DRAFT REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: A9873C

Product name: Wakil XL

Chemical active substances:

Cymoxanil, 100 g/kg

Fludioxonil, 50 g/kg

Metalaxyl-M, 169.6 g/kg

~~United Kingdom~~

Great Britain (GB)

NATIONAL ASSESSMENT

~~(Renewal of authorization)~~

Submitted to support Article 7 amendment of approval of Metalaxyl-M in GB

Applicant: Syngenta

Submission date: 21/10/2021

Finalisation date: 31/01/2024

Version history

When	What
October 2021	Applicant submission to support amendment of approval under Article 7 of retained Regulation (EC) No 1107/2009
December 2023	HSE (GB) assessment added in green boxes

This is an application from Syngenta for the renewal of WAKIL XL (A9873C) under Article 43 of Regulation (EC) No. 1107/2009 following the renewal of EU approval of the active substance metalaxyl-M.

No equivalence assessment is required.

This application follows the data requirements for the active substance laid down in Regulation (EU) No. 544/2011 and the data requirements for the plant protection product laid down in Regulation (EU) No. 545/2011, also called 'old' data requirements. Metalaxyl-M is an 'AIR-2' substance which approval has been renewed in accordance with Regulation (EU) No 1141/2010, therefore Regulations (EU) No 283/2013 and (EU) No 284/2013 are not applicable to the renewal of authorizations for metalaxyl-M-containing plant protection products (derogation by Commission Regula-tion (EU) No 2015/1475; further details in the guidance document SANTE/11509/2013 rev. 5.2).

Following the renewal of EU approval of the active substance metalaxyl-M, the submission for the product renewal of WAKIL XL (A9873C) was made by 01 September 2020, in accordance with Article 43 of Regulation (EC) No 1107/2009.
All data relied on are provided with this application. The reference lists at Appendix 1 of dRR Part B Sections 1-10 define the data owner and data access. Data protection is a national concern and is addressed in Part A, Appendix 4.

The guidance on Renewal of Authorization according to Art 43 (SANCO/2010/13170 rev 14) requests that within the dRR 'changes to the risk assessment are highlighted'. This is the first submission of WAKIL XL (A9873C) in the dRR format of April 2015, consequently all of the summary text is previously unreviewed and should be considered as 'changed'. To facilitate the review, Syngenta has highlighted the summaries of reports not previously reviewed by the zRMS in yellow.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**
Reviewer's comments	The applicant, Syngenta Crop Protection AG, submitted this application to amend the conditions of approval of metalaxyl-M in accordance to Article 7 of Regulation 1107/2009 in Great Britain (GB). On the 5 May 2020 the Commission Implementing Regulation (EU) 2020/617 renewing the approval of the active substance metalaxyl-M, and restricting the use of seed treated with a plant protection product containing it to be sown only in greenhouses, was published[1]. The renewal of metalaxyl-M applies since 1 June 2020. Since this was before

[1] Commission Implementing Regulation (EU) 2020/617 of 5 May 2020 renewing the approval of the active substance metalaxyl-M, and restricting the use of seeds treated with plant protection products containing it, in accord-

UK withdrawal from the EU, the Commission Implementing Regulation for the renewal of metalaxyl-M applies direct in GB.

Two representative formulations were considered in the renewal of approval for metalaxyl-M, 'Apron XL' (A9642C) and 'Ridomil Gold Mz'/68 WG Fubol Gold' (A9651D). For this Article 7 amendment application in GB, two different formulations have been considered. The formulation 'Vibrance SB' (A20607B) containing 14.4 g/L metalaxyl-M, 22.5 g/L fludioxonil and 15.0
g/L sedaxane to support the field seed treatment use on sugar and fodder beet, and the formulation 'Wakil XL' (A9873C) containing 169.6 g/Kg metalaxyl-M, 100 g/Kg cymoxanil and 50 g/Kg fludioxonil) to support
the field seed treatment use on peas (vining) are the basis of this Article 7 application for metalaxyl-M to GB.

The applicant has re-submitted the draft registration reports prepared for the product renewals of 'Vibrance SB' and 'Wakil XL' under Article 43 of Regulation No 1107/2009 following the renewal of approval of the active substance metalaxyl-M. The information and data submitted within these draft registration reports have been considered previously by HSE for the applications for authorisation of a new product under Article 33 of Regulation No 1107/2009. Where relevant, re-evaluation of data or information has not occurred where studies have been performed in accordance with the current requirements and the results have been deemed acceptable.

This draft registration report has been provided by the applicant, where required, comments have been inserted in green boxes by HSE or the text amended by the HSE in green (applicant's text has been struck through in green where necessary).

HSE notes that the product authorisations for 'Vibrance SB' and 'Wakil XL' were withdrawn in GB by the applicant. This was based on the approval restriction provided for in Commission Implementing Regulation (EU) 2020/617 that only the treatment of seeds intended to be sown in greenhouses may be authorised. Since all authorised GB uses of 'Vibrance SB' and 'Wakil XL' products are on seeds which are direct drilled in the field, these products do not comply with the restriction and therefore could not be renewed under Article 43 of Regulation No 1107/2009. HSE notes that no authorisation for 'Vibrance SB' or 'Wakil XL' is sought within this Article 7 amendment application. Therefore, HSE has only considered the information presented in the draft registration reports that relate to metalaxyl-M. For a future GB authorisation of these products a separate application would be required with a full evaluation of the data and information for all active substances present in the formulation.

Note that as of 1st January 2024, The Retained EU Law (Revocation and Reform) Act 2023 has taken effect and retained EU law are now known as assimilated law. As this assessment has been prepared prior to the Retained EU Law Act taking effect, assessment may still refer to "retained" regulation as opposed to "assimilated".

ance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

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8 Fate and behaviour in the environment (KCP 9)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**

Fate & Behaviour Reviewer's comments

The applicant's draft registration report for product 'Wakil XL' has been evaluated by the inclusion of green comment boxes. All HSE comments and agreed endpoints for use in the risk assessment are referenced within these boxes.

Introduction

'Wakil XL' is a seed treatment plant protection product containing 100 g/kg cymoxanil, 50 g/kg fludioxonil and 169.6 g/kg metalaxyl-M for treatment of vining and combining pea seed. The application rate is 200 g product/100 kg seeds. The applicant has assumed that up to 225 kg seed could be planted/ha. However HSE has historically assumed a higher seed rate of up to 280 kg seed/ha for combining peas based on advice from the Processors and Growers Research Organisation (PGRO), the leading independent advisor in the UK on legume crops. The GAP table is at Table 8.1-1 and shows the applicant's proposal. Table HSE-01 shows the applicant's proposed GAP and the critical GAP parameters which HSE has used in the assessment..

As this assessment is associated only with the consideration of the Article 7 amendment of the conditions of approval of metalaxyl-M, it has been confirmed that only the metalaxyl-M component of this product needs to be taken into account. **Consequently, there is no consideration within this assessment of the environmental exposure of cymoxanil and fludioxonil as a result of use of this product.**

Table HSE-01 Proposed use pattern for metalaxyl-M as applied in 'Wakil XL'

Crop	Seed sowing rate	Application rate (g a.s./ha)	Number of applications	Application timing	Crop interception
Applicant proposed – not used by HSE					
Peas (vining and combining)	225 kg/ha	76.3 metalaxyl-M[1]	1	BBCH 00	0%
HSE used parameters for PEC calculations					
Peas (vining and combining)	280 kg/ha	95.0 metalaxyl-M[2]	1	BBCH 00	0%

[1] Applicant calculation based on 200 g product/100 kg seeds; product contains 169.6 g/kg metalaxyl-M. Therefore dose is 76.3 g metalaxyl-M/ha based on 225 kg seed planted/ha. Note seed rate of 225 kg/ha is for vining peas; a lower rate of 200 kg seed/ha is stated for combining peas leading to lower dose of 67.84 g a.s./ha for combining peas.

[2] HSE calculation based on 200 g product/100 kg seeds; product contains 169.6 g/kg metalaxyl-M. Therefore dose is 95.0 g metalaxyl-M/ha based on 280 kg seed planted/ha. Note seed rate of 280 kg/ha has been used in previous assessments based on planting rate for combining peas; a lower rate of 267 kg seed/ha has been used by HSE for vining peas leading to lower dose of 90.6 g a.s./ha for vining peas. Combining peas used as worst case.

As the use is on peas, only a single 'application' per year in the field is considered. HSE consider it unlikely that there will be more than one crop grown in the same field each year.

Metalaxyl-M is approved in GB and NI by virtue of being approved in the EU at the time of EU

Exit.

Metalaxyl-M is subject of an EFSA Conclusion (EFSA Journal 2015;13(3):3999). The Implementing Regulation states that, with particular relevance to Environmental Fate and Behaviour assessment, Member States must pay particular attention to the potential for groundwater contamination. In addition, the Implementing Regulation stated that treated seeds could only be sown in greenhouses. The applicant is attempting to remove this restriction on the approval via an Article 7 submission. It should be noted that this restriction is related to ecotoxicological concerns and is not related to the Environmental Fate and Behaviour assessment. Hence no part of the Environmental Fate assessment is pertinent to the Article 7 submission.

There were no data gaps identified in the EFSA Conclusion which relate to environmental fate and behaviour.

The applicant has stated that as part of the Article 7 consideration of metalaxyl-M they wish to refine the formation fraction used in environmental exposure modelling, particularly groundwater modelling, for the metalaxyl-M metabolite SYN546520. The applicant submitted new data to support this change in formation fraction. However, the EFSA Conclusion indicates that this metabolite was not considered to be a relevant metabolite and appeared to pass the appropriate risk assessments in the EU Review with predicted concentrations of >10 µg/L. The applicant has not justified why it is necessary to refine the formation fraction of this metabolite for the GB assessment. Given the absence of an appropriate justification for attempting to refine the formation fraction, the data have not been assessed.

The applicant has not requested to risk envelope the environmental exposure of metalaxyl-M from any other authorised products.

Metabolites

With respect to metabolites, the EFSA Conclusion lists only metalaxyl-M as an ecotoxicologically relevant compound with respect to soil, water, sediment and groundwater. However, with respect to the assessment of groundwater for human health, the following metabolites are included in the assessment:

Metabolites included in groundwater assessment
NOA 409045
CGA67868
SYN546520

Consequently, the metabolites are only considered in the assessment of groundwater exposure.

Summary of PEC values

Table HSE-03 Final PEC values for use in risk assessments for the product ‘Wakil XL’.

Substance	**PEC value**	**Notes**
PECsoil (mg/kg)		
Metalaxyl-M	0.127	
Formulation	0.747	
PECgw (µg/L)		
Metalaxyl-M	<0.001	All scenarios and models
NOA409045	4.809	PEARL, Hamburg
CGA67868	0.142	PEARL, Hamburg
SYN546520	14.642	PEARL, Hamburg
PECsw (µg/L) – note all values calculated only from drainage; spray drift not a		

relevant route of exposure due to use as seed treatment		
Metalaxyl-M	13.885	
PECsed (µg/kg) – note all values calculated only from drainage; spray drift not a relevant route of exposure due to use as seed treatment		
Metalaxyl-M	13.073	

Conclusion

Based on the fate assessment authorisation can be recommended by Environmental Fate for the proposed use of 'Wakil XL' subject to confirmation from the HSE Ecotoxicology evaluator that the critical PEC values are acceptable.

8.1 Critical GAP and overall conclusions

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

1	2	3	4	5	6	7	8	9	10	11		12	13	14	15
Use-No. *	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**				PHI (days)	Remarks: e.g. g safener / synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop / season	Min. interval between applications (days)	g product /100 kg seeds	g as/100kg seeds 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	g as/ha 1) Metalaxyl-M 2) Cymoxanil 3) Fludioxonil	Slurry volume L/ha min / max			Groundwater
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)															
Minor uses according to Article 51 (interzonal uses)															
15	UK	Combining peas [PIBSS]	I	*Peronospora viciae, Ascochyta complex : Ascochyta pisi, Mycosphaerella pinodes, Phoma medicaginis var. Pinodella, Pythium spp.*	Seed treatment	BBCH 00	1	n/a	200	1) 33.9 2) 20 3) 10	1) 67.8 2) 40 3) 20	3500	n/a	Seeding rate maximum 200 kg seeds/ha TGW: 250 g Use: Field Varieties of common pea (*Pisum sativum*) harvested when fully mature Sowing density: 800000 seeds/ha	
			F		Sowing	BBCH 00									
			n.a.		Trans-planting	n.a.									
17	UK	Vining peas [PIBSS]	I	*Peronospora viciae, Ascochyta complex: Ascochyta pisi, Mycosphaerella pinodes, Phoma medicaginis var. pinodella Pythium spp.,*	Seed treatment	BBCH 00	1	n/a	200 g product / 100 kg seeds or *40 g product / 100 000 seeds*	1) 33.9 / *30.15* 2) 20 / *17.78* 3) 10 / *8.89*	1) 76.3 / *67.8* 2) 45 / *40* 3) 22.5/ *20*	3500	n/a	Seeding rate: maximum 225 kg seeds/ha TGW:min 225 g Use: Field Varieties of common pea (*Pisum sativum*) harvested green for canning, freezing or marketing fresh. *Seeding density: 1000000 seeds/ha*	
			F		Sowing	BBCH 00									
			n.a.		Trans-planting	n.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

Please note: Blue colour font - *Alternative dose expression*

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

Remarks columns:

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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener / synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Southern Europe	Lettuce	F	*Bremia lactucae*	Spray	BBCH 40-49	3-4	7	n.a.	a) 240 g a.s./ha	500-800	10	Oxon. Product Name: CYM 50 (500 g a.s./kg)
2	Northern Europe	Potatoes	F	*Phytophthora infestans*	Spray	BBCH 21-95	4	7-10	n.a.	a) 120 g a.s./ha	200-450	7	Oxon. Product Name: CYM 50 (500 g a.s./kg)
	Southern Europe				Spray	BBCH 21-95	5	7	n.a.	a) 120 g a.s./ha	500-1000	7	Oxon. Product Name: CYM 50 (500 g a.s./kg)
	Northern Europe		F	*Phytophthora infestans*	Spray	BBCH 21-95	6-8	7-10	n.a.	a) 175 g a.s./ha	300-600	14	DuPont. Product Name: Tanos (250 g a.s./kg)

* 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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener / synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	Southern and Northern Europe	Wine grapes	F	*Botrytis cinerea, Aspergillus carbonarius*	Foliar spray	BBCH 55-81	2	21	a) 1 kg/ha b) 2 kg/ha (Switch 62.5 WG)	a) 250 b) 500	100 / 1000	21	-
2	Southern Europe	Table grapes	F			BBCH 60-85						7	-
3	Southern and Northern Europe	Wheat	F	*Microdochium nivale Fusarium spp. Tiletia carie, Septoria sp., Helminthosporium sp.*	Seed treatment	BBCH 00	1	-	0.35 L/ha (Celest 025 FS)	a) 5.00 b) 8.75	0 / 2.625	-	Sowing rate: 100-175 kg/ha

* 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

Table 8.1-4: Assessed (critical) uses during approval of metalaxyl-M concerning the Section Environmental Fate

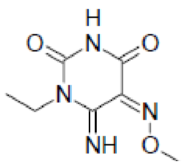
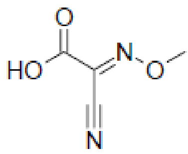
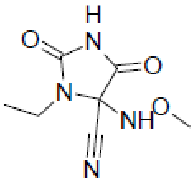
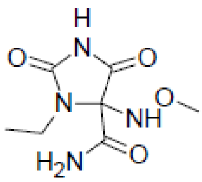
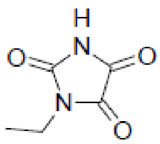
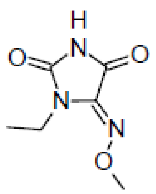
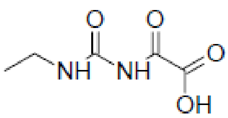
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I *	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener / synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product / ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Zonal uses (field or outdoor uses, certain types of protected crops)													
1	N-EU C-EU S-EU	Sunflower	F	*Plasmopara helianthi*	Seed treatment	-	1	-	a) 0.018 L / ha b) 0.018 L / ha	a) 6.1 b) 6.1	-	-.	Sowing rate is 40,000-80,000seeds/ha. Typical TGW is 75g. 0.0763 mg MXM/seed
2	N-EU C-EU S-EU	Spinach	F	*Peronospora farinosa, Pythium spp.*	Seed treatment	-	1	-	a) 0.240 L / ha b) 0.240 L / ha	a) 81.4 b) 81.4	-	-	Based on TGW of 10g. Sowing rate is 4,000,000-12,000,000 seeds/ha
3	N-EU C-EU	Tomato	F	*Phytophtora infestans, Alternaria spp.*	Foliar spray	BBCH 15-89	3	7	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	200-800	3	-
4	S-EU	Tomato	F	*Phytophtora infestans, Alternaria spp.*	Foliar spray	BBCH 15-89	3	7	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	500-1000	7	-
5	N-EU C-EU	Vines	F	*Plasmopara viticola, Pseudopezicula tracheiphila, Phomopsis viticola*	Foliar spray	BBCH 15-81	3	10	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	500-1000	56	-
6	S-EU	Vines	F	*Plasmopara viticola*	Foliar spray	BBCH 15-81	3	10	a) 2.5 kg / ha b) 7.5 kg / ha	a) 97 b) 291	200-1000	28	-

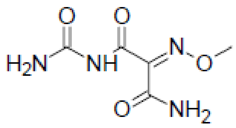
* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

Cymoxanil

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

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
IN-U3204	198.2		Soil: > 10% of a.s. Water: > 10% of a.s. Sediment: < 5% of a.s.	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
IN-W3595	128.1		Soil: > 10% of a.s. Water: > 10% of a.s. Sediment: < 5% of a.s.	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
IN-JX915	198.2		Soil: > 10% of a.s. Water: > 10% of a.s. (photolysis) Sediment: < 5% of a.s.	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
IN-KQ960	216.2		Soil: > 5% of a.s. in 2 sequential measurements Water: > 10% of a.s. Sediment: < 10% of a.s.	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
IN-T4226	142.1		Soil: < 5% of a.s. Water: > 10% of a.s. Sediment: < 5% of a.s.	$PEC_{SW/SED}$: not covered by EU assessment
IN-R3273	171.2		Soil: < 5% of a.s. Water: > 10% of a.s. (photolysis) Sediment: < 5% of a.s.	$PEC_{SW/SED}$: not covered by EU assessment
IN-KP533	160.1		Soil: < 5% of a.s. Water: > 10% of a.s. Sediment: < 10% of a.s.	$PEC_{SW/SED}$: not covered by EU assessment

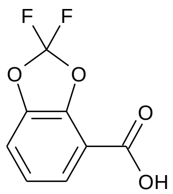
Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
M5[a]	198.2		Soil: < 5% of a.s. Water: > 10% of a.s. Sediment: 0% of a.s.	$PEC_{SW/SED}$: not covered by EU assessment

[a] Metabolite fraction M5

Fludioxonil

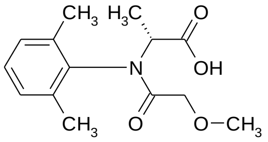
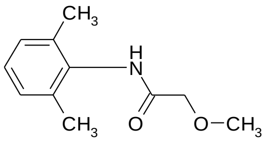
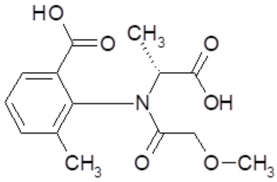
In soil, major metabolites of fludioxonil are formed through photolysis. Although endpoints are given in the EFSA conclusion for the metabolites CGA265378, CGA339833 and CGA192155, it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis. Since the present use is a seed treatment, exposure to light and thus formation of the metabolites in soil is not relevant. Therefore, no assessment of PEC_S and PEC_{GW} was done for these metabolites. For $PEC_{SW/SED}$ calculations, the metabolite CGA192155 was considered as relevant and assessed because it may also be formed in water.

Table 8.2-2: Metabolites of fludioxonil potentially relevant for exposure assessment

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
CGA192155	202.1		Soil: > 10 % of a.s. (soil photolysis study) Water: > 10 % of a.s. (water/sediment study under light exposure) Sediment: > 5 % of a.s. (water/sediment study under light exposure)	$PEC_{SW/SED}$: not covered by EU assessment

Metalaxyl-M

Table 8.2-3: Metabolites of metalaxyl-M potentially relevant for exposure assessment

Metabolite	**Molar mass (g/mol)**	**Chemical structure**	**Maximum observed occurrence in compartments (%)**	**Exposure assessment required due to**
NOA409045	265.3		Soil: > 10 % of a.s. Water: > 10 % of a.s. Sediment: > 10 % of a.s.	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
CGA67868	193.2		Soil: > 5% of a.s. in 2 sequential measurements Water: * Sediment: *	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment
SYN546520	295.3		Soil: < 5 % of a.s. and maximum of formation not yet reached at the end of the study Water: * Sediment: *	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment

* During the EU Review the metabolites CGA67868 and SYN546520 were not included in the definition of residues that require further assessment in surface water/sediment (Metalaxyl-M, EFSA Journal 2015;13(3):3999) and thus not considered in the $PEC_{SW/SED}$ risk assessment.

The codenames for R-enantiomer parent metalaxyl-M and respective metabolites, and racemic parent metalaxyl and its metabolites are in the table below.

Table 8.2-4: Code names for R-enantiomer and racemic parent metalaxyl-M and their respective metabolites

Enantiomer composition	**Parent**	**Acid metabolite**	**Diacid metabolite**	**Amide metabolite**
R-enantiomer	metalaxyl-M, CGA329351	NOA409045	SYN546520	CGA67868[a]
Racemate (R/S)	metalaxyl, CGA48988	CGA62826	CGA108906[b]	CGA67868[a]

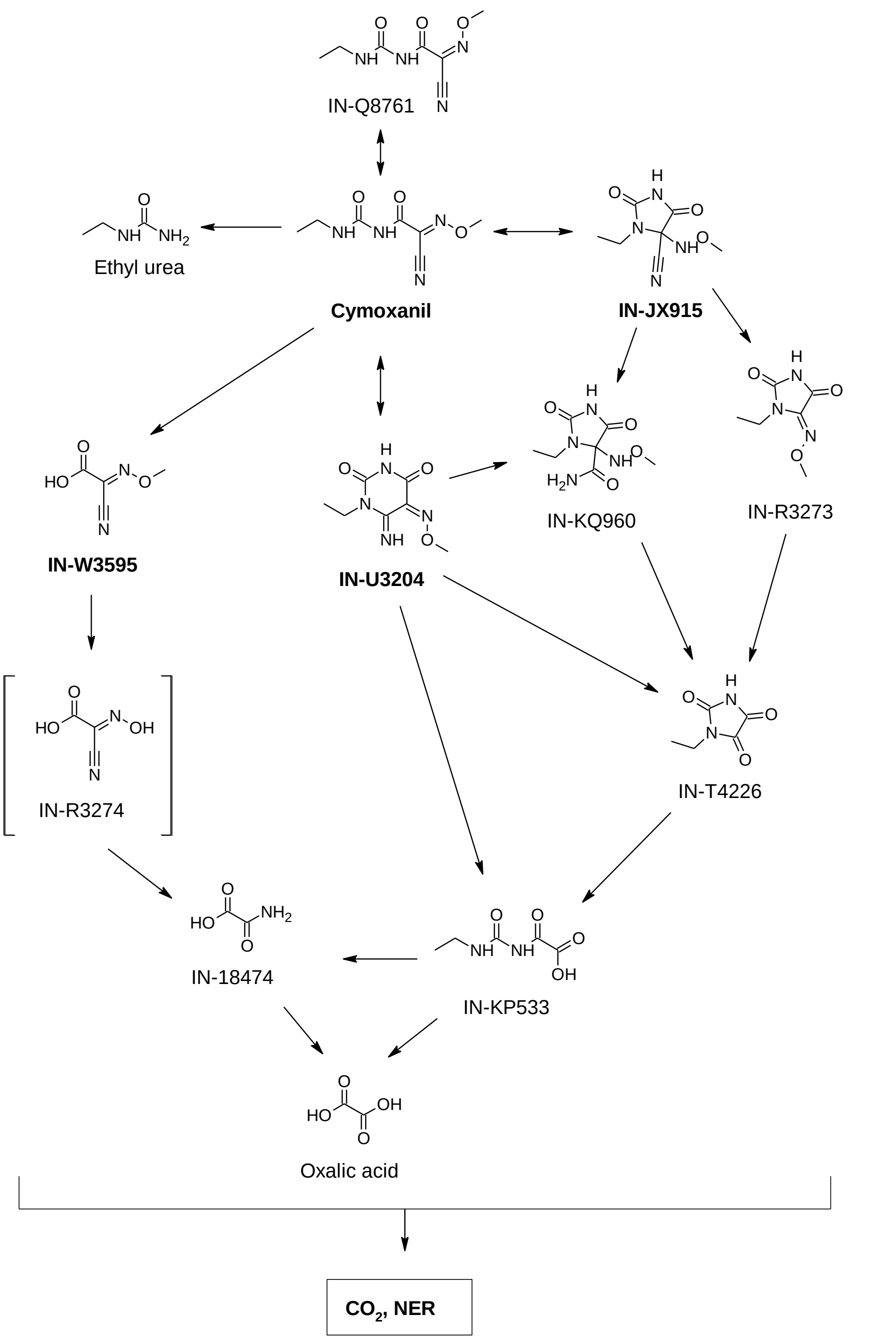
[a] Non-chiral CGA67868 is formed from both metalaxyl-M and metalaxyl
[b] CGA108906 was used historically as a reference material in metalaxyl-M dosed studies. More recently the R-enantiomer SYN546520 was synthesised and utilized in sorption and rate of degradation studies

8.3 Rate of degradation in soil (KCP 9.1.1)

Cymoxanil

The rate of degradation in soil of cymoxanil was evaluated during the EU Review. The fate and behaviour of cymoxanil and its metabolites IN-U3204, IN-W3595, IN-JX915 and IN-KQ960 in soil are discussed in detail in the corresponding document of the EU review dossier where the study references can be found. All other metabolites shown in the degradation pathway of cymoxanil in soil (see Figure 8.3-1) are minor metabolites.

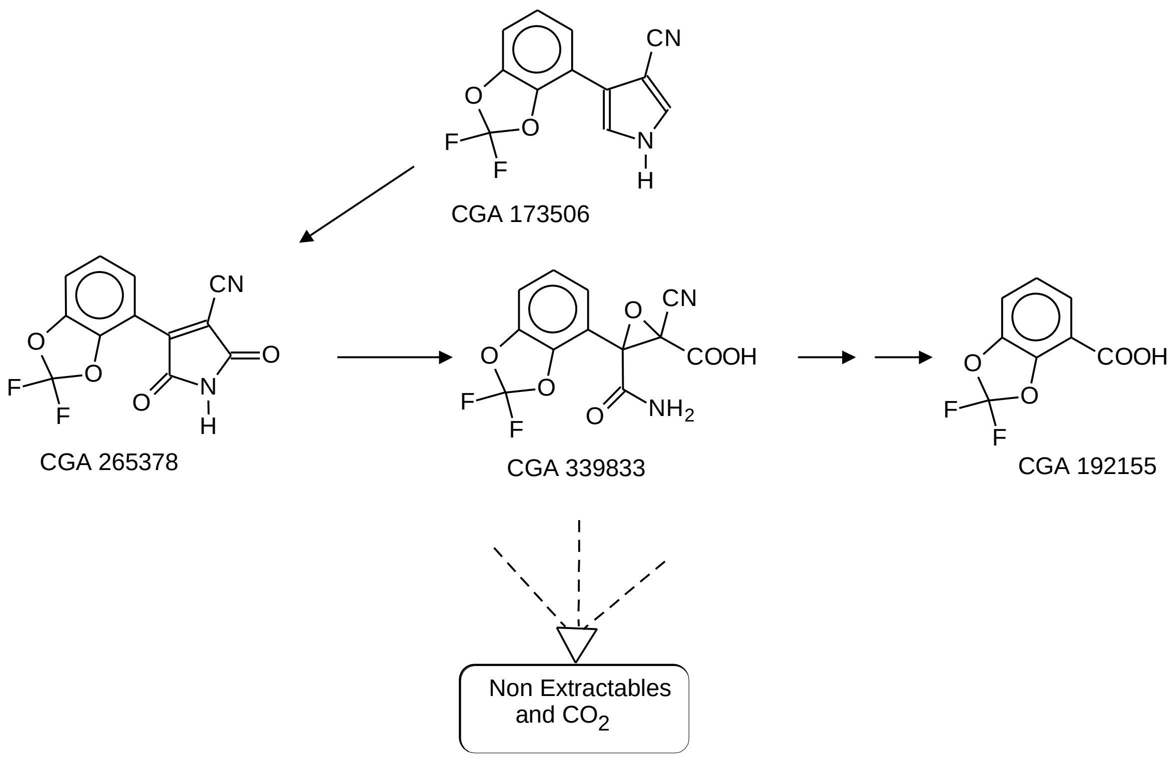
Figure 8.3-1: Proposed pathway of cymoxanil in soil



Fludioxonil

The rate of degradation in laboratory soil of fludioxonil was evaluated for Annex I Inclusion. The EU review concluded that no additional laboratory data were required at national re-registration for the rate of degradation in soils. The fate and behaviour of fludioxonil in soil is discussed in detail in the corresponding document of the EU dossier where the study references can be found. Photolysis can play a major role for the degradation pathway and degradation rate of fludioxonil in soil. Major soil metabolites are formed in light but not in the dark. Although endpoints are given in the EFSA Scientific Report for the metabolites CGA265378, CGA339833 and CGA192155, it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis. Therefore, no assessment of PEC_S and PEC_{GW} was done for these metabolites. For PEC_{SW} calculations, the metabolite CGA192155 was considered as relevant and also assessed since it is also formed in water.

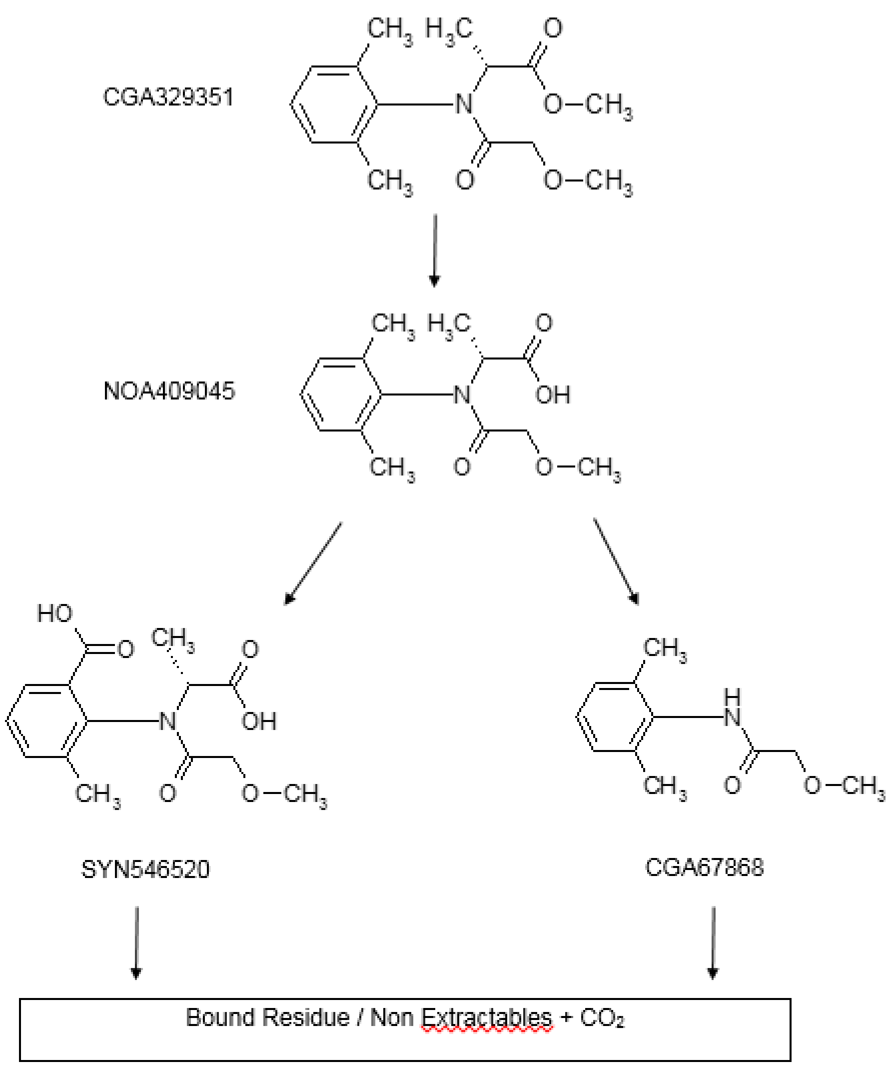
Figure 8.3-2: Proposed pathway of fludioxonil in soil



Metalaxyl-M

The rate of degradation in soil of metalaxyl-M was evaluated during the EU Review. The fate and behaviour of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 in soil are discussed in detail in the corresponding document of the EU review dossier where the study references can be found. All other metabolites shown in the degradation pathway of metalaxyl-M in soil (see Figure 8.3-3) are minor metabolites.

Figure 8.3-3: Proposed pathway of metalaxyl-M in soil



8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Cymoxanil and its metabolites

Studies on the aerobic degradation rates of cymoxanil and its metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 are considered to be data provided in support of the active substance. Unless otherwise stated, all relevant detailed experimental information has been submitted for EU review of cymoxanil (**Cymoxanil, EFSA Journal 2008; 167,1-116**).

The EU review concluded the following data should be considered at national re-registration: Rate of degradation of IN-KQ960 in soil. These data have been provided in Appendix 2 of this document.

Table 8.3-1: Summary of aerobic degradation rates for cymoxanil - laboratory studies

Cymoxanil, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (-)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Arrow	Sandy loam	6.0[a]	20	40	0.1	0.5	0.2[b]	1.4	FOMC	Yes / EFSA (2008)
Sassafras	Sandy loam	6.4[a]	25	75 (1/3 bar)	1.2	18.8	5.8[b]	17.6	FOMC	Yes / EFSA (2008)
Black Andosol	Sandy clay loam	6.8[a]	25	50	0.2	0.8	0.4[b]	5.9	FOMC	Yes / EFSA (2008)
Probstei	Sandy loam	6.5[a]	20	50	2.3	13.1	3.1[b]	6.9	FOMC	Yes / EFSA (2008)
Sermoise	Sandy loam	7.8[a]	20	50	0.7	2.3	0.6[b]	16.7	FOMC	
Evensham	Sandy clay loam	5.7[a]	20	50	2.5	33.3	7.3[b]	6.5	FOMC	
Cranfield 230	Sandy loam	4.3 ($CaCl_2$)	20	40	4.3	23.7	6.1[b]	4.3	FOMC	Yes / EFSA (2008)
Cranfield 164	Silt loam	6.4 ($CaCl_2$)	20	40	0.9	3.1	0.8	2.6	SFO	
Cranfield 115	Clay loam	7.5 ($CaCl_2$)	20	40	0.2	0.8	0.2	5.7	SFO	
Geometric mean (n=9)							1.2			
Maximum							7.3[c]			
pH-dependency:							Yes[d]			

[a] Matrix of pH-measurement not stated.
[b] SFO-DT_{50} re-calculated from FOMC-DT_{90} (FOMC-DT_{90} / 3.32).
[c] Used for 'worst case' PEC_{GW} calculations.
[d] From the degradation data for cymoxanil, EFSA concluded that the soil DT_{50} is significantly ($p < 0.05$) depending on soil pH (lower under acidic conditions).

Table 8.3-2: Summary of aerobic degradation rates for IN-U3204 - laboratory studies

IN-U3204, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (-)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction[a]**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Black Andosol	Sandy clay loam	6.8[b]	25	50	0.6	1.9	0.48	0.9	11.0	P_{SFO} -> M_{SFO}	Yes / EFSA (2008)
Cranfield 164	Silt loam	6.4 ($CaCl_2$)	20	40	0.4	1.3	0.24	0.3	26.2	P_{SFO} -> M_{SFO}	Yes / EFSA (2008)
Cranfield 115	Clay loam	7.5 ($CaCl_2$)	20	40	0.2	0.6	0.36	0.2	12.2	P_{SFO} -> M_{SFO}	
Geometric mean (n=3)								0.4			
Arithmetic mean (n=3)							0.36				
pH-dependency:							No				

[a] Formation fraction from parent.
[b] Matrix of pH-measurement not stated.

Table 8.3-3: Summary of aerobic degradation rates for IN-W3595 - laboratory studies

IN-W3595, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (-)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction[a]**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Black Andosol	Sandy clay loam	6.8 [b]	25	50	1.7	5.5	0.15	2.5	14.5	P_{SFO} -> M_{SFO}	Yes / EFSA (2008)
Sermoise	Sandy loam	7.8 [b]	20	50	2.8	9.4	0.07	2.2	69.3	P_{SFO} -> M_{SFO}	Yes / EFSA (2008)
Maximum (n=2)							0.15[c]	2.5[c]			
pH-dependency:							No				

[a] Formation fraction from parent.
[b] Matrix of pH-measurement not stated.
[c] Maximum values used in PEC calculations.

Table 8.3-4: Summary of aerobic degradation rates for IN-KQ960 - laboratory studies

IN-KQ960, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (H_2O/ $CaCl_2$)**	**t. (ºC)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction[a]**	**DT_{50} (d) 20°C pF2/10kPa**	**r^2 (-)**	**Kinetic model**	**Evaluated on EU level / Reference**
Black Andosol	Sandy clay loam	6.8[b]	25	50	7.6	25.2	0.16	11.2	19.2[c]	P_{SFO} -> $M1_{SFO}$ -> $M2_{SFO}$[d]	Yes / EFSA (2008)
Speyer 2.2	Sand	6.1/6.0	20	8.1 (1/3 bar)	2.6	8.8	-[e]	2.6	0.997	SFO	No / [redacted] (2010), DuPont-28466
Tama	Silty clay loam	6.8/6.4	20	31.1 (1/3 bar)	2.0	6.6	-[e]	2.0	0.995	SFO	No / [redacted] (2010), DuPont-28466
Lleida	Clay loam	7.9/7.7	20	26.5 (1/3 bar)	4.2	14	-[e]	4.2	0.997	SFO	No / [redacted] (2010), DuPont-28466
Nambsheim	Sandy loam	7.6/7.4	20	12.6 (1/3 bar)	3.5	11.7	-[e]	3.5	0.989	SFO	No / [redacted] (2010), DuPont-28466
Sassafras	Sandy loam	5.5/4.9	20	10.4 (1/3 bar)	2.1	7.1	-[e]	2.1	0.991	SFO	No / [redacted] (2010), DuPont-28466
						Maximum	0.16	11.2[f]			
						Geometric mean (n=6)	-	3.5			
						Geometric mean (n=5)	-	2.8[g]			
						pH-dependency:	No				

[a] Formation fraction from IN-U3204.
[b] Matrix of pH-measurement not stated.
[c] Chi^2 (%) value.
[d] M1 = IN-U3204, M2 = IN-KQ960.
[e] No data avialable, metabolite dosed study.
[f] Worst case DT_{50} value, used in PEC_S and $PEC_{SW/SED}$ calculations.
[g] Calculated excluding the soil 'Black Andosol', used in PEC_{GW} calculations.

Table 8.3-5: Summary of aerobic degradation rates for IN-JX915 - laboratory studies

IN-JX915, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (-)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction[a]**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Black Andosol	Sandy clay loam	6.8[b]	25	50	0.6	1.9	0.10	1.0	27	P_{SFO} -> M_{SFO}	Yes / EFSA (2008)
						Maximum	0.10	1.0			
						pH-dependency:	No				

[a] Formation fraction from parent.
[b] Matrix of pH-measurement not stated.

8.3.1.2 Fludioxonil and its metabolites

Studies on the degradation rates of fludioxonil and its metabolite CGA192155 are considered to be data provided in support of the active substance. Unless otherwise stated, all relevant detailed experimental information has been submitted for EU review of fludioxonil (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**).

Photolytic degradation in soil

The metabolic pathway for fludioxonil degradation in soil was determined from laboratory data. Fludioxonil is rapidly degraded in laboratory photolysis studies to form several degradation products, whilst degradation under the conditions of laboratory soil metabolism studies conducted in the absence of light was slower and no degradation products were isolated or identified. Therefore, for seed treatment use, these metabolites are not considered in PEC_S and PEC_{GW} assessments. For PEC_{SW} calculations, the metabolite CGA192155 was considered as relevant and also assessed since it is also formed in water.

Degradation in soil under dark conditions

The rate of degradation of fludioxonil under aerobic, dark conditions was investigated in various soils in the laboratory, generally at 20°C and at concentrations corresponding to application rates of 0.05 to 10 kg a.s./ha, using [4 ^{14}C]-pyrrole- and [U ^{14}C]-phenyl-labelled material under aerobic as well as under anaerobic conditions.

The observed disappearance times for 50% of fludioxonil (DT_{50lab}) under aerobic laboratory conditions were in the range of 79 days to > 365 days, mostly based on two-compartment first order degradation kinetics. In the original EU submission, re-calculation of the data was done by applying first order one compartment kinetics and normalisation to 20°C and a moisture content of 100% at pF 2. All studies were included, taking values of > 365 days as 365 days.

The RMS for the EU review proposed (DAR, 2006) that soils from the same type, which have been used in one study, were grouped together and a single mean value calculated for each soil. This further grouping of DT_{50} values for the relevant application rate subset (0.05-0.8 mg/kg) resulted in a median DT_{50lab} value of 204 days. EFSA provided another recalculation of the DT_{50lab} at pF 2 and 20°C. This gave a revised geometric mean value (n = 9) of 174.6 days (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**).

Table 8.3-6: Summary of aerobic degradation rates for fludioxonil - laboratory studies

Soil name	Soil type (USDA)	pH	t. (°C)	% FC	DT_{50} (d)	DT_{50} (d) 20°C, pF2/10kPa	DT_{50} (d) grouped[a]	Chi² (%)	Kinetic model	Evaluated on EU level / Reference
Les Evouettes	Sandy Loam	5.4	20	60 %	> 365	> 365	160	n.a.	SFO	Yes / EFSA (2007)
	Sandy Loam			30 %	365	255				
	Sandy Loam			60 %	365	352				
	Sandy Loam		10	60 %	365	347	-[b]	n.a.	-	
Stein	Sandy Loam	7.0	20	58 %	373	218	186	n.a.	SFO	Yes / EFSA (2007)
Neuhofen	Sand	6.6		93 %	> 365	> 365	569	n.a.	SFO	
Stein	Sandy Loam	7.0	20	56 %	151	100	100	n.a.	SFO	Yes / EFSA (2007)
	Sandy Loam		30	56 %	79	123	-[b]	n.a.	SFO	
Stein	Sandy Loam	7.0	20	56 %	313	204	169	n.a.	SFO	Yes / EFSA (2007)
Collombey	Loamy Sand	7.2	20	61 %	350	248	177	n.a.	SFO	Yes / EFSA (2007)
Les Evouettes	Silt Loam	7.3	20	52 %	342	216	151	n.a.	SFO	
Les Evouettes	Silt Loam	7.0	20	75 %	143	146	120	n.a.	SFO	Yes / EFSA (2007)
	Silt Loam		20	75 %	220	200				
	Silt Loam		20	75 %	183	168				
Les Evouettes	Silt Loam	7.0	20	75 %	232	190	164	n.a.	SFO	Yes / EFSA (2007)
						Geometric mean (n=9)	174.6[c]			
						pH-dependency:	No			

[a] Grouping and re-fitting of normalised values detailed in [redacted] (2006)
[b] Duplicated trial excluded from calculation
[c] The overall DT_{50} value used in the PEC_{GW} modelling has been re-calculated from the list of endpoints (median 164 days, EFSA, 2007), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of median. The individual DT_{50} values from which the geometric mean is calculated, are those established in Fludioxonil, EFSA Scientific Report (2007) 110,1-85.

Table 8.3-7: Summary of aerobic degradation rates for CGA192155 - laboratory studies

CGA192155, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (-)**	**t. (ºC)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	Silt loam	7.18[a]	20	40	15.7	52.1	-[b]	9.56[c]	n.a.	SFO	Yes / EFSA (2007)
Pappelacker	Loamy sand	7.43[a]	20	40	23.8	79.1	-[b]	18.3	n.a.	SFO	
Weide	Sandy loam	7.36[a]	20	40	16.1	53.5	-[b]	10.8	n.a.	SFO	
Artihmetic mean (n=3)								12.9			
Geometric mean (n=3)								12.36			
pH-dependency:								No			

[a] Matrix of pH-measurement not stated.
[b] No data avialable, metabolite dosed study.
[c] Value from the original study report [redacted]., 2002, wrongly reported in the EFSA Scientific Report (2007); 110,1-85 as 8.56.

8.3.1.3 Metalaxyl-M and its metabolites

Studies on aerobic degradation rates of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 are considered to be data provided in support of the active substance. Unless otherwise stated, all relevant detailed experimental information has been submitted for EU review of metalaxyl-M, where all references can be found **(Metalaxyl-M, EFSA Journal 2015; 13(3):3999)**.

Table 8.3-8: Summary of aerobic degradation rates for metalaxyl-M - laboratory studies

Metalaxyl-M, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	loam	7.25	20ºC	40%	3.97	13.2	2.6[a]	3.66	SFO	Yes / EFSA (2015)
Gartenacker	loam	7.25	20ºC	40%	5.73	19.0	3.75[a]	3.75	SFO	Yes / EFSA (2015)
Gartenacker	silt loam	7.6	20ºC	pF2	3.3	10.9	3.3	3.3	SFO	Yes / EFSA (2015)
Les Evouettes	silt loam	7.3	20ºC	40%	3.90	13.0	2.38	7.31	SFO	Yes / EFSA (2015)
Collombey	loamy sand	7.4	20ºC	40%	8.13	27.0	6.28	1.38	SFO	Yes / EFSA (2015)
Birkenheide	sandy loam	5.6	20ºC	40%	26.4	87.6	22.5	2.70	SFO	Yes / EFSA (2015)
Pappelacker	sandy	7.5	20ºC	40%	10.1	33.6	6.69	4.43	SFO	Yes /

Metalaxyl-M, Laboratory studies, aerobic conditions										
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
	loam									EFSA (2015)
Marsillargues	silty clay	8.0	20ºC	pF2	14.6	48.5	14.6	5.6	SFO	Yes / EFSA (2015)
Gardner	sandy loam	7.7	20ºC	pF2	8.2	27.3	8.2	6.5	SFO	Yes / EFSA (2015)
18 Acres	sandy clay loam	5.8	20°C	pF2	3.8	12.7	3.8	4.5	SFO	Yes / EFSA (2015)
San Miguel	Sandy loam	7.4	20°C	pF2	73.1	243	73.1	2.3	SFO	Yes / EFSA (2015)
Median (n=10)							6.5			
Geometric mean (n=10)							7.74[b]			
pH-dependency:							No			

[a] For similar soils geometric mean values were generated before calculating the overall geometric mean DT_{50}.
[b] The overall DT_{50} value used in the PEC_{GW} modelling has been re-calculated from the list of endpoints (median 6.5 days, EFSA, 2015), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of median. The individual DT_{50} values from which the geometric mean is calculated, are those established in metalaxyl-M, EFSA Journal 2015;13(3):3999.

Table 8.3-9: Summary of aerobic degradation rates for NOA409045 - laboratory studies

NOA409045, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (ºC)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	loam	7.25	20ºC	40%	4.15	13.8	0.70	2.72[a]	9.04	SFO	Yes / EFSA (2015)
Gartenacker	loam	7.25	20ºC	40%	15.5	51.4	0.72	10.2[a]	9.80	SFO	Yes / EFSA (2015)
Gartenacker	silt loam	7.6	20°C	pF2	7.1	23.7	1	7.1	13.6	SFO	Yes / EFSA (2015)
Birkenheide	sandy loam	5.57	20ºC	40%	96.6	321	0.66	82.3[a]	2.61	SFO	Yes / EFSA (2015)
Birkenheide	sandy loam	5.57	20ºC	40%	69.4	230	-	59.1[a]	2.18	SFO	Yes / EFSA (2015)
Pappelacker	sandy loam	7.5	20ºC	40%	7.88	26.2	0.83	5.22	10.3	SFO	Yes / EFSA (2015)
Marsillargues	silty clay	8.0	20°C	pF2	161	536	0.78	161	8.8	SFO	Yes / EFSA (2015)
Gardner	sandy loam	7.7	20°C	pF2	52.4	174	0.91	52.4	11.0	SFO	Yes / EFSA (2015)
18 Acres	sandy clay loam	5.8	20°C	pF2	32.3	107	0.81	32.3	12.8	SFO	Yes / EFSA (2015)
San Miguel	sandy loam	7.4	20°C	pF2	200	666	0.56	200	5.2	SFO	Yes / EFSA (2015)
Geometric mean (n=8)							-	30.5[b]			
Arithmetic mean (n=8)							0.783[c]				
pH-dependency:								No			

[a] For similar soils geometric mean values were generated before calculating the overall geometric mean DT_{50}.
[b] The overall DT_{50} value used in the PEC_{GW} modelling has been re-calculated. The geomean value of 31.3 days EFSA, 2015 was incorrectly calculated according to treatment for point [a] above, followed by determining geomean for the eight different soils. The individual DT_{50} values from which the geometric mean is calculated, are those established in Metalaxyl-M, EFSA Journal 2015;13(3):3999.
[c] Kinetic formation fraction from parent

Table 8.3-10: Summary of aerobic degradation rates for CGA67868 - laboratory studies

CGA67868, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	silt loam	7.6	20°C	pF2	1.6	5.4	0.53	1.6[a]	10.9	SFO	Yes / EFSA (2015)
Gartenacker	silt loam	7.2	20°C	pF2	2.1	6.8	-	2.1[a]	9.1	SFO	Yes / EFSA (2015)
18 Acres	sandy loam	5.9	20°C	pF2	2.6	8.7	-	2.6	5.6	SFO	Yes / EFSA (2015)
Gardner	sandy loam	7.6	20°C	pF2	4.9	16.2	-	4.9	3.3	SFO	Yes / EFSA (2015)
Geometric mean (n=3)								2.9[b]			
Formation fraction (n=1)							0.53[c]				
pH-dependency:								No			

[a] For similar soils geometric mean value generated before calculating the overall geometric mean DT_{50}.
[b] Geometric mean 2.9 days EFSA, 2015
[c] Kinetic formation fraction from NOA409045

Table 8.3-11: Summary of aerobic degradation rates for SYN546520 - laboratory studies

SYN546520, Laboratory studies, aerobic conditions											
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t (°C)**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**Formation fraction**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Gartenacker	silt loam	7.4	20°C	pF2	42.1	139.8	-	42.1	5.5	SFO	Yes / EFSA (2015)
Marsillargues	silty clay	8.1	20°C	pF2	74.9	248.7	-	74.9	4.3	SFO	Yes / EFSA (2015)
18 Acres	sandy clay loam	6.2	20°C	pF2	287.9	956.5	-	287.9	1.9	SFO	Yes / EFSA (2015)
Geometric mean (n=3)								96.8[a]			
Formation fraction (from NOA409045)							0.47[b] / 0.1[c]				
pH-dependency:							No				

[a] Geometric mean DT_{50} 96.8 days, EFSA 2015
[b] Kinetic formation fraction from NOA409045. Calculated as 1 – f.f.(CGA67868), EFSA 2015; used as Tier 1 in PEC_{GW} calculations.
[c] Formation fraction derived from inverse modelling, EFSA 2015; used as Tier 2 in PEC_{GW} calculations.

The EU active substance zRMS Belgium has agreed to review the new kinetics data for deriving the formation fraction for SYN546520 (as this was an open point in the EFSA conclusion). The outcome should be available in time for the product renewal evaluation.

However, if this is not the case please review the new kinetics evaluations in Appendix A 3.1 and A 3.2, leading to the conclusion that 0.1 formation fraction for SYN546520 is the appropriate modelling endpoint based on available study data.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

8.3.2.1 Cymoxanil and its metabolites

Studies on anaerobic degradation rates of cymoxanil and its metabolites are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of cymoxanil (**Cymoxanil, EFSA Journal 2008; 167:1-116**).

From the EU Review it was concluded that degradation of cymoxanil and its metabolites under anaerobic conditions is not considered relevant and no anaerobic studies are required (**Cymoxanil, EFSA Journal 2008; 167:1-116**).

8.3.2.2 Fludioxonil and its metabolites

Studies on anaerobic degradation rates of fludioxonil and its metabolites are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of fludioxonil (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**).

The laboratory soil degradation studies of the active substance showed that under light exclusion aerobic biological degradation represents the main dissipation process, furthermore as a seed treatment the product is unlikely to be exposed to anaerobic conditions and therefore anaerobic degradation is not considered to be relevant and no anaerobic studies are required.

8.3.2.3 Metalaxyl-M and its metabolites

Studies on anaerobic degradation rates of metalaxyl-M are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

From the EU Review it was concluded that metalaxyl-M degrades more slowly under anaerobic conditions than under aerobic conditions with the same route of degradation (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

8.4 Field studies (KCP 9.1.1.2)

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

Studies on field dissipation rates, while commonly performed with a formulation, are considered to be data provided in support of the active substance.

8.4.1.1 Cymoxanil and its metabolites

Field dissipation studies were not submitted and not required for cymoxanil since aerobic degradation in the laboratory resulted in half-lives far below the trigger of 60 days (**Cymoxanil, EFSA Journal 2008; 167:1-116**).

8.4.1.2 Fludioxonil and its metabolites

Studies on field dissipation rates, while commonly performed with a formulation, are considered to be data provided in support of the active substance. The rate of degradation in soil of fludioxonil was evaluated during the Annex I Inclusion (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**). However, the maximum DT_{50} of 43 days given by EFSA (2007) is not relevant for seed treatment uses as it includes photolytic degradation.

The following study on field dissipation rates performed on fludioxonil has not previously been submitted for review/reviewed under Council Directive 91/414/EEC and is provided in support of this assessment. A summary of this study is supplied in Appendix 2 of this document.

A trial was carried out in Switzerland during 2003 to compare dissipation of fludioxonil when applied as a seed treatment, a topical spray and a topical spray incorporated ([redacted], 2004). The residue data from the seed treatment was erratic and did not allow the calculation of a dissipation rate. The broadcast spray with incorporation, however, gave a DT_{50} of 137 days and it is considered that this is an appropriately conservative value to use for field dissipation. The results of this study are summarised in Table 8.4-1.

Trigger endpoints

Table 8.4-1: Summary of aerobic degradation rates for fludioxonil - field studies: Trigger endpoints ([redacted], 2004)

Fludioxonil, Field studies – Trigger endpoints									
Soil type (USDA)	**Plot No./ plot type**	**pH (KCl)**	**Sampling depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Kinetic parameters**	**r^2 (-)**	**Kinetic model**	**Evaluated on EU level / Reference**
Applied as a seed treatment									
Sandy Loam	1 / bare soil	7.3[a]	0-30	NC	NC	-	NC	-	No / [redacted] (2004)
	2 / bare soil, sterilised seed		0-30	NC	NC	-	NC	-	No / [redacted] (2004)
	3 / over-sown with turf		0-30	NC	NC	-	NC	-	No / [redacted] (2004)

Fludioxonil, Field studies – Trigger endpoints									
Soil type (USDA)	**Plot No./ plot type**	**pH (KCl)**	**Sampling depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Kinetic parameters**	**r^2 (-)**	**Kinetic model**	**Evaluated on EU level / Reference**
			Maximum (n=3)	-	-				
Applied and incorporated									
Sandy Loam	4 / bare soil	7.3[a]	0-30	137	NC	-	0.804	FOMC	No / [redacted] (2004)
	5 / covered		0-30	55	NC	-	0.935	FOMC	No / [redacted] (2004)
	6 / over-sown with turf		0-30	112	NC	-	0.761	FOMC	No / [redacted] (2004)
			Maximum (n=3)	137					
Applied and not incorporated									
Sandy Loam	7 / bare soil	7.3[a]	0-30	19	72	-	0.762	FOMC	No / [redacted] (2004)
	8 / covered		0-30	NC	NC	-	NC	-	No / [redacted] (2004)
	9 / over-sown with turf		0-30	12	NC	-	0.973	FOMC	No / [redacted] (2004)
			Maximum (n=3)	19					

[a] Mean value representing depth of 0-30 cm (n=3)
NC: Not calculable within the 90 day timescale of the study

Modelling endpoints

Normalised field aerobic degradation modelling endpoints for fludioxonil and its metabolites are currently not available.

8.4.1.3 Metalaxyl-M and its metabolites

The field dissipation rate of metalaxyl-M and its metabolites was evaluated during the EU review. No additional studies have been performed. Unless otherwise stated, all relevant detailed experimental information has been submitted for EU review of metalaxyl-M, where all references can be found (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

Trigger endpoints

Table 8.4-2: Summary of aerobic degradation rates for metalaxyl-M - field studies: Trigger endpoints

Metalaxyl-M, Field studies – Trigger endpoints								
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Applied to bare ground								
Sandy loam	Elena (IT)	7.5	0-30	11.9	39.6	18.1	SFO	Yes / EFSA (2015)
Silty clay loam	Marsillargues (FR)	7.4	0-30	13.5	44.7	26.5	SFO	Yes / EFSA (2015)
Silty clay loam	Bastia di Rovo-lon (IT)	7.3	0-30	18.1	60.1	14.9	SFO	Yes / EFSA (2015)
Loam	Vouvry (CH)	7.4	0-30	4.6	15.3	12.5	SFO	Yes / EFSA (2015)
Silty clay	Vouvry (CH)	7.1	0-30	12.4	41.3	14.2	SFO	Yes / EFSA (2015)
Loamy sand	Sevilla (SP)	7.8	0-30	15.3	50.9	9.02	SFO	Yes / EFSA (2015)
Loam	Aimargues (FR)	7.4	0-30	30.9	102.6	11.4	SFO	Yes / EFSA (2015)
Loamy sand	Middelfart (DK)	6.9	0-30	20.9	69.5	5.74	SFO	Yes / EFSA (2015)
Loam	Sept Saux (FR)	7.8	0-30	9.3	30.7	14.8	SFO	Yes / EFSA (2015)
Silty loam	Lower Saxony (DE)	6.0	0-30	19.7	65.4	11.6	SFO	Yes / EFSA (2015)
Geometric mean (n=10)				14.1	46.7			
Maximum				**30.9**	102.6			

Table 8.4-3: Summary of aerobic degradation rates for NOA409045 - field studies: Trigger endpoints

NOA409045, Field studies – Trigger endpoints								
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Applied to bare ground								
Sandy loam	Elena (IT)	7.5	0-30	16.0	53.3	26.8	SFO	Yes / EFSA (2015)
Silty clay loam	Marsillargues (FR)	7.4	0-30	20.5	68.0	16.4	SFO	Yes / EFSA (2015)
Silty clay loam	Bastia di Rovo-lon (IT)	7.3	0-30	14.9	49.6	59.0	SFO	Yes / EFSA (2015)

NOA409045, Field studies – Trigger endpoints								
Soil type (USDA)	**Location**	**pH (H_2O)**	**Depth (cm)**	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Loam	Vouvry (CH)	7.4	0-30	5.8	19.2	25.7	SFO	Yes / EFSA (2015)
Silty clay	Vouvry (CH)	7.1	0-30	8.3	27.7	44.7	SFO	Yes / EFSA (2015)
Loamy sand	Sevilla (SP)	7.8	0-30	Uncertain[a]	Uncertain[a]	n.a.	SFO	Yes / EFSA (2015)
Loam	Aimargues (FR)	7.4	0-30	15.9	52.8	20.7	SFO	Yes / EFSA (2015)
Loamy sand	Middelfart (DK)	6.9	0-30	39.8	132.2	20.9	SFO	Yes / EFSA (2015)
Loam	Sept Saux (FR)	7.8	0-30	27.1	89.9	34.5	SFO	Yes / EFSA (2015)
Silty loam	Lower Saxony (DE)	6.0	0-30	30.2	100	22.3	SFO	Yes / EFSA (2015)
Geometric mean (n=9)				17.1	56.6			
Maximum				**39.8**	132.2			

[a] No reliable endpoint could be derived, due to poor kinetic fitting. The default value of 1000 days for an uncertain kinetic fit was not considered relevant as sufficient other data was available.

Modelling endpoints

Modelling endpoints derived from field dissipation studies were not used in the risk assessment.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 Cymoxanil

Based on laboratory data, cymoxanil, IN-U3204, IN-W359, JX915 and IN-KQ960 are not likely to accumulate in soil. Hence, calculations to estimate potential accumulation were not undertaken.

8.4.2.2 Fludioxonil

The low use rates and the observed dissipation half-lives under environmental conditions indicate that soil accumulation of fludioxonil resulting from seed treatment is not of concern. However, given the field DT_{50} and DT_{90} of fludioxonil are > 100 d and 365 d, respectively, the potential for accumulation of fludioxonil has been assessed by calculation (see chapter 8.7).

8.4.2.3 Metalaxyl-M and its metabolites

Based on laboratory and field dissipation data, metalaxyl-M, NOA409045 and CGA67868 are not likely to accumulate in soil. Hence, calculations to estimate potential accumulation were not undertaken.
Given the DT_{50} and DT_{90} of SYN546520 are > 100 d and 365 d respectively, as shown in chapter 8.3.1, the potential for accumulation has been assessed by calculation (see chapter 8.7).

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.

8.5.1 Cymoxanil and its metabolites

The mobility in soil of cymoxanil and its metabolites was evaluated during the EU review (**Cymoxanil, EFSA Journal 2008; 167:1-116**) and unless otherwise stated all relevant experimental information and references can be found therein. Additional data were not required as a result of the review, however, in order to meet the latest guideline (EFSA Journal 2013; 11(2):3114) which recommends the use of the geometric mean instead of the arithmetic mean, K_{OC} geometric mean value was recalculated. The individual values from which the geometric mean is calculated, are those established in **Cymoxanil, EFSA Journal 2008; 167:1-116**. Additional information on the sorption behavior of metabolite KQ960 is detailed in Appendix 2 and used for calculation of K_{OC} geometric mean.

The soil adsorption data for of cymoxanil and its metabolites IN-W3595, IN-R3273, IN-JX915 IN-U3204, IN-KQ960, IN-T4226 and IN-KP533 are presented in Table 8.5-1 to Table 8.5-8.

Table 8.5-1: Summary of soil adsorption/desorption for cymoxanil

Cymoxanil							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Speyer 2.1, DE	silt loam	0.59	6.9	0.090	15.1	0.88	Yes / EFSA (2008)
Midwest 1, US	sandy loam	1.0	5.7	0.910	87.1	0.87	Yes / EFSA (2008)
Cranfield 115, UK	loamy sand	1.6	8.1	0.462	28.9	0.81	Yes / EFSA (2008)
Cranfield 164, UK	clay	2.0	7.2	0.856	43.4	0.87	Yes / EFSA (2008)
				Geometric mean (n=4)	**35.8**[a]		
				Arithmetic mean (n=4)	**43.6**	**0.86**	
				pH-dependency:	No		

[a] K_{FOC} value used in PEC_{GW} modelling has been re-calculated from the list of endpoints (arithmetic mean K_{FOC} 43.6, EFSA 2008), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of arithmetic mean. The individual K_{FOC} values from which the geometric mean is calculated, are those established in Cymoxanil, EFSA Journal 2008; 167:1-116.

Table 8.5-2: Summary of soil adsorption/desorption for IN-W3595

IN-W3595							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (-)[a]**	**K_D (mL/g)**	**K_{OC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Loamy sand, US	loamy sand	2.3	4.6	0.63	27.4	-	Yes / EFSA (2008)
Sandy loam	sandy loam	0.99	7.6	0.026	2.6	-	Yes / EFSA (2008)
Silt loam, US	silt loam	3.2	7.8	0.074	2.3	-	Yes / EFSA (2008)
Sandy loam, US	sandy loam	0.46	6.4	0.020	4.3		Yes / EFSA (2008)
Arithmetic mean (n=4)					**9.2**	**1.0[b]**	
Worst case (n=4)					**2.3[c]**	-	
K_{OC} acidic					**33.3[d]**	-	
K_{OC} alkaline					**2.3[d]**	-	
pH-dependency:					Yes (pK_a = 5.2)		

[a] Matrix of pH measurement unknown.
[b] PRAPeR 32 agreed default value.
[c] Worst case K_{FOC} value used in PEC_{SW} calculations
[d] Used in PEC_{GW} calculations with FOCUS PEARL in accordance with Cymoxanil, EFSA Journal 2008; 167,1-116.

Table 8.5-3: Summary of soil adsorption/desorption for IN-R3273

IN-R3273							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (-)[a]**	**K_D (mL/g)**	**K_{OC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Loamy sand, US	loamy sand	2.3	4.6	0.59	25.7	-	Yes / EFSA (2008)
Sandy loam	sandy loam	0.99	7.6	0.49	49.5	-	Yes / EFSA (2008)
Silt loam, US	silt loam	3.2	7.8	1.5	46.9	-	Yes / EFSA (2008)
Sandy loam, US	sandy loam	0.46	6.4	0.21	45.7	-	Yes / EFSA (2008)
Arithmetic mean (n=4)					**42**	**1.0[b]**	
Worst case (n=4)					**25.7[c]**	-	
pH-dependency:					Yes		

[a] Matrix of pH measurement unknown.
[b] PRAPeR 32 agreed default value.
[c] Worst case K_{FOC} value used in PEC_{SW} calculations

Table 8.5-4: Summary of soil adsorption/desorption for IN-JX915

IN-JX915							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (-)[a]**	**K_D (mL/g)**	**K_{OC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Loamy sand, US	loamy sand	2.3	4.6	0.13	5.4	-	Yes / EFSA (2008)
Sandy loam	sandy loam	0.99	7.6	0.34	34.3	-	Yes / EFSA (2008)
Silt loam, US	silt loam	3.2	7.8	0.66	20.6	-	Yes / EFSA (2008)
Sandy loam, US	sandy loam	0.46	6.4	0.021	4.4	-	Yes / EFSA (2008)
				Geometric mean (n=4)	**11.38[c]**		
				Arithmetic mean (n=4)	**16.2**	**1.0[b]**	
				pH-dependency:	No		

[a] Matrix of pH measurement unknown.
[b] PRAPeR 32 agreed default value.
[c] K_{FOC} value used in PEC_{GW} modelling has been re-calculated from the list of endpoints (arithmetic mean K_{FOC} 16.2, EFSA 2008), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of arithmetic mean. The individual K_{FOC} values from which the geometric mean is calculated, are those established in Cymoxanil, EFSA Journal 2008; 167:1-116.

Table 8.5-5: Summary of soil adsorption/desorption for IN-U3204

IN-U3204						
Soil type	**OC (%)**	**pH (H_2O)**	**K_D (mL/g)**	**K_{OC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
HPLC method	-	-	-	**27.9**	**1.0[a]**	Yes / EFSA (2008)
		pH-dependency:	Not applicable			

[a] PRAPeR 32 agreed default value.

Table 8.5-6: Summary of soil adsorption/desorption for IN-KQ960

IN-KQ960							
Soil name	**Soil type**	**OC (%)**	**pH (H_2O)**	**K_D (mL/g)**	**K_{OC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
-	HPLC method	-	-	-	21.6[a]	1.0[a,b]	Yes / EFSA (2008)
Gross-Umstadt (GER)	Loam	1.1	6.7	0.0357	3.23	0.83	No / [redacted] (2010), DuPont-28467
Drummer (USA)	Clay loam	3.1	5.8	0.1747	5.56	0.84	No / [redacted] (2010), DuPont-28467
Lleida (ESP)	Clay loam	1.2	7.7	0.1097	8.99	0.96	No / [redacted] (2010), DuPont-28467
Nambsheim (FRA)	Sandy loam	2.8	7.4	0.0459	2.82	0.85	No / [redacted] (2010), DuPont-28467
Sassafras (USA)	Sandy loam	1.3	4.9	0.0178	2.36	1.07	No / [redacted] (2010), DuPont-28467
				Geometric mean (n=5)	**4.0**		
				Arithmetic mean (n=5)	**4.6**	**0.91**	
				pH-dependency:	No		

[a] Excluded from calculations of mean values.
[b] PRAPeR 32 agreed default value.

Table 8.5-7: Summary of soil adsorption/desorption for IN-T4226

IN-T4226						
Soil type	**OC (%)**	**pH (H_2O)**	**K_D (mL/g)**	**K_{OC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
HPLC method	-	-	-	**17.7**	**1.0[a]**	Yes / EFSA (2008)
		pH-dependency:	Not applicable			

[a] PRAPeR 32 agreed default value

Table 8.5-8: Summary of soil adsorption/desorption for IN-KP533

IN-KP533						
Soil type	**OC (%)**	**pH (H_2O)**	**K_D (mL/g)**	**K_{OC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
HPLC method	-	-	-	**12.9**	**1.0**[a]	Yes / EFSA (2008)
pH-dependency:			Not applicable			

[a] PRAPeR 32 agreed default value

8.5.2 Fludioxonil and its metabolites

The mobility in soil of fludioxonil and its metabolite was evaluated during the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**) and unless otherwise stated all relevant experimental information and references can be found therein. Additional data were not required as a result of the review, however, in order to meet the latest guideline (EFSA Journal 2013; 11(2):3114) which recommends the use of the geometric mean instead of the arithmetic mean, K_{OC} geometric mean value was recalculated. The individual values from which the geometric mean is calculated, are those established in **Fludioxonil, EFSA Scientific Report (2007); 110:1-85**.

The soil adsorption data for fludioxonil and CGA192155 are presented in Table 8.5-9 to Table 8.5-10.

Table 8.5-9: Summary of soil adsorption/desorption for fludioxonil

Fludioxonil							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Gleadthorpe	Sand	1.7	6.4	770	46000	0.95	Yes / EFSA (2007)
Somersham	Sandy loam	2.4	6.5	290	12000	0.81	
Sandiacre	Sandy silt loam	3.5	6.9	7300	210000	1.14	
Goole	Sandy silt loam	2.8	7.9	2100	75000	0.92	
Ramsey	Silty clay loam	15.8	6.6	61000	385000	1.19	
Geometric mean (n=5)					**80341**[a]	-	
Artihmetic mean (n=5)					**145600**	**1.0**	
pH-dependency					No		

[a] K_{FOC} value used in PEC_{GW} modelling has been re-calculated from the list of endpoints (arithmetic mean K_{FOC} 145600, EFSA 2007), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of arithmetic mean. The individual K_{FOC} values from which the geometric mean is calculated, are those established in Fludioxonil, EFSA Scientific Report (2007); 110:1-85.

Table 8.5-10: Summary of soil adsorption/desorption for CGA192155

CGA192155							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Lakeland	Sand	0.58	5.3	0.246	42.4	0.798	Yes / EFSA (2007), [redacted] (1996c)
Hanford	Sandy loam	0.23	7.4	0.063	27.3	0.841	
Collamer	Loam	2.15	6.5	0.266	12.4	0.811	
Niagara	Loam	2.38	6.7	0.278	11.7	0.769	
				Arithmetic mean (n=4)	**23.5**	**0.80**	
				pH-dependency:	No		

8.5.3 Metalaxyl-M and its metabolites

The mobility in soil of metalaxyl-M and its metabolites was evaluated during the EU review (**Metalaxyl-M; EFSA Journal 2015; 13(3):3999**) and unless otherwise stated all relevant experimental information and references can be found therein. Additional data were not required as a result of the review, however, in order to meet the latest guideline (EFSA Journal 2013; 11(2):3114) which recommends the use of the geometric mean instead of the arithmetic mean, K_{OC} geometric mean value was recalculated. The individual values from which the geometric mean is calculated, are those established in **Metalaxyl-M, EFSA Journal 2015; 13(3):3999**.

The soil adsorption data for metalaxyl-M, NOA409045, CGA67868 and SYN546520 are presented in Table 8.5-11 to Table 8.5-14.

Table 8.5-11: Summary of soil adsorption/desorption for metalaxyl-M

Metalaxyl-M							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Maryland	clay	2.82	5.9	8.01	283.8	1.16	Yes / EFSA (2015)
Maryland	sand	0.53	6.5	0.157	29.6	0.795	Yes / EFSA (2015)
Mississippi	loam	0.71	7.6	1.41	199.8	1.31	Yes / EFSA (2015)
Collombey	sand	1.28	7.8	0.43	33.6	0.83	Yes / EFSA (2015)
Lakeland	sand	0.696	6.3	0.48	69.0	0.79	Yes / EFSA (2015)
Les Evouettes	loam	2.09	6.1	0.87	41.6	0.77	Yes / EFSA (2015)
Vetroz	sandy clay	3.25	6.7	1.40	43.1	0.83	Yes /

Metalaxyl-M							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
	loam						EFSA (2015)
Mississippi	clay	1.33	7.0	7.61	570	1.45	Yes / EFSA (2015)
Maryland	sand	0.348	5.4	0.0700	20	0.892	Yes / EFSA (2015)
Washington	loam	1.51	7.0	1.30	86	1.05	Yes / EFSA (2015)
Borstel	loamy sand	1.2	5.0	0.480	40.0	0.923	Yes / EFSA (2015)
Pappelacker	loamy sand	1.1	7.6	0.318	28.9	0.900	Yes / EFSA (2015)
Gartenacker	silt loam	2.08	7.3	0.644	31.0	0.908	Yes / EFSA (2015)
Vetroz	silt loam	4.7	7.2	1.67	35.5	0.928	Yes / EFSA (2015)
Illarsaz	silt loam	19.8	6.7	7.88	39.8	0.929	Yes / EFSA (2015)
Birkenheide	sandy loam	0.84	5.57	0.339	40.4	0.963	Yes / EFSA (2015)
Pappelacker	sandy loam	1.56	7.47	0.480	30.8	0.956	Yes / EFSA (2015)
Gartenacker	silt loam	1.81	7.30	0.700	38.7	0.937	Yes / EFSA (2015)
Vetroz	silt loam	1.77	7.70	0.717	40.5	0.934	Yes / EFSA (2015)
Birkenheide	sandy loam	0.94	5.65	0.372	39.6	0.92	Yes / EFSA (2015)
Gartenacker	silt loam	1.97	7.6	0.5	26	0.979	Yes / EFSA (2015)
18 Acres	sandy clay loam	3.19	5.8	0.9	29	0.910	Yes / EFSA (2015)
Marsillargues	silty clay	1.04	8	0.7	58	0.942	Yes / EFSA (2015)
Gardner	sandy loam	2.84	7.7	1.9	67	0.923	Yes / EFSA (2015)
Work Ranch	sandy loam	2.44	7.4	1.3	52	0.954	Yes / EFSA (2015)
				Geometric mean (n=25)	**50.63**[a]		
				Median (n=25)	**40**		
				Arithmetic Mean (n=25)		**0.955**	
				pH-dependency:	No		

[a] K_{FOC} value used in PEC_{GW} modelling has been re-calculated from the list of endpoints (median K_{FOC} 40, EFSA 2015), following

the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of median. The individual K_{FOC} values from which the geometric mean is calculated, are those established in Metalaxyl-M, EFSA Journal 2015; 13(3):3999.

Table 8.5-12: Summary of soil adsorption/desorption for NOA409045

NOA409045							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Mississippi	clay	1.22	6.1	0.875	72	0.947	Yes / EFSA (2015)
Maryland	sand	0.348	5.4	0.124	36	0.927	Yes / EFSA (2015)
California	sandy loam	0.58	6.9	0.0175	3	0.867	Yes / EFSA (2015)
Washington	loam	1.28	7.0	0.105	8	0.909	Yes / EFSA (2015)
Arizona	clay loam	0.58	7.9	0.0992	17	0.929	Yes / EFSA (2015)
Les Evouettes	loam	1.4	5.5	0.3	22	0.91	Yes / EFSA (2015)
Staffort	sandy loam	0.77	5.2	0.120	15.4	0.935	Yes / EFSA (2015)
Gartenacker	loam	2.40	7.2	0.210	8.88	0.960	Yes / EFSA (2015)
Vetroz	silt loam	4.39	7.1	0.440	9.94	0.956	Yes / EFSA (2015)
Birkenheide	sandy loam	0.84	5.57	0.131	15.6	0.907	Yes / EFSA (2015)
Pappelacker	sandy loam	1.56	7.47	0.139	8.9	0.940	Yes / EFSA (2015)
Gartenacker	silt loam	1.81	7.30	0.205	11.3	0.918	Yes / EFSA (2015)
Vetroz	silt loam	1.77	7.70	0.173	9.8	0.930	Yes / EFSA (2015)
Birkenheide	sandy loam	0.94	5.65	0.122	12.9	0.956	Yes / EFSA (2015)
				Geometric mean (n=14)	**13.44[a]**		
				Median (n=14)	**12.1**		
				Arithmetic Mean (n=14)		**0.928**	
				pH-dependency:	No		

[a] K_{FOC} value used in PEC_{GW} modelling has been re-calculated from the list of endpoints (median K_{FOC} 12.1, EFSA 2015), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of arithmetic mean or median. The individual K_{FOC} values from which the geometric mean is calculated, are those established in Metalaxyl-M, EFSA Journal 2015; 13(3):3999.

Table 8.5-13: Summary of soil adsorption/desorption for CGA67868

CGA67868							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Gartenacker	silt loam	2.0	7.6	0.4	20	0.822	Yes / EFSA (2015)
18 Acres	sandy clay loam	3.2	5.5	0.5	16	0.879	Yes / EFSA (2015)
Marsillargues	silty clay	1.2	7.8	0.2	20	0.794	Yes / EFSA (2015)
Gardner	sandy loam	2.8	7.3	0.5	19	0.816	Yes / EFSA (2015)
Madera	sandy loam	0.7	6.9	0.1	20	1.169	Yes / EFSA (2015)
				Geometric mean (n=5)	**18.93**[a]		
				Arithmetic Mean (n=5)	**19.0**	**0.896 (rounded to 0.9)**	
				pH-dependency:	No		

[a] K_{FOC} value used in PEC_{GW} modelling has been re-calculated from the list of endpoints (arithmetic mean K_{FOC} 19, EFSA 2015), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of arithmetic mean. The individual K_{FOC} values from which the geometric mean is calculated, are those established in Metalaxyl-M, EFSA Journal 2015; 13(3):3999.

Table 8.5-14: Summary of soil adsorption/desorption for SYN546520

SYN546520							
Soil Name	**Soil Type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Gartenacker	silt loam	2.7	7.2	0.1	3	1.131	Yes / EFSA (2015)
18 Acres	sandy clay loam	2.4	5.9	0.4	15	0.964	Yes / EFSA (2015)
Seven Springs	loamy sand	0.5	5.8	0.2	41	0.951	Yes / EFSA (2015)
Gardner	sandy loam	2.7	7.6	0.1	2	1.366	Yes / EFSA (2015)
				Geometric mean (n=4)	**7.79**[a]		
				Arithmetic Mean (n=4)	**15.2**	**1.1**	
				pH-dependency:	No		

[a] K_{FOC} value used in PEC_{GW} modelling has been re-calculated from the list of endpoints (arithmetic mean K_{FOC} 15.2, EFSA 2015), following the latest guideline (EFSA Journal 2013; 11(2):3114) recommending geometric mean instead of arithmetic mean. The individual K_{FOC} values from which the geometric mean is calculated, are those established in Metalaxyl-M, EFSA Journal 2015; 13(3):3999.

8.5.4 Column leaching (KCP 9.1.2.1)

Studies on column leaching are considered to be data provided in support of the active substance.

8.5.4.1 Cymoxanil and its metabolites

Column leaching studies on cymoxanil are not triggered. No studies were performed.

8.5.4.2 Fludioxonil and its metabolites

All column leaching studies on fludioxonil have been evaluated in the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**). Standard soil columns with four different soils with unaged fludioxonil eluted with 200 mm artificial rain showed a leaching of 0.02-0.1% AR, confirming that fludioxonil is immobile in soil. The leaching of aged ^{14}C-fludioxonil in standard soil columns was studied in two soils. In both cases, the soil residues were mainly in the top 2 cm or top 4 cm of the soil profile. The leachates contained up to 3.6% AR. The radioactivity in the leachate was not identified.

8.5.4.3 Metalaxyl-M and its metabolites

All column leaching studies on metalaxyl-M have been reviewed under Council Directive 1107/2009 and confirm the adsorption/desorption results, indicating the high mobility of metalaxyl-M (mobility of CGA62826, racemate of NOA409045, is even higher).

8.5.5 Lysimeter studies (KCP 9.1.2.2)

Where undertaken, lysimeter studies are considered to be data provided in support of the active substance.

8.5.5.1 Cymoxanil and its metabolites

A field lysimeter study was performed in Lower Saxony, Germany and has been evaluated in the EU review (**Cymoxanil, EFSA Journal 2008; 167:1-116)**. Cymoxanil was applied at a rate of 3 x 320 g/ha on Lower Saxony soil (loamy sand soil, pH of 5.4) at1.2 m depth soil monoliths. Cymoxanil and the investigated metabolites were never found in the leachates above 0.1 µg/L (cymoxanil < LOQ; identified metabolites ≤ 0.03 µg/L). However, some commonly observed and mobile soil metabolites (e.g. IN-W3595 or IN-KQ960) were not investigated.

8.5.5.2 Fludioxonil and its metabolites

No lysimeter study has been performed with fludioxonil in view of the results of the soil degradation and mobility studies and of the predicted extremely low environmental concentrations in soil and groundwater.

8.5.5.3 Metalaxyl-M and its metabolites

The following lysimeter studies have been evaluated in the EU review (**Metalaxyl-M; EFSA Journal 2015; 13(3):3999**). Racemic metalaxyl was applied at a rate of 330 to 365 g a.s./ha on four vegetated soils. The concentrations of metalaxyl in the combined leachate of one year varied between <0.01 and 0.05 µg/L. The metabolite CGA62826 (racemate of NOA409045) was found at concentrations of 0.25 -

4.12 µg/L. CGA108906 (racemate of SYN546520) was recovered at the concentration of 0.48 - 1.11 µg/L.

8.5.6 Field leaching studies (KCP 9.1.2.3)

Where undertaken, field leaching studies are considered to be data provided in support of the active substance.

8.5.6.1 Cymoxanil and its metabolites

No field leaching study has been performed with cymoxanil.

8.5.6.2 Fludioxonil and its metabolites

No field leaching study has been performed with fludioxonil in view of the results of the soil degradation and mobility studies and of the predicted extremely low environmental concentrations in soil and groundwater.

8.5.6.3 Metalaxyl-M and its metabolites

Three field leaching studies have been performed, were concentrations of <1 to 2000 µg a.s./L could be observed. As the quality of the studies is questionable, the field leaching studies received low weight in the final assessment (**Metalaxyl-M; EFSA Journal 2015; 13(3):3999**).

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.

8.6.1 Cymoxanil and its metabolites

The rate of degradation in water/sediment systems of cymoxanil was evaluated during the EU review (**Cymoxanil, EFSA Journal 2008; 167:1-116)**. No additional studies have been performed.

Table 8.6-1: Summary of degradation in water/sediment of cymoxanil

Cymoxanil Distribution (max. sediment 3.9% after 1 day)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[a]	0.5	1.7	SFO	0.5	1.7	SFO	-[b]	-	Yes / EFSA (2008)
Sand	5.3 / 5.1[a]	1.6	5.3	SFO	1.5	5.0	SFO	-[b]	-	Yes / EFSA (2008)
Silty clay loam	8.3 / 7.5 ($CaCl_2$)	0.1	0.2	SFO	0.1	0.2	SFO	-[b]	-	Yes / EFSA (2008)
Silt loam	8.3 / 7.5 ($CaCl_2$)	0.2	0.5	SFO	0.2	0.5	SFO	-[b]	-	Yes / EFSA (2008)
Geometric mean (n=4)		**0.3**	1.0		0.3	1.0		-		

[a] Matrix of pH measurement unknown
[b] Not calculated

Table 8.6-2: Summary of degradation in water/sediment of IN-U3204

IN-U3204 Distribution (max. water 24.7% after 0.13 day, max. sediment 0.5% after 3 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[a]	0.6	2.0	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Silty clay loam	8.3 / 7.5 ($CaCl_2$)	0.2	0.5	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Silt loam	8.3 / 7.5 ($CaCl_2$)	0.5	1.7	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Geometric mean (n=3)		**0.4**	1.2		-	-		-		

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-3: Summary of degradation in water/sediment of IN-W3595

IN-W3595 Distribution (max. water 26.1% after 0.25 day, max. sediment 2.3% after 1 day)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[a]	3.6	12.1	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Silty clay loam	8.3 / 7.5 ($CaCl_2$)	2.7	9.0	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Silt loam	8.3 / 7.5 ($CaCl_2$)	2.7	8.9	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Geometric mean (n=3)		**3.0**	9.9		-	-		-		

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-4: Summary of degradation in water/sediment of IN-KQ960

IN-KQ960 Distribution (max. water 13.0% after 1 day, max. sediment 5.5% after 30 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[a]	154	521	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Sand	5.3 / 5.1[a]	45.4	151	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Silt loam	8.3 / 7.5 ($CaCl_2$)	15.2	50.5	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Geometric mean (n=3)		**47.4**	158		-	-		-		

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-5: Summary of degradation in water/sediment of IN-T4226

IN-T4226 Distribution (max. water 11.1% after 3 days, max. sediment 1.0% after 8 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[a]	3.9	12.9	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Sand	5.3 / 5.1[a]	5.4	17.9	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Geometric mean (n=2)		**4.6**	15.2		-	-		-		

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-6: Summary of degradation in water/sediment of IN-JX915

IN-JX915 Distribution (max. water 7.2% after 1 day, max. sediment 1.2% after 1 day)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[a]	2.5	8.3	SFO	0.5	1.7	SFO	-[b]	-	Yes / EFSA (2008)
Sand	5.3 / 5.1[a]	1.1	3.7	SFO	1.5	5.0	SFO	-[b]	-	Yes / EFSA (2008)
Silty clay loam	8.3 / 7.5 ($CaCl_2$)	2.1	7.1	SFO	0.1	0.2	SFO	-[b]	-	Yes / EFSA (2008)
Silt loam	8.3 / 7.5 ($CaCl_2$)	1.5	5.1	SFO	0.2	0.5	SFO	-[b]	-	Yes / EFSA (2008)
Geometric mean (n=4)		**1.7**	5.8		0.3	1.0		-		

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-7: Summary of degradation in water/sediment of IN-R3273

IN-R3273 Distribution (max. water 5.0% after 3 days, max. sediment 0.5% after 3 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[a]	6.0	19.9	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Sand	5.3 / 5.1[a]	6.7	22.2	SFO	-[b]	-[b]	-	-[b]	-	Yes / EFSA (2008)
Geometric mean (n=2)		**6.3**	21.0		-	-		-		

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-8: Summary of degradation in water/sediment of IN-KP533

IN-KP533 Distribution (max. water 20.5% after 10 days, max. sediment 6.5% after 1 day)[a]										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Sand	7.4 / 7.0[b]	2.3	7.5	SFO	-[c]	-[c]	-	-[c]	-	Yes / EFSA (2008)
Sand	5.3 / 5.1[b]	3.0	10.0	SFO	-[c]	-[c]	-	-[c]	-	Yes / EFSA (2008)
Geometric mean (n=2)		**2.6**	8.7		-	-		-		

[a] Worst-case assessment, individual amounts of IN-KP533 in two of four water/sediment systems not known (in two systems maximal 8.0 % of AR in the entire system).
[b] Matrix of pH measurement unknown.
[c] Not calculated.

Table 8.6-9: Summary of degradation in water/sediment of M5

M5 Distribution (max. water 22.9% after 1 day, max. sediment 0.0%)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Silty clay loam	8.3 / 7.5 ($CaCl_2$)	1.2	4.0	SFO	0.1	0.2	SFO	-[a]	-	Yes / EFSA (2008)
Silt loam	8.3 / 7.5 ($CaCl_2$)	1.6	5.2	SFO	0.2	0.5	SFO	-[a]	-	Yes / EFSA (2008)
Geometric mean (n=2)		**1.4**	4.6		0.3	1.0		-		

[a] Not calculated.

Table 8.6-10: Summary of observed metabolites

Metabolite	Maximum observed value in water/sediment system	Evaluated on EU level / Reference
IN-U3204	Max. in water 24.7% after 0.13 d, max. in sediment 0.5% after 3 d	Yes / EFSA (2008)
IN-W3595	Max. in water 26.1% after 0.25 d, max. in sediment 2.3% after 1 d	Yes / EFSA (2008)
IN-KQ960	Max. water 13.0% after 1 d, max. in sediment 5.5% after 30 d	Yes / EFSA (2008)
IN-T4226	Max. water 11.1% after 3 d, max. in sediment 1.0% after 8 d	Yes / EFSA (2008)
IN-JX915	Max. water 7.2% after 1 d, max. in sediment 1.2% after 1 d	Yes / EFSA (2008)
IN-R3273	Max. water 5.0% after 3 d, max. in sediment 0.5% after 3 d	Yes / EFSA (2008)
IN-KP533	Max. water 20.5% after 10 d, max. in sediment 6.5% after 1 d	Yes / EFSA (2008)
M5	Max. water 22.9% after 1 d, max. in sediment 0.0%	Yes / EFSA (2008)

8.6.2 Fludioxonil and its metabolites

The rate of degradation in water/sediment systems of fludioxonil was evaluated during the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85)**. No additional studies have been performed.

Table 8.6-11: Summary of degradation in water/sediment of fludioxonil under dark conditions

Fludioxonil distribution (max. sediment 83.5 % after 177 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Tugbach (Pond)	8.4 / 6.9[a]	699	2323	SFO	~ 1	-[b]	SFO	-[b]	-	Yes / EFSA (2007)
River Rhine	8.4 / 7.2[a]	451	1499	SFO	~ 2	-[b]	SFO	-[b]	-	
Fröschweiher (Pond)	7.4-9 / 7.2[a]	>1000	>1000	SFO	6.7	21.3	SFO	-[b]	-	Yes / EFSA (2007)
River Rhine	8-8.9 / 7.2[a]	>1000	>1000	SFO	6.4	22.3	SFO	-[b]	-	

[a] Matrix of pH measurement unknown.
[b] Not calculated.

Table 8.6-12: Summary of degradation in water/sediment of fludioxonil under light exposure

Fludioxonil distribution (max. sediment 83.5 % after 177 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
Fröschweiher (Pond)	7.4-9 / 7.2[a]	18.8	133	SFO	1.7	9.8	SFO	57.8	SFO	Yes / EFSA (2007)
River Rhine	8-8.9 / 7.2[a]	25.2	148	SFO	1.8	14.5	SFO	65.4	SFO	
Geometric mean (n=2)		**21.77**	140.3		1.75	11.92		61.48		

[a] Matrix of pH measurement unknown.

Table 8.6-13: Summary of observed metabolites

Metabolite	**Maximum observed value in water/sediment system**	**Evaluated on EU level / Reference**
CGA192455 Water/sediment system (light exposed)	Max. in water/sediment 17.3 % after 100 d (River Rhine, ^{14}C-pyrrole label)	Yes / EFSA (2007)

8.6.3 Metalaxyl-M and its metabolites

The rate of degradation in water/sediment systems of metalaxyl-M was evaluated during the EU review (**Metalaxyl-M; EFSA Journal 2015; 13(3):3999**). No additional studies have been performed. Data for the degradation rates of metalaxyl-M metabolites CGA67868 and SYN546520 in water/sediment are not currently available.

Table 8.6-14: Summary of degradation in water/sediment of racemic metalaxyl

Racemic metalaxyl Distribution (max. water 105.7% after 0 days, max. sediment 20.4% after 7 days)										
Water / sediment system	**pH water / sed.**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**Kinetic model**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**Kinetic model**	**$DissT_{50}$ sed. (d)**	**Kinetic model**	**Evaluated on EU level / Reference**
River	7.9 / 7.5[a]	47.1	157	SFO	37.2	124	SFO	51.7	SFO	Yes / EFSA (2015)
Pond	8.2 / 6.9[a]	21.9	72.7	SFO	16.6	55.2	SFO	19.6	SFO	Yes / EFSA (2015)
Geometric mean (n=2)		32.1	106.8		24.8	82.7		31.8		
Maximum (n=2)		**47.1**	157		37.2	124		51.7		

[a] Matrix of pH measurement unknown.

Table 8.6-15: Summary of observed metabolites

Metabolite	**Maximum observed value in water/sediment system**	**Evaluated on EU level / Reference**
CGA62826 (Racemate of NOA405049) Water/sediment system	Max. in water 68.8% after 112 d. Max. in sediment 23% after 56 days	Yes / EFSA (2015)

8.7 Predicted Environmental Concentrations in soil (PEC$_S$) (KCP 9.1.3)

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**

Fate & Behaviour Reviewer's comments

PECsoil

This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECsoil values for the other active substances, cymoxanil and fludioxonil, have not been evaluated by HSE. As noted in the introductory green box, metalaxyl-M is considered to be the only ecotoxicologically relevant substance for soil. Therefore PECsoil values are only calculated for metalaxyl-M.

Input values used in PECsoil calculations are shown in the table below. For the a.s. these are in agreement with the list of agreed endpoints in the EFSA Conclusion.

Table HSE 8.7-01: Substance input parameters used for calculating PEC$_{soil}$ values for 'Wakil XL' and metalaxyl-M.

Parameter	**Formulation**	**Active**
SFO Soil DT$_{50}$ (days)	-	30.9
Application Rate (g/ha)	560 [a]	95.0
Crop Interception (%)	0	0

[a] Formulation application rate based on a maximum individual dose of 200 g product/100 kg seed and 280 kg seed planted/ha.

As the a.s. has a relatively short DT50, no calculation of accumulation is required.

HSE disagree with the applicants calculated values in Table 8.7-9 as the applicant used a lower assumed seed planting rate in their calculation. The initial PECsoil values are reproduced below.

Table HSE 8.7-02: PECsoil values for metalaxyl-M and the formulation 'Wakil XL'.

Substance	**PECsoil (mg/kg)**	**PECsoil(accumulation) (mg/kg)**
Formulation	0.747	N/A
Metalaxyl-M	0.127	N/A

The calculated PEC values are suitable for use in risk assessment for the product 'Wakil XL'.

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU reviews of cymoxanil (**Cymoxanil, EFSA Journal 2008; 167: 1-116),** fludioxonil (**Fludioxonil, EFSA Scientific Report (2007); 110: 1-85)** and metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999)**.

8.7.1 Justification for new endpoints

EU agreed endpoints were used for PEC$_S$ calculations of cymoxanil, metalaxyl-M and their respective metabolites.

Assessment of the PEC in soil (PEC_S) of fludioxonil was done following a tiered approach using the worst case laboratory DT_{50} value of 569 days reported in the **EFSA Scientific Report (2007)** (Tier I) and the maximum DT_{50} value of 137 days (Tier II) derived from field dissipation trials including soil incorporation of the substance ([redacted], 2004). These trials are not yet EU evaluated. The available EU agreed endpoint list only contains field dissipation trials in which the substance is exposed to sunlight. This type of studies should not be used for the assessment of seed treatments.

8.7.2 Active substances and relevant metabolites

The following PEC_S calculations for cymoxanil, fludioxonil, metalaxyl-M and their respective metabolites. have not previously been reviewed and are provided in support of this assessment in Appendix 3 of this document.

Table 8.7-1: Input parameters related to application for PEC_S calculations

Use No.	15, 17
Crop	Peas
Application rate (g as/ha)	Metalaxyl-M: 76.3 Fludioxonil: 22.5 Cymoxanil: 45
Pseudo application rate Metabolites (g a.s./ha)[a]	NOA409045: 52.18 CGA67868: 3.17 SYN546520: 3.23 IN-U3204: 11.12 IN-W3595: 2.94 IN-JX915: 4.91 IN-KQ960: 3.09
Number of applications/interval (d)	1 / -
Crop interception (%)	0
Depth of soil layer (relevant for $PEC_{S,plateau}$) (cm)	20 (with tillage)
Models used for calculation	CRD PECsoil Excel Spreadsheet[2]

[a] Application of the parent compound adjusted for formation percentage (maximum percentage observed in soil) and molecular weight difference relative to parent

[2] https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/pec-tools-2015/PEC%20Soil.xlsx (accessed 2020/04/27)

Table 8.7-2: Input parameter for active substance(s) and relevant metabolite(s) for PEC_S calculation

Compound	Molar mass (g/mol)	Mol weight correction factor	Max. occurrence (%)	DT_{50} (d)	Value in accordance to EU endpoint / Reference
Cymoxanil	198.2	-	-	7.3 (maximum of laboratory study)	Yes / EFSA (2008)
IN-U3204	198.2	1.0	24.7	0.9 (maximum of laboratory study)	Yes / EFSA (2008)
IN-W3595	128.1	0.646	10.1	2.5 (maximum of laboratory study)	Yes / EFSA (2008)
IN-JX915	198.2	1.0	10.9	1 (maximum of laboratory study, sole value)	Yes / EFSA (2008)
IN-KQ960	216.2	1.091	6.3	11.2 (maximum of laboratory study, sole value)	Yes / EFSA (2008)
Fludioxonil	248.2	-	-	569[a] / 137[b]	Yes / EFSA (2007) / No / [redacted] (2004)
Metalaxyl-M	279.3	-	-	30.9 (maximum, field studies)	Yes / EFSA (2015)
NOA409045	265.3	0.950	72	39.8 (maximum, field studies)	Yes / EFSA (2015)
CGA67868	193.2	0.692	6	4.9 (SFO, maximum of laboratory studies conducted at 20°C and pF 2)	Yes / EFSA (2015)
SYN546520	295.3	1.057	4	287.9 (SFO, maximum of laboratory studies conducted at 20°C and pF 2)	Yes / EFSA (2015)

[a] Tier 1: worst case lab DT_{50}
[b] Tier 2: worst case non-ormalised field DT_{50}

8.7.2.1 Cymoxanil and its metabolites

Given the DT_{50} and DT_{90} of cymoxanil are < 100 d and 365 d respectively, as shown in Section 8.3, calculations to estimate potential accumulation of cymoxanil were not undertaken.

Table 8.7-3: PEC_S for cymoxanil on peas (1 x 45 g a.s./ha)

PEC_S (mg/kg)		Peas			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.060	-	-	-
Short term	24h	0.055	0.057	-	-
	2d	0.050	0.055	-	-
	4d	0.041	0.050	-	-
Long term	7d	0.031	0.044	-	-
	14d	0.016	0.033	-	-
	21d	0.008	0.026	-	-
	28d	0.004	0.021	-	-
	50d	0.001	0.013	-	-
	100d	<0.001	0.006	-	-

PEC_S of metabolites

Given the DT_{50} and DT_{90} of IN-U3204, IN-W359, JX915 and IN-KQ960 are < 100 d and 365 d respectively, as shown in chapter 8.3.1, calculations to estimate potential accumulation of IN-U3204, IN-W359, JX915 and IN-KQ960 were not undertaken.

Table 8.7-4: PEC_S for IN-U3204

Crop	PEC_S (mg/kg)	Single application	Multiple applications
Peas (1 x 45 g cymoxanil / ha)	$PEC_{s,ini}$	0.015	-

Table 8.7-5: PEC_S for IN-W3595

Crop	PEC_S (mg/kg)	Single application	Multiple applications
Peas (1 x 45 g cymoxanil / ha)	$PEC_{s,ini}$	0.004	-

Table 8.7-6: PEC_S for IN-JX915

Crop	PEC_S (mg/kg)	Single application	Multiple applications
Peas (1 x 45 g cymoxanil / ha)	$PEC_{s,ini}$	0.007	-

Table 8.7-7: PEC_S for IN-KQ960

Crop	PEC_S (mg/kg)	Single application	Multiple applications
Peas (1 x 45 g cymoxanil / ha)	$PEC_{s,ini}$	0.004	-

8.7.2.2 Fludioxonil

A tiered approach was followed for the PECs assessment of fludioxonil using the worst case laboratory DT_{50} value of 569 days reported in the EFSA Scientific Report (2007) in Tier I and the maximum DT_{50} value of 137 days in Tier II derived from field dissipation trials including soil incorporation of the substance ([redacted], 2004). These trials are not yet EU evaluated.

Given the DT_{50} and DT_{90} of fludioxonil are > 100 d and 365 d respectively, as shown in chapter 8.3, calculations to estimate potential accumulation of fludioxonil were undertaken.

Table 8.7-8: PEC_S for fludioxonil on peas (1 x 22.5 g a.s./ha)

PEC_S (mg/kg)		Tier I[a]		Tier II[b]	
		Actual	TWA	Actual	TWA
Initial		0.030	-	0.030	-
Short term	24h	0.030	0.030	0.030	0.030
	2d	0.030	0.030	0.030	0.030
	4d	0.030	0.030	0.029	0.030
Long term	7d	0.030	0.030	0.029	0.029
	14d	0.029	0.030	0.028	0.029
	21d	0.029	0.030	0.027	0.028
	28d	0.029	0.029	0.026	0.028
	50d	0.028	0.029	0.023	0.027
	100d	0.027	0.028	0.018	0.024
$PEC_{s,steady\ state}$ (20 cm) with tillage		0.013	-	0.001	-
$PEC_{s,accumulation}$ ($PEC_{s,accumulation} = PEC_{s,ini} + PEC_{s,steady\ state}$)		0.043	-	0.031	-

[a] worst case lab DT_{50}
[b] worst case non-ormalised field DT_{50}

PEC_S of metabolites

The metabolic pathway for fludioxonil degradation in soil was determined from laboratory data. Fludioxonil is rapidly degraded in laboratory photolysis studies to form several degradation products, whilst degradation under the conditions of laboratory soil metabolism studies conducted in the absence of light was slower and no degradation products were isolated or identified. Since the present use is a seed treatment, exposure to light and thus formation of the metabolites is not relevant.

8.7.2.3 Metalaxyl-M and its metabolites

Given the DT_{50} and DT_{90} of metalaxyl-M are < 100 d and 365 d respectively, as shown in Section 8.3, calculations to estimate potential accumulation of metalaxyl-M were not undertaken.

Table 8.7-9: PEC_S for metalaxyl-M on peas (1 x 76.3 g a.s./ha)

PEC_S (mg/kg)		Peas			
		Single application		Multiple applications	
		Actual	TWA	Actual	TWA
Initial		0.102	-	-	-
Short term	24h	0.099	0.101	-	-
	2d	0.097	0.099	-	-
	4d	0.093	0.097	-	-
Long term	7d	0.087	0.094	-	-
	14d	0.074	0.087	-	-
	21d	0.064	0.081	-	-
	28d	0.054	0.076	-	-
	50d	0.033	0.061	-	-
	100d	0.011	0.041	-	-

PEC_S of metabolites

Given the DT_{50} and DT_{90} of NOA409045 and CGA67868 are < 100 d and 365 d respectively, as shown in chapter 8.3.1, calculations to estimate potential accumulation of NOA409045 and CGA67868 were not undertaken.

Given the DT_{50} and DT_{90} of SYN546520 are > 100 d and 365 d respectively, as shown in chapter 8.3.1, calculations to estimate potential accumulation of SYN546520 were undertaken.

Table 8.7-10: PEC_S for NOA409045

Crop	PEC_S (mg/kg)	Single application	Multiple applications
Peas (1 x 76.3 g metalaxyl-M / ha)	$PEC_{s,ini}$	0.070	-

Table 8.7-11: PEC_S for CGA67868

Crop	PEC_S (mg/kg)	Single application	Multiple applications
Peas (1 x 76.3 g metalaxyl-M / ha)	$PEC_{s,ini}$	0.004	-

Table 8.7-12: PEC_S for SYN546520

Crop	PEC_S (mg/kg)	Single application	Multiple applications
Peas (1 x 76.3 g metalaxyl-M / ha)	$PEC_{s,ini}$	0.004	-
	$PEC_{s,steady\ state}$ (20 cm) with tillage	0.001	-
	$PEC_{s,accumulation}$ ($PEC_{s,ini}$ + $PEC_{s,steady\ state}$)	0.005	-

8.7.2.4 PEC_S of A9873C

Table 8.7-13: PEC_S for A9873C on peas

Active substance/ formulation	Application rate (g/ha)	$PEC_{S,ini}$ (mg/kg)	21d $PEC_{S,twa}$ (mg/kg)	Tillage depth (cm)	$PEC_{S,steady\ state}$ (mg/kg)	$PEC_{S,accumulation}$ (mg/kg)
A9873C[a]	450	0.600	-[b]	20[b]	-[b]	-[b]

[a] The rate of formulation was based on a maximum application of 450 g product/ha.
[b] Not relevant for formulated products – only the initial PEC_S in a single year was calculated

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**

Fate & Behaviour Reviewer's comments

PECgw

This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECgw values for the other active substances, cymoxanil and fludioxonil, have not been evaluated by HSE.

The applicant's choice of input parameters for metalaxyl-M and its soil metabolites in FOCUS groundwater modelling are shown in Table 8.8-16. Deviations from the values used in the groundwater modelling presented in the EFSA Conclusion are highlighted in Table 8.8-16 by HSE in yellow and explained below. In general, it appears that the applicant has applied more recent guidance for calculating geometric mean degradation and soil adsorption modelling endpoints resulting in deviations from the agreed endpoints. In general it is desirable to use agreed a.s. and metabolite endpoints except where there is a demonstrated need to apply new guidance or where an error may have been made in the agreed endpoints.

- Metalaxyl-M DT50, geometric mean of 7.74 days. This is a case of the applicant applying later guidance than was available at the time of the submission. The EFSA Conclusion used a median value of 6.5 days from 10 DT50 values. The guidance on selection of input parameters for FOCUSgw modelling most likely to be in place at the time of assessment (Generic guidance version 2.1 of December 2012) stated that generally the geometric mean DT50 should be used but where a large number of data points were available a median 'may be more appropriate'. A footnote gave the following clarification with respect to the circumstances in which the median might be used: "*Those carrying out simulations may wish to be aware that as a 'rule of thumb' evaluating experts from Member States competent authorities consider 9 or more reliable values constitutes a large enough number of data points to consider using a median value.*" Given the relatively large database of values, the use of the median DT50 of 6.5 days in the EFSA Conclusion appears to be appropriate according to the guidance in place at that time. As there is no inherent error in the value used in the EU review of metalaxyl-M and no demonstrable need to use the geometric mean the agreed endpoint of 6.5 days is used in the HSE assessment.
- Metalaxyl-M Koc, geometric mean of 50.63 (Kom 29.37). The EFSA Conclusion list of endpoints presents a median Koc of 40 mL/g and an arithmetic mean of 78.9 mL/g from a database of 25 values. The median of 40 mL/g was used in modelling. The guidance on selection of input parameters for FOCUSgw modelling most likely to be in place at the time of assessment (Generic guidance version 2.1 of December 2012) stated that generally the arithmetic mean Koc (or Kom for PEARL) should be used but where a large number of data points were available a median 'may be more appropriate'. A footnote gave the following clarification with respect to the circumstances in which the median might be used: "*Those carrying out simulations may wish to be aware that as a 'rule of thumb' evaluating experts from Member States competent authorities consider 9 or more reliable values constitutes a large enough number of data points to consider using a median value.*" Given the large database of values, the use of the median Koc of 40 mL/g in the EFSA Conclusion is appropriate according to the guidance in place at that time. Therefore for the purposes of this assessment, the median Koc value of 40 mL/g (Kom 23.2 mL/g) has been used by HSE. HSE notes that this will provide a more

conservative assessment of groundwater leaching potential, at least for the a.s., than the value proposed by the applicant.

- NOA409045 geometric mean DT50 of 30.5 days used instead of geometric mean DT50 of 31.3 days used in EFSA Conclusion. The difference of opinion arises from the fact that there are two soils within the laboratory dataset for this metabolite where there are two results for each soil. In the EFSA Conclusion, the arithmetic mean of the two results for each soil was taken and these were used in the calculation of the overall geometric mean for the dataset. The applicant states that this is an incorrect calculation and has calculated the geometric mean of the two results for each soil and then used these in the calculation of the overall geometric mean for the dataset. HSE notes that over the history of the EU review process there has been much discussion over the best approach to take in such situations. At the time it was common for averaging of multiple values for the same soil to be performed before the overall geomean of the data set was calculated. It is likely that there were examples where either arithmetic mean or geometric mean of the 'same' soils was calculated before calculating the overall geometric mean for the dataset. A more definitive principle to deciding on whether multiple results are from the 'same' soil has subsequently been developed by EFSA in a more general way, this being in the EFSA Opinion on Aged Sorption Guidance (EFSA Journal 2018;16(8):5382). However this guidance post-dates the EFSA Conclusion on metalaxyl-M by three years and should not be applied. In addition this EFSA Opinion does not equivocally state whether arithmetic or geometric mean should be used in these instances. The applicant's approach taken in this submission seems more consistent with the approach of calculating a geometric mean value for the entire dataset and HSE can accept the change. HSE also notes that the original motivation for adopting geometric mean of degradation parameters was that use of arithmetic mean could lead to inconsistency between averaging of DT50 values and averaging of rate constants, i.e. the DT50 calculated from the arithmetic mean of a dataset of rate constants will be different to the arithmetic mean of the same dataset of DT50 values. Use of geometric mean avoids such inconsistency. The change in DT50 from 31.3 days to 30.5 days is unlikely to result in a major change in predicted concentrations in groundwater.
- NOA409045 geometric mean Koc/Kom 13.44 / 7.80 mL/g. In the EFSA Conclusion List of End Points both an arithmetic mean and a median value are listed. This is because there are 14 soil adsorption data points. As noted in the discussion of Koc/Kom value for metalaxyl-M, at the time of assessment the guidance allowed the use of a median value where there were a large number of data points, i.e. 9 or more. In this case, the Koc used in groundwater modelling described in the EFSA Conclusion is 12.1 mL/g, which is the median value. However the EFSA Conclusion incorrectly states in the description of the groundwater modelling input parameters that this is the arithmetic mean value. As the median value was used in the EFSA Conclusion modelling it is more appropriate to use the median rather than the geometric mean as that was the guidance at the time of assessment. HSE notes that the median value will lead to a more conservative groundwater exposure assessment for this metabolite.
- CGA67868 1/n arithmetic mean of 0.896 used instead of 0.9. The EFSA Conclusion indicates that the value of 0.9 was used as a parameter in FOCUSgw modelling . However the listing of the soil adsorption endpoints for this metabolites lists the arithmetic mean 1/n as 0.896. Thus the use of the more precise value is acceptable.
- SYN546520 Tier 2 formation fraction of 0.10. Whilst the EFSA Conclusion lists a formation fraction of 0.10 in the agreed list of endpoints, this value was not used in the FOCUSgw modelling presented in the EFSA Conclusion. The text in section 4 of the EFSA Conclusion indicates that the use of the formation fraction of 0.47 was consistent with the FOCUS Kinetics (2006) guidance. It was stated that the inverse-modelled value of 0.10 from a single lysimeter study soil could be used within the context of calculating an arithmetic mean when more data were available. Thus the EFSA Conclusion makes it clear that using the formation fraction of 0.10 is not possible without additional data. The applicant submitted new data to support this change in formation fraction.

However, the EFSA Conclusion indicates that this metabolite was not considered to be a relevant metabolite and appeared to pass the appropriate risk assessments in the EU Review with predicted concentrations of >10 µg/L. The applicant has not justified why it is necessary to refine the formation fraction of this metabolite for the GB assessment. Given the absence of an appropriate justification for attempting to refine the formation fraction, the data have not been assessed. Consequently, HSE does not agree with the Tier 2 parameters for modelling SYN546520.

- Geometric mean Koc/Kom values used for metabolites CGA67868 and SYN546520. The EFSA Conclusion used arithmetic mean values for these metabolites. As for some other parameters, this is a case of the applicant applying later guidance than that available at the time of the EU review. There is no demonstrable need to apply later guidance to the selection of the input parameters, therefore the agreed arithmetic mean Koc/Kom endpoints of 19.0/11.0 mL/g for CGA67868 and 15.2 / 8.82 mL/g for SYN546520 have been used in HSE modelling.
- Values of molecular weight and water solubility were not listed in the EFSA Conclusion with the data used for groundwater modelling. However the values were presented in the CP documents in the RAR and can be accepted.

The metabolism scheme at Figure 8.8-2 is appropriate and in accordance with the information given in the EFSA Conclusion for the conduct of the FOCUSgw modelling.

The applicant modelled a dose of 78.75 g a.s./ha. As noted at the beginning of the application, HSE considers that this under-estimates the worst case seed planting rate. HSE consider the dose assuming a higher seed rate should be 95 g a.s./ha.

Given the difference in opinion in some input parameters and the assumed application dose, HSE performed simulations using PEARL, PELMO and MACRO. Whilst MACRO is restricted to modelling primary metabolites, the secondary metabolites were simulated in MACRO because predicted concentrations of both secondary metabolites using PEARL and PELMO were close to the highest 80th percentile annual average concentrations reported in the EFSA Conclusion. However it should be borne in mind that as these are secondary metabolites, attempts to model them with MACRO are likely to be compromised as the input parameters must be altered to compensate for the fact that formation via NOA409045 cannot be simulated. In this case, the formation of each secondary metabolties was simulated using an accepted methodology of:

formation fraction primary metabolite x formation fraction secondary metabolite corrected for molecular weight of parent.

Details of parameters used in HSE simulations are given below.

Table HSE 8.8-01: HSE application input parameters used for calculating PECgw values

Parameter	Value
Crop Type	Peas
Crop Interception	0%
Dose Reaching Soil (g a.s./ha)	95
Number of Applications	1
Application Interval (days)	Not applicable
Application Date (scenario definition planting dates in FO-	Chateaudun: 25 March (Julian day 84) Hamburg: 25 March

CUSgw Generic Guidance v 2.2)	Okehampton: 25 March
Application Type	Annual
Other application details	Seed treatment, therefore residue placed at 5cm depth[1].

[1] Applicant set incorporation/injection depth to 2cm. 5cm depth chosen by HSE as conservative value for leaching assessment. Processors and Growers Research Organisation advice is for drilling depth so that at least 3cm soil covers the seed. Depth used by HSE is in-line with mixing depth assumed for standard PECsoil calculations and therefore is conservative compared to the minimum 3cm depth used by the applicant.

It is noted that the simulation of annual applications is likely to be worst-case for peas as this crop would normally be grown on a longer rotation.

Table HSE 8.8-02: HSE selection of substance input parameters used for calculating PECgw values.

Parameter	Metalaxyl-M	NOA409045	CGA67868	SYN546520
Molecular Mass (g/mol)	279.3	265.3	193.2	295.3
Solubility (mg/L at 25°C)	26000	265000	45800	265000
Vapour Pressure (Pa)	0.0033 (25°C)	1 x 10^{-5} (20°C)	1 x 10^{-5} (20°C)	1 x 10^{-5} (20°C)
DT50 (d)	6.5	30.5	2.9	96.8
Koc / Kom (mL/g)	40 / 23.2	12.1 / 7.02	19.0 / 11.0	15.2 / 8.82
1/n	0.955	0.928	0.896	1.1
Formation Fraction	-	0.783 from a.s.	0.53 from NOA409045	0.47 from NOA409045
Metabolite conversion factor for MACRO	-	0.744	0.2871	0.3891
Q10	2.58	2.58	2.58	2.58
Plant Uptake Factor	0	0	0	0

PECgw from HSE simulations are shown below.

Table HSE 8.8-03: PECgw values for metalaxyl-M and its soil metabolites. Calculated by the HSE evaluator using PEARL 4.4.4.

Scenario	**80th Percentile PECgw at 1 m soil depth (µg/L)**			
	Metalaxyl-M	NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	1.105	0.030	8.713
Hamburg	<0.001	4.809	0.142	14.642
Okehampton	<0.001	2.265	0.066	5.699

Table HSE 8.8-04: PECgw values for metalaxyl-M and its soil metabolites. Calculated by the HSE evaluator using PELMO 5.5.3.

Scenario	**80th Percentile PECgw at 1 m soil depth (µg/L)**			
	Metalaxyl-M	NOA409045	CGA67868	SYN546520

Châteaudun	<0.001	0.727	0.019	7.019
Hamburg	<0.001	2.917	0.077	10.175
Okehampton	0.001	2.385	0.067	5.286

Table HSE 8.8-05: PECgw values for metalaxyl-M and its soil metabolites. Calculated by the HSE evaluator using MACRO 5.5.4.

Scenario	**80th Percentile PECgw at 1 m soil depth (µg/L)**			
	Metalaxyl-M	NOA409045	CGA67868	SYN546520
Châteaudun	<0.001	0.754	<0.001	5.22

Table HSE 5.4-06: Maximum PECgw values suitable for use in the environmental risk assessment of 'Wakil XL'.

Substance	**Max PECgw (µg/L)**	**Note**
Metalaxyl-M	<0.001	All scenarios and models
NOA409045	4.809	PEARL, Hamburg
CGA67868	0.142	PEARL, Hamburg
SYN546520	14.642	PEARL, Hamburg

It is noted that the highest predicted 80th percentile cocntrations of the metabolties in the EFSA Conclusion were higher than the values predicted from the use of 'Wakil XL'. The highest values presented in the EFSA Conclusion are shown below.

Table HSE 5.4-07: Highest 8-0th percentile cocntrations of metalaxyl-M and its soil metabolites in EFSA Conclusion.

Substance	**Max PECgw (µg/L)**	**Note**
Metalaxyl-M	0.003	Spinach, PEARL and PELMO, Hamburg
NOA409045	5.37	Spinach, PEARL, Hamburg
CGA67868	0.152	Spinach, PEARL, Hamburg
SYN546520	15.8	Vines, PELMO, Thiva

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU reviews of cymoxanil (**Cymoxanil, EFSA Journal 2008; 167:1-116),** fludioxonil (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85)** and metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999)**.

8.8.1 Justification for new endpoints

According to the latest guideline (EFSA Journal 2013;11(2):3114) the use of the geometric mean instead of the arithmetic mean for K_{OC} and DT_{50} is recommended. Therefore, for all compounds, the individual values from which the geometric mean is calculated, are those established in the EU reviews of cymoxanil (**Cymoxanil, EFSA Journal 2008; 167:1-116**), fludioxonil (**Fludioxonil, EFSA Scientific Report**

(2007); 110:1-85) and metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999**).

The PEC_{GW} of cymoxanil and its metabolites has been assessed using the endpoints proposed in Section 8.3 to 8.5 based on EU agreed and new data provided for this assessment. For the cymoxanil metabolite IN-KQ960 it has been deemed appropriate to consider an additional laboratory soil degradation study ([redacted] (2010), DuPont-28466) and adsorption study ([redacted] (2010), DuPont-28467).

All other input values used for modelling of cymoxanil, fludioxonil, metalaxyl-M and their respective metabolites are EU agreed endpoints.

8.8.2 Active substances and relevant metabolites (KCP 9.2.4.1)

The following PEC_{GW} modelling for of cymoxanil, fludioxonil, metalaxyl-M and their respective metabolites in soil has not previously been reviewed and is provided in support of this assessment in Appendix 3 of this document.

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

Use No.	15, 17
Crop	Peas
FOCUS crop	PEARL & PELMO: Peas MACRO: Legumes
Application rate (g a.s./ha)	Metalaxyl-M: 78.75[a] Fludioxonil: 22.5 Cymoxanil: 45
Number of applications/interval (d)	1 / -
BBCH growth stage	00
Crop interception (%)	0
Frequency of application	Annually
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4

[a] The PEC_{GW} risk assessment for metalaxyl-M and its soil metabolites was conducted at an elevated rate of 78.75 g a.s./ha instead of the maximum application rate of 76.3 g a.s./ha as given in the critical GAP.

Table 8.8-2: Application dates used for groundwater risk assessment

Crop	Application method	Scenario	Application date[a]
Peas	Seed treatment	Châteaudun	25-Mar (84)
		Hamburg	25-Mar
		Jokioinen	10-May
		Okehampton	25-Mar

[a] Values in parentheses are the application date as entered in MACRO v5.5.4 for the scenario Châteaudun

8.8.2.1 Cymoxanil and its metabolites

Table 8.8-3: Input parameters related to cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 for PEC_{GW} calculations

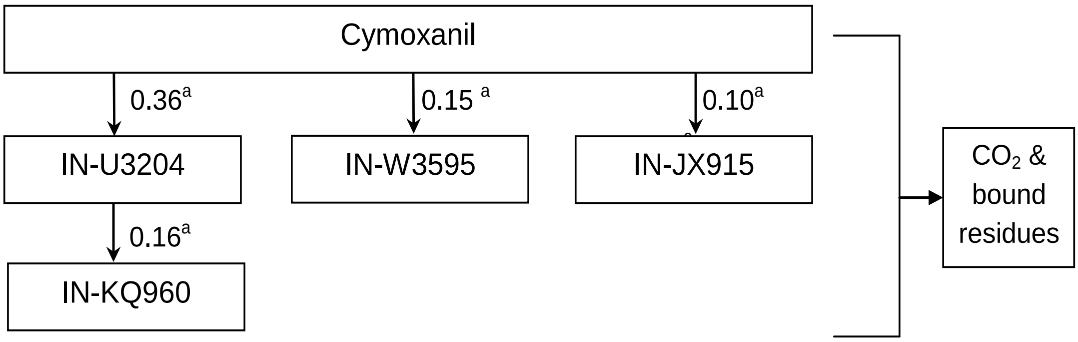
Compound	Cymoxanil	IN-U3204	IN-W3595	IN-KQ960	IN-JX915	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	198.2	198.2	128.1	216.2	198.2	Yes / EFSA (2008)
Water Solubility (mg/L) (20°C)	783	783	783	783	783	Yes / EFSA (2008)
Saturated vapour pressure (Pa) (20°C)	1.5×10^{-4}	0	0	0	0	Yes / EFSA (2008)
DT_{50} in soil (d)	1.2 / 7.3[a] Geometric mean n= 9 / worst case (normalised at 20°C and pF2)	0.4 Geometric mean n= 3 (normalised at 20°C and pF2)	2.5 Worst case	2.8* Geometric mean n= 5 (normalised at 20°C and pF2)	1.0 Worst case	Yes / EFSA (2008) * No / [redacted] (2010), DuPont-28466)
Transformation rate (PELMO)	0.20794 / 0.03418 (cymoxanil →IN-U3204) 0.08664 / 0.01424 (cymoxanil →IN-W3595) 0.05776 / 0.00950 (cymoxanil →IN-JX915)	0.27726 (IN-U3204 →IN-KQ960) 1.45561 (IN-U3204 →CO_2)	0.27726 (IN-W3595 → CO_2)	0.24755 (IN-KQ960 → CO_2)	0.69315 (IN-JX915 → CO_2)	Calculated

Compound	Cymoxanil	IN-U3204	IN-W3595	IN-KQ960	IN-JX915	Value in accordance with EU endpoint / Reference
	0.22527 / 0.03703 (cymoxanil→CO_2)					
Formation fraction	-	0.36 (from parent)	0.15 (from parent)	0.16 (from IN-U3204)	0.10 (from parent)	Yes / EFSA (2008)
K_{FOC} / K_{FOM} (mL/g)[b]	35.8 / 20.77 Geometric mean n= 4	27.9 / 16.18 HPLC method	PEARL: Acidic: 33.3 / 19.3 Alkaline: 2.3 / 1.33 PELMO (scenario specific): C: 2.4 / 1.39 H: 4.3 / 2.49 J: 5.3 / 3.07 N: 8.9 / 5.16 pH dependent sorption	4.0 / 2.32[**] Geometric mean n= 5	11.38 / 6.60 Geometric mean n=4	No[c]/ EFSA (2008) [**]No / [redacted] (2010), DuPont-28467
1/n	0.86 Arithmetic mean, n=4	1.0 Default value	1.0 Default value	0.91[***] Arithmetic mean, n=5	1.0 Default value	Yes / EFSA (2008) [***]No / [redacted] (2010), DuPont-28467
Plant uptake factor	0	0	0	0	0	-

[a] In accordance with EFSA (2008) an additional simulation was performed using a worst case DT_{50} value of 7.3 days.
[b] K_{FOC} values used in the modelling have been re-calculated from the list of endpoints (EFSA, 2008) – see Chapter 8.5.1
[c] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2013; 11(2):3114) recommends the use of the geometric mean instead of the arithmetic mean or median. The individual values from which the geometric mean is calculated, are those established in Cymoxanil, EFSA Journal 2008; 167: 1-116.

The degradation pathways of cymoxanil in soil, as used to simulate leaching potential, are shown schematically in Figure 8.8-1.

Figure 8.8-1: Schematic of the modelled route of degradation of cymoxanil used in ground-water modelling



[a] Formation fraction

Table 8.8-4: PEC_{GW} for cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 using the geomean DT_{50} value for cymoxanil with FOCUS PEARL 4.4.4 (A 3.6, [redacted] 2020, VV-631545)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
		Cymoxanil	IN-U3204	IN-W3595		IN-KQ960	IN-JX915
				Acidic	Alkaline		
Peas 1 x 45 g a.s./ha BBCH 00	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
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 8.8-5: PEC_{GW} for cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 using the worst case DT_{50} value for cymoxanil with FOCUS PEARL 4.4.4 (A 3.6, [redacted] 2020, VV-631545)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
		Cymoxanil	IN-U3204	IN-W3595		IN-KQ960	IN-JX915
				Acidic	Alkaline		
Peas 1 x 45 g a.s./ha BBCH 00	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
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 8.8-6: **PEC_{GW} for cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 using the <u>geomean DT_{50} value</u> for cymoxanil with FOCUS PELMO 5.5.3 (A 3.6, [redacted] 2020, VV-631545)**

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
		Cymoxanil	IN-U3204	IN-W3595		IN-KQ960	IN-JX915
				Acidic	Alkaline		
Peas 1 x 45 g a.s./ha BBCH 00	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
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 8.8-7: **PEC_{GW} for cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 using the <u>worst case DT_{50} value</u> for cymoxanil with FOCUS PELMO 5.5.3 (A 3.6, [redacted] 2020, VV-631545)**

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
		Cymoxanil	IN-U3204	IN-W3595		IN-KQ960	IN-JX915
				Acidic	Alkaline		
Peas 1 x 45 g a.s./ha BBCH 00	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
	Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table 8.8-8: **PEC_{GW} for cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 on peas and beans using the <u>geomean DT_{50} value</u> for cymoxanil with FOCUS MACRO 5.5.4 (A 3.6, [redacted] 2020, VV-631545)**

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
		Cymoxanil	IN-U3204	IN-W3595		IN-KQ960	IN-JX915
				Acidic	Alkaline		
Legumes* 1 x 45 g a.s./ha BBCH 00	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

* Covering applications on peas

Table 8.8-9: PEC$_{GW}$ for cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 on peas and beans using the worst case DT$_{50}$ value for cymoxanil with FOCUS MACRO 5.5.4 (A 3.6, [redacted] 2020, VV-631545)

Crop	Scenario	80th percentile PEC$_{GW}$ at 1 m soil depth [µg/L]					
		Cymoxanil	IN-U3204	IN-W3595		IN-KQ960	IN-JX915
				Acidic	Alkaline		
Legumes 1 x 45 g a.s./ha BBCH 00	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

* Covering applications on peas

Table 8.8-10: Summary of maximum PEC$_{GW}$ across all models for cymoxanil, IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 (A 3.6, [redacted] 2020, VV-631545)

Substance	80th Percentile PEC$_{GW}$ (µg/L)	Crop	Application	Model and Version Number	Scenario
Cymoxanil	<0.001	Peas	1 x 45 g a.s./ha BBCH 00	All models	All scenarios
IN-U3204	<0.001	Peas	1 x 45 g a.s./ha BBCH 00	All models	All scenarios
IN-W3595	<0.001	Peas	1 x 45 g a.s./ha BBCH 00	All models	All scenarios
IN-KQ960	<0.001	Peas	1 x 45 g a.s./ha BBCH 00	All models	All scenarios
IN-JX915	<0.001	Peas	1 x 45 g a.s./ha BBCH 00	All models	All scenarios

8.8.2.2 Fludioxonil

Major soil metabolites of fludioxonil are formed through photolysis. Although endpoints are given in the EFSA Conclusion for the metabolites CGA265378, CGA339833 and CGA192155, it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis, thus in the light rather than in the dark. Therefore, for seed treatment use, these metabolites are not considered further.

Table 8.8-11: Input parameters related to fludioxonil for PEC_{GW} calculations

Compound	Fludioxonil	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	248.2	Yes / EFSA (2007)
Water Solubility (mg/L) (25°C)	1.8	Yes / EFSA (2007)
Saturated vapour pressure (Pa) (25°C)	0	Yes / EFSA (2007)
DT_{50} in soil (d)[a]	174.6 Geometric mean value of lab. data n= 9 (normalized at 20°C and pF2)	No[c] / EFSA (2007)
Transformation rate (PELMO)	0.003971 (fludioxonil → CO_2)	Calculated
K_{FOC} / K_{FOM} (mL/g)[b]	80341 / 46601 Geometric mean n= 5	No[c] / EFSA (2007)
1/n	1.0 Arithmetic mean n=5	Yes / EFSA (2007)
Plant uptake factor	0	-

[a] DT_{50} values used in the modelling have been re-calculated from the list of endpoints (EFSA, 2007) – see Chapter 8.3.1.2
[b] K_{FOC} values used in the modelling have been re-calculated from the list of endpoints (EFSA, 2007) – see Chapter 8.5.2
[c] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2013; 11(2):3114) recommends the use of the geometric mean instead of the arithmetic mean or median. The individual values from which the geometric mean is calculated, are those established in Fludioxonil, EFSA Scientific Report (2007); 110:1-85.

Table 8.8-12: PEC_{GW} for fludioxonil with FOCUS PEARL 4.4.4 (A 3.7, [redacted] 2020, VV-631541)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]
		Fludioxonil
Peas 1 x 22.5 g a.s./ha BBCH 00	Châteaudun	<0.001
	Hamburg	<0.001
	Jokioinen	<0.001
	Okehampton	<0.001

Table 8.8-13: PEC_{GW} for fludioxonil with FOCUS PELMO 5.5.3 (A 3.7, [redacted] 2020, VV-631541)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]
		Fludioxonil
Peas 1 x 22.5 g a.s./ha BBCH 00	Châteaudun	<0.001
	Hamburg	<0.001
	Jokioinen	<0.001
	Okehampton	<0.001

Table 8.8-14: PEC_{GW} for fludioxonil with FOCUS MACRO 5.5.4 (A 3.7, [redacted] 2020, VV-631541)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]
		Fludioxonil
Legumes* 1 x 22.5 g a.s./ha BBCH 00	Châteaudun	<0.001

* Covering applications on peas

Table 8.8-15: Summary of maximum PECGW across all models for fludioxonil (A 3.7, [redacted] 2020, VV-631541)

Substance	80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Fludixonil	<0.001	Peas	1 x 22.5 g a.s./ha BBCH 00	All models	All scenarios

8.8.2.3 Metalaxyl-M and its metabolites

Table 8.8-16: Input parameters related to metalaxyl-M, NOA409045, CGA67868 and SYN546520 for PEC_{GW} calculations

Compound	Metalaxyl-M	NOA409045	CGA67868	SYN546520	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	279.3	265.3	193.2	295.3	Yes / EFSA (2015)
Water Solubility (mg/L) (25°C)	26000	265000	45800 [redacted] (2012)	265000 not available, value of NOA409045 used	Yes / EFSA (2015)
Saturated vapour pressure (Pa) (25°C)	0.0033	1 x 10^{-5}	1 x 10^{-5}	1 x 10^{-5}	Yes / EFSA (2015)
DT_{50} in soil (d)[b]	7.74[*] Geometric mean n= 10 (normalised at 20°C and pF2)	30.5 Geometric mean n= 8 (normalised at 20°C and pF2)	2.9 Geometric mean n= 3 (normalised at 20°C and pF2)	96.8 Geometric mean n= 3 (normalised at 20°C and pF2)	Yes / EFSA (2015) [*]No[d] / EFSA (2015)
Formation fraction	-	0.783 from parent	0.53 (from NOA409045)	0.47 (**Tier 1**) / 0.1 (**Tier 2**)[a] (from NOA409045)	Yes / EFSA (2015)
Transformation rate (PELMO)	0.070121 (Metalaxyl-M→NOA409045) 0.019433 (Metalaxyl-M→ CO_2)	**Tier 1:** 0.010681 (NOA409045→ SYN546520) 0.012045 (NOA409045→ CGA678768) 0 (NOA409045→ CO_2) **Tier 2:** 0.002273 (NOA409045→ SYN546520) 0.012045 (NOA409045→ CGA678768) 0.008409 (NOA409045→ CO_2)	0.239016 (CGA678768→ CO_2)	0.007161 (SYN546520→ CO_2)	Calculated
K_{FOC}/ K_{FOM} (mL/g)[c]	50.63 / 29.37 Geometric mean n= 25	13.44 / 7.80 Geometric mean n= 14	18.93 / 10.98 Geometric mean n= 5	7.79 / 4.52 Geometric mean n= 4	No[d] / EFSA (2015)

Compound	Metalaxyl-M	NOA409045	CGA67868	SYN546520	Value in accordance with EU endpoint / Reference
1/n	0.955 Arithmetic mean n=25	0.928 Arithmetic mean n=14	0.896 (rounded to 0.9) Arithmetic mean n=5	1.1 Arithmetic mean n=4	Yes / EFSA (2015)
Plant uptake factor	0	0	0	0	-

[a] As a tiered approach, the PEC_{GW} were calculated with two different formation fractions of 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2, derived from inverse modelling, EFSA 2015) for SYN546520 – see Chapter 8.3.1.1

[b] DT_{50} values used in the modelling have been re-calculated from the list of endpoints (EFSA, 2015). The geomean value of 31.3 days (EFSA, 2015) was incorrectly calculated and thus has been re-calculated. The individual DT_{50} values from which the geometric mean is calculated, are those established in Metalaxyl-M, EFSA Journal 2015; 13(3):3999 – see Chapter 8.3.1.3

[c] K_{FOC} values used in the modelling have been re-calculated from the list of endpoints (EFSA, 2015) – see Chapter 8.5.3

[d] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2013; 11(2):3114) recommends the use of the geometric mean instead of the arithmetic mean or median. The individual values from which the geometric mean is calculated, are those established in Metalaxyl-M, EFSA Journal 2015; 13(3):3999

The degradation pathways of metalaxyl-M in soil, as used to simulate leaching potential, are shown schematically in Figure 8.8-2.

Figure 8.8-2: Schematic of the modelled route of degradation of metalaxyl-M used in groundwater modelling

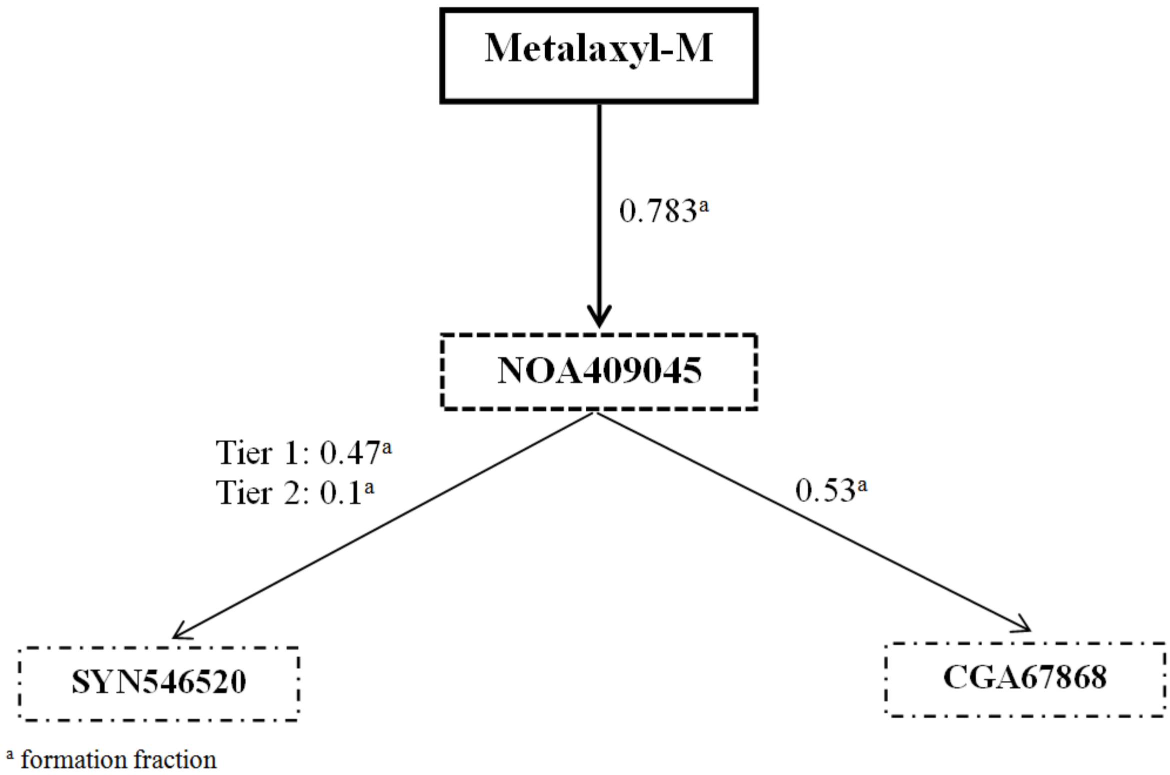


Table 8.8-17: PEC_{GW} for metalaxyl-M, NOA409045, CGA67868 and SYN546520 with FOCUS PEARL 4.4.4 (A 3.8, [redacted] 2020, VV-631540)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]				
		Metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Peas 1 x 78.75 g a.s./ha BBCH 00	Châteaudun	<0.001	0.781	8.13	1.77	0.022
	Hamburg	<0.001	3.53	13.4	2.89	0.107
	Jokioinen	<0.001	2.72	13.2	2.89	0.065
	Okehampton	0.001	1.73	5.25	1.13	0.053

Table 8.8-18: PEC_{GW} for metalaxyl-M, NOA409045, CGA67868 and SYN546520 with FOCUS PELMO 5.5.3 (A 3.8, [redacted] 2020, VV-631540)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]				
		Metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Peas 1 x 78.75 g a.s./ha BBCH 00	Châteaudun	<0.001	0.528	6.51	1.41	0.014
	Hamburg	<0.001	2.23	8.99	1.93	0.063
	Jokioinen	<0.001	2.70	11.0	2.38	0.057
	Okehampton	0.001	1.81	4.77	1.03	0.052

Table 8.8-19: PEC_{GW} for metalaxyl-M, NOA409045, CGA67868 and SYN546520 with FOCUS MACRO 5.5.4 (A 3.8, [redacted] 2020, VV-631540)

Crop	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]				
		Metalaxyl-M	NOA409045	SYN546520		CGA67868
				Tier 1	Tier 2	
Legumes* 1 x 78.75 g a.s./ha BBCH 00	Châteaudun	<0.001	1.11	6.22	1.35	0.024

* Covering applications on peas

Table 8.8-20: Summary of maximum PEC_{GW} across all models for metalaxyl-M, NOA409045, CGA67868 and SYN546520 (A 3.8, [redacted] 2020, VV-631540)

Substance	80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Metalaxyl-M	0.001	Peas	1 x 78.75 g a.s./ha BBCH 00	PELMO v5.5.3 / PEARL v4.4.4	Okehampton
NOA409045	3.53	Peas	1 x 78.75 g a.s./ha BBCH 00	PEARL v4.4.4	Hamburg
CGA67868	0.107	Peas	1 x 78.75 g a.s./ha BBCH 00	PEARL v4.4.4	Hamburg
SYN546520, Tier 1	13.4	Peas	1 x 78.75 g a.s./ha BBCH 00	PEARL v4.4.4	Hamburg
SYN546520, Tier 2	2.89	Peas	1 x 78.75 g a.s./ha BBCH 00	PEARL v4.4.4	Hamburg / Jokionen

An assessment concluding the non-relevance of NOA409045, CGA67868 and SYN546520 in groundwater is presented in the Part B Section 10 of this submission and further discussed in Part B section 6. Thus taking the relevance of the metabolites into account metalaxyl-M is not expected to lead to an unacceptable leaching risk when applied in accordance with the intended use patterns.

The rates of the intended uses proposed for A9873C (worst case: one applications of 76.32 g a.s./ha) are noticeably lower than the amount applied in the lysimeter studies previously discussed.

In conclusion, the higher tier lysimeter study indicated that annual average residues of metalaxyl-M were < 0.1 µg/L in leachate. Residues of the two non-relevant metabolites (NOA409045, CGA67868 and SYN546520) can be expected to be well below 10 µg/L.

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**

Fate & Behaviour Reviewer's comments

PECsw

This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECsw values for the other active substances, cymoxanil and fludioxonil, have not been evaluated by HSE.

As 'Wakil XL' is a seed treatment and not applied as a spray in the field, spray drift is not a relevant route of exposure to surface water.

Standard practice for seed treatments is to assess surface water exposure via drainflow. The EFSA Conclusion lists only metalaxyl-M as an ecotoxicologically relevant compound with respect to surface water and sediment. Therefore metalaxyl-M is the only substance assessed for exposure of surface water and sediment.

The applicant input parameters for drainflow assessment are shown in Table 8.9-10. The applicant has considered metabolite NOA409045 in addition to the a.s. As this metabolite is not considered to be ecotoxicologically relevant for surface water and sediment HSE have not taken the applicant calculations for this metabolite into account.

The applicant assumptions for the a.s. are appropriate and in-line with agreed endpoints. However, as noted in the introductory green box, HSE consider the seed rate used by the applicant in the calculation of the dose/ha to be too low. The appropriate worst-case application dose is considered by HSE to be 95 g a.s./ha.

The appropriate input parameters for metalaxyl-M are given below.

Table HSE 8.9-01: Input parameters used for calculating PECsw and PECsed values of metalaxyl-M applied by 'Wakil XL'.

Parameter	**Active**
Molecular Mass (g/mol)	279.3
Peak Occurrence in Sediment (%)	20.4
Application Rate (g/ha)	95
K_{oc} (mL/g)	40
Crop Interception (%)	0

As the applicant calculations used a dose that HSE are not in agreement with, HSE do not agree with the applicant results in Table 8.9-11. Results of HSE 1st tier drainflow assessment are given below.

Table HSE 8.9-02: PECsw (drainflow) and PECsed (drainflow) values for metalaxyl-M. Calculated by the HSE evaluator using the HSE 1st tier approach.

Environmental Compartment	Active
PECsw (drainflow) (µg/L)	13.885
PECsed (drainflow) (µg/kg)	13.073

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU reviews of cymoxanil (**Cymoxanil, EFSA Journal 2008; 167:1-116),** fludioxonil (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85)** and metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999)**.

8.9.1 Justification for new endpoints

EU agreed endpoints were used for predicted concentration in surface water (PEC_{SW}) and sediment EU agreed endpoints were used for predicted concentration in surface water (PEC_{SW}) and sediment (PEC_{SED}) calculations of metalaxyl-M, fludioxonil, cymoxanil and their respective metabolites. For the cymoxanil metabolite IN-KQ960 it has been deemed appropriate to consider an additional adsorption study ([redacted] (2010), DuPont-28467), which further characterises the fate of IN-KQ960 in soil, surface water and sediment with consideration of mobility.

8.9.2 Active substances, relevant metabolites and the formulation (KCP 9.2.5)

The PEC_{SW} and PEC_{SED} of metalaxyl-M, fludioxonil and cymoxanil and their respective metabolites following entry via drainage have been assessed according to standard Tier I calculations recommended in the national requirements in the UK[3]. Since the present use is a seed treatment, spray drift can be excluded as a potential entry path to surface water. For the Tier I drainage assessments, applications of metalaxyl-M, fludioxonil and cymoxanil were assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case. The calculations used in the Tier I drainage assessment are specified in Appendix A 3.9 to A 3.11.

The EXCEL “MACRO Drainflow Tool” together with FOCUS MACRO (v4.3b) model was used for a Higher Tier drainage assessment of cymoxanil since the Tier I PEC_{SW} drainage calculation exceeded the regulatory acceptable concentration (RAC) of 4.4 µg/L. The Higher Tier drainage assessment was performed in accordance with national requirements in the UK3. A summary of the Higher Tier drainage assessment modelling for cymoxanil is provided in Appendix A 3.12.

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

Plant protection product	A9873C
Use No.	17
Crop	Peas[a]
Application rate (kg as/ha)	Metalaxyl-M: 76.3 Fludioxonil: 22.5 Cymoxanil: 45
Number of applications/interval (d)	1 / -
Application timing (No. days until drainage period)	0[b]
Application method	Seed treatment

[3] https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/index.htm (accessed 2020/04/27)

Max crop interception (%)	0

[a] As the application method is a seed treatment and interception is irrelevant.

[b] Application of metalaxyl-M was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case used in drainage calculation

8.9.2.1 Cymoxanil and its metabolites

The following surface water/sediment modelling on cymoxanil, IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 has not previously been reviewed and is provided in support of this national assessment.

Table 8.9-2: Input parameters related to active substance cymoxanil, IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 for $PEC_{SW/SED}$ calculations

Compound	Cymoxanil	IN-U3204	IN-W3595	IN-KQ960	IN-JX915	IN-T4226	IN-R3273	IN-KP533	M5	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	198.2	198.2	128.1	216.2	198.2	142.1	171.2	160.1	198.2	Yes / EFSA, 2008
K_{FOC} (mL/g)	43.6 (arithmetic mean, n = 4[b])	27.9 (obtained by HPLC method, n=1)	2.3 (worst case from laboratory studies, pH-dependence)	4.6* (arithmetic mean, n = 5)	16.2 (arithmetic mean, n = 4)	17.7 (obtained by HPLC method, n=1)	25.7 (worst case from laboratory studies)	12.9 (obtained by HPLC method, n=1)	2.3 (IN-W3595 value, worst case from laboratory studies)	Yes / EFSA, 2008 *No / [redacted] (2010), DuPont-28467
$DT_{50,soil}$ (d)	7.3 (worst case of laboratory studies)	0.9 (worst case from laboratory studies)	2.5 (worst case from laboratory studies)	11.2 (worst case from laboratory studies)	1 (worst case from laboratory studies)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	1000 (conservative default)	Yes / EFSA, 2008
$DT_{50,water}$ (d)	1.6 (maximum whole system value)	0.6 (maximum whole system value)	3.6 (maximum whole system value)	154 (maximum whole system value)	2.55 (maximum whole system value)	5.4 (maximum whole system value)	6.7 (maximum whole system value)	3.0 (maximum whole system value)	1.6 (maximum whole system value)	Yes / EFSA, 2008
$DT_{50,sed}$ (d)	1.6 (maximum whole system	0.6 (maximum whole system	3.6 (maximum whole system	154 (maximum whole system	2.55 (maximum whole system	5.4 (maximum whole system value)	6.7 (maximum whole system value)	3.0 (maximum whole system value)	1.6 (maximum whole system value)	Yes / EFSA, 2008

Compound	Cymoxanil	IN-U3204	IN-W3595	IN-KQ960	IN-JX915	IN-T4226	IN-R3273	IN-KP533	M5	Value in accordance to EU endpoint / Reference
	value)	value)	value)	value)	value)					
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: - Water: - Sediment: 3.9	Soil: 24.7 Water: 24.7 Sediment: 0.5	Soil: 10.1 Water: 26.1 Sediment: 2.3	Soil: 6.3 Water: 13.0 Sediment: 5.5	Soil: 10.9 Water: 52.6[a] Sediment: 1.2	Soil: 1.7 Water:11.1/ Sediment: 1.0	Soil: 2.4 Water: 35.4[a] Sediment: 0.5	Soil: 2.7 Water: 20.5 Sediment: 6.5	Soil: 0 Water: 22.9 Sediment: 0	Yes / EFSA, 2008

[a] Value from photolysis used, worst-case assessment
[b] 43.6 (arithmetic mean, n = 5) displayed in Spray drift and Tier I drainage assessment

Table 8.9-3: Input parameters related to active substance cymoxanil for FOCUS MACRO (v 4.3b) modelling

Compound	Cymoxanil	Value in accordance to EU endpoint / Reference
K_{FOC} (mL/g)	43.6 (arithmetic mean, n = 4[a])	Yes / EFSA (2008)
Freundlich exponent 1/n	0.86 (arithmetic mean, n=4)	Yes / EFSA (2008)
Plant uptake	0	FOCUS default
$DT_{50,soil}$ (d)	7.3 (worst case of laboratory studies)	Yes / EFSA (2008)
Exponent of soil temperature response	0.095 (equivalent to a Q_{10} of 2.58)	FOCUS default

[a] 43.6 (arithmetic mean, n = 5) displayed in Spray drift and Tier I drainage assessment

Cymoxanil

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I drainage

Table 8.9-4: Overall maximum $PEC_{SW/SED}$ for cymoxanil due to drainage following single application of A9873C (refer to A 3.9)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Peas 45.0 g a.s./ha BBCH 00	0[a]	6.58	1.18

[a] Application of metalaxyl-M was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Higher Tier Drainage

Table 8.9-5: Maximum daily PEC_{SW} of cymoxanil for the 30-year simulation period and each scenario following application(s) of A9873C to peas (refer to A 3.12)

Soil class	Maximum daily $PEC_{SW,drainage}$ (µg/L)		
	Weather scenario		
	Dry	Medium	Wet
Denchworth	1.07	1.67	2.12
Hanslope	0.837	1.18	1.57
Brockhurst	0.139	0.274	0.264
Clifton	0.005	0.030	0.260

Metabolites of cymoxanil

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I Drainage

Table 8.9-6: Overall maximum $PEC_{SW/SED}$ for IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 due to drainage following single application of A9873C (refer to A 3.9)

Crop	Days from application till drainage period	Metabolite	Initial $PEC_{SW,drainage}$ (µg/L)[a]	Initial $PEC_{SED,drainage}$ (µg/Kg)[b]
Peas 45.0 g a.s./ha BBCH 00	0[a]	IN-U3204	1.62	0.152
		IN-W3595	1.11	0.451
		IN-KQ960	0.933	1.82
		IN-JX915	3.46	0.364
		IN-T4226	0.523	0.218
		IN-R3273	2.01	0.131
		IN-KP533	1.09	1.59
		M5	1.51	<0.001

[a] Application of metalaxyl-M was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case
[b] Maximum occurrence across both the soil and water formation pathways, see Appendix A 3.9 for further details

8.9.2.2 Fludioxonil and its metabolites

The following surface water/sediment modelling on metalaxyl-M and its metabolite CGA192155 has not previously been reviewed and is provided in support of this national assessment.

Table 8.9-7: Input parameters related to active substance fludioxonil and CGA192155 for $PEC_{SW/SED}$ calculations

Compound	Fludioxonil	CGA192155	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	248.2	202.1	Yes / EFSA, 2007
K_{FOC} (mL/g)	145600 (arithmetic mean, n = 5)	23.5 (arithmetic mean, n = 4)	Yes / EFSA, 2007
$DT_{50,soil}$ (d)	569 (worst case from laboratory studies)	Not relevant (metabolite not fromed in soil under dark conditions)	Yes / EFSA, 2007
$DT_{50,water}$ (d)	25.2 (maximum whole system value from light exposed water/sediment study)	1000 (conservative default)	Yes / EFSA, 2007
$DT_{50,sed}$ (d)	1000 (conservative default)	1000 (conservative default)	Yes / EFSA, 2007
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: - Water: - Sediment: 83.4	Soil: 0[a] Water: 11.9 Sediment: 5.5	Yes / EFSA, 2007

[a] Metabolite not formed in soil under dark conditions

Fludioxonil

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I drainage

Table 8.9-8: Overall maximum $PEC_{SW/SED}$ for fludioxonil due to drainage following single application of A9873C (refer to A 3.10)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Peas 22.5 g a.s./ha BBCH 00	0[a]	0.014	0.053

[a] Application of fludioxonil was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Metabolites of fludioxonil

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I Drainage

Table 8.9-9: Overall maximum $PEC_{SW/SED}$ for CGA192155 due to drainage following single application of A9873C (refer to A 3.10)

Crop	Days from application till drainage period	Metabolite	Initial $PEC_{SW,drainage}$ (µg/L)[a]	Initial $PEC_{SED,drainage}$ (µg/Kg)
Peas 22.5 g a.s./ha BBCH 00	0[a]	CGA192155	0.001	0.003

[a] Application of fludioxonil was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

8.9.2.3 Metalaxyl-M and its metabolites

The following surface water/sediment modelling on metalaxyl-M and its metabolite NOA409045 has not previously been reviewed and is provided in support of this national assessment.

Table 8.9-10: Input parameters related to active substance metalaxyl-M and NOA409045 for $PEC_{SW/SED}$ calculations

Compound	Metalaxyl-M	NOA409045	Value in accordance to EU endpoint / Reference
Molar mass (g/mol)	279.3	265.3	Yes / EFSA, 2015
K_{FOC} (mL/g)	40.0 (median, n = 25)	12.1 (median, n = 14)	Yes / EFSA, 2015
$DT_{50,soil}$ (d)	30.9 (worst case from field dissipation studies)	39.8 (worst case from field dissipation studies)	Yes / EFSA, 2015
$DT_{50,water}$ (d)	47.1 (worst case from water/sediment studies)	1000 (conservative default)	Yes / EFSA, 2015
$DT_{50,sed}$ (d)	1000 (conservative default)	1000 (conservative default)	Yes / EFSA, 2015
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: - Water: - Sediment: 20.4	Soil: 72.0 Water: 68.8 Sediment: 23.0	Yes / EFSA, 2015

Metalaxyl-M

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I drainage

Table 8.9-11: Overall maximum $PEC_{SW/SED}$ for metalaxyl-M due to drainage following single application of A9873C (refer to A 3.11)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L)	Initial $PEC_{SED,drainage}$ (µg/Kg)
Peas 76.3 g a.s./ha BBCH 00	0[a]	11.2	10.5

[a] Application of metalaxyl-M was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Metabolites of metalaxyl-M

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

Tier I Drainage

Table 8.9-12: Overall maximum $PEC_{SW/SED}$ for NOA409045 due to drainage following single application of A9873C (refer to A 3.11)

Crop	Days from application till drainage period	Initial $PEC_{SW,drainage}$ (µg/L) [a]	Initial $PEC_{SED,drainage}$ (µg/Kg) [b]
Peas 76.3 g a.s/ha BBCH 00	0[a]	7.63	11.24

[a] Application of metalaxyl-M was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case
[b] Maximum occurrence across both the soil and water formation pathways, see Appendix A 3.11 for further details

8.9.2.4 PEC_{SW} of the formulation A9873C

Spray drift

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

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

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY	
Name of authority	**HSE Chemicals Regulation Division (CRD), UK**

Fate & Behaviour Reviewer's comments
PECair

This Article 7 assessment only concerns the active substance metalaxyl-M, therefore the applicant's PECsw values for the other active substances, cymoxanil and fludioxonil, have not been evaluated by HSE.

For the EU Review of metalaxyl-M the EFSA Conclusion noted that the a.s. is slightly volatile with vapour pressure of 3.3×10^{-3} Pa at 25°C and Henry's Law constant of 3.5×10^{-5} $Pa.m^3/mol$ at 25°C. However the EFSA Conclusion did not raise any particular concerns regarding exposure of air and no attempt to quantify exposure of air, (i.e. a PECair calculation) was made. It is noted that both foliar application and seed treatment uses were included in the representative uses considered in the EU review. 'Wakil XL' is a seed treatment and thus the majority of the substance will be buried by soil at the time of drilling the treated seed. This is likely to further reduce the potential for air exposure compared to an application method such as spraying.

No further consideration of air exposure is required for this product.

Studies on fate and behaviour in the air are considered to be data provided in support of the active substance.

8.10.1 Cymoxanil

The fate and behaviour in air of cymoxanil was evaluated during the EU review **(Cymoxanil, EFSA Journal 2008; 167: 1-116)**. No additional studies have been performed.
.

Compound	Cymoxanil
Direct photolysis in air	Not relevant
Quantum yield of direct phototransformation	Not relevant
Photochemical oxidative degradation in air	DT_{50}: 21.3 hours (Atkinson, 1.5 x 10^6 OH radicals/cm^3, 12 hour day)
Volatilisation	Vapour pressure (Pa): 1.5 x 10^{-4} (at 20°C) Henry's Law Constant (Pa m^3/mol): 3.3 x 10^{-5} (at 25°C, pH 5) 3.8 x 10^{-5} (at 25°C, pH 7)
Metabolites	Not studied – no data requested

Cymoxanil is directly incorporated into the soil via treated seed since A9873C is exclusively used as seed dressing. Furthermore, the vapour pressure of cymoxanil is low (1.5 x 10^{-4} Pa at 20°C), and, classifies as slightly volatile. Consequently, significant losses due to volatilisation are not expected. Thus, PEC air is deemed not required for the active substance cymoxanil.

8.10.2 Fludioxonil

The fate and behaviour in air of fludioxonil was evaluated during the EU review (**Fludioxonil, EFSA Scientific Report (2007); 110:1-85**). No additional studies have been performed.

Table 8.10-1 Summary of atmospheric degradation and behaviour of fludioxonil

Compound	Fludioxonil
Direct photolysis in air	Not relevant
Quantum yield of direct phototransformationa	Not relevant
Photochemical oxidative degradation in air	DT_{50}: 3.6 hours (Atkinson, 1.5 x 10^6 OH radicals/cm^3, 12 hour day)
Volatilisation	Vapour pressure (Pa): 3.9 x 10^{-7} (at 25°C) Henry's Law Constant (Pa m3/mol): 5.4 x 10^{-5} (at 25°C)
Metabolites	No potentially volatile metabolites

Fludioxonil is directly incorporated into the soil via treated seed since A9638A is exclusively used as seed dressing. Furthermore, the vapour pressure of fludioxonil is very low (3.9 x 10^{-7} Pa at 25°C), and, as expected, fludioxonil was found to be non-volatile from soil. Consequently, there will be no relevant atmospheric exposure or contamination of rainwater. Thus, PEC air is deemed not required for the active substance fludioxonil.

8.10.3 Metalaxyl-M

The fate and behaviour in air of metalaxyl-M was evaluated during the EU review (**Metalaxyl-M, EFSA Journal 2015;13(3):3999**). No additional studies have been performed.

Table 8.10-2: Summary of atmospheric degradation and behaviour

Compound	Metalaxyl-M
Direct photolysis in air[a]	-
Quantum yield of direct phototransformation[a]	-
Photochemical oxidative degradation in air	DT_{50} = 4.8 hours by the Atkinson method (AOP v1.92) assuming 12h dark/12 h light
Volatilisation	from plant surfaces: 35% volatilization (after 24 h, glass-house conditions) from soil: rate of volatilization (TRR) was calculated at 6-10 g/ha/day (35°C, 30l/h air flow) Vapour pressure (Pa): 3.3×10^{-3} (at 25°C) Henry's Law Constant ($Pa.m^3/mol$): 3.5×10^{-5} (at 25°C)
Metabolites[a]	-

[a] Data currently not available

The vapour pressure at 25 °C of the active substance metalaxyl-M is > 10^{-5} Pa. Hence the active substance metalaxyl-M is regarded as volatile. Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance metalaxyl-M due to volatilization with subsequent deposition should be considered. Nonetheless, as mitigation measures to reduce exposure to non-target or aquatic organisms (FOCUS Surface Water Step 4) were not required, and due to the short DT_{50} (< 2 days), the exposure by volatilisation is considered negligible. Moreover, A9873C is a seed treatment and the seeds are buried into soil which reduces volatilisation. Thus, PEC air is deemed not required for metalaxyl-M.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on (A9873C)

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

List of data submitted by the applicant and relied on (cymoxanil)

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
KCA 7.1.2.1	[redacted]	2010	^{14}C-IN-KQ960: Rate of Degradation in Five Soils. DuPont-28466. E.I. du Pont de Nemours and Company, Wilmington, DE, U.S.A Document Number: DuPont-28466	N	DuPont
KCA 7.1.3.1	[redacted]	2010	^{14}C-IN-KQ960 : Batch Equilibrium (Adsorption/Desorption) in Five Soils. DuPont-28467. E. I. du Pont de Nemours and Company, Wilmington, DE, U.S.A. Document Number: DuPont-28467	N	DuPont
KCP 9.2.4	[redacted]	2020	Cymoxanil – A Leaching Assessment for Cymoxanil and its Soil Metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU. Report Number R1520325-5. Syngenta File No ASF331_10016; VV-631545. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY GLP not applicable	N	SYN
KCP 9.2.5	[redacted]	2020	Cymoxanil - A European Environmental Fate Assessment for Cymoxanil Using the MACRO Drainflow Tool for UK Surface Water Calculations Following Seed Treatment Application to Peas Report Number R2060005-7. Syngenta File No VV-863863. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY GLP not applicable	N	SYN

List of data submitted by the applicant and relied on (fludioxonil)

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
KCA 7.1.2.2.1	[redacted]	2004	Fludioxonil - Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003 Syngenta, Environmental Sciences, Jealott's Hill, International Research Centre, Bracknell, Berkshire, RG42 6EY, UK. Laboratory Project ID 03-S602, 06 September 2004 Syngenta File No. CGA173506/5993; VV-330403	N	SYN
KCP 9.2.4	[redacted]	2020	Fludioxonil - A Leaching Assessment for Fludioxonil Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU. Report Number R1520325-2. Syngenta File No CGA173506_12279; VV-631541. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY GLP not applicable	N	SYN

List of data submitted by the applicant and relied on (metalaxyl-M)

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.1.1	[redacted]	2015	Metalaxyl-M: Calculation of the formation fraction of the soil degradate CGA108906 for use in environmental models. Report Number RAJ1079B. Syngenta File No. VV-629108. Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY UK GLP not applicable Unpublished	N	SYN
KCP 9.1.1	[redacted]	2020	CGA108906 – Kinetic evaluation of Formation Fraction. Report Number RAJ1329B. Syngenta File No: VV-742439. Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY UK GLP not applicable Unpublished	N	SYN
KCP 9.2.4	[redacted]	2020	Metalaxyl-M - A Leaching Assessment for Metalaxyl-M and its Soil Metabolites NOA409045, SYN546520 and CGA67868 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU. Report Number R1520325-1. Syngenta File No CGA329351_11831; VV-631540. RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY GLP not applicable	N	SYN

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review (A9873C

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

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

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 KCA 7.1.2.1: [redacted] (2010), DuPont-28466. IN-KQ960 degradation in soil

Reference:	KCA 7.1.2.1
Report:	^{14}C-IN-KQ960: Rate of degradation in five soils. [redacted] 2010 Document Number: DuPont-28466
Guideline(s):	OECD 307 (2002); SETAC Europe (1995); OPPTS 835.4100 (2008)
Deviations:	-
GLP:	Yes
Acceptability:	Yes

A 2.1.1 Executive summary

The aerobic biotransformation of radiolabelled IN-KQ960, a metabolite of cymoxanil, was studied in five different soil systems under aerobic conditions. The test soils were treated with [Imidazazolidine-4-^{14}C]IN-KQ960 at a concentration of 1.5 µg a.s./g dry weight soil and incubated in darkness at approximately 20 ± 2°C. The samples were incubated under aerobic conditions with a soil moisture at 50% of its 0-bar moisture during the course of the study. Soil samples were extracted with a mixture of aqueous and organic solvents at 0, 1, 2, 3, 7, 14, and 21 days after treatment and analysed for [^{14}C]IN-KQ960.

The mean recovery of total radioactivity was within 92.5 to 103.9% of the applied radioactivity for all soils. As the level of extractable radioactivity decreased, the level of unextractable residue (non-extractable residues - NER) slowly increased in the soils during the course of the study. The amount of $^{14}CO_2$ collected increased with time in each soil. During the course of the study, the amount of [^{14}C]IN-KQ960 in the extracts decreased in the tested soils.

The DT_{50} and DT_{90} values for IN-KQ960 were calculated by the single first order (SFO) model, ranging from 2.0 to 4.2 days and from 6.6 to 14 days, respectively.

A 2.1.2 Materials and methods

A. MATERIALS

Test material	[^{14}C] IN-KQ960 technical metabolite
Lot/Batch #:	4009572
Radiochemical purity:	99.1%
Specific activity:	29.4 µCi/mg
Description:	Not described
CAS#	644972-61-280
Stability of test compound:	yes

SOILS

Five soils typical of growing regions in North America and across Europe were provided. The five soils were sand from Hanhofen, Deutschland (Speyer 2.2), a silty clay loam from Stark County, Illinois (Tama), a clay loam from the Lleida Region of Spain (Lleida), a sandy loam from Nambsheim, France, and a sandy loam from Kent County, Maryland (Sassafras). Prior to use, each test soil was sieved through an approximately 2-mm mesh sieve. The soils were stored at approximately 4°C in the dark in closed bags when not in use. A summary of the physical and chemical properties of the soils is provided in Table A 1.

Table A 1: Characteristics of test soils

Characteristic	**Soil**				
Soil name	**Speyer 2.2**	**Tama**	**Lleida**	**Nambsheim**	**Sassafras**
Origin location	Hanhofen, Germany	Stark County, Illinois, USA	Lleida Region of Spain	Nambsheim, France	Kent County, Maryland, USA
pH[a]	6.1	6.8	7.9	7.6	5.5
pH[b]	6.0	6.4	7.7	7.4	4.9
% Sand (2000-50 µm)	89	17	26	66	73
% Silt (<50-2 µm)	10	52	35	23	20
% Clay (<2 µm)	1	31	39	11	7
Texture (USDA)	Sand	Silty Clay Loam	Clay Loam	Sandy Loam	Sandy Loam
% Organic matter (Walkley Black)	3.3	4.3	2.1	2.8	1.3
Cation exchange capacity (meq/100 g)	8.0	22.1	27.2	10.1	6.4
% moisture at 1/3 bar (%)	8.1	31.1	26.5	12.6	10.4

a pH in 1:1 soil:water ratio
b pH in 1:1 soil:0.01M CaCl2 (aq) ratio performed at ABC Laboratories.

B. STUDY DESIGN

EXPERIMENTAL CONDITIONS

For all soil samples to be treated with test substance, an amount of fresh soil equivalent to 50 g soil (dry weight basis) was transferred into each test vessel. For all soil samples to be used for biomass determination, an amount of soil equivalent to 250 g of soil (dry-weight basis) was transferred into each test vessel. The moisture of all samples was adjusted to 50 % of its 0-bar moisture. Vacuum pumps were used to provide a steady flow of air through the systems.

Aerobic conditions were maintained in all samples by drawing humidified air through the series containing the representative samples. During incubation, systems were maintained in the dark (except during general use of the chamber or when the samples were removed during moisture content maintenance). The test temperature in the chamber was set to 20°C for up to the duration of the test of 21 days.

SAMPLING

Duplicate soil samples were extracted with a mixture of aqueous and organic solvents at 0, 1, 2, 3, 7, 14, and 21 days after treatment and analysed for [^{14}C]IN-KQ960. Soil samples were extracted immediately and extracts stored frozen until analysis.

Untreated biomass samples were taken from each soil system at the beginning of the study and after 21 days after the initiation biomass samples were harvested and analysed by the fumigation-extraction method for biomass determination.

DESCRIPTION OF ANALYTICAL PROCEDURES

All soil extracts were stored in a freezer as quickly as possible after sampling. The soils were extracted on the day of sampling and analysed by LSC. HPLC (Agilent, Zorbax SB-C8 250 × 4.6 mm) with a gradient of 0.2% formic acid (aq) and methanol, was used as the primary method to characterize the soil extracts. A detection limit of LSC analysis permitted detection of radioactivity of <1% applied radioactivity (AR).

The treated soils were extracted three times by adding 100 mL of 50:50 methanol:20 mM sodium acetate (aq) to the Nalgene bottles, and shaking at high speed for 30 minutes. Following shaking, the samples were centrifuged for 20 minutes at approximately 3600 × g. Following centrifugation, successive supernatants were decanted into a 500-mL mixing cylinder. After decanting the supernatant from the final extraction into the cylinder, the combined extract volume was diluted to 300 mL with methanol. Aliquots of the combined extracts were analysed by LSC.

The soil extract samples were then typically concentrated for analysis using the following process. A 75-mL aliquot of each extract was concentrated to dryness using a rotary evaporator. To facilitate the removal of water, acetonitrile was periodically added to the flasks. Each flask was reconstituted with 5 mL of 20 mM sodium acetate (aq) (added with a class A volumetric pipette) and sonicated for at least 10 minutes. The concentrated extracts were filtered through 0.45 µm PTFE syringe filters into 15-mL polypropylene centrifuge tubes that were vortexed and/or sonicated for approximately five minutes. Aliquots of this sample were analysed by LSC (to verify that mass balance was maintained at 90 to 100% throughout the process) and HPLC. If recoveries were not within the acceptable range, the process was repeated.

Excess solvent left in the previously extracted soil samples was evaporated under a gentle stream of nitrogen, as needed. Samples were homogenised and triplicate aliquots of the extracted soil samples (approximately 0.5 g) were analysed by combustion followed by LSC to determine the amount of non-extractable residue (NER).

A 2.1.3 Results and discussion

Table A 2: Material balance of radioactivity for Speyer 2.2 soil treated with [14C]IN-KQ960 (% applied radioactivity)

	Rep. no.	Sampling interval (days)						
		0	**1**	**2**	**3**	**7**	**14**	**21**
Volatiles								
$^{14}CO_2$	1	N/A	4.6	10.7	15.6	31.6	42.3	46.6
	2	N/A	4.4	10.3	15.3	31.1	42.2	46.7
	Mean	N/A	4.5	10.5	15.4	31.4	42.3	46.7
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total	1	N/A	4.6	10.7	15.6	31.6	42.3	46.6
	2	N/A	4.4	10.3	15.3	31.1	42.2	46.7
	Mean	N/A	4.5	10.5	15.4	31.4	42.3	46.7
Extractable radioactivity								
Total extractable	1	98.1	83.4	73.6	60.2	31.1	13.6	8.6
	2	101.0	84.3	70.2	59.1	32.1	16.6	10.5
	Mean	99.6	83.8	71.9	59.7	31.6	15.1	9.6
Bound residue	1	2.50	12.10	18.1	24.8	36.8	37.9	36.7
	2	1.90	12.80	20.4	23.8	37.9	39.8	38.7
	Mean	2.20	12.50	19.3	24.3	37.4	38.9	37.7
Material balance	1	100.6	100.1	102.4	100.6	99.6	93.8	91.9
	2	103.0	101.5	100.9	98.3	101.1	98.7	95.9
	Mean	101.8	100.8	101.7	99.4	100.3	96.2	93.9

N/A = not applicable (no volatile traps, or traps not sampled)
Note: Values were not rounded during spreadsheet calculations.

Table A 3: Material balance of radioactivity for Tama soil treated with [14C]IN-KQ960 (% applied radioactivity)

	Rep. no.	Sampling interval (days)						
		0	**1**	**2**	**3**	**7**	**14**	**21**
Volatiles								
$^{14}CO_2$	1	N/A	4.3	9.0	12.4	18.9	29.3	33.5
	2	N/A	4.6	9.4	13.5	24.3	33.1	38.4
	Mean	N/A	4.4	9.2	12.9	21.6	31.2	35.9
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total	1	N/A	4.3	9.0	12.4	18.9	29.3	33.5
	2	N/A	4.6	9.4	13.5	24.3	33.1	38.4
	Mean	N/A	4.4	9.2	12.9	21.6	31.2	35.9
Extractable radioactivity								
Total extractable	1	98.1	78.4	66.1	54.4	31.6	22.5	13.1
	2	98.1	81.5	68.9	58.5	36.0	21.0	18.6
	Mean	98.1	79.9	67.5	56.4	33.8	21.7	15.9
Bound residue	1	3.1	17.3	25.1	31.3	45.5	42.6	40.8
	2	3.2	16.5	28.1	28.1	40.4	44.4	44.0
	Mean	3.1	16.9	26.6	29.7	42.9	43.5	42.4
Material balance	1	101.2	100.0	100.3	98.1	95.9	94.3	87.3
	2	101.2	102.6	106.4	100.0	100.6	98.5	101.0
	Mean	101.2	101.3	103.3	99.0	98.3	96.4	94.2

N/A = not applicable (no volatile traps, or traps not sampled)
Note: Values were not rounded during spreadsheet calculations.

Table A 4: Material balance of radioactivity for Lleida soil treated with [14C]IN-KQ960 (% applied radioactivity)

	Rep. no.	Sampling interval (days)						
		0	1	2	3	7	14	21
Volatiles								
$^{14}CO_2$	1	N/A	1.7	6.3	10.9	25.2	37.8	46.6
	2	N/A	1.9	3.1	10.3	23.6	38.1	45.2
	Mean	N/A	1.8	4.7	10.6	24.4	38.0	45.9
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total	1	N/A	1.7	6.3	10.9	25.2	37.8	46.6
	2	N/A	1.9	3.1	10.3	23.6	38.1	45.2
	Mean	N/A	1.8	4.7	10.6	24.4	38.0	45.9
Extractable radioactivity								
Total extractable	1	99.2	93.6	86.5	77.5	53.0	30.1	20.9
	2	101.1	95.0	87.2	78.1	54.9	30.4	20.7
	Mean	100.1	94.3	86.8	77.8	53.9	30.2	20.8
Bound residue	1	2.0	6.6	9.6	12.4	20.1	26.9	27.3
	2	1.9	6.7	10.8	12.4	21.2	29.7	28.9
	Mean	2.0	6.7	10.2	12.4	20.6	28.3	28.1
Material balance	1	101.2	101.9	102.4	100.8	98.3	94.8	94.8
	2	102.9	103.7	101.1	100.8	99.7	98.1	94.8
	Mean	102.1	102.8	101.7	100.8	99.0	96.5	94.8

N/A = not applicable (no volatile traps, or traps not sampled)
Note: Values were not rounded during spreadsheet calculations.

Table A 5: Material balance of radioactivity for Nambsheim soil treated with [14C]IN-KQ960 (% applied radioactivity)

	Rep. no.	Sampling interval (days)						
		0	1	2	3	7	14	21
Volatiles								
$^{14}CO_2$	1	N/A	1.9	7.9	12.6	31.6	47.7	53.1
	2	N/A	2.0	9.4	14.8	32.8	43.0	49.7
	Mean	N/A	2.0	8.7	13.7	32.2	45.4	51.4
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total	1	N/A	1.9	7.9	12.6	31.6	47.7	53.1
	2	N/A	2.0	9.4	14.8	32.8	43.0	49.7
	Mean	N/A	2.0	8.7	13.7	32.2	45.4	51.4
Extractable radioactivity								
Total extractable	1	100.7	92.9	82.6	72.6	38.4	9.6	3.3
	2	100.5	91.9	80.2	69.6	36.0	12.9	3.3
	Mean	100.6	92.4	81.4	71.1	37.2	11.2	3.3
Bound residue	1	1.6	6.3	11.5	15.7	28.7	37.8	37.7
	2	1.4	7.8	12.5	17.8	29.3	37.5	37.9
	Mean	1.5	7.0	12.0	16.8	29.0	37.6	37.8
Material balance	1	102.3	101.1	102.0	101.0	98.7	95.2	94.1
	2	101.9	101.6	102.1	102.2	98.0	93.4	90.9
	Mean	102.1	101.4	102.1	101.6	98.4	94.3	92.5

N/A = not applicable (no volatile traps, or traps not sampled)
Note: Values were not rounded during spreadsheet calculations.

Table A 6: Material balance of radioactivity for Sassafras soil treated with [14C]IN-KQ960 (% applied radioactivity)

	Rep. no.	Sampling interval (days)						
		0	1	2	3	7	14	21
Volatiles								
$^{14}CO_2$	1	N/A	2.8	7.5	11.2	21.1	27.2	30.9
	2	N/A	2.7	6.9	10.7	20.8	26.9	30.5
	Mean	N/A	2.8	7.2	11.0	21.0	27.1	30.7
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total	1	N/A	2.8	7.5	11.2	21.1	27.2	30.9
	2	N/A	2.7	6.9	10.7	20.8	26.9	30.5
	Mean	N/A	2.8	7.2	11.0	21.0	27.1	30.7
Extractable radioactivity								
Total extractable	1	101.1	84.2	71.7	56.1	32.4	25.3	22.5
	2	101.8	86.1	70.4	59.5	35.3	25.1	22.9
	Mean	101.4	85.2	71.1	57.8	33.9	25.2	22.7
Bound residue	1	1.6	14.5	24.4	32.5	44.3	43.4	42.1
	2	1.3	14.0	26.9	32.4	44.1	47.4	43.8
	Mean	1.4	14.2	25.6	32.5	44.2	45.4	42.9
Material balance	1	102.6	101.5	103.6	99.8	97.8	95.9	95.6
	2	103.1	102.8	104.3	102.6	100.2	99.3	97.3
	Mean	102.9	102.2	103.9	101.2	99.0	97.6	96.4

N/A = not applicable (no volatile traps, or traps not sampled)
Note: Values were not rounded during spreadsheet calculations.

Table A 7: Degradation of IN-KQ960 in Speyer 2.2 soil under aerobic conditions as %AR

Compound	Rep. no.	Sampling interval (days)[b]					
		0	1	2	3	7	14
IN-KQ960	1	93.9	77.5	65.3	45.8	16.6	0.2
	2	98.6	76.3	60.9	46.0	14.2	0.2
	Mean	96.2	76.9	63.1	45.9	15.4	0.2
Unidentified radioactivity	1	4.2	5.9	8.3	14.4	14.5	13.4
	2	2.4	8.0	9.3	13.1	17.9	16.4
	Mean	3.4	6.9	8.8	13.8	16.2	14.9
Total extractable residue[a]	1	98.1	83.4	73.6	60.2	31.1	13.6
	2	101.0	84.3	70.2	59.1	32.1	16.6
	Mean	99.6	83.8	71.9	59.7	31.6	15.1
Non-extractable residue	1	2.50	12.10	18.1	24.8	36.8	37.9
	2	1.90	12.80	20.4	23.8	37.9	39.8
	Mean	2.20	12.50	19.3	24.3	37.4	38.9
$^{14}CO_2$	1	N/A	4.6	10.7	15.6	31.6	42.3
	2	N/A	4.4	10.3	15.3	31.1	42.2
	Mean	N/A	4.5	10.5	15.4	31.4	42.3
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A
Total % recovery	1	100.6	100.1	102.4	100.6	99.6	93.8
	2	103.0	101.5	100.9	98.3	101.1	98.7
	Mean	101.8	100.8	101.7	99.4	100.3	96.2

N/A = not applicable (no volatile traps, or traps not sampled)
a The total values may differ slightly from the sum of the individual values due to rounding
b All extracts were not analyzed by HPLC.

Table A 8: Degradation of IN-KQ960 in Tama soil under aerobic conditions as %AR

Compound	Rep. no.	Sampling interval (days)[b]				
		0	1	2	3	7
IN-KQ960	1	94.5	68.7	54.3	36.8	5.5
	2	93.4	68.0	51.5	35.8	6.6
	Mean	94.0	68.4	52.9	36.3	6.1
Unidentified radioactivity	1	3.6	9.7	11.8	17.6	26.1
	2	4.7	13.5	17.4	22.7	29.4
	Mean	4.1	11.5	14.6	20.1	27.7
Total extractable residue[a]	1	98.1	78.4	66.1	54.4	31.6
	2	98.1	81.5	68.9	58.5	36.0
	Mean	98.1	79.9	67.5	56.4	33.8
Non-extractable residue	1	3.1	17.3	25.1	31.3	45.5
	2	3.2	16.5	28.1	28.1	40.4
	Mean	3.1	16.9	26.6	29.7	42.9
$^{14}CO_2$	1	N/A	4.3	9.0	12.4	18.9
	2	N/A	4.6	9.4	13.5	24.3
	Mean	N/A	4.4	9.2	12.9	21.6
Volatile organics	1	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A
Total % recovery	1	101.2	100.0	100.3	98.1	95.9
	2	101.2	102.6	106.4	100.0	100.6
	Mean	101.2	101.3	103.3	99.0	98.3

N/A = not applicable (no volatile traps, or traps not sampled)
[a] The total values may differ slightly from the sum of the individual values due to rounding
[b] All extracts were not analyzed by HPLC.

Table A 9: Degradation of IN-KQ960 in Lleida soil under aerobic conditions as %AR

Compound	Rep. no.	Sampling interval (days)[b]						
		0	**1**	**2**	**3**	**7**	**14**	**21**
IN-KQ960	1	98.6	88.0	77.4	60.9	32.5	8.3	1.8
	2	97.2	89.2	78.5	66.4	32.0	8.1	1.6
	Mean	97.9	88.6	78.0	63.7	32.3	8.2	1.7
Unidentified radioactivity	1	0.6	5.6	9.1	16.6	20.5	0.6	5.6
	2	3.9	5.8	8.7	11.7	22.9	3.9	5.8
	Mean	3.2	5.7	8.8	14.1	21.6	3.2	5.7
Total extractable residue[a]	1	99.2	93.6	86.5	77.5	53.0	30.1	20.9
	2	101.1	95.0	87.2	78.1	54.9	30.4	20.7
	Mean	101.1	94.3	86.8	77.8	53.9	30.2	20.8
Non-extractable residue	1	2.0	6.6	9.6	12.4	20.1	26.9	27.3
	2	1.9	6.7	10.8	12.4	21.2	29.7	28.9
	Mean	2.0	6.7	10.2	12.4	20.6	28.3	28.1
$^{14}CO_2$	1	N/A	1.7	6.3	10.9	25.2	37.8	46.6
	2	N/A	1.9	3.1	10.3	23.6	38.1	45.2
	Mean	N/A	1.8	4.7	10.6	24.4	38.0	45.9
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Total % recovery	1	101.2	101.9	102.4	100.8	98.3	94.8	94.8
	2	102.9	103.7	101.1	100.8	99.7	98.1	94.8
	Mean	102.1	102.8	101.7	100.8	99.0	96.5	94.8

N/A = not applicable (no volatile traps, or traps not sampled)
[a] The total values may differ slightly from the sum of the individual values due to rounding
[b] All extracts were not analyzed by HPLC.

Table A 10: Degradation of IN-KQ960 in Nambsheim soil under aerobic conditions as %AR

Compound	Rep. no.	Sampling interval (days)[b]					
		0	1	2	3	7	14
IN-KQ960	1	95.9	91.6	73.6	64.7	25.3	3.9
	2	98.6	83.1	68.7	56.8	22.7	1.6
	Mean	97.3	87.4	71.2	60.8	24.0	2.8
Unidentified radioactivity	1	4.8	1.3	9	7.9	13.1	5.7
	2	1.9	8.8	11.5	12.8	13.3	11.3
	Mean	3.3	5	10.2	10.3	13.2	8.4
Total extractable residue[a]	1	100.7	92.9	82.6	72.6	38.4	9.6
	2	100.5	91.9	80.2	69.6	36.0	12.9
	Mean	100.6	92.4	81.4	71.1	37.2	11.2
Non-extractable residue	1	1.6	6.3	11.5	15.7	28.7	37.8
	2	1.4	7.8	12.5	17.8	29.3	37.5
	Mean	1.5	7.0	12.0	16.8	29.0	37.6
$^{14}CO_2$	1	N/A	1.9	7.9	12.6	31.6	47.7
	2	N/A	2.0	9.4	14.8	32.8	43.0
	Mean	N/A	2.0	8.7	13.7	32.2	45.4
Volatile organics	1	N/A	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A	N/A
Total % recovery	1	102.3	101.1	102.0	101.0	98.7	95.2
	2	101.9	101.6	102.1	102.2	98.0	93.4
	Mean	102.1	101.4	102.1	101.6	98.4	94.3

N/A = not applicable (no volatile traps, or traps not sampled)
[a] The total values may differ slightly from the sum of the individual values due to rounding
[b] All extracts were not analyzed by HPLC.

Table A 11: Degradation of IN-KQ960 in Sassafras soil under aerobic conditions as %AR

Compound	Rep. no.	Sampling interval (days)[b]				
		0	1	2	3	7
IN-KQ960	1	99.7	77.4	54.6	38.4	4.1
	2	98.9	76.7	58.1	42.7	6.2
	Mean	99.3	77.0	56.3	40.5	5.2
Unidentified radioactivity	1	1.4	6.8	17.1	17.7	28.3
	2	2.9	9.4	12.3	16.8	29.1
	Mean	2.1	8.2	14.8	17.3	28.7
Total extractable residue[a]	1	101.1	84.2	71.7	56.1	32.4
	2	101.8	86.1	70.4	59.5	35.3
	Mean	101.4	85.2	71.1	57.8	33.9
Non-extractable residue	1	1.6	14.5	24.4	32.5	44.3
	2	1.3	14.0	26.9	32.4	44.1
	Mean	1.4	14.2	25.6	32.5	44.2
$^{14}CO_2$	1	N/A	2.8	7.5	11.2	21.1
	2	N/A	2.7	6.9	10.7	20.8
	Mean	N/A	2.8	7.2	11.0	21.0
Volatile organics	1	N/A	N/A	N/A	N/A	N/A
	2	N/A	N/A	N/A	N/A	N/A
	Mean	N/A	N/A	N/A	N/A	N/A
Total % recovery	1	102.6	101.5	103.6	99.8	97.8
	2	103.1	102.8	104.3	102.6	100.2
	Mean	102.9	102.2	103.9	101.2	99.0

N/A = not applicable (no volatile traps, or traps not sampled)
a The total values may differ slightly from the sum of the individual values due to rounding
b All extracts were not analyzed by HPLC.

MASS BALANCE

Material balance for the [^{14}C]IN-KQ960 ranged from 93.9 to 101.8% in Speyer 2.2 soil, from 94.2 to 103.3% in Tama soil, from 94.8 to 102.8% in Lleida soil, from 92.5 to 102.1% in Nambsheim soil, and from 96.4 to 103.9% in Sassafras soil, respectively.

BOUND AND EXTRACTABLE RESIDUES

The percentage of the applied radioactivity in the extractable fraction decreased from Day 0 to Day 21 for all five soils. Extractability values ranged from 99.6% AR (Day 0) to 9.6% AR (Day 21) for Speyer 2.2 soil, from 98.1% AR (Day 0) to 15.9% AR (Day 21) for Tama soil, from 100.1% AR (Day 0) to 20.8% AR (Day 21) for Lleida soil, from 100.6% AR (Day 0) to 3.3% AR (Day 21) for Nambsheim soil, and from 101.4% AR (Day 0) to 22.7% AR (Day 21) for Sassafras soil, respectively.

The level of bound residue increased throughout the course of the study with all five soils. The bound residue values increased and reached a maximum of 38.9, 43.5, 28.3, and 45.4% AR at Day 14, then decreased slightly to 37.7, 42.4, 28.1, and 42.9% AR at Day 21 for Speyer 2.2, Tama, Lleida, and Sassafras soils, respectively. For Nambsheim soil, the level of bound residue increased and reached a maximum of 37.8% AR at Day 21.

VOLATILISATION

Volatile radioactivity, identified as $^{14}CO_2$ (captured in the KOH traps) collected increased with time in each soil. Mean $^{14}CO_2$ collected values at Day 21 were 46.7, 35.9, 45.9, 51.4, and 30.7% AR for Speyer 2.2, Tama, Lleida, Nambsheim, and Sassafras soils, respectively.

TRANSFORMATION OF THE COMPOUND

During the course of the study, the amount of the metabolite [^{14}C]IN-KQ960 in the extracts decreased from an average of 96.2% AR at Day 0 to <1% AR by Day 14 in the Speyer 2.2 soil, 94.0 to 6.1% AR by Day 7 in the Tama soil, 97.9 to 1.7% AR by Day 21 in the Lleida soil, 97.3 to 2.8% AR at Day 14 in the Nambsheim soil, and 99.3 to 5.2% AR at the Day 7 in the Sassafras soil.

The DT_{50} and DT_{90} values for IN-KQ960 were calculated by the single first order (SFO) model and first-order multiple compartment (FOMC) model using ModelMaker® 4.0. The SFO provided both a good visual and statistical fit for all soils and the FOMC model did not provide a better fit with significant errors observed in the kinetic parameters. Therefore, the hockey stick and double first-order in parallel models were not tested. The SFO model first-order rate constants (kp), DT_{50}, and DT_{90} values for IN-KQ960 in each of the five soil types are summarised in the table below:

Table A 12: DT_{50} and DT_{90} values for IN-KQ960 in aerobic soil

Soil type	IN-KQ960 first-order rate constant (day^{-1})	IN-KQ960 DT_{50} (days)	IN-KQ960 DT_{90} (days)	r^2	Model
Speyer 2.2	0.262	2.6	8.8	0.997	SFO
Tama	0.347	2.0	6.6	0.995	SFO
Lleida	0.165	4.2	14	0.997	SFO
Nambsheim	0.198	3.5	11.7	0.989	SFO
Sassafras	0.324	2.1	7.1	0.991	SFO

A 2.1.4 Conclusion

IN-KQ960, a metabolite of cymoxanil, degraded at 20°C under aerobic conditions in all test soils. The DT_{50} and DT_{90} values were calculated by the single first order (SFO) model and ranged from 2.0 to 4.2 days and from 6.6 to 14 days, respectively.

A 2.2 KCA 7.1.3.1: [redacted] (2010), DuPont-28467. IN-KQ960 adsorption/desorption in soil

Reference:	KCA 7.1.3.1
Report:	14C-IN-KQ960: Batch equilibrium (adsorption/desorption) in five soils. [redacted] 2010 Document Number: DuPont-28467
Guideline(s):	OECD 106 (2000), OPPTS 835.1230 (2008)
Deviations:	-
GLP:	Yes
Acceptability:	Yes

A 2.2.1 Executive summary

The adsorption and desorption properties of [^{14}C]IN-KQ960, were investigated to assess its potential mobility in soils. The adsorption/desorption of [^{14}C]IN-KQ960 was examined on five different soils. The percent organic matter (Walkley-Black method) of the soils ranged from 1.3 to 5.4%, and the pH (1:2 soil:0.01 M $CaCl_2$) ranged from 4.9 to 7.7.

The sorption coefficients K_D, K_{OM}, and K_{OC} were calculated and ranged from 0.0183 to 0.2473 mL/g, from 1.4 to 5.7 mL/g, and from 2.4 to 9.7 mL/g, respectively.

The Freundlich adsorption isotherm parameters were derived from the linear form of the Freundlich equation and ranged from 0.0178 to 0.1747 for K_F, from 1.37 to 5.23 for K_{FOM}, from 2.36 to 8.99 for K_{FOC}, respectively. The corresponding 1/n ranged from 0.8270 to 1.0660.

Due to the low level of initial adsorption, scientifically meaningful desorption parameters could not be calculated.

A 2.2.2 Materials and Methods

A. MATERIALS

Test material	[^{14}C] IN-KQ960 technical metabolite
Lot/Batch #:	4009572
Radiochemical purity:	99.1%
Specific activity:	29.4 µCi/mg
Description:	Not described
CAS#:	644972-61-2
Stability of test compound:	91.7 – 95%

SOILS

Five soils typical of growing regions in North America and across Europe were provided. The five test soils used were a loam from Darmstaadt County, Hessen, Germany (Gross-Umstadt); a clay loam from Ogle County, Illinois, USA (Drummer); a clay loam from Lleida, Spain (Lleida); a sandy loam soil from Nambsheim, France (Nambsheim); and a sandy loam soil from Kent County, Maryland, USA (Sassafras). The soils were stored refrigerated when not in use.

Prior to use, the test soils were sieved through a No. 10 sieve (2-mm mesh). The moisture content of the sieved soils was determined after air-drying the soils on pre-weighed foil boats. A summary of the physical and chemical properties of the soils is provided in Table A 13.

Table A 13: Soil characteristics

Property	Gross-Umstadt	Drummer	Lleida	Nambsheim	Sassafras
Origin	Darmstadt County, Hessen, Germany	Ogle County, Illinois, USA	Lleida County, Catalunya, Spain	Alsace County, Haute, France	Kent County, Maryland, USA
Soil Texture (USDA Classification)	Loam	Clay Loam	Clay Loam	Sandy Loam	Sandy Loam
% Sand	44	31	26	66	73
% Silt	39	36	35	23	20
% Clay	17	33	39	11	7
pH (in 0.01 M $CaCl_2$ (aq))	6.7	5.8	7.7	7.4	4.9
Organic matter (Walkley Black) (%)	1.9	5.4	2.1	2.8	1.3
Organic carbon (%)	1.1	3.1	1.2	1.6	0.76
CEC (meq/100 g)	11.1	31.3	27.2	10.1	6.4
Moisture at 1/3 bar (%)	16.6	31.5	26.5	12.6	10.4
Bulk density (g/cm^3)	1.19	1.09	1.07	1.13	1.19

[a] Organic Carbon = Organic Matter / 1.72

B. STUDY DESIGN

EXPERIMENTAL CONDITIONS

Samples were prepared in duplicate for each concentration level to contain 15 g (dry weight) of soil. A sufficient amount of 0.01 M $CaCl_2$ was then added to bring the moisture content to 13.5 mL (*i.e.*, 90% of the total final volume of solution). The samples were equilibrated overnight at the test temperature of 20°C. Dose solutions of IN-KQ960 were prepared in 0.01 M $CaCl_2$ at nominal concentrations of 0.0151, 0.0763, 0.151, 0.749, and 1.50 µg/mL. A 1.5-mL aliquot of the corresponding dose solution was added to the respective sample on the day of dosing, thus yielding a soil to solution ratio of 1:1. The samples were shaken at 20°C for a 24-hour equilibration period. Preliminary testing of soil-less control samples and blank samples containing no test substance were performed to assess potential adsorption to the test vessels and any interferences. Following centrifugation (3050 × g for 30 minutes), the supernatant was decanted, filtered through 0.2-µm nylon filters, and aliquoted in triplicate for radioassay. Representative supernatants from the 0.10 and 1.0 µg/mL concentrations were analysed by HPLC to assess the stability of IN-KQ960 during the adsorption equilibration period.

Following the adsorption phase, the samples from the highest concentration were desorbed. Fresh 0.01 M $CaCl_2$ was added to each of these test vessels to return the total amount of solution to 15 g. The samples were equilibrated for 24 hours at 20°C, then solutions and soils were separated and quantified. The supernatants were radioassayed. The soils were subjected to a second desorption.

DESCRIPTION OF ANALYTICAL PROCEDURES

Radioactivity in the supernatants was determined by LSC. HPLC (Agilent, Zorbax, SB-C8, 5 µm (250 mm × 4.6 mm) with a gradient of 0.2% formic acid (aq) and methanol, was used as the primary method to check the radiopurity and to characterise the dose solution and adsorption supernatants from the 0.05 and 1.0 µg/mL concentrations. The effluent was passed through an UV detector (254 nm) to detect the reference standard and a radioactivity detector for peak shape comparison with UV, followed by fraction collection to determine the quantities of radiolabelled degradation products present. A detection limit of LSC analysis permitted detection of radioactivity of <1% applied radioactivity (AR).

A non-radiolabelled reference substance solution and a ^{14}C-test substance solution were analysed by HPLC on each analysis day to verify proper column and instrument operation. The retention time of [^{14}C]IN-KQ960 was determined to be approximately 14 minutes.

After the second desorption experiment, the soils from the high concentration samples were combusted, and ^{14}C levels were measured using LSC.

A 2.2.3 Results

MASS BALANCE

The material balances ranged from 91.2 to 98.2% and are within the acceptable guideline range of 90-110% of the applied radioactivity.

TRANSFORMATION OF THE COMPOUND

During the 24-hour equilibration period, no significant degradation was seen.

FINDINGS

Adsorption isotherms were calculated by linear regression analysis of the adsorption data according to the Freundlich equation. The Freundlich adsorption constants K_d values ranged from 0.0183 to 0.2473 mL/g. The adsorption coefficients were normalised to the organic matter and organic carbon contents for each test soil to calculate the soil sorption coefficients K_{OM} and K_{OC}. The K_{OM} values ranged from 1.4 to 5.7 mL/g, while the K_{OC} values ranged from 2.4 to 9.7 mL/g (Table A 14).

The values for the Freundlich adsorption isotherm parameters, K_F, ranged from 0.0178 to 0.1747. The organic matter normalised Freundlich adsorption isotherm constants K_{FOM} ranged from 1.37 to 5.23 (Table A 14), while the constants normalized for organic carbon K_{FOC} ranged from 2.36 to 8.99 (Table A 14). The values for 1/n ranged from 0.8270 to 1.066 across all the test soils. Correlation coefficients (r^2) for these analyses ranged from 0.8512 to 0.9980 for the adsorption phase (Table A 14), indicating the Freundlich equation adequately predicts the adsorption of the test substance over the concentration range studied.

Due to the low level of initial adsorption, scientifically meaningful desorption parameters could not be calculated. Thus, desorption was not reported.

Table A 14: Sorption constants of IN-KQ960 in the soils

Soil	% Organic Carbon	pH	K_D (mL/g)	K_{OM} (mL/g)	K_{OC} (mL/g)	K_F	K_{FOM}	K_{FOC}	1/n	R^2
Gross-Umstadt	1.1	6.7	0.0507	2.7	4.6	0.0357	1.88	3.23	0.8270	0.9943
Drummer	3.1	5.8	0.2473	4.6	7.9	0.1747	3.23	5.56	0.8404	0.9980
Lleida	1.2	7.7	0.1187	5.7	9.7	0.1097	5.23	8.99	0.9602	0.9969
Nambsheim	2.8	7.4	0.0621	2.2	3.8	0.0459	1.64	2.82	0.8500	0.9943
Sassafras	1.3	4.9	0.0183	1.4	2.4	0.0178	1.37	2.36	1.066	0.8512

A 2.2.4 Conclusion

The adsorption constants did not appear to correlate with the organic carbon content of the soils tested. On the basis of the results obtained it appears that [^{14}C]IN-KQ960 has a high potential soil mobility – K_{OC} values ranged from 2.4 to 9.7 mL/g.

A 2.3 KCA 7.1.2.2.1: [redacted] (2004), VV-330403. Fludioxonil – Field dissipation study (seed treatment)

Reference:	KCA 7.1.2.2.1
Report:	Fludioxonil - Field Study Comparing Seed Treatment Dissipation Against Field Dissipation in Switzerland During 2003 [redacted] 2004 Syngenta, Environmental Sciences, Jealott's Hill, International Research Centre, Bracknell, Berkshire, RG42 6EY, UK. RJ3547A, ID 03-S602 Syngenta File No. CGA173506/5993; VV-330403
Guideline(s):	SETAC 1985
Deviations:	No
GLP:	Yes
Acceptability:	Yes

A 2.3.1 Executive Summary

A field trial compared the dissipation of fludioxonil applied as a seed treatment, a topical broadcast spray and an incorporated broadcast spray. Soil samples were taken for up to 90 days after treatment. Comparisons of the fludioxonil dissipation in plots exposed to sunlight, plots covered with plastic and plots over-sown with turf were also made within each treatment.

Results were erratic for the seed treatment and no conclusions could be drawn as to degradation rate. The broadcast incorporated spray gave half-lives of 104 and 105 days for plots exposed to sunlight and under turf, respectively. The plot covered with plastic gave a half-life of 70 days and a DT_{50} of 55 days. The most rapid dissipation of fludioxonil residues occurred in the topical application trial. The half-life was determined to be 22 days, for both the plot exposed to sunlight and the plot over-sown with turf.

A 2.3.2 Materials and methods

A trial was carried out in Switzerland during 2003 to compare the dissipation of fludioxonil when applied as a seed treatment, a topical (broadcast spray) treatment and an incorporated broadcast spray treatment. Comparisons of the fludioxonil dissipation in plots exposed to sunlight, plots covered with plastic and plots over-sown with turf were also made within each trial subset, in order to evaluate the effects of the rhizosphere and of sunlight exposure on degradation.

In the seed treatment trial fludioxonil was applied as treated spring wheat seed, treated with A8348B (a 100 g/L w/v seed formulation) at a rate of 25 g a.s./100 kg seeds. A seeding rate of 300 kg seeds/ha in the plots gave an application rate equivalent to approximately 75 g a.s./ha. The rows were spaced 12 cm apart, resulting in 8 rows per square meter, resulting in around 83 seeds/m. The seeding depth was 1.5 to 3.0 cm. In the broadcast trial a single application of fludioxonil (as A7850C, a 500 g/kg w/v wettable powder formulation) was sprayed at approximately 500 g a.s./ha to the soil surface for each of the plots in the topical and incorporated trials with water volumes of 200 L/ha and 800 L/ha.

Soil samples from all the plots were nominally taken immediately after the application and on 4, 8, 16, 33, 64 and 90 DAA (Days After Application). In the seed treatment trial samples from within the rows were taken by an 8 cm corer and all other samples were taken by a 5 cm corer. Control samples were taken from each plot immediately before application. Samples were taken from the 0-30 cm soil layer, cut into three 10 cm profiles and bulked to give composite samples. Each resulting sample was homogenised (including the seeds from the seed treatment trial) and a 10 g subsample was taken for extraction and analysis. The half-life (based on unweighted simple first order kinetics, SFO), the DT_{50} and DT_{90} values (based on a first order multicompartment model, FOMC) for fludioxonil were determined for each plot using Model Manager.

A 2.3.3 Results and discussions

The residue values for each sampling interval in the seed treatment trial were erratic for each plot and no conclusions could be drawn as to the fludioxonil dissipation rate. The reasons for the erratic residues were that it could not be guaranteed that the number of seeds within each core was the same for every core sampled at each sampling interval (an 8 cm core would contain only 6-7 seeds). The major error, however, will be due to the 10 g sub-samplings (representing an equivalent amount of 0.1 treated seed grain) from the composite samples since it could also not be guaranteed that the prepared samples were homogenous, even with thorough blending, due to the localisation of the residues around the seeds.

No measurable fludioxonil residues (limit of quantification, LOQ, 0.01 mg/kg) were determined below the 0 – 10 cm soil depth for this trial (03-S602-STR), indicating no downward movement of the fludioxonil residues from seed treatments. Residues were observed between the rows at certain sampling intervals for the sterile seed plot and the seed plot over-sown with turf. However, these residue values were all obtained at sampling intervals when no germination of the seeds had occurred. It could not be guaranteed that all the cores taken at the sampling intervals were actually between the rows and not from within a row of seeds.

The broadcast spray with incorporation trial gave half-lives of 104 and 105 days for fludioxonil dissipation, for the plot exposed to sunlight and the plot over-sown with turf, respectively. The plot covered with plastic gave a half-life of 70 days and a DT_{50} of 55 days. Water condensation (formation of droplets) under the plastic were observed from 5 DAA to the end of the field phase for this plot, leading to humid conditions. These humid conditions and the fact that the fludioxonil was incorporated into the soil led to greater biochemical breakdown of the fludioxonil, which resulted in the lower DT_{50} and half-life values. No measurable fludioxonil residues (LOQ, 0.01 mg/kg) were determined below the 10 – 20 cm soil depth for this trial.

The most rapid dissipation of fludioxonil residues occurred in the topical application trial. The half-life was determined to be 22 days, for both the plot exposed to sunlight and the plot over-sown with turf. Additionally, the plot exposed to sunlight produced a DT_{90} value of 72 days. The fludioxonil dissipation was not significant in the plot covered with plastic (i.e. kept in darkness). Apart from the application day samples from each plot, no measurable fludioxonil residues (LOQ, 0.01 mg/kg) were determined below the 10 – 20 cm soil depth for this trial.

Table A 15: Summary of half-life, DT_{50} and DT_{90} values

Trial	Plot No.	Initial (day 0) recovery [%]	Half-Life [days]	Goodness of fit [r^2]	DT_{50} [days]	Goodness of fit [r^2]	DT_{90} [days]
03-S602-STR	1 (bare soil)	47	NC	NC	NC	NC	NC
	2 (bare soil)	63	NC	NC	NC	NC	NC
	3 (turf)	89	NC	NC	NC	NC	NC
03-S602-INC	4 (bare soil)	74	104	0.726	137	0.804	NC
	5 (covered)	88	70	0.838	55	0.935	NC
	6 (turf)	67	105	0.758	112	0.761	NC
03-S602-TOP	7 (bare soil)	54	22	0.757	19	0.762	72
	8 (covered)	59	NC	NC	NC	NC	NC
	9 (turf)	60	22	0.841	12	0.973	NC

NC Not calculable within the 90 day timescale of the study

Generally, the day zero recoveries were relatively low, which might be due to a fast initial degradation (triggered by biological and photochemical processes) before the highly lipophilic fludioxonil becomes strongly bound to the soil matrix, resulting in reduced bioavailability and increased shielding from light exposure. This same behaviour has been also observed in most field studies with fludioxonil. Since DT_{50} values were usually calculated based on the day zero recoveries, those values have to be considered consequently as worst case data as they do not include this fast initial decline.

A 2.3.4 Conclusion

- Sampling is a very critical parameter in field dissipation studies with treated seeds.
- Under field conditions usually a rapid initial decline of fludioxonil residues is observed.
- There was no significant effect of the rhizosphere on degradation.
- The most efficient degradation process is controlled by photolysis.
- After incorporation into field soil fludioxonil will be degraded significantly by biotic pathways with half-lives well below those observed in laboratory studies.

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

A 3.1 KCP 9.1.1: [redacted] (2015), VV-629108. Metalaxyl-M: Calculation of the formation fraction of the soil degradate CGA108906 for use in environmental models

Reference:	KCP 9.1.1
Report:	Metalaxyl-M: Calculation of the formation fraction of the soil degradate CGA108906 for use in environmental models [redacted] 2015 Report Number RAJ1079B Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY UK Syngenta file No. VV-629108
Guideline(s):	FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

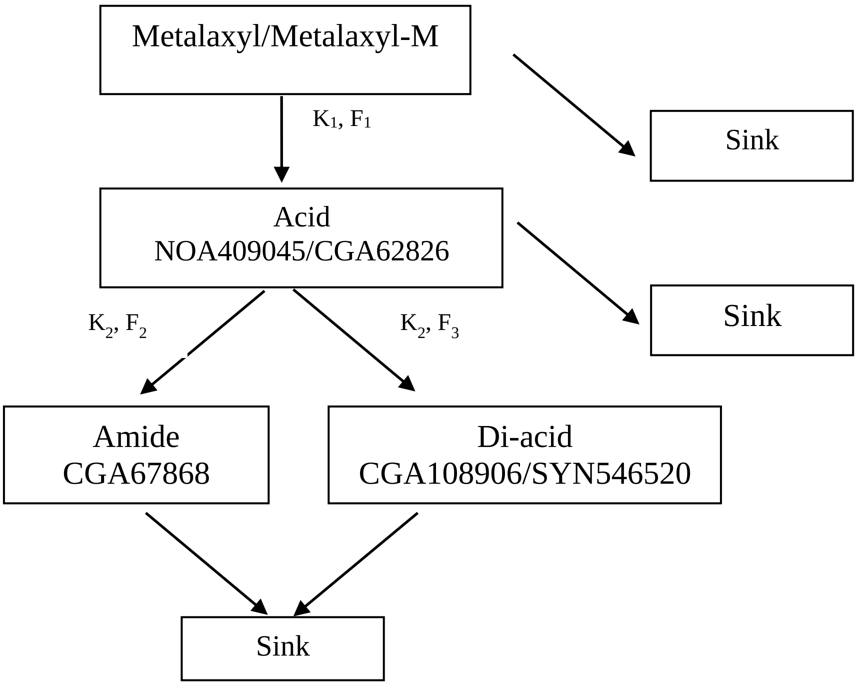
A 3.1.1 Materials and methods

This report presents the calculations to determine the degradation rate and formation fraction for the di-acid metabolite of metalaxyl/metalaxyl-M. The di-acid formed from the enantiomerically pure (R enantiomer) metalaxyl-M is referred to as SYN546520. The di-acid metabolite formed from the racemic (R/S) compound metalaxyl is also a racemic mixture and is referred to as CGA108906.

The route and rate of degradation of metalaxyl-M (R enantiomer) and metalaxyl (R/S racemate) has been studied in the laboratory in two studies in which formation and decline of di-acid was observed ([redacted] 2003a, [redacted] 2003b).

The original data from these studies was used to calculate the rate of degradation of metalaxyl-M, metalaxyl and metabolites NOA409045, CGA62826, CGA67868 and CGA108906 in soil and their formation fractions, following the guidance in FOCUS Kinetics (2006). The pathway implemented for kinetic modelling is presented in Figure A 1.

Figure A 1: Implementation of metalaxyl-m degradation pathway for kinetic fitting



K_1 degradation rate of parent
F_1 formation fraction of acid metabolite (NOA409045/CGA62826)
K_2 degradation rate of acid metabolite (NOA409045/CGA62826)
F_2 formation fraction of amide metabolite (CGA67868) from acid metabolite.
F_3 formation fraction of di-acid metabolite (CGA108906/SYN546520) from acid metabolite

Kinetic modelling following the appropriate FOCUS Kinetics (2006) flowchart was carried out using CAKE v2.0 (2013).

Confidence in the resulting parameters has been assessed visually and from the probability values for a t-test of the rate parameters for the single first order (SFO). Where the parameters for a particular model are not significantly different from zero at the 95th or 90th significance level, it has been concluded that the model is not appropriate to represent the degradation behaviour of metalaxyl-M in that soil. The $\chi 2$ error% parameter has been used to determine goodness of fit and where two models are an appropriate to fit the data, the choice of best fit has been based on the lowest value of this parameter.
In the first instance, the data were directly fitted un-weighted with the complete data set and unconstrained initial concentration (M0) for parent and M0 fixed to zero for metabolites. The acceptability of the kinetic fits was judged as follows:

Visually using a three point scale:

Poor = an unacceptable fit, the fitted curve does not represent the trend of the data points and residuals show strong deviations from random distribution;

Acceptable = the fitted curve describes the trend of the data points, residuals may show some deviation from random distribution but it is not significant;

Good = the fitted curve closely follows all the data points, residuals are randomly distributed.

Confidence of rate constants:
The FOCUS Kinetics guidelines state that the confidence that can be assigned to a parameter must be assessed (FOCUS, 2006). Parameter estimates with a significance level greater than 95% are acceptable and, if greater than 90%, may be accepted where the visual fit is acceptable or good. Where significance levels are less than 90%, the fits are not considered acceptable.

For SFO fits the assessment was based on the t-test probability value of the estimate of the degradation rate (k).

Fit to the data points (χ2 error%):
It is recommended that a χ^2 error% of 15% or less indicates acceptable fits, although for data that may include intrinsically variable data (metabolites at low levels compared to parent and field data) higher values can be tolerated if the visual fit is acceptable or good. Where two or more models are acceptable fits to the data, the χ^2 error% parameter has been used to assess goodness of fit. In these cases, the model with the lowest value of this parameter has been chosen as the best fit.

Metabolites:
Metabolites have been fitted in the step-wise procedure indicted by the guidance (FOCUS, 2006). Parent data were fitted with the best-fit model, the parameters were fixed for the metabolite fitting step and, finally, the parameters were un-fixed for a re-fit. The outputs from the final step only are given in Appendix 3 of the corresponding report.

For fits that are visually acceptable or good, but for which a robust degradation rate cannot be established, i.e. a t-test of <90% probability, then a conservative default value $DegT_{50}$ of 1000 days has been used.

A 3.1.2 Data Manipulation, Pappelacker treated with metalaxyl-M ([redacted] and [redacted] 2003a)

Zero day metabolite applied radioactivity (AR) values were added to parent metalaxyl-M. Metabolite zero day values were set to zero. Preceding values of zero were set to half of LOQ for metabolite CGA108906 for Day 2a and 2b.

A 3.1.3 Data Manipulation, Pappelacker treated with metalaxyl ([redacted] and [redacted] 2003b)

Preceding values of zero were set to half of LOQ for metabolite CGA108906 for Day 7a, 7b and 14a.

A 3.1.4 Normalisation to 20ºC and pF2

These studies were performed at standard conditions.

A 3.1.5 Results

Table A 16 to Table A 18 provide a summary and the averages for persistence and modelling endpoints for metalaxyl-M, metalaxyl and soil metabolites NOA409045, CGA62826, CGA67868, SYN546520 and CGA108906. $DegT_{50}$ values derived for parent material were very similar to those previously reported ([redacted] 2007). Formation fractions are summarised in Table A 19.

Table A 16: Parent endpoints for metalaxyl–M1 and metalaxyl2 in laboratory aerobic soil

Soil	Pappelacker[1] ([redacted] and [redacted] 2003a)	Pappelacker[2] ([redacted] and [redacted] 2003b)
Model	SFO[3]	SFO[3]
Visual Fit	Acceptable	Acceptable
Residuals (visual)	Acceptable	Acceptable
χ2 error (%)	4.88	2.94
Initial value: estimate / (range) / standard error	Pini: 97.8 (97.5 - 99.2)	Pini: 97.6 (98.9 – 99.0)
	σ: 1.047	σ: 0.917
Rate Parameters: estimate / standard error / probability (trigger:0.05)	kP: 0.06943	kP: 0.02934
	σ: 0.001686	σ: 0.000657
	$p < 0.01$	$p < 0.01$
DT_{50} (days)	9.98	23.6
DT_{90} (days)	33.2	78.5
Modelling DegT50	9.98	23.6

[1] Laboratory soil treated with metalaxyl-M
[2] Laboratory soil treated with metalaxyl
[3] Full report of selection process in [redacted] 2007

Table A 17: Modelling fits for the acid, amide and di-acid metabolites (NOA409045, CGA67868 and SYN546520) of metalaxyl-M – laboratory aerobic soil Pappelacker ([redacted] and [redacted] 2003a)

Metabolite	NOA409045	CGA67868	SYN546520
Parent Model	SFO	SFO	SFO
Metabolite Model	SFO	SFO	SFO
Visual Fit	Good	Acceptable	Good
Residuals (visual)	Good	Acceptable	Good
χ2 error (%)	10.8	29.2	37.5
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k A1: 0.08553	k A2: 0.1911	k B1: 0.00944
	σ: 0.005917	σ: 0.06404	σ: 0.004559
	$p < 0.01$	$p < 0.01$	$p < 0.01$
DT_{50} (days)	8.10	3.63	73.4
DT_{90} (days)	26.9	12.1	244
Formation fraction from Parent	0.805		
Formation fraction from NOA409045		0.367	0.026

Table A 18: Modelling fits for the acid, amide and di-acid metabolites (CGA62826, CGA67868 and CGA108906) of metalaxyl – laboratory aerobic soil Pappelacker ([redacted] and [redacted] 2003b)

Metabolite	CGA62826	CGA67868	CGA108906
Parent Model	SFO	SFO	SFO
Metabolite Model	SFO	SFO	SFO
Visual Fit	Good	Good	Acceptable
Residuals (visual)	Good	Good	Acceptable
$\chi2$ error (%)	10.5	16.7	22.5
Rate Parameters: estimate / standard error / probability (trigger:0.05)	k A1: 0.1359 σ: 0.0124 p < 0.01	k A2: 0.1085 σ: 0.02034 p < 0.01	k B1: 0.0233 σ: 0.004736 p < 0.01
DT_{50} (days)	5.10	6.39	29.8
DT_{90} (days)	17	21.2	98.8
Formation fraction from Parent	1		
Formation fraction from CGA62828		0.203	0.025

Table A 19: Summary of Formation Fractions in Pappelacker Soil

Metabolite	Derivation of value	Formation Fraction Range	Formation fraction [from]
Di-acid CGA108906/SYN546520	Arithmetic mean (n=2)	0.025-0.026	0.03 (NOA409045)
Amide CGA67868	Arithmetic mean (n=2)	0.203-0.367	0.285 (NOA409045)

A 3.1.6 Conclusions

Evaluation of CGA108906 formation fraction in a third soil, as requested by EFSA 2015, has been performed for Pappelacker. The arithmetic mean CGA108906 formation fraction value of 0.03, demonstrates that the formation fraction 0.1 value proposed at Annex 1 Renewal to be conservative.

A 3.2 KCP 9.1.1: [redacted] (2020), VV-742439. CGA108906 Kinetic evaluation of Formation Fraction

Reference:	KCP 9.1.1
Report:	Metalaxyl-M: Kinetic evaluation of Formation Fraction. [redacted] 2020 Report Number RAJ1329B Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY UK Syngenta file No. VV-742439
Guideline(s):	FOCUS (2006). Guidance document on estimating persistence and degradation kinetics from environmental fate studies on pesticides in EU registration. Report of the FOCUS Work Group on Degradation Kinetics, EC Document Reference Sanco/10058/2005, version 2.0, 434 pp. FOCUS (2014). Generic guidance for estimating modelling and degradation kinetics from environmental fate studies on pesticides in EU registration. Version 1.1, 440 pp.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.2.1 Materials and methods

This report demonstrates how the EFSA List of Endpoints SYN546520 (metabolite of metalaxyl-M) 0.47 formation fraction (ff) is both overly conservative and unrealistic, and alternatively proposes a lower value which is based on kinetic evaluation of soil study data.

From the kinetic studies of [redacted], 2012, 2015 and [redacted] 2013, metalaxyl-M and its metabolites degrade according to a single first order (SFO) degradation model for parent and its metabolites as shown in Figure A 2. These data were used as inputs to an SFO model spreadsheet using MS Excel 365 ProPlus, which uses standard kinetic equations to represent the pathway of parent to primary metabolite to secondary metabolite.

Inputs to the spreadsheet are the initial value of the parent, DT_{50} values of the parent and metabolites, and ff of the metabolites which are presented in Table A 20.

Table A 20: Inputs used to determine predicted maximum occurrence and formation fraction of metabolites

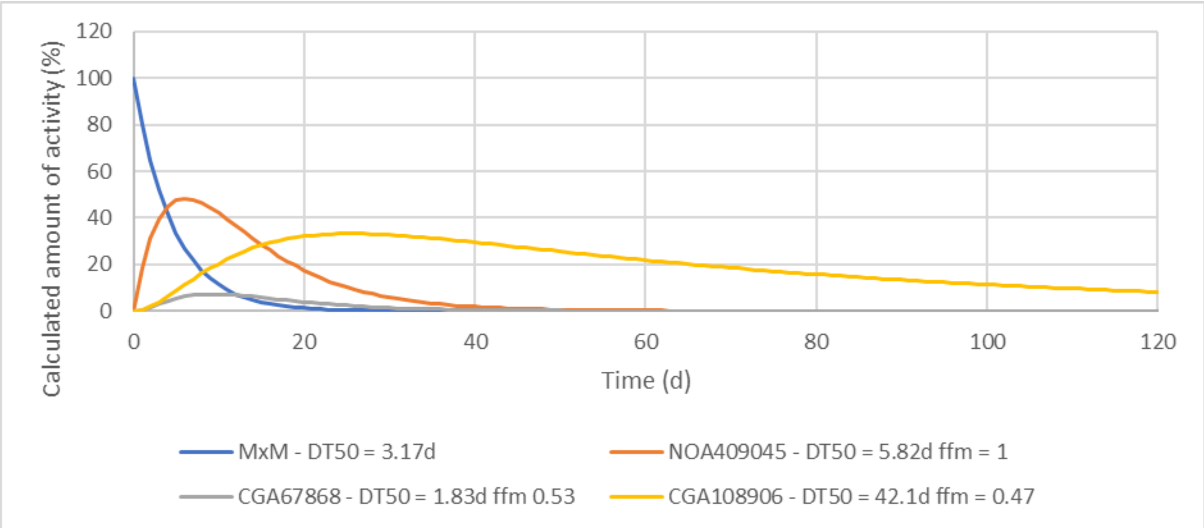
Compound	$DegT_{50}$ (d)	M0 (%)	Formation fraction	Predicted maximum occurrence (%)
Metalaxyl-M	3.17[a]	100	-	-
Acid metabolite NOA409045	5.82[a]	0	1 [a]	48.34
Amide CGA67868	1.83[a]	0	0.53[a]	7.28
Diacid metabolite SYN546520 (CGA108906)	42.1[b]	0	0.47 (Belgium RMS, Tier I) [c]	33.24
			0.1 (Tier II)	7.07
			0.033	2.33

[a] [redacted], 2012
[b] [redacted], 2015
[c] Conclusion on the peer review of the pesticide risk assessment of the active substance metalaxyl-M, 2015

Based on these inputs, the spreadsheet calculates kinetic graphs for the parent and metabolites and therefore enables analysis of the impact of ff on the maximum observed value of a metabolite.

For the Gartenacker soil, a CGA108906 ff value of 0.47 was hypothesized by RMS Belgium, whereas a value of 0.1 was proposed by Syngenta at Annex I Renewal, 2012. Both of these ff were inputted into the SFO model spreadsheet and the outputs of the model are presented in Figure A 2 and Figure A 3, respectively.

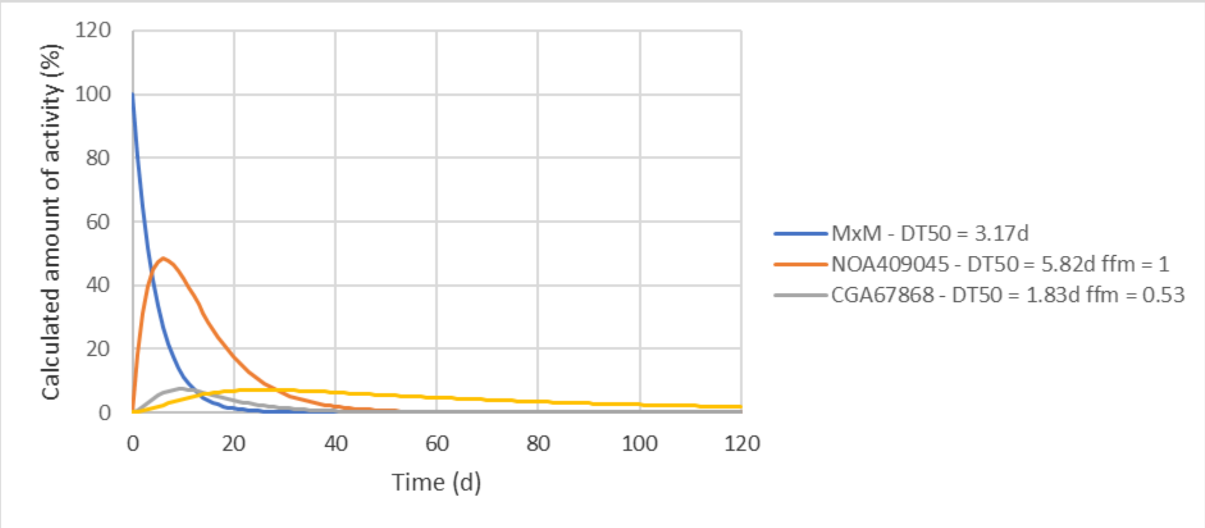
Figure A 2: Formation and decay curves of metalaxyl-M and its metabolites using CGA108906 0.47 Tier 1 ff based on DT50's derived from [redacted] 2012, 2015 and [redacted] 2013.



Max of NOA409045 predicted = 48.44%
Max of CGA67868 predicted = 7.28%
Max of CGA108906 predicted = 33.24% (overly conservative), CGA108906 was not observed <2.3%

From Figure A 2 it can be seen that a CGA108906 ff value of 0.47 leads to a maximum predicted value of CGA108906 of 33.24%. Whereas from Figure A 3 it can be seen that a CGA108906 ff value of 0.1 leads to a maximum predicted value of CGA108906 of 7.07%. Since CGA108906 was not observed in the Gartenacker soil and the maximum unidentified radioactive component was <2.3%, both of these ff values are therefore very conservative.

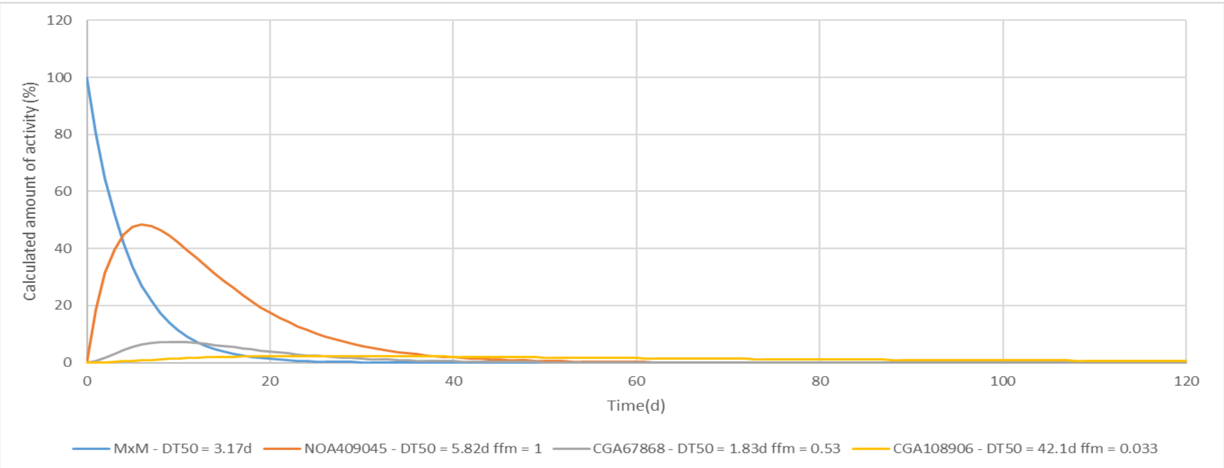
Figure A 3: **Formation and decay curves of metalaxyl-M and its metabolites using CGA108906 0.1 Tier 2 ff based on DT_{50}'s derived from [redacted] 2012, 2015 and [redacted] 2013.**



Max of NOA409045 predicted = 48.34%
Max of CGA67868 predicted = 7.28%
Max of CGA108906 predicted = 7.07% (still very conservative), CGA108906 was not observed <2.3%

Values of ff were then tested to see what is the maximum CGA108906 ff that does not lead to an exceedance of 2.3%, and Figure A 4 shows that a CGA108906 ff of 0.033 leads to a maximum predicted value of CGA108906 of 2.3%.

Figure A 4: **Formation and decay curves of metalaxyl-M and its metabolites using estimated CGA108906 0.033 ff based on DT_{50}'s derived from [redacted] 2012, 2015 and [redacted] 2013.**

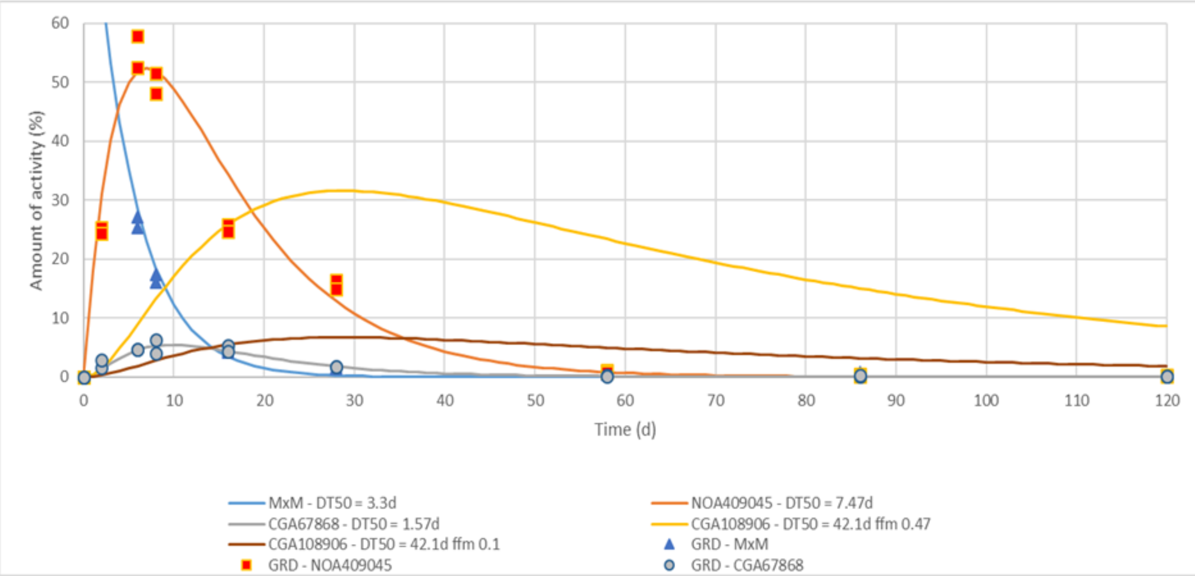


Max of NOA409045 predicted = 48.34%
Max of CGA67868 predicted = 7.28%
Max of CGA108906 predicted = 2.3%, maximum unidentified component

The CGA108906 formation fraction of 0.033 in Gartenacker soil is still considered to be conservative because CGA108906 eluted with a shorter chromatographic retention time than the maximum unidentified component in the [redacted] and [redacted], 2012a study, that is CGA108906 was < 2.3% ARR.

Figure A 5 shows the residue data from the Gartenacker soil superimposed onto the predicted data for metalaxyl-M and its metabolites, and it can be seen that there is good agreement between the residue data and predicted values. This indicates that the use of standard kinetic equations in the SFO model spreadsheet is valid and can be used to provide evidence for the formation fraction of CGA108906 as 0.033 and not 0.47 as proposed by Belgium RMS at Tier I.

Figure A 5: Formation and decay curves of metalaxyl-M and its metabolites using estimated CGA108906 0.033 ff with residue data from Gartenacker soil ([redacted] and [redacted], 2012a)



GRD = Gartenacker Residue Data

A 3.2.2 Conclusions

Re-evaluation of the Gartenacker soil data ([redacted], and [redacted], 2012a) demonstrated that a formation fraction for SYN546520 (CGA108906) of 0.47 is overly conservative and not supported by the study data.

Standard kinetic equations assuming SFO degradation were used to show that a formation fraction of 0.47 is not plausible, nor credible based on the experimental data. Should a formation fraction of 0.47 be valid, CGA10896 would be anticipated to be observed at >10% applied radioactive residue (ARR) at seven time points in the [redacted] and [redacted] 2012a study, reaching a maximum of 33% of ARR. Whereas, in the soil study, CGA108906 was never observed and the maximum unidentified component was 2.3%. Note that the origin of the 0.47 formation fraction was based on the hypothesis of one minus the amide metabolite CGA67868 formation fraction (1-0.53). However, this hypothesis fails to consider other possible sink routes, e.g. to carbon dioxide.

Assuming the maximum 2.3% unidentified component to be CGA108906, this would result in a formation fraction of 0.033 in Gartenacker soil. This is still considered to be conservative because CGA108906 eluted with a shorter chromatographic retention time than the maximum unidentified component in the [redacted] and [redacted], 2012a study, that is CGA108906 was < 2.3% ARR.

The ff of 0.033 proposed in this report for Gartenacker soil is consistent with the estimations of ff in the two other soils; 0.035 in [redacted] soil ([redacted] 2013) and 0.03 in Pappelacker ([redacted] 2015).

In conclusion and to introduce a further degree of conservatism, and considering ff < 0.04 in three soils, this report proposes that CGA108906 ff of 0.1 is appropriate to be used as a modelling endpoint.

A 3.3 KCP 9.1.3: Cymoxanil - PECs following application to peas

Simulation of $PEC_{S,ini}$, short-term and long-term PECs values were carried out using the CRD PEC_{soil} Excel Spreadsheet.

Table A 21: Example of Excel spreadsheet calculation of $PEC_{S,ini}$ of cymoxanil following an application rate of 45 g a.s./ha to peas

Number of applications	1
depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	7.3
1st Application	
Rate (g/ha)=	45
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.060	0.060
1	0.055	0.057
2	0.050	0.055
4	0.041	0.050
7	0.031	0.044
14	0.016	0.033
21	0.008	0.026
28	0.004	0.021
50	0.001	0.013
100	0.000	0.006

Table A 22: Example of Excel spreadsheet calculation of $PEC_{S,ini}$ of IN-U3204 following an application of cymoxanil at a rate of 45 g a.s./ha to peas

Number of applications	1
depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	0.9
1st Application	
Rate (g/ha)=	11.12
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.015	0.015
1	0.007	0.010
2	0.003	0.008
4	0.001	0.005
7	0.000	0.003
14	0.000	0.001
21	0.000	0.001
28	0.000	0.001
50	0.000	0.000
100	0.000	0.000

Table A 23: Example of Excel spreadsheet calculation of PECs,ini of IN-W3595 following an application of cymoxanil at a rate of 45 g a.s./ha to peas

Number of applications	1
depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	2.5
1st Application	
Rate (g/ha)=	2.94
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.004	0.004
1	0.003	0.003
2	0.002	0.003
4	0.001	0.002
7	0.001	0.002
14	0.000	0.001
21	0.000	0.001
28	0.000	0.001
50	0.000	0.000
100	0.000	0.000

Table A 24: Example of Excel spreadsheet calculation of PECs,ini of IN-JX915 following an application of cymoxanil at a rate of 45 g a.s./ha to peas

Number of applications	1
depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	1
1st Application	
Rate (g/ha)=	4.91
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.007	0.007
1	0.003	0.005
2	0.002	0.004
4	0.000	0.002
7	0.000	0.001
14	0.000	0.001
21	0.000	0.000
28	0.000	0.000
50	0.000	0.000
100	0.000	0.000

Table A 25: Example of Excel spreadsheet calculation of PECs,$_{ini}$ of IN-KQ960 following an application of cymoxanil at a rate of 45 g a.s./ha to peas

Number of applications	1

depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	11.2

1st Application	
Rate (g/ha)=	3.09
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.004	0.004
1	0.004	0.004
2	0.004	0.004
4	0.003	0.004
7	0.003	0.003
14	0.002	0.003
21	0.001	0.002
28	0.001	0.002
50	0.000	0.001
100	0.000	0.001

A 3.4 KCP 9.1.3: Fludioxonil - PEC$_S$ following application to peas

Simulation of PECs,$_{ini}$, short-term and long-term PECs values as well as PECs,$_{steady\ state}$ and PECs,$_{accumulation}$ were carried out using the CRD PEC$_{soil}$ Excel Spreadsheet.

Table A 26: Example of Excel spreadsheet calculation of PECs,$_{ini}$ of fludioxonil following an application rate of 22.5 g a.s./ha to peas (Tier 1)

Number of applications	1
depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	569
1st Application	
Rate (g/ha)=	22.5
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.030	0.030
1	0.030	0.030
2	0.030	0.030
4	0.030	0.030
7	0.030	0.030
14	0.029	0.030
21	0.029	0.030
28	0.029	0.029
50	0.028	0.029
100	0.027	0.028

Figure A 6: Graphical representation of the accumulated PEC$_S$ of fludioxonil at 20 cm soil depth for an application rate of 22.5 g a.s./ha to peas (Tier 1)

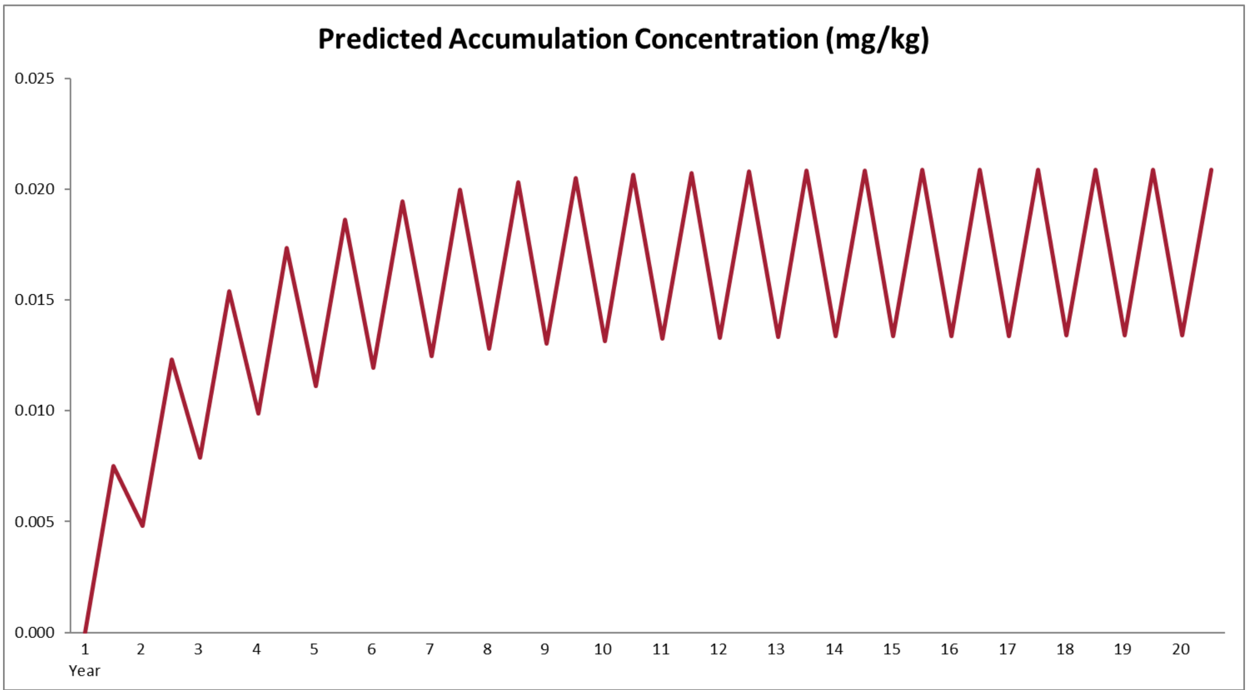
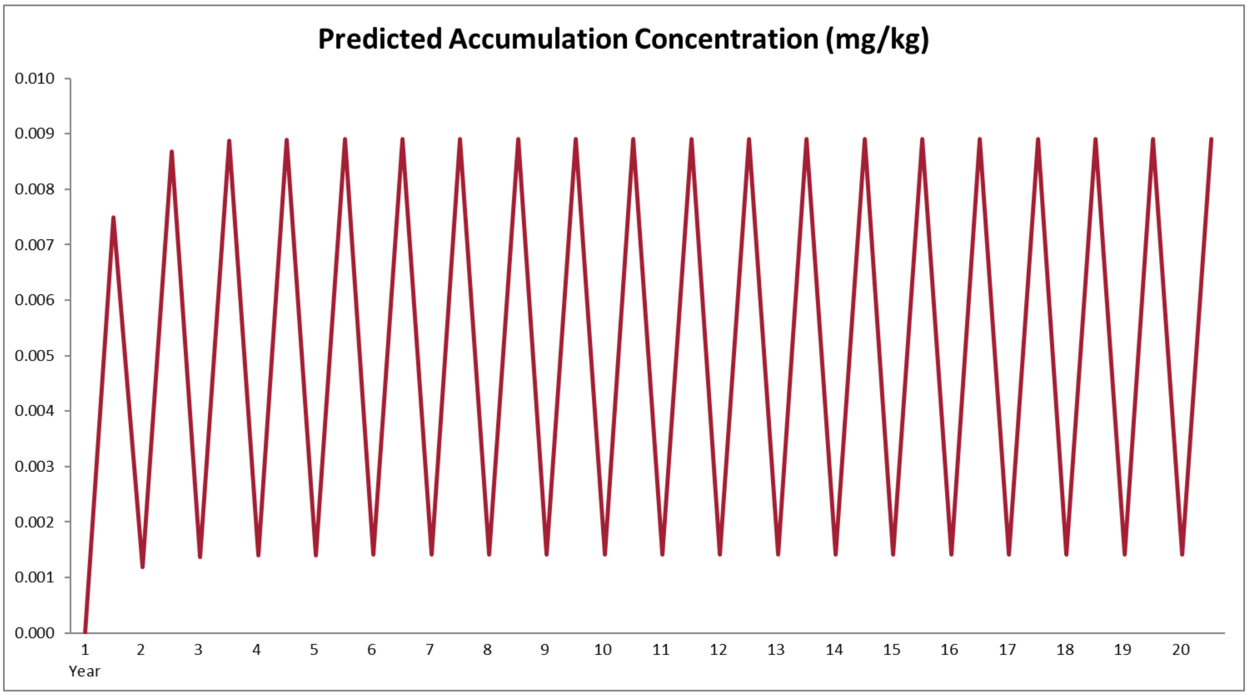


Table A 27: Example of Excel spreadsheet calculation of PECs,$_{ini}$ of fludioxonil following an application rate of 22.5 g a.s./ha to peas (Tier 2)

Number of applications	1	
depth of soil (cm) =	5	
density (g/cm3) =	1.5	
Soil DT50 =	137	
1st Application		
Rate (g/ha)=	22.5	
Crop interception (%) =	0	
		TWA
PECINI mg/kg (1st)	0.030	0.030
1	0.030	0.030
2	0.030	0.030
4	0.029	0.030
7	0.029	0.029
14	0.028	0.029
21	0.027	0.028
28	0.026	0.028
50	0.023	0.027
100	0.018	0.024

Figure A 7: Graphical representation of the accumulated PEC$_S$ of fludioxonil at 20 cm soil depth for an application rate of 22.5 g a.s./ha to peas (Tier 2)



A 3.5 KCP 9.1.3: Metalaxyl-M - PECs following application to peas

Simulation of PECs,$_{ini}$, short-term and long-term PECs values as well as PECs,$_{steady\ state}$ and PECs,$_{accumulation}$ were carried out using the CRD PEC$_{soil}$ Excel Spreadsheet.

Table A 28: Example of Excel spreadsheet calculation of PECs,$_{ini}$ of metalaxyl-M following an application rate of 76.3 g a.s./ha to peas

Number of applications	1	
depth of soil (cm) =	5	
density (g/cm3) =	1.5	
Soil DT50 =	30.9	
1st Application		
Rate (g/ha)=	76.3	
Crop interception (%) =	0	
		TWA
PECINI mg/kg (1st)	0.102	0.102
1	0.099	0.101
2	0.097	0.099
4	0.093	0.097
7	0.087	0.094
14	0.074	0.087
21	0.064	0.081
28	0.054	0.076
50	0.033	0.061
100	0.011	0.041

Table A 29: Example of Excel spreadsheet calculation of PECs,$_{ini}$ of NOA409045 following an application of metalaxyl-M at a rate of 76.3 g a.s./ha to peas

Number of applications	1	
depth of soil (cm) =	5	
density (g/cm3) =	1.5	
Soil DT50 =	39.8	
1st Application		
Rate (g/ha)=	52.18	
Crop interception (%) =	0	
		TWA
PECINI mg/kg (1st)	0.070	0.070
1	0.068	0.069
2	0.067	0.068
4	0.065	0.067
7	0.062	0.065
14	0.055	0.062
21	0.048	0.058
28	0.043	0.055
48	0.030	0.047
100	0.012	0.033

Table A 30: Example of Excel spreadsheet calculation of PECs,$_{ini}$ of CGA67868 following an application of metalaxyl-M at a rate of 76.3 g a.s./ha to peas

Number of applications	1
depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	4.9
1st Application	
Rate (g/ha)=	3.17
Crop interception (%) =	0

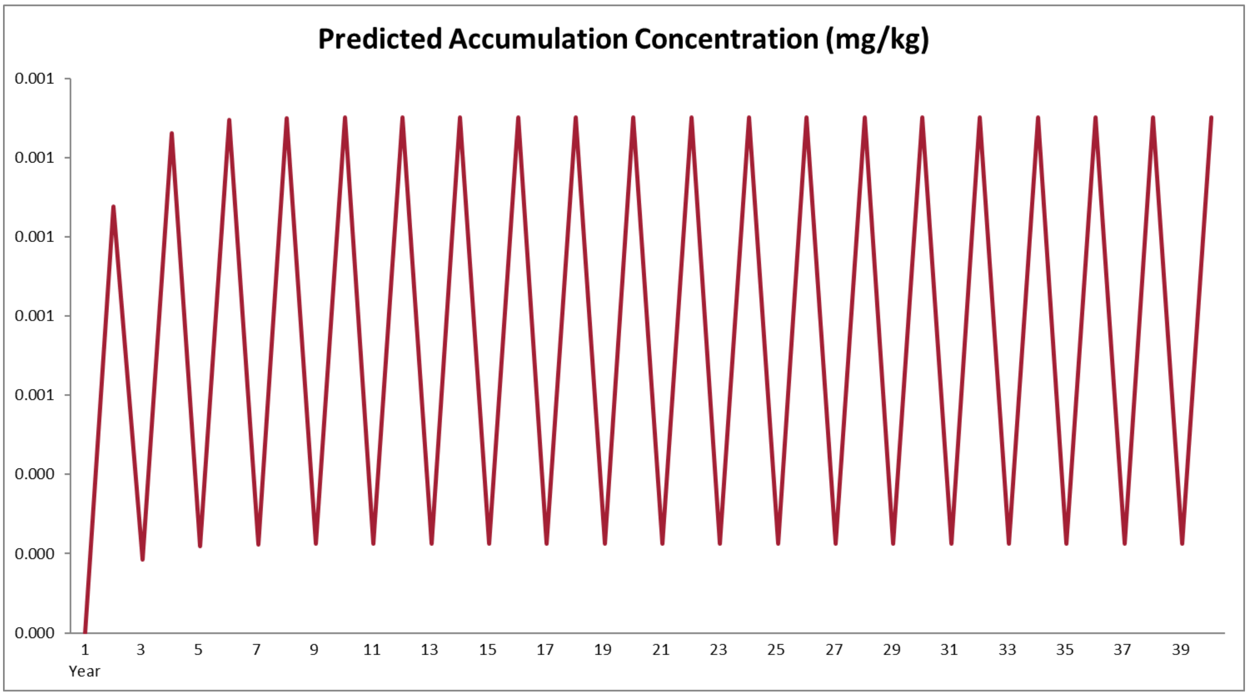
		TWA
PECINI mg/kg (1st)	0.004	0.004
1	0.004	0.004
2	0.003	0.004
4	0.002	0.003
7	0.002	0.003
14	0.001	0.002
21	0.000	0.001
28	0.000	0.001
48	0.000	0.001
100	0.000	0.000

Table A 31: Example of Excel spreadsheet calculation of PECs,$_{ini}$ of SYN546520 following an application of metalaxyl-M at a rate of 76.3 g a.s./ha to peas.

Number of applications	1
depth of soil (cm) =	5
density (g/cm3) =	1.5
Soil DT50 =	287.9
1st Application	
Rate (g/ha)=	3.23
Crop interception (%) =	0

		TWA
PECINI mg/kg (1st)	0.004	0.004
1	0.004	0.004
2	0.004	0.004
4	0.004	0.004
7	0.004	0.004
14	0.004	0.004
21	0.004	0.004
28	0.004	0.004
48	0.004	0.004
100	0.003	0.004

Figure A 8: **Graphical representation of the accumulated PEC_S of SYN546520 at 20 cm soil depth for an application of metalaxyl-M at a rate of 76.3 g a.s./ha to peas.**



A 3.6 KCP 9.2.4: [redacted] (2020), VV-631545. Cymoxanil – PEC_{GW} following application to peas

Reference: KCP 9.2.4

Report: Cymoxanil – A Leaching Assessment for Cymoxanil and its Soil Metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU.
[redacted] 2020
Report Number R1520325-5
Syngenta File No VV-631545
RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY

Guideline(s): FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC document reference Sanco/321/2000 rev. 2, 202 pp.

FOCUS (2014a). Generic Guidance for Tier 1 FOCUS Ground Water Assessments. Version 2.2. FOCUS groundwater scenarios working group.

FOCUS (2014b). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. The Final Report of the Ground Water Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their USe) Sanco/13144/2010, version 3, 10 October 2014.

Deviations: No

GLP: Not applicable

Acceptability: Yes

A 3.6.1 Materials and methods

This report describes a FOCUS groundwater modelling study that examined the potential of cymoxanil and its soil metabolites IN-U3204, IN-W3595, IN-KQ960 and IN-JX915 to reach groundwater following application to peas in Europe. The FOCUS simulation models FOCUS-PEARL (v 4.4.4), FOCUS-PELMO (v 5.5.3) and FOCUS-MACRO (v 5.5.4) were used in the modelling study. A single application as seed treatment was considered for peas at a rate of 45 g/ha. Detailed information on the use pattern included in the modelling is presented in Table A 32, below.

Table A 32: Application patterns of cymoxanil to peas used in the modelling

Crop	Application method	Application timing	Application rate [g a.s./ha]	No. of applications	Frequency of application	FOCUS crop interception at application [%]	Resulting soil deposit per application [g a.s./ha]
Peas	Seed treatment*	BBCH 00	45	1	Annually	0	45

* In FOCUS-PEARL 'injection' was selected as application method.

Application dates were set at the lowest BBCH value according to AppDate 3.06 ([redacted], 2019). The dates are presented Table A 33, below. Simulations carried out using the MACRO model were only considered with the Châteaudun scenario.

Simulations were carried out over 26 years as proposed by FOCUS for pesticides that are applied annually, using the FOCUS standard crop ‘peas’ in FOCUS-PEARL and FOCUS-PELMO, and ‘legumes’ in FOCUS-MACRO. No crop interception was assumed for seed treatments. An incorporation depth of 4 cm was simulated. The first 6 years are intended to be a ‘warm up’ period, thus the following 20 years were taken into account for the assessment of the leaching behaviour.

Table A 33: Application dates of cymoxanil to peas used in the modelling

Crop	Application method	Scenario	Application date[a]
Peas	Seed treatment	Châteaudun	25-Mar (84)
		Hamburg	25-Mar
		Jokioinen	10-May
		Okehampton	25-Mar

[a] Values in parentheses are the application dates as entered in MACRO v5.5.4 for the scenario Châteaudun

The input parameters of cymoxanil used in modelling are shown in the table below. The modelled metabolic pathway in soil is shown in Figure A 9.

Table A 34: Summary of input parameters for cymoxanil and its metabolites for the leaching simulation models FOCUS-PEARL (v 4.4.4), FOCUS-PELMO (v 5.5.3) and MACRO (v 5.5.4)

Physical chemistry properties			
	Molecular weight [g/mol]	**Water solubility [mg/L]**	**Vapour pressure [Pa]**
Cymoxanil	198.2	783 (20°C)	1.5×10^{-4} (20°C)
Remarks	EFSA, 2008	EFSA, 2008	EFSA, 2008
IN-U3204	198.2	783 (20°C)	0 (25°C)
Remarks	EFSA, 2008	EFSA, 2008	EFSA, 2008
IN-W3595	128.1	783 (20°C)	0 (25°C)
Remarks	EFSA, 2008	EFSA, 2008	EFSA, 2008
IN-KQ960	216.2	783 (20°C))	0 (25°C)
Remarks	EFSA, 2008	EFSA, 2008	EFSA, 2008
IN-JX915	198.2	783 (20°C)	0 (25°C)
Remarks	EFSA, 2008	EFSA, 2008	EFSA, 2008

Degradation in soil			
	DT_{50} laboratory soil [days][b]	**Formation fraction [-]**	**Transformation rate[a] [1/day]**
Cymoxanil	1.2 / 7.3	-	0.20794 / 0.03418 (cymoxanil→IN-U3204) 0.0.08664 / 0.01424 (cymoxanil→IN-W3595) 0.05776 / 0.00950 (cymoxanil→IN-JX915) 0.22527 / 0.03703 (cymoxanil→CO_2)
Remarks	Geometric mean (n = 9) / worst case[c] EFSA, 2008	-	Calculated
IN-U3204	0.4	0.36	0.27726 (IN-U3204→IN-KQ960) 1.45561 (IN-U3204→CO_2)
Remarks	Geometric mean (n = 3) EFSA, 2008	EFSA, 2008	Calculated
IN-W3595	2.5	0.15	0.27726 (IN-W3595→CO_2)
Remarks	Worst case EFSA, 2008	EFSA, 2008	Calculated
IN-KQ960	2.8	0.16	0.24755 (IN-KQ960→CO_2)
Remarks	Geometric mean (n=5) [redacted] (2010), DuPont-28466	EFSA, 2008	Calculated
IN-JX915	1.0	0.10	0.69315 (IN-JX915→CO_2)
Remarks	Worst case EFSA, 2008	EFSA, 2008	Calculated

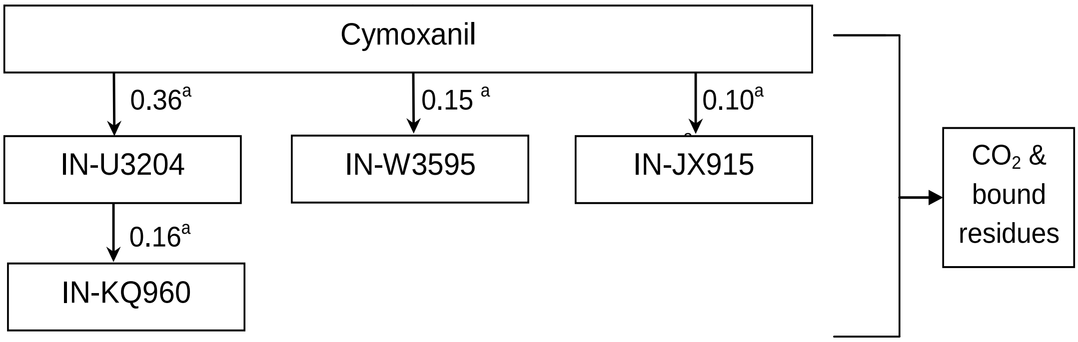
[a] For PELMO; (ln(2) / DT50) * FFm
[b] Values of DT_{50} used in the modelling have been re-calculated from the list of endpoints (EFSA, 2008)
[c] In the EFSA conclusion for cymoxanil (EFSA, 2008) an additional simulation was performed for the worst case scenarios with a worst case pseudo SFO DT50 value of 7.3 days.

Sorption to soil			
	K_{FOC} [L/kg][d]	**K_{FOM} [L/kg]**	**Freundlich exponent 1/n [-]**
Cymoxanil	35.8	20.77	0.86
Remarks	Geometric mean (n = 4) EFSA, 2008	$=K_{FOC}/1.724$	Arithmetic mean (n= 5) EFSA, 2008
IN-U3204	27.9	16.18	1
Remarks	Obtained by HPLC method EFSA, 2008	$=K_{FOC}/1.724$	Default value
IN-W3595	FOCUS-PEARL: Acidic value = 33.3 Alkaline value = 2.3 FOCUS-PELMO: Châteaudun = 2.4 Hamburg = 4.3 Jokioinen = 5.3 Okehampton = 8.9	FOCUS-PEARL: Acidic value = 19.3 Alkaline value = 1.33 FOCUS-PELMO: Châteaudun = 1.39 Hamburg = 2.49 Jokioinen = 3.07 Okehampton = 5.16	1
Remarks	pH-dependent sorption EFSA, 2008	$=K_{FOC}/1.724$	Default value
IN-KQ960	4.0	2.32	0.91
Remarks	Geomoetric mean (n = 5) [redacted] (2010), DuPont-28467	$=K_{FOC}/1.724$	[redacted] (2010), DuPont-28467
IN-JX915	11.38	6.6	1
Remarks	Geometric mean (n = 4) EFSA, 2008	$=K_{FOC}/1.724$	Default value

[d] Values of K_{FOC} used in the modelling have been re-calculated from the list of endpoints (EFSA, 2008)

Crop parameters	
	Crop uptake factor [-]
Cymoxanil	0
Remarks	Default value
IN-U3204	0
Remarks	Default value
IN-W3595	0
Remarks	Default value
IN-KQ960	0
Remarks	Default value
IN-JX915	0
Remarks	Default value

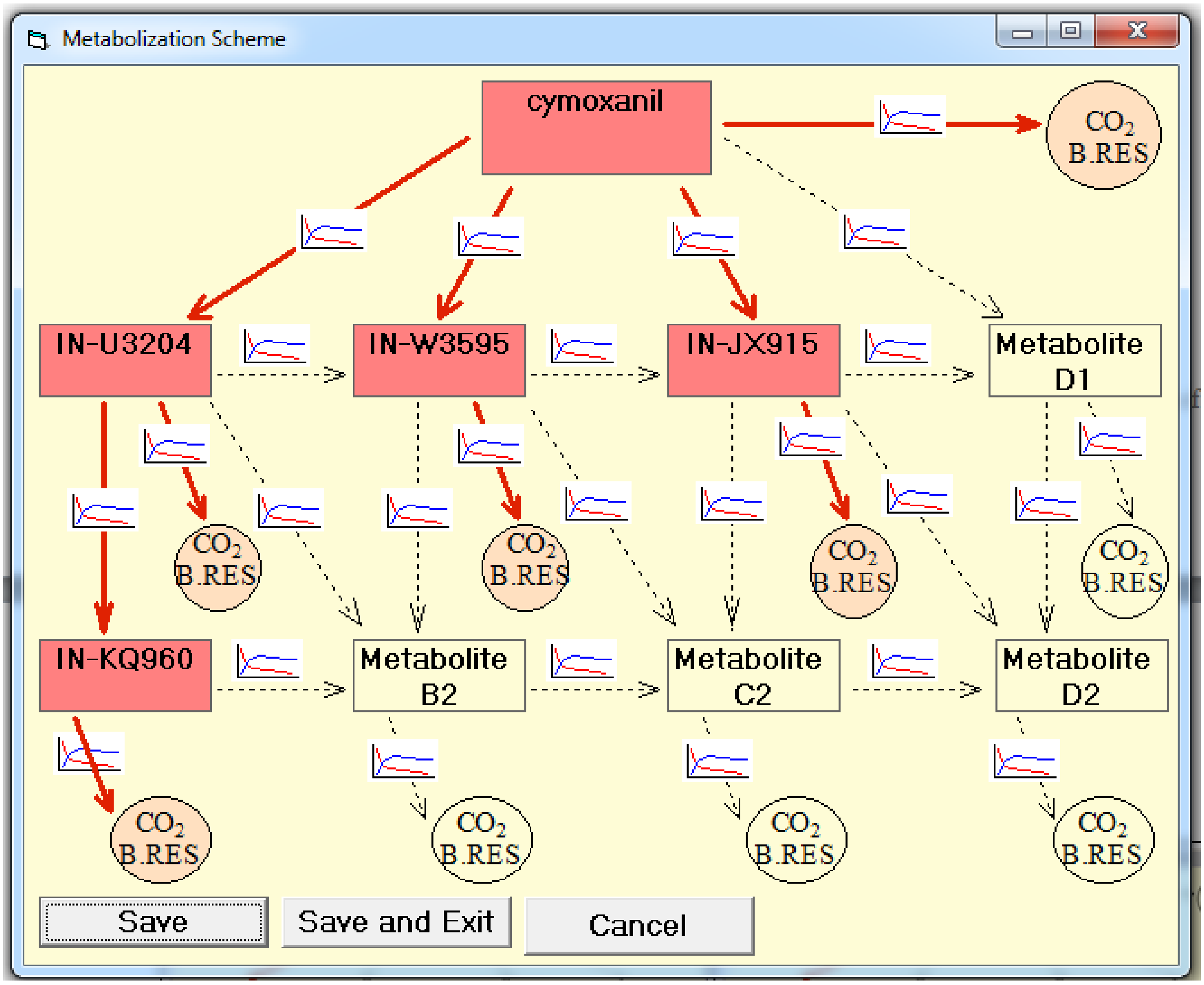
Figure A 9: **Schematic representation of the modelled route of degradation of cymoxanil used in groundwater modelling**



[a] Formation fraction

Simulations using FOCUS-PELMO were performed following the metabolic pathway presented in Figure A 10, below.

Figure A 10: **Implementation of the cymoxanil metabolic pathway in FOCUS-PELMO**



Route	Kinetic fraction [-]	Partial degradation rate k [1/d] (Geomean DT_{50} for parent)	Partial degradation rate k [1/d] (Worst case DT_{50} for parent)
cymoxanil → IN-U3204	0.36	0.20794	0.03418
cymoxanil → IN-W3595	0.15	0.08664	0.01424
cymoxanil → IN-JX915	0.10	0.05776	0.00950
cymoxanil → CO_2	0.39	0.22527	0.03703
IN-U3204 → IN-KQ960	0.16	0.27726	0.27726
IN-U3204 → CO_2	0.84	1.45561	1.45561
IN-W3595 → CO_2	1	0.27726	0.27726
IN-JX915 → CO_2	1	0.69315	0.69315
IN-KQ960 → CO_2	1	0.24755	0.24755

A 3.6.2 Results

The predicted environmental concentrations for cymoxanil and its metabolites in groundwater (PEC_{GW}) were calculated for the use on peas in Europe in accordance with FOCUS guidelines (FOCUS 2000, 2014a, 2014b). The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO simulations are given in Table A 35 to Table A 40, respectively.

Table A 35: PEC_{GW} of cymoxanil and its metabolites following application to peas using the geomean DT_{50} value for cymoxanil (FOCUS-PEARL)

FOCUS Crop	Application rate [g a.s./ha]	No. of appl.	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
					Cymoxanil	IN-U3204	IN-W3595 acidic	IN-W3595 alkaline	IN-KQ960	IN-JX915
Peas	45	1	00	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
				Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table A 36: PEC_{GW} of cymoxanil and its metabolites following application to peas using the worst case DT_{50} value for cymoxanil (FOCUS-PEARL)

FOCUS Crop	Application rate [g a.s./ha]	No. of appl.	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
					Cymoxanil	IN-U3204	IN-W3595 acidic	IN-W3595 alkaline	IN-KQ960	IN-JX915
Peas	45	1	00	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
				Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table A 37: PEC_{GW} of cymoxanil and its metabolites following application to peas using the geomean DT_{50} value for cymoxanil (FOCUS-PELMO)

FOCUS Crop	Application rate [g a.s./ha]	No. of appl.	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
					Cymoxanil	IN-U3204	IN-W3595 acidic	IN-W3595 alkaline	IN-KQ960	IN-JX915
Peas	45	1	00	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
				Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table A 38: PEC_{GW} of cymoxanil and its metabolites following application to peas and using the worst case DT_{50} value for cymoxanil (FOCUS-PELMO)

FOCUS Crop	Application rate [g a.s./ha]	No. of appl.	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
					Cymoxanil	IN-U3204	IN-W3595 acidic	IN-W3595 alkaline	IN-KQ960	IN-JX915
Peas	45	1	00	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
				Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table A 39: PEC_{GW} of cymoxanil and its metabolites following application to peas and using the geomean DT_{50} value for cymoxanil (FOCUS-MACRO)

FOCUS Crop	Application rate [g a.s./ha]	No. of appl.	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
					Cymoxanil	IN-U3204	IN-W3595 acidic	IN-W3595 alkaline	IN-KQ960	IN-JX915
Legumes	45	1	00	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

Table A 40: PEC_{GW} of cymoxanil and its metabolites following application to peas and using the worst case DT_{50} value for cymoxanil (FOCUS-MACRO)

FOCUS Crop	Application rate [g a.s./ha]	No. of appl.	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]					
					Cymoxanil	IN-U3204	IN-W3595 acidic	IN-W3595 alkaline	IN-KQ960	IN-JX915
Legumes	45	1	00	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

A 3.7 KCP 9.2.4: [redacted] (2020), VV-631541. Fludioxonil – PEC_{GW} following application to peas

Reference:	KCP 9.2.4
Report:	Fludioxonil - A Leaching Assessment for Fludioxonil Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU. [redacted] 2020 Report Number R1520325-2 Syngenta File No CGA173506_12279; VV-631541 RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY
Guideline(s):	FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC document reference Sanco/321/2000 rev. 2, 202 pp. FOCUS (2014a). Generic Guidance for Tier 1 FOCUS Ground Water Assessments. Version 2.2. FOCUS groundwater scenarios working group. FOCUS (2014b). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. The Final Report of the Ground Water Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their USe) Sanco/13144/2010, version 3, 10 October 2014.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.7.1 Materials and methods

This report describes a FOCUS groundwater modelling study that examined the potential of fludioxonil to reach groundwater following application to peas in Europe. Although endpoints are given in the EFSA Conclusion for the metabolites CGA265378, CGA339833 and CGA192155 (EFSA 2007), it is also stated that the degradation following seed treatment use differs to foliar use as these metabolites are formed primarily through photolysis. Therefore, for seed treatment use these metabolites are not considered further.

The FOCUS simulation models FOCUS-PEARL (v 4.4.4), FOCUS-PELMO (v 5.5.3) and FOCUS-MACRO (v 5.5.4) were used in the modelling study. A single application as seed treatment was considered for peas at a rate of 22.5 g/ha. Detailed information on the use pattern included in the modelling is presented in the table, below.

Table A 41: Application patterns of fludioxonil to beans used in the modelling

Crop	Application method	Application timing	Application rate [g a.s./ha]	No. of appli-cations	Frequency of application	FOCUS crop interception at application [%]	Resulting soil deposit per application [g a.s./ha]
Peas	Seed treatment*	BBCH 00	22.5	1	Annually	0	22.5

* In FOCUS-PEARL ‘injection’ was selected as application method

Application dates were set at the lowest BBCH value according to AppDate 3.06 ([redacted], 2019). The dates are presented in Table A 42, below. Simulations carried out using the MACRO model were only considered with the Châteaudun scenario.

Simulations were carried out over 26 years as proposed by FOCUS for pesticides that are applied annually, using the FOCUS standard crop ‘peas’ in FOCUS-PEARL and FOCUS-PELMO, and ‘legumes’ in FOCUS-MACRO. No crop interception was assumed for seed treatments. An incorporation depth of 4 cm was simulated. The first 6 years are intended to be a ‘warm up’ period, thus the following 20 years were taken into account for the assessment of the leaching behaviour.

Table A 42: Application dates of fludioxonil to peas used in the modelling

Crop	Application method	Scenario	Application date[a]
Peas	Seed treatment	Châteaudun	25-Mar (84)
		Hamburg	25-Mar
		Jokioinen	10-May
		Okehampton	25-Mar

[a] Values in parentheses are the application dates as entered in MACRO v5.5.4 for the scenario Châteaudun

The input parameters of fludioxonil used in modelling are shown in the table, below.

Table A 43: Summary of input parameters for fludioxonil for the leaching simulation models FOCUS-PEARL (v 4.4.4), FOCUS PELMO (v 5.5.3) and FOCUS MACRO (v 5.5.4)

Physical chemistry properties			
	Molecular weight [g/mol]	**Water solubility [mg/L]**	**Vapour pressure [Pa]**
Fludioxonil	248.2	1.8 (25°C)	0 (25°C)
Remarks	EFSA, 2007	EFSA, 2007	Worst case

Degradation in soil			
	DT_{50} laboratory soil [days][b]	**Formation fraction [-]**	**Transformation rate[a] [1/day]**
Fludioxonil	174.6	-	0.00397 (fludioxonil → CO2)

Degradation in soil			
	DT_{50} laboratory soil [days][b]	**Formation fraction [-]**	**Transformation rate[a] [1/day]**
Remarks	Geometric mean (n = 9) EFSA, 2007	-	Calculated

[a] For PELMO; (ln(2) / DT_{50}) * FFm
[b] Values of DT_{50} used in the modelling have been re-calculated from the list of endpoints (EFSA, 2007)

Sorption to soil			
	K_{FOC} [L/kg][c]	**K_{FOM} [L/kg]**	**Freundlich exponent 1/n [-]**
Fludioxonil	80341	46601	1
Remarks	Geometric mean (n = 5) EFSA, 2007	$=K_{FOC}/1.724$	Arithmetic mean (n= 5) EFSA, 2007

[c] Values of K_{FOC} used in the modelling have been re-calculated from the list of endpoints (EFSA, 2007)

Crop parameters	
	Crop uptake factor [-]
Fludioxonil	0
Remarks	Default value

A 3.7.2 Results

The predicted environmental concentrations for fludioxonil in groundwater (PEC_{GW}) were calculated for the use on peas in Europe in accordance with FOCUS guidelines (FOCUS 2000, 2014a, 2014b). The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO simulations are given in Table A 44 to Table A 46, respectively.

Table A 44: PEC_{GW} of fludioxonil following application to peas (FOCUS-PEARL)

FOCUS Crop	Application rate [g a.s./ha]	No. of applications	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]
					Fludioxonil
Peas	22.5	1	00	Châteaudun	<0.001
				Hamburg	<0.001
				Jokioinen	<0.001
				Okehampton	<0.001

Table A 45: PEC$_{GW}$ of fludioxonil following application to peas (FOCUS-PELMO)

FOCUS Crop	Application rate [g a.s./ha]	No. of applications	BBCH [-]	Scenario	80th percentile PEC$_{GW}$ at 1 m soil depth [µg/L]
					Fludioxonil
Peas	22.5	1	00	Châteaudun	<0.001
				Hamburg	<0.001
				Jokioinen	<0.001
				Okehampton	<0.001

Table A 46: PEC$_{GW}$ of fludioxonil following application to peas (FOCUS-MACRO)

FOCUS Crop	Application rate [g a.s./ha]	No. of applications	BBCH [-]	Scenario	80th percentile PEC$_{GW}$ at 1 m soil depth [µg/L]
					Fludioxonil
Peas	22.5	1	00	Châteaudun	<0.001

A 3.8 KCP 9.2.4: [redacted] (2020), VV-631540. Metalaxyl-M – PEC_{GW} following application to peas

Reference:	KCP 9.2.4
Report:	Metalaxyl-M - A Leaching Assessment for Metalaxyl-M and its Soil Metabolites NOA409045, SYN546520 and CGA67868 Using the FOCUS-PEARL 4.4.4, PELMO 5.5.3 and MACRO 5.5.4 Groundwater Models Following Seed Treatment Application to Peas in the EU. [redacted] 2020 Report Number R1520325-1 Syngenta File No CGA329351_11831, VV-631540 RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY
Guideline(s):	FOCUS (2000). FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS groundwater scenarios workgroup, EC document reference Sanco/321/2000 rev. 2, 202 pp. FOCUS (2014a). Generic Guidance for Tier 1 FOCUS Ground Water Assessments. Version 2.2. FOCUS groundwater scenarios working group. FOCUS (2014b). Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU. The Final Report of the Ground Water Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their USe) Sanco/13144/2010, version 3, 10 October 2014.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.8.1 Materials and methods

This report describes a FOCUS groundwater modelling study that examined the potential of metalaxyl-M and its soil metabolites NOA409045, SYN546520 and CGA67868 to reach groundwater following application to peas in Europe. The FOCUS simulation models FOCUS-PEARL (v 4.4.4), FOCUS-PELMO (v 5.5.3) and FOCUS-MACRO (v 5.5.4) were used in the modelling study.

A single application as seed treatment was considered for beans at a rate of 78.75 g/ha. Detailed information on the use pattern included in the modelling is presented in the table, below.

Table A 47: Application patterns of metalaxyl-M to peas used in the modelling

Crop	Application method	Application timing	Application rate [g a.s./ha]	No. of applications	Frequency of application	FOCUS crop interception at application [%]	Resulting soil deposit per application [g a.s./ha]
Peas	Seed treatment*	BBCH 00	78.75	1	Annually	0	78.75

* In FOCUS-PEARL ‘injection’ was selected as application method

Application dates were set at the lowest BBCH value according to AppDate 3.06 ([redacted], 2019). The dates are presented in Table A 48, below. Simulations carried out using the MACRO model were only considered with the Châteaudun scenario.

Simulations were carried out over 26 years as proposed by FOCUS for pesticides that are applied annually, using the FOCUS standard crop 'beans' in FOCUS-PEARL and FOCUS-PELMO, and 'legumes' in FOCUS-MACRO. No crop interception was assumed for seed treatments. An incorporation depth of 4 cm was simulated. The first 6 years are intended to be a 'warm up' period, thus the following 20 years were taken into account for the assessment of the leaching behaviour.

Table A 48: Application dates of metalaxyl-M to peas used in the modelling

Crop	Application method	Scenario	Application date[a]
Peas	Seed treatment	Châteaudun	25-Mar (84)
		Hamburg	25-Mar
		Jokioinen	10-May
		Okehampton	25-Mar

[a] Values in parentheses are the application dates as entered in MACRO v5.5.4 for the scenario Châteaudun

The input parameters of metalaxyl-M and its metabolites used in modelling are shown in the table, below. The modelled metabolic pathway in soil is shown in Figure A 11.

Table A 49: Summary of input parameters for metalaxyl-M and its metabolites for the leaching simulation models FOCUS-PEARL (v 4.4.4), FOCUS PELMO (v 5.5.3) and MACRO (v 5.5.4)

Physical chemistry properties			
	Molecular weight [g/mol]	**Water solubility [mg/L] (25°C)**	**Vapour pressure [Pa]**
Metalaxyl-M	279.3	26000	0.0033 (at 25°C)
Remarks	EFSA, 2015	EFSA, 2015	EFSA, 2015
NOA409045	265.3	265000	1 x 10^{-5} (at 20°C)
Remarks	EFSA, 2015	EFSA, 2015	EFSA, 2015
SYN546520	295.3	265000	1 x 10^{-5} (at 20°C)
Remarks	EFSA, 2015	Not available, value of NOA409045 used	EFSA, 2015
CGA67868	193.2	45800	1 x 10^{-5} (at 20°C)
Remarks	EFSA, 2015	[redacted] (2012)	EFSA, 2015

Degradation in soil			
	DT_{50} laboratory soil [days][c]	**Formation fraction [-]**	**Transformation rate[a] [1/day]**
Metalaxyl-M	7.74	-	0.07012 (Metalaxyl-M→NOA409045) 0.019433 (Metalaxyl-M→ CO2)
Remarks	Geometric mean (n = 10) EFSA, 2015		Calculated
NOA409045	30.5	0.783(from parent)	Tier 1: 0.010681 (NOA409045→SYN546520) 0.012045 (NOA409045→CGA67868) 0 (NOA409045→CO_2)
			Tier 2: 0.002273 (NOA409045→SYN546520) 0.012045 (NOA409045→CGA67868) 0.008409 (NOA409045→CO_2)
Remarks	Geometric mean (n = 8) EFSA, 2015	EFSA, 2015	Calculated
SYN546520	96.8	0.47 (Tier 1) / 0.1 (Tier 2)[b] (from NOA409045)	0.007161 (SYN546520→CO_2)
Remarks	Geometric mean (n = 3) EFSA, 2015	EFSA, 2015	Calculated
CGA67868	2.9	0.53 (from NOA409045)	0.2390 (CGA67868→CO_2)
Remarks	Geometric mean (n = 3) EFSA, 2015	EFSA, 2015	Calculated

[a] For PELMO; (ln(2) / DT_{50}) * FFm
[b] As a tiered approach, the PEC_{GW} were calculated with two different formation fractions of 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2) for SYN546520
[c] Values of DT_{50} used in the modelling have been re-calculated from the list of endpoints (EFSA, 2015).

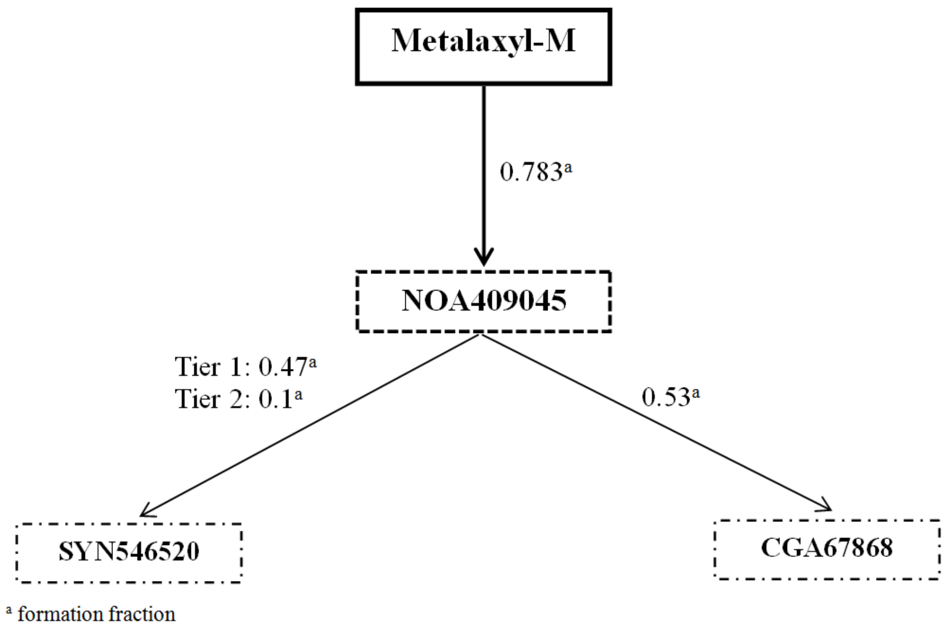
Sorption to soil			
	K_{FOC} [L/kg][d]	**K_{FOM} [L/kg]**	**Freundlich exponent 1/n [-]**
Metalaxyl-M	50.63	29.37	0.955
Remarks	Geometric mean (n = 25) EFSA, 2015	=K_{FOC}/1.724	Arithmetic mean (n= 25) EFSA
NOA409045	13.44	7.80	0.928
Remarks	Geometric mean (n = 14)	=K_{FOC}/1.724	Arithmetic mean (n=14)

Sorption to soil			
	K_{FOC} [L/kg][d]	**K_{FOM} [L/kg]**	**Freundlich exponent 1/n [-]**
	EFSA, 2015		EFSA
SYN546520	7.79	4.52	1.1
Remarks	Geometric mean (n = 4) EFSA, 2015	$=K_{FOC}/1.724$	Arithmetic mean (n=4) EFSA
CGA67868	18.93	10.98	0.9
Remarks	Geometric mean (n = 5) EFSA, 2015	$=K_{FOC}/1.724$	Arithmetic mean (n=5) EFSA

[d] Values of K_{FOC} used in the modelling have been re-calculated from the list of endpoints (EFSA, 2015)

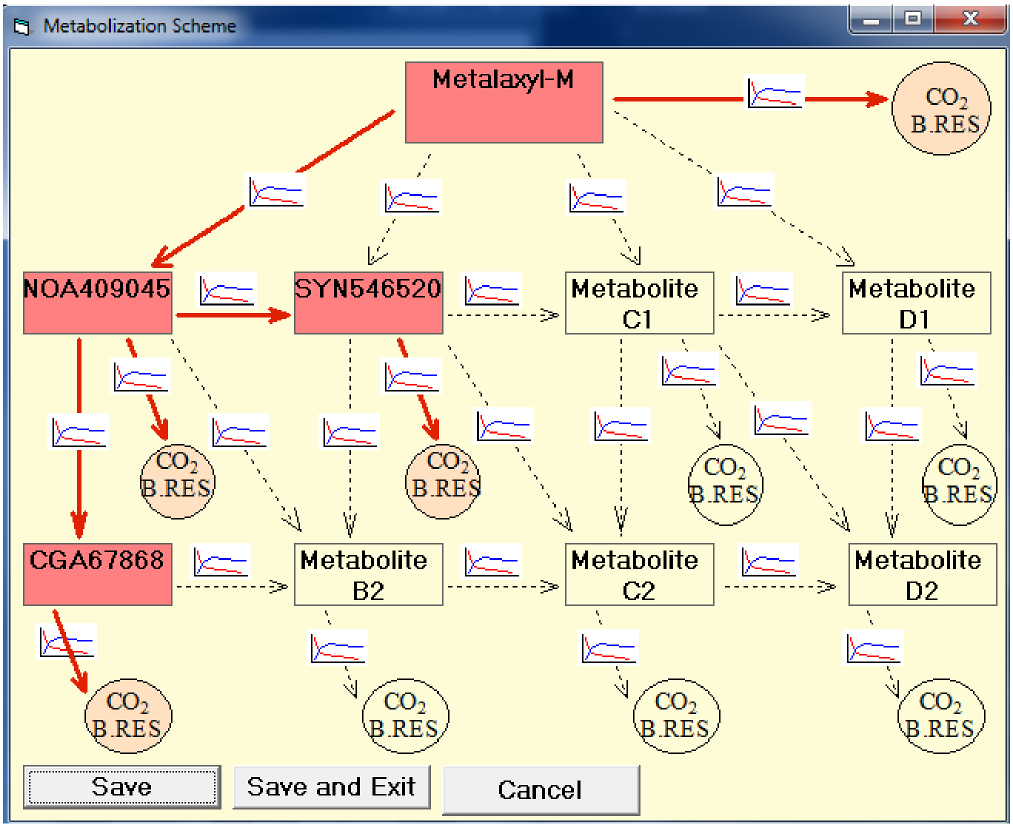
Crop parameters	
	Crop uptake factor [-]
Metalaxyl-M	0
Remarks	Default value
NOA409045	0
Remarks	Default value
SYN546520	0
Remarks	Default value
CGA67868	0
Remarks	Default value

Figure A 11: Schematic representation of the modelled route of degradation of metalaxyl-M used in groundwater modelling



Simulations using FOCUS-PELMO were performed following the metabolic pathway presented in Figure A 12, below.

Figure A 12: Implementation of the metalaxyl-M metabolic pathway in FOCUS-PELMO



A 3.8.2 Results

The predicted environmental concentrations for metalaxyl-M and its metabolites in groundwater (PEC_{GW}) were calculated for the use on peas in Europe in accordance with FOCUS guidelines (FOCUS 2000, 2014a, 2014b). The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS-PEARL, FOCUS-PELMO and FOCUS-MACRO simulations are given in Table A 50 to Table A 52, respectively.

Table A 50: PEC_{GW} of metalaxyl-M and its metabolites following application to beans (FOCUS-PEARL)

FOCUS Crop	Application rate [g a.s./ha]	No. of applica-tions	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]				
					Metalaxyl-M	NOA409045	SYN546520		CGA67868
							Tier 1	Tier 2	
Peas	78.75	1	00	Châteaudun	<0.001	0.781	8.13	1.77	0.022
				Hamburg	<0.001	3.53	13.4	2.89	0.107
				Jokioinen	<0.001	2.72	13.2	2.89	0.065
				Okehampton	0.001	1.73	5.25	1.13	0.053

Table A 51: PEC_{GW} of metalaxyl-M and its metabolites following application to beans (FOCUS-PELMO)

FOCUS Crop	Application rate [g a.s./ha]	No. of applica-tions	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]				
					Metalaxyl-M	NOA409045	SYN546520		CGA67868
							Tier 1	Tier 2	
Peas	78.75	1	00	Châteaudun	<0.001	0.528	6.51	1.41	0.014
				Hamburg	<0.001	2.23	8.99	1.93	0.063
				Jokioinen	<0.001	2.70	11.0	2.38	0.057
				Okehampton	0.001	1.81	4.77	1.03	0.052

Table A 52: PEC_{GW} of metalaxyl-M and its metabolites following application to beans (FOCUS-MACRO)

FOCUS Crop	Application rate [g a.s./ha]	No. of applica-tions	BBCH [-]	Scenario	80th percentile PEC_{GW} at 1 m soil depth [µg/L]				
					Metalaxyl-M	NOA409045	SYN546520		CGA67868
							Tier 1	Tier 2	
Legumes	78.75	1	00	Châteaudun	<0.001	1.11	6.22	1.35	0.024

A 3.9 Spray drift and Tier I drainage assessments for cymoxanil and its relevant metabolites IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5

A 3.9.1 Spray drift assessment

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

A 3.9.2 Tier I drainage assessment

A9873C is to be applied on peas within the drainflow period of 1st October to 30th April. The PEC_{SW} and PEC_{SED} values of cymoxanil and its relevant metabolites following entry *via* drainage have been determined according to standard Tier I calculations recommended for such applications in the UK national requirements[3].

Active substance

The PEC_{SW} and PEC_{SED} values of cymoxanil following entry *via* drainage has been calculated using the CRD 'PEC $_{sw\text{-}sed}$ (drainage)' spreadsheet (v 1.0). The Tier I drainage assessment assumes that following a rainfall event, a proportion of the applied compound in a given hectare will be lost in 10mm of drainflow (equivalent to 100,000L water). The percentage of compound lost is assumed to be dependent on its soil adsorption (K_{OC}), and is defined in the national guidance[3]. The 100,000L of drainflow is then added to a stream on 30,000L (same as the standard water body used in the drift assessment) to give a total volume of 130,000L. By definition these concentrations are transitory as dilution and adsorption to sediments quickly dissipate the compounds. Bulk density of sediment is assumed to be 1.3g/cm^3.

The soil residue available for drainage, R, was calculated following SFO kinetics according to the following equation:

$$R\,[g/ha] = A \cdot (1 - I) \cdot \frac{(1 - e^{-n \cdot k \cdot i})}{(1 - e^{-k \cdot i})}$$

Where:
A = application rate [g a.s./ha]
I = fraction crop interception [-]
k = degradation rate constant in soil (= ln(2) / DT_{50}) [1/d]
i = minimum interval between applications [d]
n= maximum number of applications [-]

The PEC_{SW} *via* drainage is calculated as follows:

$$PEC_{SW,drainage}\,[\mu g/L] = \frac{R \cdot Flux \cdot 10^6}{130000}$$

Where:
R = soil residue available for drainage [g/ha]
Flux = fraction of pesticide loss in drainflow [-]

The PEC_{SED} *via* drainage is calculated as follows:

$$PEC_{SED,drainage}\,[\mu g/Kg] = \left(PEC_{SW,drainage} \cdot \text{ Fraction in sediment } / (1000 \cdot 5000 \cdot 1.3)\right) \cdot 30000$$

Table A 53: Percentage of cymoxanil loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
Cymoxanil	43.6 (arithmetic mean, n = 5)	1.9

[a] In accordance with PSD guidance

Table A 54: Overall maximum $PEC_{SW/SED}$ for cymoxanil due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)
Peas 45.0 g a.s/ha BBCH 00	1/-	0[c]	0.060	45.0	0.855	6.58	1.18

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm³ soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Metabolite(s)

The formation of IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273 and IN-KP533 was observed in soil and water. As such, the $PEC_{SW/SED}$ drainflow of IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273 and IN-KP533 has been determined for two pathways: the formation of the metabolite in soil and the subsequent entry into the waterbody *via* drainage and; the formation of the metabolite in the waterbody after the parent substance entered *via* drainage. The highest $PEC_{SW/SED}$ value obtained across the two routes is then reported.

The formation of M5 was observed in water. As such, the $PEC_{SW/SED}$ drainflow of M5 has only been determined for the pathway where the metabolite is formed in the waterbody after the parent substance entered *via* drainage.

For metabolites formed via the soil pathway

PEC_{SW} values of IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273 and IN-KP533 following formation in soil and subsequent entry into the water body *via* drainage, were calculated based on maximum PEC_S values after application and using the equation given above for the active substance. Thereby the PEC_S of IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273 and IN-KP533 are calculated on the basis of the maximum total dose of cymoxanil, adjusted for the maximum occurrence in the soil and corrected for the molecular weight difference relative to parent. Pseudo-application rates used to calculate PEC_S of IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273 and IN-KP533 were calculated according to the following equation:

$$A_{metabolite}\,[g/ha] = A_{parent} \times \frac{MaxAR_{metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

Where:
A_{parent} = application rate of parent substance [g/ha]
$MaxAR_{metabolite}$ = maximum percentage of metabolite observed in soil [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Otherwise, the PEC_{SW} and PEC_{SED} values of IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273 and IN-KP533 following entry *via* drainage have been calculated using the CRD ‘PEC $_{sw\text{-}sed}$ (drainage)’ spreadsheet (v 1.0), in the same way as the active substance cymoxanil.

For metabolites formed in the waterbody
PEC_{SW} and PEC_{SED} values of IN-U3204, IN-W3595, IN-KQ960, IN-JX915, IN-T4226, IN-R3273, IN-KP533 and M5 following formation in the waterbody after the parent substance entered *via* drainage, were calculated based on the maximum parent PEC_{SW} value, adjusted for the maximum occurrence in the surface water and sediment, respectively, and corrected for the molecular weight difference relative to parent according to the following equations:

$$PEC_{SW,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SW,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

$$PEC_{SED,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SED,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}} \cdot 4.615$$

Where:
$PEC_{SW,parent}$ = PEC_{SW} of the parent after entry via drainage [µg/L]
$MaxAR_{SW,metabolite}$ = maximum percentage of metabolite observed in water [%]
$MaxAR_{SED,metabolite}$ = maximum percentage of metabolite observed in sediment [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Table A 55: Percentage of pesticide loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
IN-U3204	27.9 (obtained by HPLC method, n=1)	1.9
IN-W3595	2.3 (worst case from laboratory studies)	1.9
IN-KQ960	4.6 (arithmetic mean, n = 5)	1.9
IN-JX915	16.2 (arithmetic mean, n = 4)	1.9
IN-T4226	17.7 (obtained by HPLC method, n=1)	1.9
IN-R3273	25.7 (worst case from laboratory studies)	1.9
IN-KP533	12.9 (obtained by HPLC method, n=1)	1.9
M5	2.3 (IN-W3595 value, worst case from laboratory studies)	1.9

[a] In accordance with PSD guidance

Table A 56: Overall maximum $PEC_{SW/SED}$ for IN-U3204 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drain-age period	Max PEC_S (mg/kg)[a]	Avai-lable comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							For-mation in soil	For-mation in water body	For-mation in soil	For-mation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	0.015	11.12	0.211	6.58	1.62	1.62	0.037	0.152

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Table A 57: Overall maximum $PEC_{SW/SED}$ for IN-W3595 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drain-age period	Max PEC_S (mg/kg) [a]	Avai-lable comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							For-mation in soil	For-mation in water body	For-mation in soil	For-mation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	0.004	2.94	0.056	6.58	0.429	1.11	0.046	0.451

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Table A 58: Overall maximum $PEC_{SW/SED}$ for IN-KQ960 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drain-age period	Max PEC_S (mg/kg) [a]	Avai-lable comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							For-mation in soil	For-mation in water body	For-mation in soil	For-mation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	0.004	3.09	0.059	6.58	0.452	0.933	0.115	1.82

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Table A 59: Overall maximum $PEC_{SW/SED}$ for IN-JX915 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drain-age period	Max PEC_S (mg/kg) [a]	Avai-lable comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							For-mation in soil	For-mation in water body	For-mation in soil	For-mation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	0.007	4.91	0.093	6.58	0.717	3.46	0.040	0.364

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Table A 60: Overall maximum $PEC_{SW/SED}$ for IN-T4226 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drain-age period	Max PEC_S (mg/kg) [a]	Avai-lable comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							For-mation in soil	For-mation in water body	For-mation in soil	For-mation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	0.001	0.55	0.010	6.58	0.080	0.523	0.004	0.218

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density.
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Table A 61: Overall maximum $PEC_{SW/SED}$ for IN-R3273 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drain-age period	Max PEC_S (mg/kg) [a]	Avai-lable comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							For-mation in soil	For-mation in water body	For-mation in soil	For-mation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	0.001	0.93	0.018	6.58	0.136	2.01	0.003	0.131

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density.
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Table A 62: Overall maximum $PEC_{SW/SED}$ for IN-KP533 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							Formation in soil	Formation in water body	Formation in soil	Formation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	0.001	0.98	0.019	6.58	0.143	1.09	0.043	1.59

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density.
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Table A 63: Overall maximum $PEC_{SW/SED}$ for M5 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							Formation in soil	Formation in water body	Formation in soil	Formation in water body
Peas 45.0 g a.s/ha BBCH 00	1	0[c]	n.r.[d]	n.r.[d]	n.r.[d]	6.58	n.r.[d]	1.51	n.r.[d]	<0.001

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density.
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case
[d] Not relevant, metabolite not formed in soil

A 3.10 Spray drift and Tier I drainage assessments for fludioxonil and its relevant metabolite CGA192155

A 3.10.1 Spray drift assessment

Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

A 3.10.2 Tier I drainage assessment

A9873C is to be applied on peas within the drainflow period of 1st October to 30th April. The PEC_{SW} and PEC_{SED} values of fludioxonil and its relevant metabolite CGA192155 following entry *via* drainage have been determined according to standard Tier I calculations recommended for such applications in the UK national requirements[3].

Active substance

The PEC_{SW} and PEC_{SED} values of fludioxonil following entry *via* drainage has been calculated using the CRD 'PEC $_{sw-sed}$ (drainage)' spreadsheet (v 1.0). The Tier I drainage assessment assumes that following a rainfall event, a proportion of the applied compound in a given hectare will be lost in 10mm of drainflow (equivalent to 100,000L water). The percentage of compound lost is assumed to be dependent on its soil adsorption (K_{OC}), and is defined in the national guidance[3]. The 100,000L of drainflow is then added to a stream on 30,000L (same as the standard water body used in the drift assessment) to give a total volume of 130,000L. By definition these concentrations are transitory as dilution and adsorption to sediments quickly dissipate the compounds. Bulk density of sediment is assumed to be 1.3g/cm^3.

The soil residue available for drainage, R, was calculated following SFO kinetics according to the following equation:

$$R\,[\text{g/ha}] = A \cdot (1 - I) \cdot \frac{(1 - e^{-n \cdot k \cdot i})}{(1 - e^{-k \cdot i})}$$

Where:
A = application rate [g a.s./ha]
I = fraction crop interception [-]
k = degradation rate constant in soil (= ln(2) / DT_{50}) [1/d]
i = minimum interval between applications [d]
n= maximum number of applications [-]

The PEC_{SW} *via* drainage is calculated as follows:

$$PEC_{SW,drainage}\,[\mu g/L] = \frac{R \cdot Flux \cdot 10^6}{130000}$$

Where:
R = soil residue available for drainage [g/ha]
Flux = fraction of pesticide loss in drainflow [-]

The PEC_{SED} *via* drainage is calculated as follows:

$$PEC_{SED,drainage}\,[\mu g/Kg] = \left(PEC_{SW,drainage} \cdot \text{ Fraction in sediment } / (1000 \cdot 5000 \cdot 1.3)\right) \cdot 30000$$

Table A 64: Percentage of fludioxonil loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
Fludixonil	145600 (arithmetic mean, n = 5)	0.008

[a] In accordance with PSD guidance

Table A 65: Overall maximum $PEC_{SW/SED}$ for fludioxonil due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)
Peas 22.5 g a.s/ha BBCH 00	1/-	0[c]	0.030	22.5	0.002	0.014	0.053

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case.

Metabolite(s)

The formation of CGA192155 was observed in soil and water under light exposure. Since the use is a seed treatment the formation of CGA192155 in soil is not considered relevant within the $PEC_{SW/SED}$ risk assessment. Therefore, the $PEC_{SW/SED}$ drainflow of CGA192155 has only been determined for the pathway where the metabolite is formed in the waterbody after the parent substance entered *via* drainage.

For metabolites formed in the waterbody

PEC_{SW} and PEC_{SED} values of CGA192155 following formation in the waterbody after the parent substance entered *via* drainage, were calculated based on the maximum parent PEC_{SW} value, adjusted for the maximum occurrence in the surface water and sediment, respectively, and corrected for the molecular weight difference relative to parent according to the following equations:

$$PEC_{SW,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SW,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

$$PEC_{SED,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SED,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}} \cdot 4.615$$

Where:
$PEC_{SW,parent}$ = PEC_{SW} of the parent after entry via drainage [µg/L]
$MaxAR_{SW,metabolite}$ = maximum percentage of metabolite observed in water [%]
$MaxAR_{SED,metabolite}$ = maximum percentage of metabolite observed in sediment [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Table A 66: Percentage of pesticide loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
CGA192155	23.5 (arithmetic mean, n = 4)	1.9

[a] In accordance with PSD guidance

Table A 67: Overall maximum $PEC_{SW/SED}$ for CGA192155 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drain-age period	Max PEC_S (mg/kg)[a]	Avai-lable comp. (g/ha)[b]	Mass of comp. lost to drain-age (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							For-mation in soil	For-mation in water body	For-mation in soil	For-mation in water body
Peas 22.5 g a.s/ha BBCH 00	1	0[c]	n.r.[d]	n.r.[d]	n.r.[d]	0.014	n.r.[d]	0.001	n.r.[d]	0.003

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case
[d] Not relevant, metabolite not formed in soil

A 3.11 Spray drift and Tier I drainage assessments for metalaxyl-M and its relevant metabolite NOA409045

A 3.11.1 Spray drift assessment

Active Since the use is a seed treatment, spray drift can be excluded as a potential entry path to surface water.

A 3.11.2 Tier I drainage assessment

A9873C is to be applied on peas within the drainflow period of 1st October to 30th April. The PEC_{SW} and PEC_{SED} values of metalaxyl-M and its relevant metabolite NOA409045 following entry *via* drainage have been determined according to standard Tier I calculations recommended for such applications in the UK national requirements[3].

Active substance

The PEC_{SW} and PEC_{SED} values of metalaxyl-M following entry *via* drainage has been calculated using the CRD 'PEC $_{sw-sed}$ (drainage)' spreadsheet (v 1.0). The Tier I drainage assessment assumes that following a rainfall event, a proportion of the applied compound in a given hectare will be lost in 10mm of drainflow (equivalent to 100,000L water). The percentage of compound lost is assumed to be dependent on its soil adsorption (K_{OC}), and is defined in the national guidance[3]. The 100,000L of drainflow is then added to a stream on 30,000L (same as the standard water body used in the drift assessment) to give a total volume of 130,000L. By definition these concentrations are transitory as dilution and adsorption to sediments quickly dissipate the compounds. Bulk density of sediment is assumed to be 1.3g/cm^3.

The soil residue available for drainage, R, was calculated following SFO kinetics according to the following equation:

$$R\,[g/ha] = A \cdot (1 - I) \cdot \frac{(1 - e^{-n \cdot k \cdot i})}{(1 - e^{-k \cdot i})}$$

Where:
A = application rate [g a.s./ha]
I = fraction crop interception [-]
k = degradation rate constant in soil (= ln(2) / DT_{50}) [1/d]
i = minimum interval between applications [d]
n= maximum number of applications [-]

The PEC_{SW} *via* drainage is calculated as follows:

$$PEC_{SW,drainage}\,[\mu g/L] = \frac{R \cdot Flux \cdot 10^6}{130000}$$

Where:
R = soil residue available for drainage [g/ha]
Flux = fraction of pesticide loss in drainflow [-]

The PEC_{SED} *via* drainage is calculated as follows:

$$PEC_{SED,drainage}\,[\mu g/Kg] = \left(PEC_{SW,drainage} \cdot \text{ Fraction in sediment } / (1000 \cdot 5000 \cdot 1.3)\right) \cdot 30000$$

Table A 68: Percentage of metalaxyl-M loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
Metalaxyl-M	40 (median, n = 25)	1.9

[a] In accordance with PSD guidance

Table A 69: Overall maximum $PEC_{SW/SED}$ for metalaxyl-M due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Initial PEC_{SW} (µg/L)	Initial PEC_{SED} (µg/Kg)
Peas 76.3 g a.s/ha BBCH 00	1/-	0[c]	0.102	76.3	1.45	11.2	10.5

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

Metabolite(s)

The formation of NOA409045 was observed in soil and water. As such, the $PEC_{SW/SED}$ drainflow of NOA409045 has been determined for two pathways: the formation of the metabolite in soil and the subsequent entry into the waterbody *via* drainage and; the formation of the metabolite in the waterbody after the parent substance entered *via* drainage. The highest $PEC_{SW/SED}$ value obtained across the two routes is then reported.

For metabolites formed via the soil pathway

PEC_{SW} values of NOA409045 following formation in soil and subsequent entry into the water body *via* drainage, were calculated based on maximum PEC_S values after application and using the equation given above for the active substance. Thereby the PEC_S of NOA409045 is calculated on the basis of the maximum total dose of metalaxyl-M, adjusted for the maximum occurrence in the soil and corrected for the molecular weight difference relative to parent. Pseudo-application rates used to calculate PEC_S of NOA409045 were calculated according to the following equation:

$$A_{metabolite}\,[g/ha] = A_{parent} \times \frac{MaxAR_{metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

Where:
A_{parent} = application rate of parent substance [g/ha]
$MaxAR_{metabolite}$ = maximum percentage of metabolite observed in soil [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Otherwise, the PEC_{SW} and PEC_{SED} values of NOA409045 following entry *via* drainage have been calculated using the CRD 'PEC $_{sw\text{-}sed}$ (drainage)' spreadsheet (v 1.0), in the same way as the active substance metalaxyl-M.

For metabolites formed in the waterbody

PEC_{SW} and PEC_{SED} values of NOA409045 following formation in the waterbody after the parent substance entered *via* drainage, were calculated based on the maximum parent PEC_{SW} value, adjusted for the maximum occurrence in the surface water and sediment, respectively, and corrected for the molecular weight difference relative to parent according to the following equations:

$$PEC_{SW,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SW,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

$$PEC_{SED,metabolite}\,[g/ha] = PEC_{SW,parent} \times \frac{MaxAR_{SED,metabolite}}{100} \times \frac{MM_{metabolite}}{MM_{parent}} \cdot 4.615$$

Where:
$PEC_{SW,parent}$ = PEC_{SW} of the parent after entry via drainage [µg/L]
$MaxAR_{SW,metabolite}$ = maximum percentage of metabolite observed in water [%]
$MaxAR_{SED,metabolite}$ = maximum percentage of metabolite observed in sediment [%]
MM_{parent} = molecular mass of parent [g/mol]
$MM_{metabolite}$ = molecular mass of metabolite [g/mol]

Table A 70: Percentage of pesticide loss in drainflow

Compound	K_{FOC} (mL/g)	Flux (% pesticide transported per 10mm drain water)[a]
NOA409045	12.1 (median, n=14)	1.9

[a] In accordance with PSD guidance

Table A 71: Overall maximum $PEC_{SW/SED}$ for NOA409045 due to drainage following single application of A9873C

Crop	No. of appl.	Days from appl. till drainage period	Max PEC_S (mg/kg)[a]	Available comp. (g/ha)[b]	Mass of comp. lost to drainage (g/ha)	Max parent PEC_{SW} (µg/L)	Initial PEC_{SW} (µg/L)		Initial PEC_{SED} (µg/Kg)	
							Formation in soil	Formation in water body	Formation in soil	Formation in water body
Peas 76.3 g a.s/ha BBCH 00	1	0[c]	0.070	52.18	0.99	11.2	7.63	7.29	8.10	11.24

[a] Calculated from the PEC_S assuming distribution in the top 5cm of soil and 1.5g/cm^3 soil bulk density (Section 8.7)
[b] Soil residue available for drainage (R), see equation above for active substance
[c] Application was assumed to occur within the drainage period (i.e. 1st October – 30th April) as a worst-case

A 3.12 KCP 9.2.5: [redacted] (2020), VV-863863. Cymoxanil – Higher Tier Drainage PEC_{SW} following application to peas.

Reference:	KCP 9.2.5
Report:	Cymoxanil - A European Environmental Fate Assessment for Cymoxanil Using the MACRO Drainflow Tool for UK Surface Water Calculations Following Seed Treatment Application to Peas. [redacted] 2020 Report Number R2060005-7 Syngenta File No VV-863863 RIFCON GmbH, Goldbeckstr. 13, 69493 Hirschberg, GERMANY GLP not applicable
Guideline(s):	The modelling simulations were carried out in accordance with the FOCUS surface water scenarios workgroup guidelines: FOCUS (2014). Generic guidance for Tier 1 FOCUS groundwater assessments, version 2.2 FOCUS groundwater scenarios working group. FOCUS (2015). Generic Guidance for FOCUS Surface Water Scenarios, version 1.4. HSE (2020).“Higher tier drainflow from MACRO”. https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/fate/macro.htm (visited on 18/06/2020)
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.12.1 Materials and methods

This report describes a modelling study that examined the potential for cymoxanil to reach surface water via drainage following foliar application to peas. In the modelling study, the automated Excel tool (Multiple Applications with Metabolite - Macro4_vers.1.1.xlsm) provided by HSE was used which enables MACRO simulations as a higher tier refinement of surface water exposure via drainflow for UK (EXCEL tool including the operational model MACRO v4.3). The automated EXCEL tool and associated scenarios were developed by HSE to harmonise this area of the exposure assessment. Simulations are generated for four vulnerable drained soil classes (Denchworth, Hanslope, Brockhurst, Clifton) with dry, medium and wet weather climate scenarios. The tool includes a step-by-step user guide along with the necessary soil and climate files. After entering the relevant application and substance parameter into the EXCEL tool, MACRO input files (*.par) for each scenario are created automatically by a VBA macro. The MACRO v4.3 model are then started via a batch-file. Results from MACRO are evaluated in the EXCEL tool by a VBA macro automatically.

Seed treatment application at a rate of 45 g a.s./ha, from growth stage BBCH 00 was considered. The input parameters relating to application are shown below.

Table A 72: Input parameters related to application for PEC_{SW} calculations

Use No.	1
Crop	Peas
Application rate (g a.s./ha)	45
Number of applications/interval (d)	1 / -
BBCH growth stage	00
Interception	0%
Models used for calculation	EXCEL “MACRO Drainflow Tool” v1.1, including MACRO v4.3

The application date was set at the lowest BBCH value according to AppDate 3.06 ([redacted], 2019) for the FOCUS scenario Okehampton. The application windows used for each scenario are shown in the table below.

Table A 73: Application dates for PEC_{SW} calculations for the application of cymoxanil

Crop	Application scenario	Cymoxanil	
		Application date	Interception
Peas (Legumes)	Seed treatment (BBCH 00)	25-Mar	0%

The input parameters for cymoxanil as used in the modelling are shown in Table A 74.

Table A 74: Input parameters related to active substance cymoxanil for PEC_{SW} calculations

Compound	Cymoxanil	Value in accordance to EU endpoint / Reference
K_{FOC} (mL/g)	43.6 (arithmetic mean, n = 5)	Yes / EFSA (2008)
Freundlich exponent 1/n	0.86 (arithmetic mean, n=4)	Yes / EFSA (2008)
Plant uptake	0	FOCUS default
$DT_{50,soil}$ (d)	7.3 (worst case of laboratory studies)	Yes / EFSA (2008)
Exponent of soil temperature response	0.095 (equivalent to a Q_{10} of 2.58)	FOCUS default

A 3.12.2 Results

The lowest Regulatory Acceptable Concentration (RAC) of 4.4 µg/L for cymoxanil in surface water was derived from a fish chronic study (*Oncorhynchus mykiss*). This value was compared against the calculated concentrations. The following table gives the number of years of the 30-year simulation period and the maximum daily ditch concentrations on at least one day.

Table A 75: Maximum ditch concentration and number of years with daily ditch concentrations above the RAC of 4.4 µg/L on at least one day

Soil	Maximum calculated daily concentration in the ditch [µg/L]			Number of years (out of the 30 year period) with daily maximum PEC_{SW} > RAC		
	Dry	Medium	Wet	Dry	Medium	Wet
	Peas, application on 25^{h} of March, 0% interception					
Denchworth	1.072	1.672	2.122	0 / 30	0 / 30	0 / 30
Hanslope	0.837	1.182	1.566	0 / 30	0 / 30	0 / 30
Brockhurst	0.139	0.274	0.264	0 / 30	0 / 30	0 / 30
Clifton	0.005	0.030	0.260	0 / 30	0 / 30	0 / 30

The maximum daily concentration in ditch was 2.122 µg/L from Denchworth-wet scenario. As shown above, there are no exceedances of the RAC in any of the scenarios. Thus it can be concluded that there is no unacceptable risk for surface water organisms.