2012)
Water solubility [mg/L]	3.44	pH 7 at 20°C LoEP (EFSA, 2012)
Vapor pressure [Pa]	2.7×10^{-9} Pa	At 20°C, physico-chemical properties in LoEP (EFSA, 2012)
DT_{50} (soil) [d]	151	Geometric mean, n=6, field, normalized to 20°C, pF2, Q_{10} = 2.58, SFO and slow phase of HS
K_{FOC} [L/kg]	728	Arithmetic mean, n=7 (EFSA, 2012)
K_{FOM} [L/kg]	422	K_{FOC} / 1.724
1/n [-]	0.914	Arithmetic mean, n=7 (EFSA, 2012)
DT_{50} water [d]	1000	Worst-case default
DT_{50} sediment [d]	1000	Worst-case default
Crop uptake factor [-]	0	Worst-case default

Table 8.9.2.1-3: Summary of input data for FOCUS Step 1-2 calculations – M700F001

Parameter	Value	Remarks
Molecular weight [g/mol]	176.1	-
Water solubility [mg/L]	39990	Value used in modelling in LoEP in EFSA (2012)
DT_{50} (soil) [d]	5.4	Geometric mean, n=4, lab DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (DAR, 2010; EFSA, 2012)
Maximum occurrence in soil [%]	12.1	Value used in modelling in EFSA (2012)
K_{FOC} [L/kg]	2.6	Arithmetic mean, n=7 (DAR, 2010; EFSA, 2012)
DT_{50} total aquatic system [d] (Step 1)	1000	Worst-case default
DT_{50} water [d] (Step 2)	1000	Worst-case default
DT_{50} sediment [d] (Step 2)	1000	Worst-case default
Maximum occurrence in w/s systems [%]	10.9	EFSA (2012)

Table 8.9.2.1-4: Summary of input data for FOCUS Step 1-2 calculations – M700F002

Parameter	Value	Remarks
Molecular weight [g/mol]	162	-
Water solubility [mg/L]	31580	Value used in modelling in LoEP in EFSA (2012)
DT_{50} (soil) [d]	25.9	Geometric mean, n=4, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2012)
Maximum occurrence in soil [%]	70.5	Value used in modelling in LoEP in EFSA (2012)
K_{FOC} [L/kg]	7.6	Arithmetic mean, n=7 (DAR, 2010; EFSA, 2012)
DT_{50} total aquatic system [d] (Step 1)	1000	Worst-case default
DT_{50} water [d] (Step 2)	1000	Worst-case default
DT_{50} sediment [d] (Step 2)	1000	Worst-case default
Maximum occurrence in w/s systems [%]	0.01	Value used due to technical reasons

Table 8.9.2.1-5: Summary of input data for FOCUS Step 1-2 calculations – M700F007

Parameter	Value	Remarks
Molecular weight [g/mol]	175.1	-
Water solubility [mg/L]	1770	Value reported in EFSA (2012) as "determined experimentally"
DT_{50} (soil) [d]	1000	Metabolite not found in soil, conservative assumption
Maximum occurrence in soil [%]	0.0001	Value used due to technical reasons
K_{FOC} [L/kg]	1	Worst-case default
DT_{50} total aquatic system [d] (Step 1)	1000	Worst-case default
DT_{50} water [d] (Step 2)	1000	Worst-case default
DT_{50} sediment [d] (Step 2)	1000	Worst-case default
Maximum occurrence in w/s systems [%]	17.7	Max. formation, plus remaining parent in water phase as concentration still increasing at study termination (EFSA, 2012)

$PEC_{sw/sed}$

Table 8.9.2.1-6: FOCUS <u>Step 1</u> PEC_{sw} and PEC_{sed} for fluxapyroxad and its metabolites following single application of ADM.03503.F.1.A to cereals

Compound	Step 1		
	Cereals 1×93.75 g/ha		
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]
	Maximum	21d TWA	Maximum
Fluxapyroxad	16.720	16.187	118.546
M700F001	3.351	3.327	0.087
M700F002	9.268	9.200	0.704
M700F007	2.607	2.588	0.026

Table 8.9.2.1-7: FOCUS <u>Step 2</u> PEC_{sw} and PEC_{SED} for fluxapyroxad and its metabolites following single application of ADM.03503.F.1.A to cereals

Compound	Step 2						
	Cereals 1×93.75 g/ha, average crop cover						Scenario/ Season
	North Europe			South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	
	Max.	21d TWA	Max.	Max.	21d TWA	Max.	
Fluxapyroxad	3.013	2.908	21.296	5.504	5.381	39.419	Mar-May
				4.259	4.145	30.358	Jun-Sep
M700F001	0.456	0.453	0.012	0.869	0.863	0.023	Mar-May
				0.663	0.658	0.017	Jun-Sep
M700F002	1.332	1.323	0.101	2.665	2.645	0.203	Mar-May
				1.998	1.984	0.152	Jun-Sep
M700F007	0.468	0.465	0.005	0.867	0.861	0.009	Mar-May
				0.668	0.663	0.007	Jun-Sep
Compound	Step 2						
	Cereals 1×93.75 g/ha, full canopy						Scenario/ Season
	North Europe			South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	
	Max.	21d TWA	Max.	Max.	21d TWA	Max.	
Fluxapyroxad	1.456	1.363	9.970	2.391	2.290	16.766	Mar-May
				1.924	1.826	13.368	Jun-Sep
M700F001	0.198	0.197	0.005	0.353	0.350	0.009	Mar-May
				0.275	0.273	0.007	Jun-Sep
M700F002	0.500	0.496	0.038	0.999	0.992	0.076	Mar-May
				0.749	0.742	0.057	Jun-Sep
M700F007	0.219	0.218	0.002	0.369	0.366	0.004	Mar-May
				0.294	0.292	0.003	Jun-Sep

Table 8.9.2.1-8: FOCUS Step 3-4 PEC$_{sw}$ for fluxapyroxad following single application of ADM.03503.F.1.A to winter cereals

Scenario	Appl. rate [g/ha]	Step 3				Step 4, 10 m db+vfs			
		Appl. date	Date of max	Global max PECsw [µg/L]	21 d TWA PECsw [µg/L]	Appl. Date	Date of max	Global max PECsw [µg/L]	21 d TWA PECsw [µg/L]
D1 Ditch	93.75	29-Mar-1982	21-Dec-1982	1.840	1.686	29-Mar-1982	21-Dec-1982	1.840	1.686
D1 Stream	93.75	29-Mar-1982	21-Dec-1982	1.152	1.041	29-Mar-1982	21-Dec-1982	1.152	1.041
D3 Ditch	93.75	20-Apr-1992	20-Apr-1992	0.593	0.029	20-Apr-1992	20-Apr-1992	0.085	0.004
D4 Pond	93.75	19-Mar-1985	30-Dec-1985	0.246	0.238	19-Mar-1985	30-Dec-1985	0.245	0.237
D4 Stream	93.75	19-Mar-1985	19-Mar-1985	0.439	0.150	19-Mar-1985	07-Dec-1985	0.350	0.150
D5 Pond	93.75	08-Apr-1978	14-Feb-1979	0.136	0.128	08-Apr-1978	14-Feb-1979	0.134	0.127
D5 Stream	93.75	08-Apr-1978	08-Apr-1978	0.478	0.052	08-Apr-1978	24-Jan-1978	0.226	0.052
D6 Ditch	93.75	27-Feb-1986	27-Feb-1986	0.626	0.159	27-Feb-1986	09-Feb-1986	0.569	0.148
R1 Pond	93.75	26-Apr-1984	21-Jun-1984	0.067	0.060	26-Apr-1984	21-Jun-1984	0.029	0.026
R1 Stream	93.75	26-Apr-1984	20-May-1984	0.463	0.033	26-Apr-1984	20-May-1984	0.211	0.015
R3 Stream	93.75	28-Mar-1980	20-Apr-1980	0.630	0.032	28-Mar-1980	20-Apr-1980	0.287	0.014
R4 Stream	93.75	04-Feb-1980	19-Mar-1980	0.874	0.043	04-Feb-1980	19-Mar-1980	0.397	0.019

Highlighted cells indicate relevant entry route: drift (blue), runoff (green) or drainage (grey), global maximum PECsw highlighted red.
D2 scenario is not shown here since it is not considered relevant in the Central Zone. For all results see Weber et al., 2022a.

Table 8.9.2.1-9: FOCUS Step 3-4 PEC$_{sw}$ for fluxapyroxad following single application of ADM.03503.F.1.A to spring cereals

Scenario	Appl. rate [g/ha]	Step 3				Step 4, 10 m db+vfs			
		Appl. date	Date of max	Global max PECsw [µg/L]	21 d TWA PECsw [µg/L]	Appl. Date	Date of max	Global max PECsw [µg/L]	21 d TWA PECsw [µg/L]
D1 Ditch	93.75	17-Jun-1982	26-Oct-1982	1.591	1.449	17-Jun-1982	26-Oct-1982	1.591	1.449
D1 Stream	93.75	17-Jun-1982	26-Oct-1982	0.998	0.901	17-Jun-1982	26-Oct-1982	0.998	0.901
D3 Ditch	93.75	04-May-1992	04-May-1992	0.594	0.033	04-May-1992	04-May-1992	0.085	0.005
D4 Pond	93.75	30-May-1985	29-Dec-1985	0.233	0.226	30-May-1985	29-Dec-1985	0.232	0.224
D4 Stream	93.75	30-May-1985	30-May-1985	0.486	0.143	30-May-1985	07-Dec-1985	0.333	0.143
D5 Pond	93.75	14-Apr-1978	14-Feb-1979	0.138	0.130	14-Apr-1978	14-Feb-1979	0.137	0.129
D5 Stream	93.75	14-Apr-1978	14-Apr-1978	0.501	0.052	14-Apr-1978	24-Jan-1978	0.234	0.052
R4 Stream	93.75	04-May-1984	18-May-1984	0.803	0.105	04-May-1984	18-May-1984	0.365	0.047

Highlighted cells indicate relevant entry route: drift (blue), runoff (green) or drainage (grey), global maximum PECsw highlighted red.

zRMS comments:

Input parameters presented in Tables 8.9.2.1-1 to 8.9.2.1-5 and considered by the Applicant in surface water modelling for fluxapyroxad and its metabolite are in line with EU agreed endpoints reported in EFSA Journal 2012;10(1):2522.

At Step 3 PUF value of 0 was assumed for fluxapyroxad and it is in line with current recommendations.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors and were validated by the zRMS for convenience of the concerned Member States that consider FOCUS simulations as Step 4 at the national level.

The surface water exposure was independently validated by the zRMS in additional modelling using the same parameters indicated above. Obtained PEC_{sw} and PEC_{sed} were in good agreement with values calculated by the Applicant. Thus, surface water exposure reported in Tables 8.9.2.1-6 to 8.9.2.1-9 is relevant for the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.2 Prothioconazole and its metabolites

Table 8.9.2.2-1: Summary of input data for FOCUS Step 1-2 calculations – prothioconazole

Parameter	Value	Remarks
Molecular weight [g/mol]	344.26	EFSA (2007)
Water solubility [mg/L]	300	20°C, pH 8 (EFSA, 2007)
DT_{50} (soil) [d]	1.2	Geometric mean, n=8, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2007)
K_{FOC} [L/kg]	1765	Single value from aged soil column leaching study (EFSA, 2007)
DT_{50} total aquatic system [d] (Step 1)	2.1	Geometric mean, hockey stick, n=2, total system (EFSA, 2007)
DT_{50} water [d]	2.1 (correct value from LoEP: 1.0 d)	Geometric mean, hockey stick, n=2, total system (EFSA, 2007)
DT_{50} sediment [d]	2.1 (correct value: 1.0 d)	Geometric mean, hockey stick, n=2, total system (EFSA, 2007)

Table 8.9.2.2-2: Summary of input data for FOCUS Step 3-4 calculations – prothioconazole

Parameter	Value	Remarks
Molecular weight [g/mol]	344.26	(EFSA, 2007)
Water solubility [mg/L]	300	20°C, pH 8 (EFSA, 2007)
Vapor pressure [Pa]	4.0×10^{-7}	20°C (EFSA, 2007)
DT_{50} (soil) [d]	1.2	Geometric mean, n=8, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2007)
K_{FOC} [L/kg]	1765	Single value from aged soil column leaching study (EFSA, 2007)
K_{FOM} [L/kg]	1023.8	K_{FOC} / 1.724
1/n [-]	0.9	Default value used in EFSA (2007)
DT_{50} water [d]	2.1 (correct value from LoEP: 1.0 d)	Geometric mean, hockey stick, n=2, total system (EFSA, 2007)
DT_{50} sediment [d]	1000	Default worst-case value
Crop uptake factor [-]	0	Worst-case default

Table 8.9.2.2-3: Summary of input data for FOCUS Step 1-2 calculations –JAU 6476-S-methyl (M01)

Parameter	Value	Remarks
Molecular weight [g/mol]	358.3	-
Water solubility [mg/L]	300	Parent value, 20°C, pH 8 (EFSA, 2007)
DT_{50} (soil) [d]	15.7	Geometric mean, n=4, laboratory DT_{50} non-normalized (EFSA, 2007)
Maximum occurrence in soil [%]	14.6	at day 7 (EFSA, 2007)
K_{FOC} [L/kg]	2556.3	Arithmetic mean, n=4 (EFSA, 2007)
DT_{50} total aquatic system [d] (Step 1)	40.2	Max. whole system value, n = 2 (Table 8.63 of the DAR, 2005)
DT_{50} water [d]	40.2	Max. whole system value, n = 2 (Table 8.63 of the DAR, 2005)
DT_{50} sediment [d]	40.2	Max. whole system value, n = 2 (Table 8.63 of the DAR, 2005)
Maximum occurrence in w/s systems [%]	12.7 77	Aerobic conditions Anaerob conditions in sediment after 240 d (EFSA, 2007)

Table 8.9.2.2-4: Summary of input data for FOCUS Step 1-2 calculations – JAU 6476-desthio (M04)

Parameter	Value	Remarks
Molecular weight [g/mol]	312.2	-
Water solubility [mg/L]	300	Parent value, 20°C, pH 8 (EFSA, 2007)
DT_{50} (soil) [d]	22.7	Geometric mean, n=8, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2007)
Maximum occurrence in soil [%]	57.1	Max. from field studies (EFSA, 2007)
K_{FOC} [L/kg]	575.4	Arithmetic mean, n=4 (EFSA, 2007)
DT_{50} total aquatic system [d] (Step 1)	49.9	Max. whole system value, n = 2 (Table 8.63 of the DAR, 2005)
DT_{50} water [d]	49.9	Max. whole system value, n = 2 (Table 8.63 of the DAR, 2005)
DT_{50} sediment [d]	49.9	Max. whole system value, n = 2 (Table 8.63 of the DAR, 2005)
Maximum occurrence in w/s systems [%]	54.6	Max. from 2 water sediment systems 32.3% in water + 22.3% in sediment at 7 d Max in sediment 26.9% at 14 d (Table 8.54 of the DAR (2005))

Table 8.9.2.2-5: Summary of input data for FOCUS Step 3-4 calculations – JAU 6476-desthio (M04)

Parameter	Value	Remarks
Molecular weight [g/mol]	312.2	(EFSA, 2007)
Water solubility [mg/L]	300	Parent value, 20°C, pH 8 (EFSA, 2007)
Vapor pressure [Pa]	4.0×10^{-7}	Parent value, 20°C, pH 8 (EFSA, 2007)
DT_{50} (soil) [d]	22.7	Geometric mean, n=8, field DT_{50} Normalized to 20°C, pF2, Q_{10} = 2.58 (EFSA, 2007)
K_{FOC} [L/kg]	575.4	Arithmetic mean, n=4 (EFSA, 2007)
K_{FOM} [L/kg]	333.8	K_{FOC} / 1.724
1/n [-]	0.81	Arithmetic mean, n=4 (EFSA, 2007)
DT_{50} water [d]	1000 [1)] ~~49.9~~	Max. whole system value, n = 2 (Table 8.63 of the DAR, 2005)
DT_{50} sediment [d]	49.9 [1)] ~~1000~~	Default worst-case value
Crop uptake factor [-]	0	Worst-case default
Formation from parent	0.571 in soil 0.323 in water 0.269 in sediment	Conversion factor parent -> metabolite (EFSA, 2007; DAR, 2005)

[1)] Combination giving worst case PEC_{SW} at Steps 3&4 (for details, see zRMS comment at the end of this chapter)

Table 8.9.2.2-6: Summary of input data for FOCUS Step 1-2 calculations – 1,2,4-triazole

Parameter	Value	Remarks
Molecular weight [g/mol]	69.1	-
Water solubility [mg/L]	730000	25°C (EFSA, 2014 on tebuconazole)
DT_{50} (soil) [d]	1000	Worst-case default
Maximum occurrence in soil [%]	0.0001	No soil metabolite, value used due to technical reasons
K_{FOC} [L/kg]	89	Arithmetic mean, n=4 (EFSA, 2014)
DT_{50} total aquatic system [d] (Step 1)	1000	Worst-case default
DT_{50} water [d]	1000	Worst-case default
DT_{50} sediment [d]	1000	Worst-case default
Maximum occurrence in w/s systems [%]	41.8	Max. from 2 water sediment systems (DAR, 2005) 37.2% in water (UK) + 4.6% in sediment at 121 d

$PEC_{SW/SED}$

Table 8.9.2.2-7: FOCUS Step 1 PEC_{sw} and PEC_{SED} for prothioconazole and its metabolites following single application of ADM.03503.F.1.A to cereals

Compound	Step 1		
	Cereals 1×187.5 g/ha		
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]
	Maximum	21d TWA	Maximum
Prothioconazole	20.363	2.796	328.964
JAU 6476-S-methyl (M01)	14.898	11.628	347.485
JAU 6476-desthio (M04)	36.680	31.501	206.141
1,2,4-triazole	4.832	4.782	4.284

Table 8.9.2.2-8: FOCUS Step 2 PEC_{sw} and PEC_{SED} for prothioconazole and its metabolites following single application of ADM.03503.F.1.A to cereals

Compound	Step 2						
	Cereals 1×187.5 ~~93.75~~ g/ha, average crop cover						Scenario/ Season
	North Europe			South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	
	Max.	21d TWA	Max.	Max.	21d TWA	Max.	
Prothioconazole	1.724	0.178	7.325	1.724	0.228	12.547	Mar-May
				1.724	0.203	9.936	Jun-Sep
JAU 6476-S-methyl (M01)	1.382	0.664	19.142	1.382	1.005	30.932	Mar-May
				1.382	0.834	25.037	Jun-Sep
JAU 6476-desthio (M04)	3.42 3.406	3.15 2.889	18.96 18.887	6.277	5.379	35.180	Mar-May
				4.841	4.134	27.034	Jun-Sep
1,2,4-triazole	0.208	0.202	0.181	0.283	0.276	0.247	Mar-May
				0.245	0.239	0.214	Jun-Sep
Compound	Step 2						
	Cereals 1×187.5 ~~93.75~~ g/ha, full canopy						Scenario/ Season
	North Europe			South Europe			
	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	PEC_{SW} [µg/L]		PEC_{SED} [µg/kg]	
	Max.	21d TWA	Max.	Max.	21d TWA	Max.	
Prothioconazole	1.724	0.147	4.350	1.724	0.165	6.020	Mar-May
				1.724	0.156	5.040	Jun-Sep
JAU 6476-S-methyl (M01)	1.382	0.451	11.773	1.382	0.579	16.194	Mar-May
				1.382	0.515	13.984	Jun-Sep
JAU 6476-desthio (M04)	1.63 1.611	1.46 1.332	8.78 8.704	2.71 2.688	2.47 2.266	14.89 14.814	Mar-May
				2.17 2.150	1.96 1.799	11.84 11.759	Jun-Sep
1,2,4-triazole	0.162	0.156	0.140	0.190	0.184	0.164	Mar-May
				0.176	0.170	0.152	Jun-Sep

Table 8.9.2.2-9: FOCUS Step 3-4 PEC$_{sw}$ for prothioconazole following single application of ADM.03503.F.1.A to winter cereals

Scenario	Appl. rate [g/ha]	Step 3				Step 4, 10 m db+vfs			
		Appl. date	Date of max	Global max PEC$_{SW}$ [µg/L]	21 d TWA PEC$_{SW}$ [µg/L]	Appl. Date	Date of max	Global max PEC$_{SW}$ [µg/L]	21 d TWA PEC$_{SW}$ [µg/L]
D1 Ditch	187.5	29-Mar-1982	29-Mar-1982	1.189	0.095	29-Mar-1982	29-Mar-1982	0.171	0.014
D1 Stream	187.5	29-Mar-1982	29-Mar-1982	0.925	0.002	29-Mar-1982	29-Mar-1982	0.179	<0.001
D3 Ditch	187.5	20-Apr-1992	20-Apr-1992	1.185	0.054	20-Apr-1992	20-Apr-1992	0.170	0.008
D4 Pond	187.5	19-Mar-1985	19-Mar-1985	0.041	0.018	19-Mar-1985	19-Mar-1985	0.025	0.011
D4 Stream	187.5	19-Mar-1985	19-Mar-1985	0.876	0.002	19-Mar-1985	19-Mar-1985	0.170	<0.001
D5 Pond	187.5	08-Apr-1978	08-Apr-1978	0.041	0.014	08-Apr-1978	08-Apr-1978	0.025	0.009
D5 Stream	187.5	08-Apr-1978	08-Apr-1978	0.946	0.002	08-Apr-1978	08-Apr-1978	0.183	<0.001
D6 Ditch	187.5	27-Feb-1986	27-Feb-1986	1.171	0.025	27-Feb-1986	27-Feb-1986	0.168	0.004
R1 Pond	187.5	26-Apr-1984	26-Apr-1984	0.041	0.013	26-Apr-1984	26-Apr-1984	0.025	0.008
R1 Stream	187.5	26-Apr-1984	26-Apr-1984	0.781	0.008	26-Apr-1984	26-Apr-1984	0.151	0.002
R3 Stream	187.5	28-Mar-1980	28-Mar-1980	1.097	0.014	28-Mar-1980	28-Mar-1980	0.212	0.003
R4 Stream	187.5	04-Feb-1980	04-Feb-1980	0.784	0.008	04-Feb-1980	04-Feb-1980	0.152	0.001

Highlighted cells indicate relevant entry route: drift (blue), runoff (green) or drainage (grey), global maximum PEC$_{SW}$ highlighted red.
D2 scenario is not shown here since it is not considered relevant in the Central Zone. For all results see Weber et al., 2022b.

Table 8.9.2.2-10: FOCUS Step 3-4 PEC$_{sw}$ and for prothioconazole following single application of ADM.03503.F.1.A to spring cereals

Scenario	Appl. rate [g/ha]	Step 3				Step 4, 10 m db+vfs			
		Appl. date	Date of max	Global max PEC$_{SW}$ [µg/L]	21 d TWA PEC$_{SW}$ [µg/L]	Appl. Date	Date of max	Global max PEC$_{SW}$ [µg/L]	21 d TWA PEC$_{SW}$ [µg/L]
D1 Ditch	187.5	17-Jun-1982	17-Jun-1982	1.199	0.280	17-Jun-1982	17-Jun-1982	0.172	0.040
D1 Stream	187.5	17-Jun-1982	17-Jun-1982	1.049	0.042	17-Jun-1982	17-Jun-1982	0.203	0.008
D3 Ditch	187.5	04-May-1992	04-May-1992	1.186	0.055	04-May-1992	04-May-1992	0.170	0.008
D4 Pond	187.5	30-May-1985	30-May-1985	0.041	0.010	30-May-1985	30-May-1985	0.025	0.006
D4 Stream	187.5	30-May-1985	30-May-1985	0.970	0.004	30-May-1985	30-May-1985	0.188	0.001
D5 Pond	187.5	14-Apr-1978	14-Apr-1978	0.041	0.014	14-Apr-1978	14-Apr-1978	0.025	0.009
D5 Stream	187.5	14-Apr-1978	14-Apr-1978	0.996	0.003	14-Apr-1978	14-Apr-1978	0.193	0.001
R4 Stream	187.5	04-May-1984	04-May-1984	0.784	0.031	04-May-1984	04-May-1984	0.152	0.012

Highlighted cells indicate relevant entry route: drift (blue), runoff (green) or drainage (grey), global maximum PEC$_{SW}$ highlighted red.

Table 8.9.2.2-11: FOCUS Step 3-4 PEC_{sw} for JAU 6476-desthio (M04) following single application of ADM.03503.F.1.A to winter cereals

Scenario	Appl. rate [g a.s./ha]	Step 3				Step 4, 10 m db+vfs			
		Appl. date	Date of max	Global max PEC_{SW} [µg/L]	21 d TWA PEC_{SW} [µg/L]	Appl. Date	Date of max	Global max PEC_{SW} [µg/L]	21 d TWA PEC_{SW} [µg/L]
D1 Ditch	187.5	29-Mar-1982	30-Mar-1982	0.019	0.004	29-Mar-1982	30-Mar-1982	0.004	0.001
D1 Stream	187.5	29-Mar-1982	29-Mar-1982	0.039	0.001	29-Mar-1982	29-Mar-1982	0.008	0.001
D3 Ditch	187.5	20-Apr-1992	21-Apr-1992	0.019	0.001	20-Apr-1992	21-Apr-1992	0.003	<0.001
D4 Pond	187.5	19-Mar-1985	13-Apr-1985	0.006	0.005	19-Mar-1985	12-Apr-1985	0.003	0.003
D4 Stream	187.5	19-Mar-1985	19-Mar-1985	0.022	<0.001	19-Mar-1985	19-Mar-1985	0.004	<0.001
D5 Pond	187.5	08-Apr-1978	28-Apr-1978	0.007	0.007	08-Apr-1978	28-Apr-1978	0.004	0.004
D5 Stream	187.5	08-Apr-1978	08-Apr-1978	0.033	<0.001	08-Apr-1978	08-Apr-1978	0.006	<0.001
D6 Ditch	187.5	27-Feb-1986	27-Feb-1986	0.010	<0.001	27-Feb-1986	27-Feb-1986	0.001	<0.001
R1 Pond	187.5	26-Apr-1984	30-May-1984	0.035	0.028	26-Apr-1984	30-May-1984	0.015	0.012
R1 Stream	187.5	26-Apr-1984	20-May-1984	0.332	0.023	26-Apr-1984	20-May-1984	0.151	0.010
R3 Stream	187.5	28-Mar-1980	20-Apr-1980	0.408	0.019	28-Mar-1980	20-Apr-1980	0.186	0.009
R4 Stream	187.5	04-Feb-1980	19-Mar-1980	0.603	0.030	04-Feb-1980	19-Mar-1980	0.274	0.013

Highlighted cells indicate global maximum PEC_{SW}
D2 scenario is not shown here since it is not considered relevant in the Central Zone. For all results see Weber et al., 2022b.

Table 8.9.2.2-12: FOCUS Step 3-4 PEC_{sw} for JAU 6476-desthio (M04) following single application of ADM.03503.F.1.A to spring cereals

Scenario	Appl. rate [g a.s./ha]	Step 3				Step 4, 10 m db+vfs			
		Appl. date	Date of max	Global max PEC_{SW} [µg/L]	21 d TWA PEC_{SW} [µg/L]	Appl. Date	Date of max	Global max PEC_{SW} [µg/L]	21 d TWA PEC_{SW} [µg/L]
D1 Ditch	187.5	17-Jun-1982	28-Jun-1982	0.155	0.144	17-Jun-1982	27-Jun-1982	0.022	0.020
D1 Stream	187.5	17-Jun-1982	17-Jun-1982	0.059	0.003	17-Jun-1982	17-Jun-1982	0.011	0.002
D3 Ditch	187.5	04-May-1992	05-May-1992	0.038	0.003	04-May-1992	05-May-1992	0.005	<0.001
D4 Pond	187.5	30-May-1985	12-Jun-1985	0.008	0.007	30-May-1985	12-Jun-1985	0.005	0.004
D4 Stream	187.5	30-May-1985	30-May-1985	0.025	<0.001	30-May-1985	30-May-1985	0.005	<0.001
D5 Pond	187.5	14-Apr-1978	04-May-1978	0.007	0.007	14-Apr-1978	04-May-1978	0.004	0.004
D5 Stream	187.5	14-Apr-1978	14-Apr-1978	0.035	<0.001	14-Apr-1978	14-Apr-1978	0.007	<0.001
R4 Stream	187.5	04-May-1984	18-May-1984	0.521	0.073	04-May-1984	18-May-1984	0.237	0.033

Highlighted cells indicate global maximum PEC_{SW}

zRMS comments:

Input parameters used for surface water modelling for prothioconazole and its metabolites presented in Tables 8.9.2.2-1 to 8.9.2.2-6 are in general in line with EU agreed endpoints with following remarks:

- For prothioconazole DT_{50} in water of 2.1 days was used instead of 1.0 days agreed in the course of the EU review. Nevertheless, in opinion of the zRMS this deviation is not expected to have significant impact on the obtained results.
- For the metabolite JAU 6476 S-Methyl Applicant used the maximum occurrence in water/sediment system of 77%, but such formation of JAU 6476 S-Methyl was observed only in sediment in the anaerobic water/sediment study. In the aerobic water/sediment study the maximum occurrence of 12.7% was observed in the whole system. Nevertheless, as assumed 77% represents worst case, and it was accepted by the zRMS for Step 1-2 calculations.
- It is noted that at the EU level no separate DT_{50} values for metabolite JAU 6476-desthio were determined for water and sediment compartments and DT_{50} of 49.9 days is relevant for the whole system. Nevertheless, in line with indications of the FOCUS Surface Water Generic Guidance (2015), at Steps 1&2 the whole system DT_{50} may be also attributed to particular compartments.
- With regard to parametrisation of the model at Step 3 and 4, it is noted that the K_{FOC} of JAU 6476-desthio is between 100 and 2000 mL/g and guidance indicates that in such case the whole system degradation values should be applied to one compartment (water or sediment) and a default of 1000 days applied to the other compartment. The same applies to the parent with EU agreed K_{OC} of 1765 mL/g. This approach gives four combinations for parent and metabolite modelling. Since the risk is driven by exposure via water and not sediment (endpoints for sediment dwellers are expressed in terms of mg/L) the four combinations indicated in table below were tested by the zRMS in order to check which gives the highest PEC_{SW} values. It turned out that the worst case combination was when the shortest DT_{50} value was applied to prothioconazole and the default of 1000 days was applied to JAU 6476-desthio in the water phase (combination 2 in table below). This combination was then used in the zRMS modelling performed for purposes of validation of the Applicants' results.

Potential combinations of water and sediment DT_{50} values for use in Step 3 modelling.

Component	Endpoint	Combination run in FOCUS Step 3 modelling			
		1	2	3	4
Prothioconazole	DT_{50} (water phase)	2.1	**2.1**	1000	1000
	DT_{50} (sediment)	1000	**1000**	2.1	2.1
JAU 6476-desthio	DT_{50} (water phase)	49.9	**1000**	49.9	1000
	DT_{50} (sediment)	1000	**49.9**	1000	49.9

Considering all deviation mentioned above respective changes were introduced in Tables 8.9.2.2-1 to 8.9.2.2-5.

At Step 3 PUF value of 0 was assumed for prothioconazole and JAU 6476-desthio and it is in line with current recommendations.

Step 4 simulations were performed according to recommendations of the FOCUS work group on landscape and mitigation factors and were validated by the zRMS for convenience of the concerned Member States that consider FOCUS simulations as Step 4 at the national level.

The surface water exposure was independently validated by the zRMS in additional modelling with modified input parameters discussed above.

Results for prothioconazole at Step 1-4 were in general in good agreement with results obtained by the Applicant. PEC_{SW} at Step 3-4 were the same, whereas PEC_{SED} values obtained by the zRMS were slightly higher due to modified combination of DT_{50} values considered in simulations performed for parent+metabolite (JAU 6476-desthio). However, observed differences were slight and with no impact on the outcome of the risk assessment, which was driven by exposure of aquatic species via the water column.
Overall, the surface water exposure reported in Tables 8.9.2.2-9 to 8.9.2.2-10 may be used in the aquatic risk assessment.

$PEC_{SW/SED}$ for metabolite JAU 6476 S-Methyl calculated by the zRMS at Step 1-2 were considerably lower comparing to these obtained by the Applicant due to much higher maximum occurrence assumed in Applicants' simulations. $PEC_{SW/SED}$ for metabolite JAU 6476-desthio and metabolite 1,2,4-triazole calculated by the zRMS at Steps 1-2 were the same comparing to these obtained by the Applicant. Overall, values in Tables 8.9.2.2-7 and 8.9.2.2-8 may be used further in the aquatic risk assessment.

$PEC_{SW/SED}$ for metabolite JAU 6476-desthio calculated by the zRMS at Steps 3-4 for the correct input parameters were the same or lower comparing to these obtained by the Applicant. Overall, the surface water exposure reported in Tables 8.9.2.2-11 and 8.9.2.2-12 may be used in the aquatic risk assessment.

Please note that additional surface water modelling may be required by the concerned Member States that do not accept simulations performed according to FOCUS recommendations.

8.9.2.3 PEC_{SW} of ADM.03503.F.1.A

Table 8.9.2.3-1: Rautmann drift PEC_{SW} of the formulation ADM.03503.F.1.A

Distance [m]	Rautmann drift entry [%]*	PEC_{SW} [µg/L]	PEC_{SW} [µg/L] 50 % nozzle reduction	PEC_{SW} [µg/L] 75 % nozzle reduction	PEC_{SW} [µg/L] 90 % nozzle reduction
0	100	449.667	224.833	112.417	44.967
1	2.77	12.456	6.228	3.114	1.246
3	0.95	4.272	2.136	1.068	0.427
5	0.57	2.563	1.282	0.641	0.256
10	0.29	1.304	0.652	0.326	0.130
15	0.20	0.899	0.450	0.225	0.090
20	0.15	0.675	0.337	0.169	0.067

The application rate of the formulation was based on a specific density of 1.0792 g/mL with an application rate of 1.25 L/ha, resulting in 1349 g product/ha.
* 90^{th} percentiles (single application) drift values calculated with function $y = 2.7705 \times distance^{-0.9787}$ for field crops from Rautmann et al. (2001)[1].

Table 8.9.2.3-2: FOCUS drift PEC_{SW} of the formulation ADM.03503.F.1.A

Distance [m]	Waterbody	Drift entry [%]	PEC_{SW} [µg/L]	PEC_{SW} [µg/L] 50 % nozzle reduction	PEC_{SW} [µg/L] 75 % nozzle reduction	PEC_{SW} [µg/L] 90 % nozzle reduction
FOCUS	Ditch	1.9274	8.6668	4.3334	2.1667	0.8667
	Pond	0.2191	0.2955	0.1478	0.0739	0.0296
	Stream	1.4304	6.4319	3.2160	1.6080	0.6432
1	Ditch/Stream	1.9274	8.6668	4.3334	2.1667	0.8667
	Pond	0.3282	0.4427	0.2214	0.1107	0.0443
3	Ditch/Stream	0.8160	3.6693	1.8347	0.9173	0.3669
	Pond	0.2321	0.3131	0.1566	0.0783	0.0313
5	Ditch/Stream	0.5224	2.3492	1.1746	0.5873	0.2349
	Pond	0.1896	0.2557	0.1279	0.0639	0.0256
10	Ditch/Stream	0.2771	1.2459	0.6230	0.3115	0.1246
	Pond	0.1363	0.1838	0.0919	0.0460	0.0184
15	Ditch/Stream	0.1893	0.8510	0.4255	0.2128	0.0851
	Pond	0.1086	0.1465	0.0733	0.0366	0.0147
20	Ditch/Stream	0.1440	0.6474	0.3237	0.1619	0.0647
	Pond	0.0910	0.1228	0.0614	0.0307	0.0123

The application rate of the formulation was based on a specific density of 1.0792 g/mL with an application rate of 1.25 L/ha, resulting in 1349 g product/ha.

[1] Rautmann, D., Streloke, M. and Winkler, R. (2001): New basic drift values in the authorisation procedure for plant protection products.

zRMS comments:
The surface water exposure to formulation was validated by the zRMS using Spray Drift Calculator. Obtained results were in agreement with these reported in above and may be used in the aquatic risk assessment.

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

8.10.1 Fluxapyroxad

Table 8.10.1-1: Summary of atmospheric degradation and behaviour - fluxapyroxad

Compound	Fluxapyroxad
Direct photolysis in air	Not studied - no data requested
Quantum yield of direct phototransformation	Not studied - no data requested
Photochemical oxidative degradation in air	DT50 of 0.69 days derived by the Atkinson model (Version 1.92) OH (12 h) concentration assumed = 1.5×10^{6} radicals cm^{-3}
Volatilisation	Vapour pressure (Pa): 2.7×10^{-9} (20°C), 8.1×10^{-9}(25°C) Henry's Law Constant (Pa.m3/mol): 3.028×10^{-7}
Metabolites	none

The vapour pressure at 20 °C of the active substance fluxapyroxad is < 10^{-5} Pa. Hence the active substance fluxapyroxad is regarded as non-volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance fluxapyroxad due to volatilization with subsequent deposition are not considered.

zRMS comments:
Provided above information is in line with EU agreed data reported in EFSA Journal 2012;10(1):2522. Taking into account the low vapour pressure (<10^{-5} Pa) and DT_{50} <2 days, fluxapyroxad is not expected to be subject to volatilisation and the long- or short-range transport. Taking this into account the contamination of the atmosphere with fluxapyroxad from the intended uses of ADM.03503.F.1.A is considered to be negligible.

8.10.2 Prothioconazole

The fate and behaviour of prothioconazole in air were evaluated during the EU review and the following information was provided in EFSA Journal 2007; 106; 1-98.

Table 8.10.2-1: Summary of atmospheric degradation and behaviour - prothioconazole

Compound	Prothioconazole
Direct photolysis in air	Not studied – no data requested
Quantum yield of direct phototransformation	Not studied – 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, 1.5x106 OH radicals/cm3) prothioconazole-desthio *(M04)*: Half-life: 14.2 hours Chemical lifetime: 20.5 hours Calculated according to Atkinson (AOPWIN v. 1.87, 12 hour day, 1.5x106 OH radicals/cm3)
Volatilisation	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.
Metabolites	*

* Based on the results concerning vapour pressure, Henry Law constant and photo oxidative stability in ambient air, it can be concluded that neither emission of prothioconazole into the air, nor accumulation and contamination by wet or dry deposition are to be expected for the parent compound and its metabolite prothioconazole-desthio (M04).

The vapour pressure at 20 °C of the active substance prothioconazole is < 10^{-5} Pa. Hence prothioconazole is regarded as non-volatile. Therefore, an assessment of the exposure of adjacent surface waters and terrestrial ecosystems by the active substance prothioconazole due to volatilisation with subsequent deposition is not triggered and not performed.

zRMS comments:
Provided above information is in line with EU agreed data reported in EFSA Scientific Report (2007) 106, 1-98. Taking into account the low vapour pressure (<10^{-5} Pa) and DT_{50} in air <2 days, prothioconazole is not expected to be subject to volatilisation and the long- or short-range transport. Taking this into account the contamination of the atmosphere with prothioconazole from the intended uses of ADM.03503.F.1.A is considered to be negligible.

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 9.2.4 / 01	Brauer, M., Jarvis, T.	2022a	Fluxapyroxad - Predicted environmental concentrations in groundwater after post-emergence application of fluxapyroxad to cereals in the Central Zone of the European Union - FOCUS groundwater calculations Exponent report no.: 2005459.UK0-6014 Sponsor no: 000110467 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	ADM
KCP 9.2.4 / 02	Brauer, M., Jarvis, T.	2022b	Prothioconazole - Predicted environmental concentrations in groundwater after post-emergence application of prothioconazole to cereals in the Central Zone of the European Union - FOCUS groundwater calculations Exponent report no.: 2005459.UK0-6810 Sponsor no: 000110468 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	ADM
KCP 9.2.5 / 01	Brauer, M., Weber, D., Jarvis, T.	2022c	Fluxapyroxad - Predicted environmental concentrations in surface water after post-emergence application of fluxapyroxad to cereals in the Central Zone of the European Union - FOCUS Step 1-2 calculations Exponent report no.: 2005459.UK0-8413 Sponsor no: 000110469 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	ADM
KCP 9.2.5 / 02	Brauer, M., Weber, D., Jarvis, T.	2022d	Prothioconazole - Predicted environmental concentrations in surface water after post-emergence application of prothioconazole to cereals in the Central Zone of the European Union - FOCUS Step 1-2 calculations Exponent report no.: 2005459.UK0-0492 Sponsor no: 000110471 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	ADM

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 9.2.5 / 03	Weber, D., Brauer, M., Jarvis, T.	2022a	Predicted environmental concentrations in surface water after post-emergence application of fluxapyroxad to winter and spring cereals in the Central Zone of the European Union - FOCUS Step 3-4 calculations Exponent report no.: 2005459.UK0-0194 Sponsor no: 000110472 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	ADM
KCP 9.2.5 / 04	Weber, D., Brauer, M., Jarvis, T.	2022b	Predicted environmental concentrations in surface water after post-emergence application of prothioconazole to winter and spring cereals in the Central Zone of the European Union - FOCUS Step 3-4 calculations Exponent report no.: 2005459.UK0-7090 Sponsor no: 000110473 Exponent International Ltd., Basel, Switzerland Not GLP, not published	N	ADM

ADM = Property of ADAMA Agricultural Solutions and all affiliates.
Under Article 59 of Regulation 1107/2009/EC, the Sponsor Company claims data protection for all ADM studies.

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
As all endpoints for the active substances and its metabolites were taken from the EU review of fluxapyroxad and prothioconazole, for the list of respective studies please refer to Volume 2 of the RAR.					

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
There were no data submitted by the Applicant and not relied on.					

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
There were no data relied on and not submitted by the Applicant					

Appendix 2 Detailed evaluation of the new Annex II studies

No additional active substance studies have been submitted.

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

A 3.1 KCP 9.1.3: Fluxapyroxad - PEC_S following application to field crops

Simulation of $PEC_{S,ini}$, short-term and long-term PEC_S values as well as $PEC_{S,plateau}$ and $PEC_{S,accumulation}$ were carried out using the tool ESCAPE (v. 2.0). ESCAPE output files for fluxapyroxad and its metabolites M700F001 and M700F002 are presented below.

Fluxapyroxad → M700F001, 1 × 93.75 g a.s/ha, at 5 cm depth

E S C A P E
Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 18-02-2022, 13:06:29
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Fluxa_cereals_1x93.75g
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Application date: 4 May
Application rate (g/ha): 93.75
Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Active compound and a single metabolite

Compound	Molecular mass(g/mol)	Formation (%)	
Fluxapyroxad	381.31		
M700F001	176.1	2.6	100

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Active compound and a single metabolite

Kinetics for Fluxapyroxad: Single First order (SFO)
DT50 (d): 370
Rate constant (1/d): 0.0019
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for M700F001: Single First order (SFO)
DT50 (d): 10
Rate constant (1/d): 0.0693
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and a single metabolite

RESULTS FOR: Fluxapyroxad

Calculations over one year

Maximum annual total soil concentration for Fluxapyroxad over 5 cm(mg/kg): 0.0250 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Fluxapyroxad after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0250	0.0250	0	1
2	0.0249	0.0250	0	2
4	0.0248	0.0249	0	4
7	0.0247	0.0248	0	7
14	0.0244	0.0247	0	14
21	0.0240	0.0245	0	21
28	0.0237	0.0244	0	28
42	0.0231	0.0240	0	42
50	0.0228	0.0239	0	50
100	0.0207	0.0228	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Fluxapyroxad over 20 cm(mg/kg): 0.0064**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0064

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Fluxapyroxad over 5 cm considering accumulation* (mg/kg) 0.0314
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Fluxapyroxad(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0313	0.0313	0	1
2	0.0313	0.0313	0	2
4	0.0312	0.0313	0	4
7	0.0310	0.0312	0	7
14	0.0307	0.0310	0	14
21	0.0304	0.0309	0	21
28	0.0301	0.0307	0	28
42	0.0295	0.0304	0	42
50	0.0291	0.0302	0	50
100	0.0271	0.0292	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

RESULTS FOR: M700F001

Calculations over one year

Maximum annual total soil concentration for M700F001 over 5 cm(mg/kg): 0.0003 occurring on day 54^
(^ This is 0.63 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for M700F001 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0003	0.0003	53	54
2	0.0003	0.0003	53	55
4	0.0003	0.0003	52	56
7	0.0003	0.0003	50	57
14	0.0003	0.0003	47	61
21	0.0003	0.0003	44	65
28	0.0003	0.0003	42	70
42	0.0003	0.0003	37	79
50	0.0003	0.0003	35	85
100	0.0002	0.0003	26	126

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for M700F001 over 20 cm(mg/kg): 0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for M700F001 over 5 cm considering accumulation* (mg/kg) 0.0004
(* a tillage depth of 20 cm was considered for calculating the background concentration)

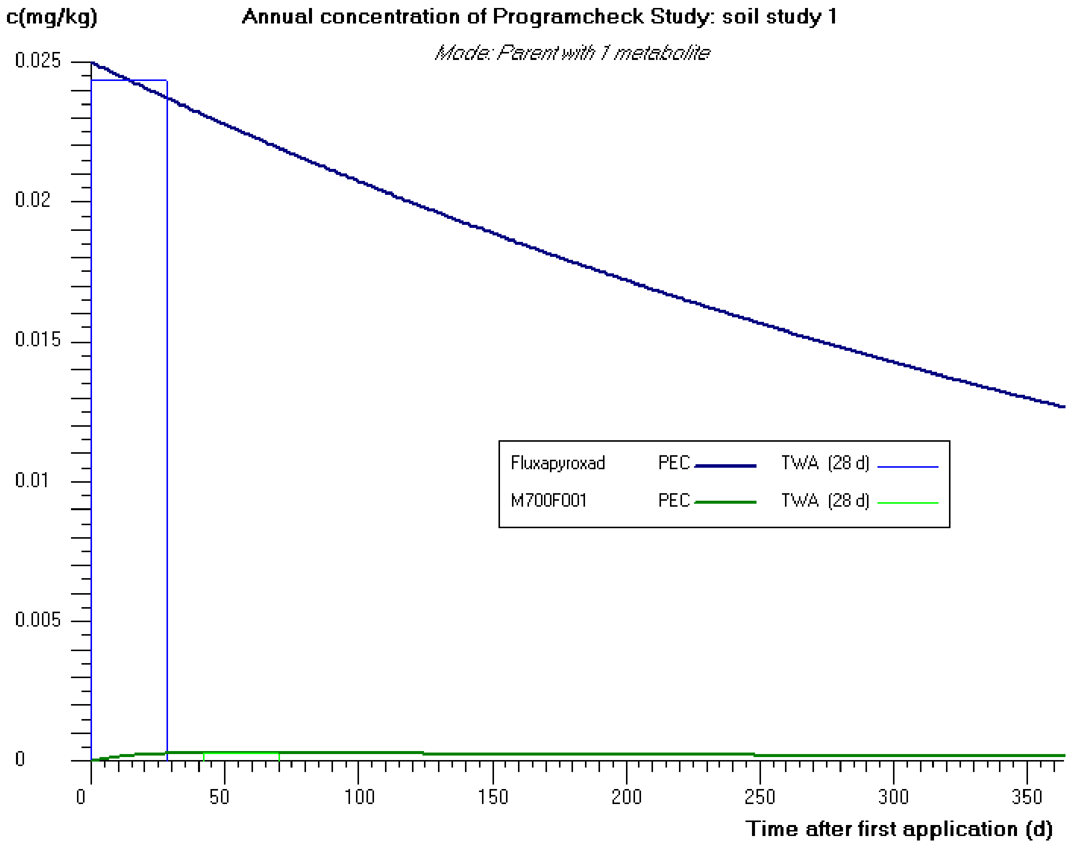
Calculated time dependent total soil concentrations over 5 cm for M700F001(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0004	0.0004	53	54
2	0.0004	0.0004	53	55
4	0.0004	0.0004	52	56
7	0.0004	0.0004	50	57
14	0.0004	0.0004	47	61
21	0.0004	0.0004	44	65
28	0.0004	0.0004	42	70
42	0.0004	0.0004	37	79

50	0.0004	0.0004	35	85
100	0.0003	0.0004	26	126

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION



Fluxapyroxad, 1 × 93.75 g a.s/ha, at 5 cm depth (FOMC, PECaccu)

E S C A P E
Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 10-03-2022, 16:28:58
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Fluxa_cereals_1x93.75g
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Application date: 4 May
Application rate (g/ha): 93.75
Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Parent compound without metabolites

Kinetics for Programcheck: First Order Multi Compartment (FOMC)
Alpha: 0.2059
Beta: 13.134
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.0250 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0246	0.0248	0	1
2	0.0243	0.0246	0	2
4	0.0237	0.0243	0	4
7	0.0229	0.0239	0	7
14	0.0215	0.0230	0	14
21	0.0205	0.0223	0	21
28	0.0198	0.0218	0	28
42	0.0186	0.0209	0	42
50	0.0181	0.0205	0	50
100	0.0160	0.0187	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg): 0.0063**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0063

Calculations of concentrations considering accumulation after many years of application

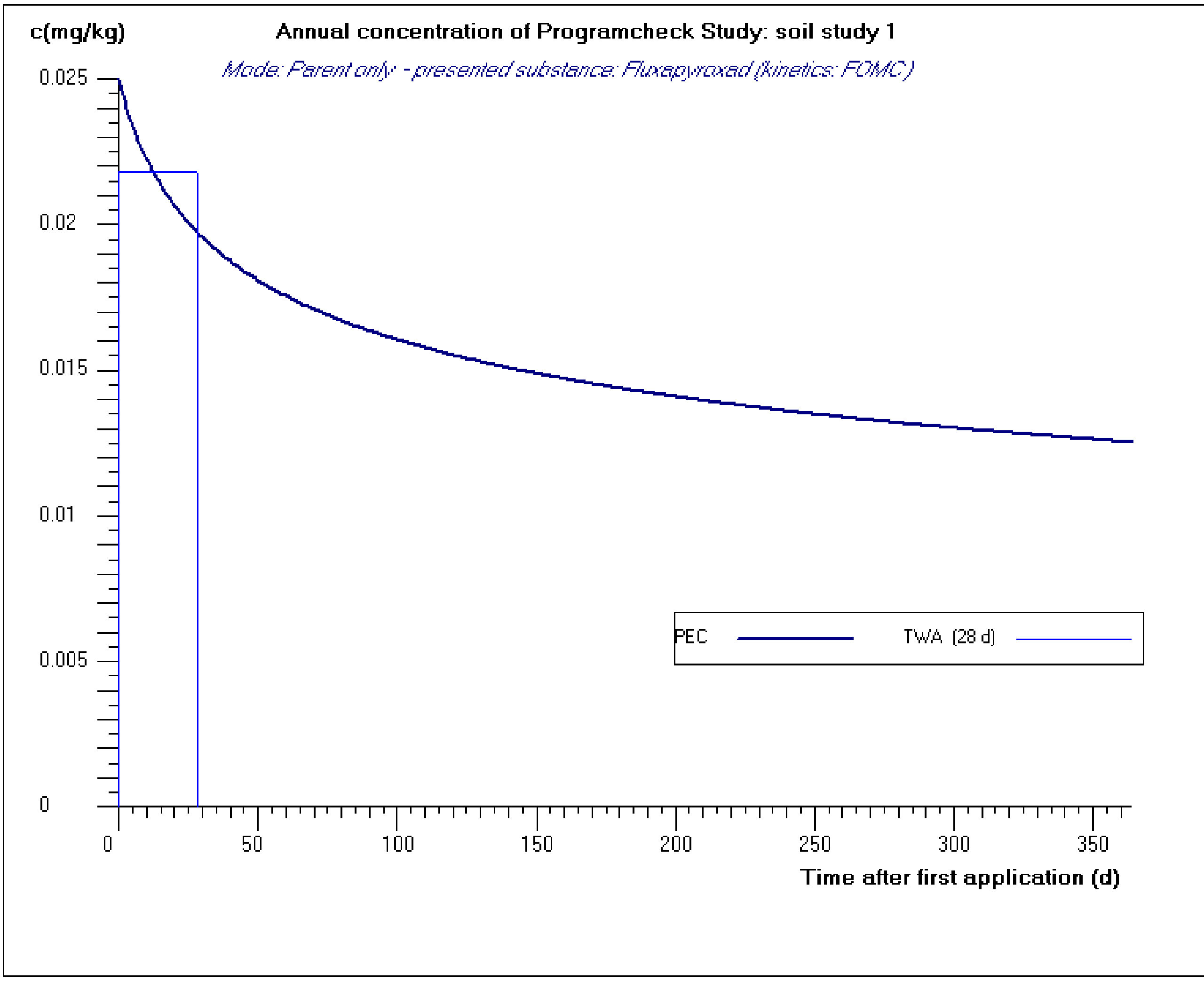
Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.0313
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0309	0.0311	0	1
2	0.0305	0.0309	0	2
4	0.0299	0.0306	0	4
7	0.0292	0.0301	0	7
14	0.0278	0.0293	0	14
21	0.0268	0.0286	0	21
28	0.0260	0.0281	0	28
42	0.0249	0.0272	0	42
50	0.0244	0.0268	0	50
100	0.0223	0.0250	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

GRAPHIC REPRESENTATION OF THE CALCULATION


c(mg/kg)
Annual concentration of Programcheck Study: soil study 1
Mode: Parent only: - presented substance: Fluxapyroxad (kinetics: FOMC)
0.025
0.02
0.015
0.01
0.005
0
0
50
100
150
200
250
300
350
Time after first application (d)
PEC
TWA (28 d)

M700F002 as parent, 1 × 28.08 g a.s/ha, at 5 cm depth

9 Fluxapyroxad cereals (B)

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04-01-2022, 09:42:14
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: M700F002_cereals_1x28.08g
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Application date: 4 May
Application rate (g/ha): 28.08
Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Parent compound without metabolites

Kinetics for Programcheck: First Order Multi Compartment (FOMC)
Alpha: 2.4056
Beta: 117.5
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Programcheck

Calculations over one year

Maximum annual total soil concentration for Programcheck over 5 cm(mg/kg): 0.0075 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Programcheck after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0073	0.0074	0	1
2	0.0072	0.0073	0	2
4	0.0069	0.0072	0	4
7	0.0065	0.0070	0	7
14	0.0057	0.0065	0	14
21	0.0050	0.0062	0	21
28	0.0045	0.0058	0	28
42	0.0036	0.0052	0	42
50	0.0032	0.0049	0	50
100	0.0017	0.0036	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Programcheck over 20 cm(mg/kg): 0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0001

Calculations of concentrations considering accumulation after many years of application

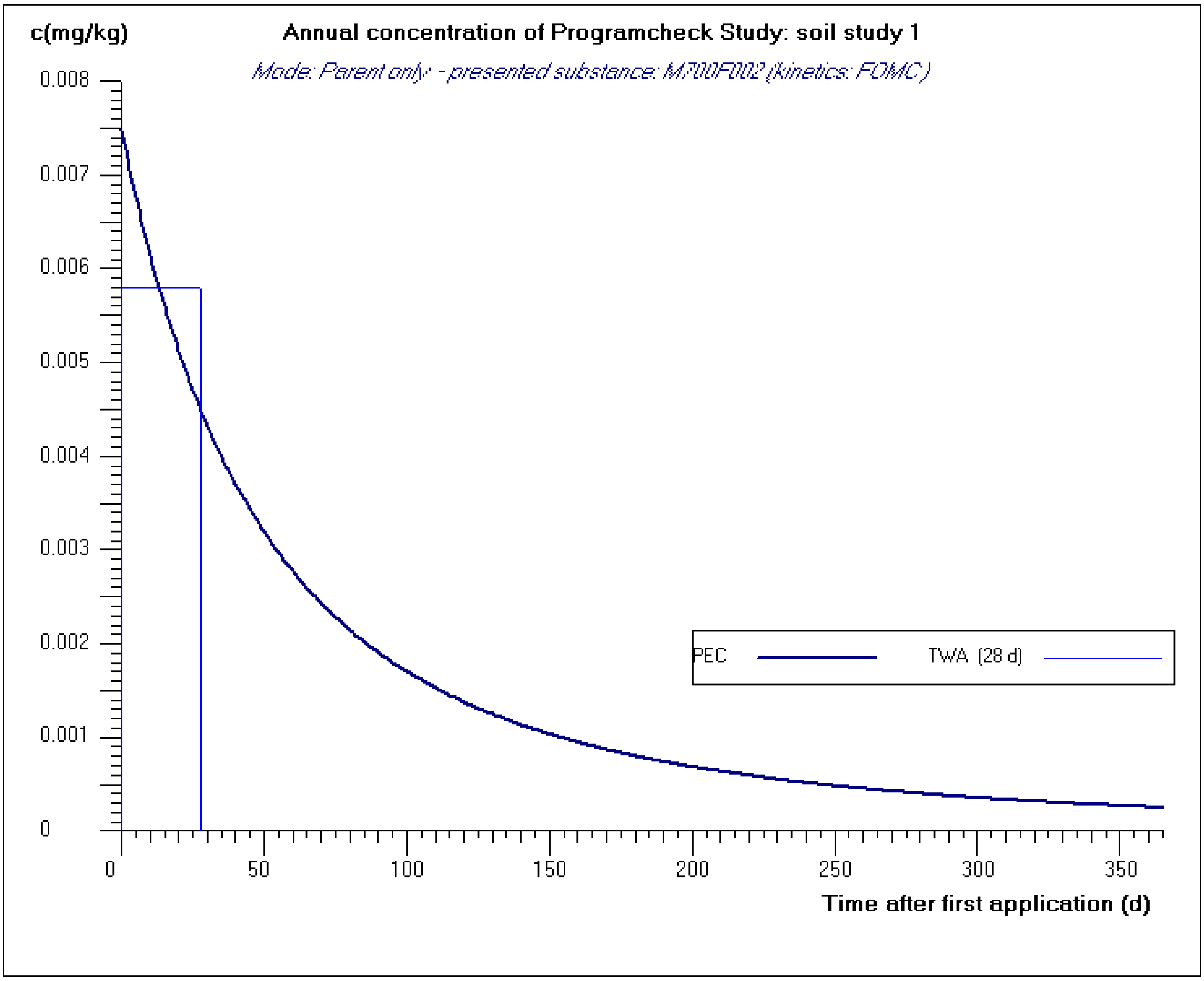
Maximum total soil concentration for Programcheck over 5 cm considering accumulation* (mg/kg) 0.0076
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Programcheck(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0074	0.0075	0	1
2	0.0073	0.0074	0	2
4	0.0070	0.0073	0	4
7	0.0066	0.0071	0	7
14	0.0058	0.0066	0	14
21	0.0051	0.0062	0	21
28	0.0045	0.0059	0	28
42	0.0037	0.0053	0	42
50	0.0033	0.0050	0	50
100	0.0018	0.0037	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

GRAPHIC REPRESENTATION OF THE CALCULATION


c(mg/kg)
Annual concentration of Programcheck Study: soil study 1
Mode: Parent only - presented substance: M700F002 (kinetics: FOMC)
0.008
0.007
0.006
0.005
0.004
0.003
0.002
0.001
0
PEC
TWA (28 d)
0
50
100
150
200
250
300
350
Time after first application (d)

A 3.2 KCP 9.1.3: Prothioconazole - PEC_S following application to field crops

Simulation of $PEC_{S,ini}$, short-term and long-term PEC_S values as well as $PEC_{S,plateau}$ and $PEC_{S,accumulation}$ were carried out using the tool ESCAPE (v. 2.0). ESCAPE output files for prothioconazole and its metabolites M01 and M04 are presented below.

Prothioconazole → M01 and M04, 1 × 187.5 g a.s/ha, at 5 cm depth

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version:	2.0 (26 November 2019)
Date of this simulation:	21-02-2022, 15:12:10
Calculation problem:	Programcheck

PROGRAM SETTINGS

Calculation mode:	Residues from different applications are considered separately over one year
Application mode:	Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario:	Prothio_cereals_1x187.5g
Name of the soil:	Borstel
Soil density (kg/L):	1.5
Soil depth (cm):	5
Tillage depth (cm)*:	20
Organic carbon content (%):	1.5
Field capacity (Vol%):	29.2
Wilting point (Vol%):	6.4
Climatic conditions:	20 °C constant

(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation:	every year
Application date:	4 May
Application rate (g/ha):	187.5
Crop interception (%):	80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

Compound	Molecular mass(g/mol)	KOC(L/kg)	Formation (%)
Prothioconazole	344.26		
M01	358.3	2556.3	14.6
M04	312.2	575.4	57.1

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme:	Active compound and two parallel metabolites
Kinetics for Prothioconazole:	Single First order (SFO)
DT50 (d):	2.8
Rate constant (1/d):	0.2476
Q10-factor:	2.58
Walker-exponent:	0.7
Ref. temperature (°C):	20
Kinetics for M01:	Single First order (SFO)
DT50 (d):	46
Rate constant (1/d):	0.0151
Q10-factor:	2.58
Walker-exponent:	0.7
Ref. temperature (°C):	20
Kinetics for M04:	Single First order (SFO)
DT50 (d):	54.7
Rate constant (1/d):	0.0127
Q10-factor:	2.58
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and two parallel metabolites

RESULTS FOR: Prothioconazole

Calculations over one year

Maximum annual total soil concentration for Prothioconazole over 5 cm(mg/kg): 0.0500 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Prothioconazole after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0390	0.0445	0	1
2	0.0305	0.0396	0	2
4	0.0186	0.0319	0	4
7	0.0088	0.0239	0	7
14	0.0016	0.0140	0	14
21	0.0003	0.0096	0	21
28	<0.0001	0.0072	0	28
42	<0.0001	0.0048	0	42
50	<0.0001	0.0041	0	50
100	<0.0001	0.0020	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Prothioconazole over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Prothioconazole over 5 cm considering accumulation* (mg/kg) 0.0500
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Prothioconazole(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0390	0.0445	0	1
2	0.0305	0.0396	0	2
4	0.0186	0.0319	0	4
7	0.0088	0.0239	0	7
14	0.0016	0.0140	0	14
21	0.0003	0.0096	0	21
28	<0.0001	0.0072	0	28
42	<0.0001	0.0048	0	42
50	<0.0001	0.0041	0	50
100	<0.0001	0.0020	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

RESULTS FOR: M01

Calculations over one year

Maximum annual total soil concentration for M01 over 5 cm(mg/kg): 0.0064 occurring on day 12^
(^ This is 3.07 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for M01 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0064	0.0064	12	13
2	0.0063	0.0064	11	13
4	0.0063	0.0064	10	14
7	0.0060	0.0063	9	16
14	0.0055	0.0062	7	21
21	0.0050	0.0060	6	27
28	0.0045	0.0058	5	33
42	0.0036	0.0054	3	45
50	0.0032	0.0052	3	53
100	0.0015	0.0039	1	101

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for M01 over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for M01 over 5 cm considering accumulation* (mg/kg) 0.0064
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for M01(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0064	0.0064	12	13
2	0.0064	0.0064	11	13

4	0.0063	0.0064	10	14
7	0.0061	0.0063	9	16
14	0.0055	0.0062	7	21
21	0.0050	0.0060	6	27
28	0.0045	0.0058	5	33
42	0.0036	0.0054	3	45
50	0.0032	0.0052	3	53
100	0.0015	0.0039	1	101

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

RESULTS FOR: M04

Calculations over one year

Maximum annual total soil concentration for M04 over 5 cm(mg/kg): 0.0222 occurring on day 13^
(^ This is 12.24 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for M04 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0221	0.0222	12	13
2	0.0220	0.0222	12	14
4	0.0217	0.0221	11	15
7	0.0211	0.0221	10	17
14	0.0195	0.0217	8	22
21	0.0178	0.0212	6	27
28	0.0163	0.0206	5	33
42	0.0137	0.0193	4	46
50	0.0124	0.0185	3	53
100	0.0066	0.0145	1	101

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for M04 over 20 cm(mg/kg): 0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0001

Calculations of concentrations considering accumulation after many years of application

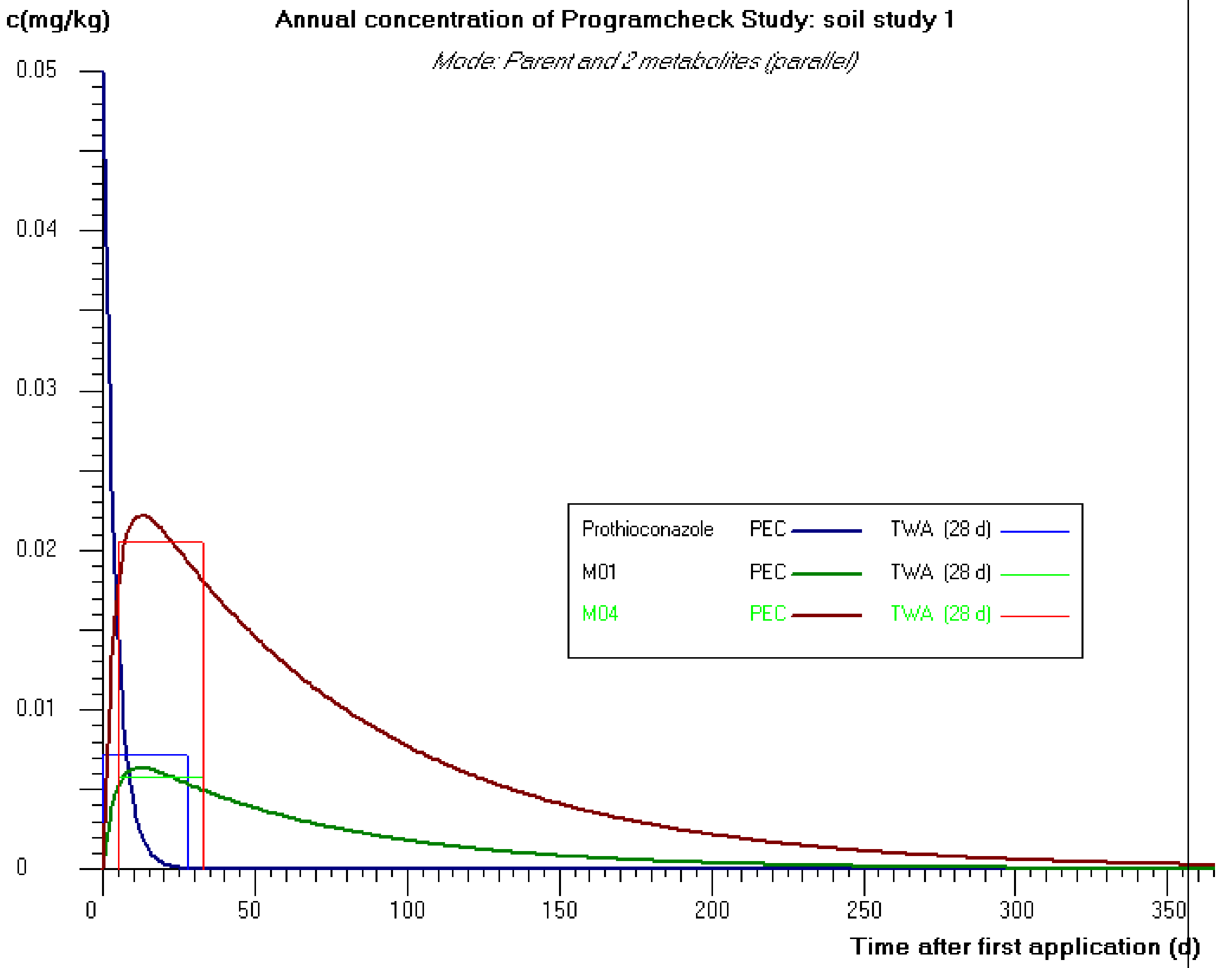
Maximum total soil concentration for M04 over 5 cm considering accumulation* (mg/kg) 0.0223
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for M04(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0222	0.0222	12	13
2	0.0221	0.0222	12	14
4	0.0218	0.0222	11	15
7	0.0212	0.0221	10	17
14	0.0195	0.0217	8	22
21	0.0179	0.0212	6	27
28	0.0164	0.0206	5	33
42	0.0137	0.0193	4	46
50	0.0124	0.0186	3	53
100	0.0066	0.0146	1	101

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION



Prothioconazole → M01 → M04, 1 × 187.5 g a.s/ha, at 5 cm depth

E S C A P E
Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 21-02-2022, 15:13:21
Calculation problem: Programcheck

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Single annual application pattern (calculation period 1 year)

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: Prothio_cereals_1x187.5g
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

Climatic conditions: 20 °C constant
(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Application date: 4 May
Application rate (g/ha): 187.5
Crop interception (%): 80

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Active compound and a sequence of two metabolites

Compound Molecular mass(g/mol) Formation (%)
Prothioconazole 344.26
M01 358.3 2556.3 14.6
M04 312.2 575.4 100

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: soil study 1

Metabolism scheme: Active compound and a sequence of two metabolites

Kinetics for Prothioconazole:Single First order (SFO)
DT50 (d): 2.8
Rate constant (1/d): 0.2476
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for M01: Single First order (SFO)
DT50 (d): 46
Rate constant (1/d): 0.0151
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

Kinetics for M04: Single First order (SFO)
DT50 (d): 54.7
Rate constant (1/d): 0.0127
Q10-factor: 2.58
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Active compound and a sequence of two metabolites

RESULTS FOR: Prothioconazole

Calculations over one year

Maximum annual total soil concentration for Prothioconazole over 5 cm(mg/kg): 0.0500 occurring on day 0

Calculated time dependent total soil concentrations over 5 cm for Prothioconazole after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0390	0.0445	0	1
2	0.0305	0.0396	0	2
4	0.0186	0.0319	0	4
7	0.0088	0.0239	0	7
14	0.0016	0.0140	0	14
21	0.0003	0.0096	0	21
28	<0.0001	0.0072	0	28
42	<0.0001	0.0048	0	42
50	<0.0001	0.0041	0	50
100	<0.0001	0.0020	0	100

(* PECact values are related to the time after the first application)

Calculation of background concentrations after many years

Final Background concentration in total soil for Prothioconazole over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for Prothioconazole over 5 cm considering accumulation* (mg/kg) 0.0500
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for Prothioconazole(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0390	0.0445	0	1
2	0.0305	0.0396	0	2
4	0.0186	0.0319	0	4

7	0.0088	0.0239	0	7
14	0.0016	0.0140	0	14
21	0.0003	0.0096	0	21
28	<0.0001	0.0072	0	28
42	<0.0001	0.0048	0	42
50	<0.0001	0.0041	0	50
100	<0.0001	0.0020	0	100

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the first application)

RESULTS FOR: M01

Calculations over one year

Maximum annual total soil concentration for M01 over 5 cm(mg/kg): 0.0064 occurring on day 12^
(^ This is 3.07 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for M01 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0064	0.0064	12	13
2	0.0063	0.0064	11	13
4	0.0063	0.0064	10	14
7	0.0060	0.0063	9	16
14	0.0055	0.0062	7	21
21	0.0050	0.0060	6	27
28	0.0045	0.0058	5	33
42	0.0036	0.0054	3	45
50	0.0032	0.0052	3	53
100	0.0015	0.0039	1	101

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for M01 over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for M01 over 5 cm considering accumulation* (mg/kg) 0.0064
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for M01(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0064	0.0064	12	13
2	0.0064	0.0064	11	13
4	0.0063	0.0064	10	14
7	0.0061	0.0063	9	16
14	0.0055	0.0062	7	21
21	0.0050	0.0060	6	27
28	0.0045	0.0058	5	33
42	0.0036	0.0054	3	45
50	0.0032	0.0052	3	53
100	0.0015	0.0039	1	101

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

RESULTS FOR: M04

Calculations over one year

Maximum annual total soil concentration for M04 over 5 cm(mg/kg): 0.0027 occurring on day 77^
(^ This is 1.47 % of the theoretical maximum concentration of the metabolite)

Calculated time dependent total soil concentrations over 5 cm for M04 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0027	0.0027	77	78
2	0.0027	0.0027	76	78
4	0.0027	0.0027	75	79
7	0.0027	0.0027	74	81
14	0.0026	0.0027	70	84
21	0.0026	0.0027	67	88
28	0.0025	0.0026	64	92
42	0.0024	0.0026	58	100
50	0.0023	0.0026	55	105
100	0.0016	0.0025	38	138

(* PECact values are related to the time after the maximum concentration)

Calculation of background concentrations after many years

Final Background concentration in total soil for M04 over 20 cm(mg/kg): <0.0001**

(** according to the estimation 100% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): <0.0001

Calculations of concentrations considering accumulation after many years of application

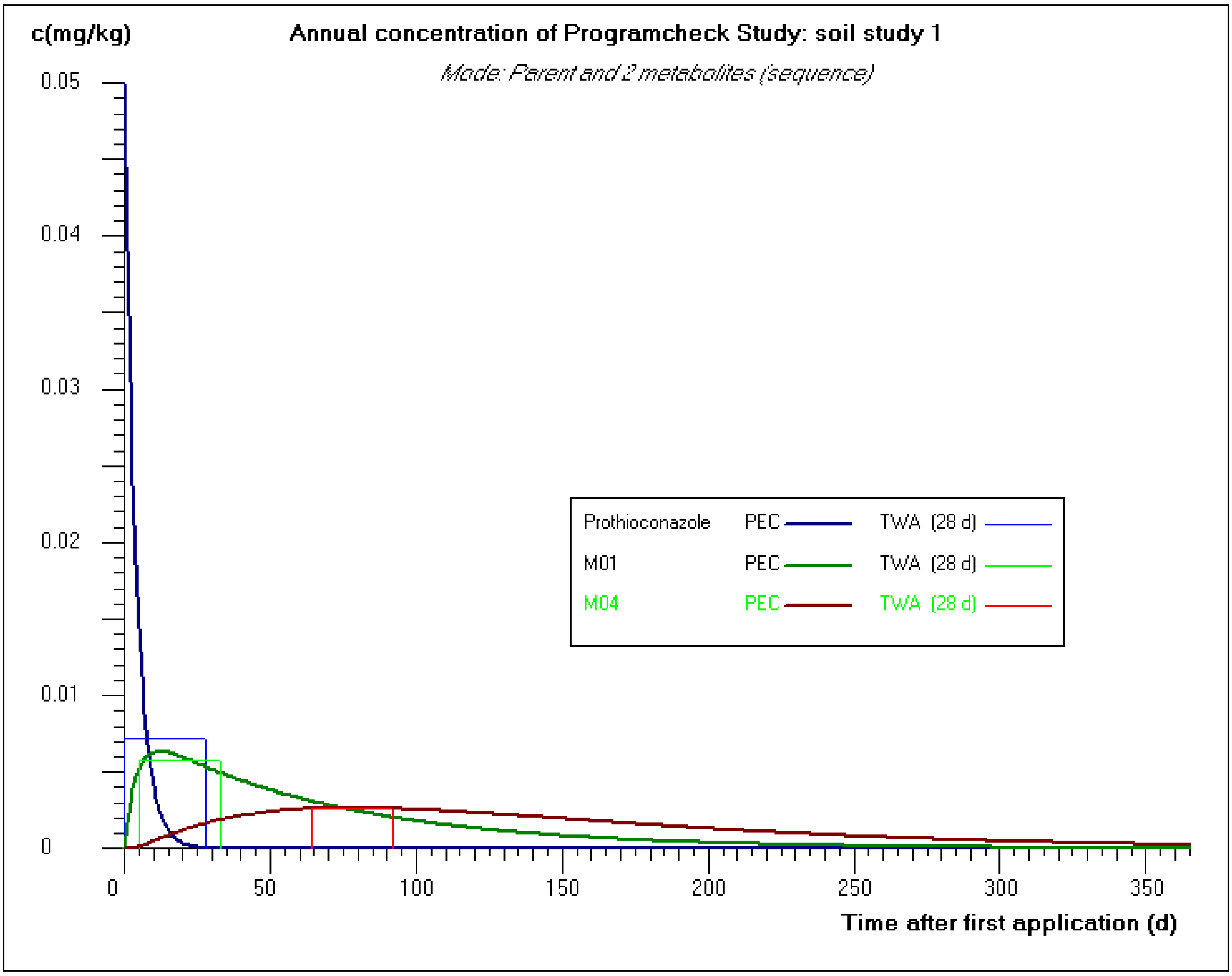
Maximum total soil concentration for M04 over 5 cm considering accumulation* (mg/kg) 0.0027
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for M04(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0027	0.0027	77	78
2	0.0027	0.0027	76	78
4	0.0027	0.0027	75	79
7	0.0027	0.0027	74	81
14	0.0026	0.0027	70	84
21	0.0026	0.0027	67	88
28	0.0025	0.0027	64	92
42	0.0024	0.0027	58	100
50	0.0023	0.0026	55	105
100	0.0016	0.0025	38	138

(* a tillage depth of 20 cm was considered for calculating the background concentration)
(** PECact values are related to the time after the maximum concentration)'

GRAPHIC REPRESENTATION OF THE CALCULATION


c(mg/kg)
Annual concentration of Programcheck Study: soil study 1
Mode: Parent and 2 metabolites (sequence)
0.05
0.04
0.03
0.02
0.01
0
0
50
100
150
200
250
300
350
Time after first application (d)
Prothioconazole PEC TWA (28 d)
M01 PEC TWA (28 d)
M04 PEC TWA (28 d)