REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: A23109A

Product name: **ORONDIS VIP**

Chemical active substances:

Metalaxyl-M, 174.4 g/L
Oxathiapiprolin, 30 g/L

Interzonal

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(New authorisation)

Applicant: Syngenta
Submission date: June 2022
Evaluation date: December 2022
MS Finalisation date: December 2023

Version history

When	What
July 2022	dRR submitted by applicant to the Polish Ministry of Agriculture and Rural Development
September 2022	Submission to the evaluation unit
December 2022	izRMS finalized dRR evaluation
December 2023	Udates following comments from cMS

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8 Fate and behaviour in the environment (KCP 9)

Review Comments:

This document describes the acceptable use conditions required for registration of A23109A, a dispersible concentrate containing 174.4 g/L metalaxyl-M and 30 g/L oxathiapiprolin, for use as a fungicide on field and protected vegetable crops.

This Part B document only reviews data and additional information that has not previously been considered within the EU review process.

Since this document is based on the information provided by the applicant, all review comments, additions and corrections have been made using commenting boxes or highlighted in grey.

Please note, that the risk assessment was performed as for field uses. Thus, it cover all protected crops (greenhouses and crops grown under cover).

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	11a	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 saf-ener/ synergist per ha**	**Conclusion**
					Method / Kind	**Timing / Growth stage of crop & season**	**Max. number** **a) per use** **b) per crop/ season**	**Min. interval between applications (days)**	**kg or L product/ha** **a) max. rate per appl.** **b) max. total rate per crop/season**	**g MFX/ha a) max. rate per appl.** **b) max. total rate per crop/season**	**g OXTP/ha a) max. rate per appl.** **b) max. total rate per crop/season**	**Water 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)															
PL-53	Poland	Lettuce	G	*Bremia lactucae*	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	max 2 app per year in same field	R
FR-36	France	Lettuce	G	*Bremia lactucae*	Foliar	BBCH 12 - 49	a) 2 b) 2	7	a) 0.5 b) 1	a) 87.2 b) 174.4	a) 15 b) 30	200-800	10	max 2 app per year in same field	R

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1. The critical use patterns are reported only for Poland and France, as they cover all the other intended uses as listed in the GAP table in Part B, Section 0.

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

Explanation for column 15 "Conclusion"

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

Remarks table:

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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				Application rate				
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product/ha a) max. rate per appl. b) max. total rate per crop/season	g as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max	PHI (days)	Remarks: e.g. g safener / synergist per ha
n/a	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 40,000-80,000 seeds/ha. Typical TGW is 75g. 0.0763 mg MXM/seed
n/a	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
n/a	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	-

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
Use-No. *	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**	**PHI (days)**	**Remarks: e.g. g safener / synergist per ha**
n/a	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	-
n/a	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	-
n/a	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	-

* 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

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

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
Use-No. *	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**	**PHI (days)**	**Remarks: e.g. g safener / synergist per ha**
n/a	AU, DE (NEU)	Grape (VITVI) wine	F	*Plasmopara viticola*	Hydraulic sprayer with or w'out air assistance/ Atomizer/ Backpack	BBCH 13-89 Spring	Max 2	10 days	a) 0.06 b) 0.12	a) 60 b) 120	300-1600	28	(Max rate/ha) Do not use more than 60 g/ha. Basis Aufwand = 16 g/ha; BBCH 61 = 32 g/ha; BBCH 71 = 48 g/ha; BBCH >75 = 60 g/ha max.
n/a	CY, EL, IT, MT (SEU)	Grape (VITVI) table	F	*Plasmopara viticola*	Hydraulic sprayer with or w'out air assistance/ Atomizer/ Backpack	BBCH 13-89 Spring	Max 2	10 days	a) 0.06 b) 0.12	a) 60 b) 120	300-1500	14 (berries) 1 (leaves)	(Max rate /ha) Includes pergola vines The use on grape vine leaves for Greece, Spain and Portugal only
n/a	CY, EL, IT, MT (SEU)	Grape (VITVI) wine	F	*Plasmopara viticola*	Hydraulic sprayer with or w'out air assistance/ Atomizer/ Backpack	BBCH 13-83 Spring	Max 2	10 days	a) 0.06 b) 0.12	a) 60 b) 120	300-1500	28 (berries) 1 (leaves)	(Max rate/ha) Includes pergola vines The use on grape vine leaves for Greece, Spain and Portugal only
n/a	ES, PT (SEU)	Grape (VITVI) table	F	*Plasmopara viticola*	Hydraulic sprayer with or w'out air assistance/ Atomizer/ Backpack	BBCH 13-89 Spring	Max 2	10 days	a) 0.04 b) 0.08	a) 40 b) 80	300-1000	14 (berries) 1 (leaves)	Includes pergola vines The use on grape vine leaves for Greece, Spain and Portugal only

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
Use-No. *	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**	**PHI (days)**	**Remarks: e.g. g safener / synergist per ha**
n/a	ES, PT (SEU)	Grape (VITVI) wine	F	*Plasmopara viticola*	Hydraulic sprayer with or w'out air assistance/ Atomizer/ Backpack	BBCH 13-83 Spring	Max 2	10 days	a) 0.04 b) 0.08	a) 40 b) 80	300-1000	28 (berries) 1 (leaves)	Includes pergola vines The use on grape vine leaves for Greece, Spain and Portugal only
n/a	FR (NEU and SEU)	Grape (VITVI) table	F	*Plasmopara viticola*	Hydraulic sprayer with or w'out air assistance/ Atomizer/ Backpack	BBCH 13-79 Spring	Max 2	10 days	a) 0.04 b) 0.08	a) 40 b) 80	100-600	14 (berries)	(Max in use spray concentration)
n/a	FR (NEU and SEU)	Grape (VITVI) wine	F	*Plasmopara viticola*	Hydraulic sprayer with or w'out air assistance/ Atomizer/ Backpack	BBCH 13-79 Spring	Max 2	10 days	a) 0.04 b) 0.08	a) 40 b) 80	100-600	28 (berries)	(Max in use spray concentration)
n/a	IR, UK, FR (NEU and SEU for FR only)	Potato (SOLTU)	F	*Phythophthora infestans*	Hydraulic sprayer	BBCH 10 to PHI May-Aug	Max 4	7 days	a) 0.015 b) 0.06	a) 15 b) 60	100-400	7	Water volume varies by country
n/a	CY, EL, ES, IT, MT, PT (SEU)	Potato (SOLTU)	F	*Phythophthora infestans*	Hydraulic sprayer	BBCH 10 to PHI All year	Max 4	7 days	a) 0.015 b) 0.06	a) 15 b) 60	300-1000	7	(Min in use spray concentration)
n/a	FI, SE, AU, BE, DE, LU, NL (NEU)	Potato (SOLTU)	F	*Phythophthora infestans*	Hydraulic sprayer	BBCH 10 to PHI May-Aug	Max 4	7 days	a) 0.015 b) 0.06	a) 15 b) 60	100-400	14	Water volume varies by country

1	2	3	4	5	6	7	8	9	10	11	12	13	14
					Application				**Application rate**				
Use-No. *	**Member state(s)**	**Crop and/or situation (crop destination / purpose of crop)**	**F, Fn, Fpn G, Gn, Gpn or I ****	**Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)**	**Method / Kind**	**Timing / Growth stage of crop & season**	**Max. number a) per use b) per crop/ season**	**Min. interval between applications (days)**	**L product/ha a) max. rate per appl. b) max. total rate per crop/season**	**g as/ha a) max. rate per appl. b) max. total rate per crop/season**	**Water L/ha min/max**	**PHI (days)**	**Remarks: e.g. g safener / synergist per ha**
n/a	CY, EL, ES, FR, IT, MT, PT (SEU and NEU for FR only)	Tomato/ Aubergine (SOLLY/ SOLME) Vertical crops	F	*Phythophthora infestans*	Hydraulic sprayer / air assistance, atomizer	BBCH 15-89	Max 3	7 days	a) 0.03 b) 0.09	a) 30 b) 90	200-1500	3	Apply a minimum of 20 g a.s./ha Above 1000 L/ha use a concentration of 2 g a.s./hL Max water volume varies between countries
n/a	CY, EL, ES, FR, IT, MT, PT (SEU and NEU for FR only)	Tomato/ Aubergine (SOLLY/ SOLME) Industrial use, horizontal crop	F	*Phythophthora infestans*	Hydraulic sprayer	BBCH 15-89	Max 3	7 days	a) 0.02 b) 0.06	a) 20 b) 60	200-1000	3	Max water volume varies between countries

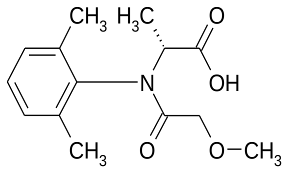
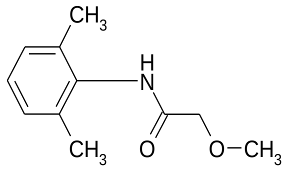
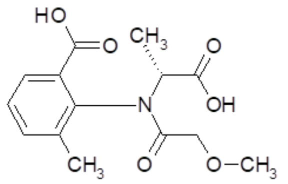
* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

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

8.2 Metabolites considered in the assessment

Metalaxyl-M

Table 8.2-1: 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 8.2-2: Code names for R-enantiomer metalaxyl-M and racemic parent metalaxyl and their respective metabolites

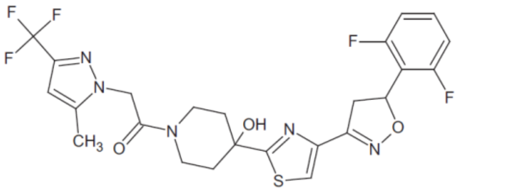
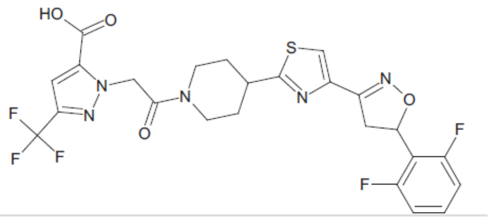
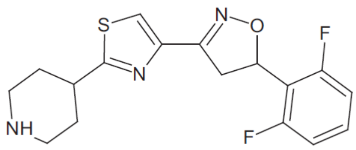
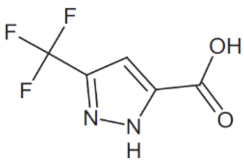
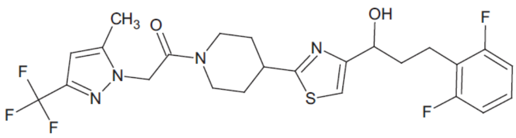
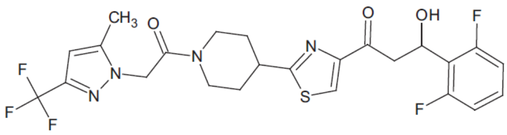
Enantiomer composition	Parent	Acid metabolite	Diacid metabolite	Amide metabolite
R-enantiomer	Metalaxyl-M, CGA329351	NOA409045	SYN546520	CGA67868[a]
Racemate (R/S)	Metalaxyl, CGA48988	CGA62826	CGA108906[b]	CGA67868[a]

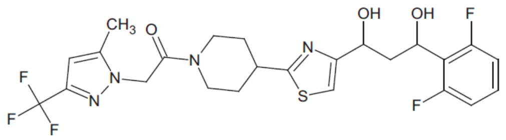
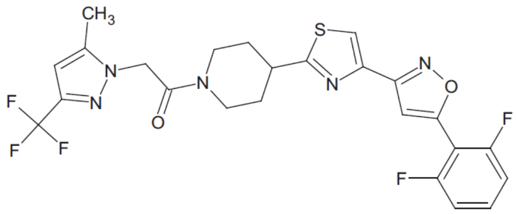
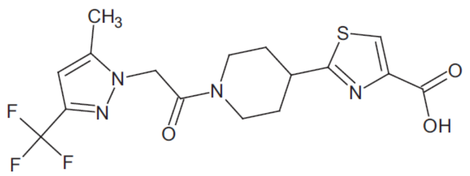
[a] Non-chiral CGA67868 is formed from both metalaxyl-M and metalaxyl

[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

Oxathiapiprolin

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

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments (%)	Exposure assessment required due to
IN-RDT31	555.53		Soil: > 5 % of as in 2 sequential measurements Water: nr Sediment: nr	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment
IN-RAB06	569.51		Soil: > 10 % of a.s. Water: nr Sediment:nr Total System: 9.5%	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment $PEC_{SW/SED}$: not covered by EU assessment
IN-QPS10	349.41		Soil: 8.7 % Water: nr Sediment: nr	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment
IN-E8S72	180.09		Soil: > 10 % of a.s. Water: nr Sediment: nr	PEC_S: not covered by EU assessment PEC_{GW}: not covered by EU assessment
IN-S2K66	528.54		Soil: nr Water: nr Sediment: > 5 % of a.s. and maximum of formation not yet reached at the end of the study (8.7%)	$PEC_{SW/SED}$: not covered by EU assessment
IN-RSE01	542.53		Soil: nr Water: nr Sediment: nr Total System:> 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
IN-RYJ52	544.54		Soil: nr Water: nr Sediment:> 10 % of a.s. (14.7%) (isomers combined) Max in total system: 16.0%[a]	$PEC_{SW/SED}$: not covered by EU assessment
IN-Q7D41	537.51		Soil: nr Water: nr Sediment:> 10 % of a.s. Max. in total system: > 10 % of a.s.	$PEC_{SW/SED}$: not covered by EU assessment
IN-P3X26	402.40		Soil: nr Water: > 10 % of a.s. (14%, aqueous photolysis, maximum value of two systems (natural water and buffer solution) Sediment: nr	PECSW/SED: not covered by EU assessment

nr: not relevant

[a] Maximum sum occurrence of two metabolites in the total system was observed for Calwich Abbey Lake system with thiazole label: isomer IN-RYJ52-A at 10.04% AR and isomer IN-RYJ52-B at 5.97% AR. Therefore, the sum of these two values of 16.0% AR was calculated

8.3 Rate of degradation in soil (KCP 9.1.1)

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

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. Since the EU review on metalaxyl-M, no further studies have been conducted on the degradation behaviour. The degradation pathway of metalaxyl-M in soil is shown below (see Figure 8.3-1).

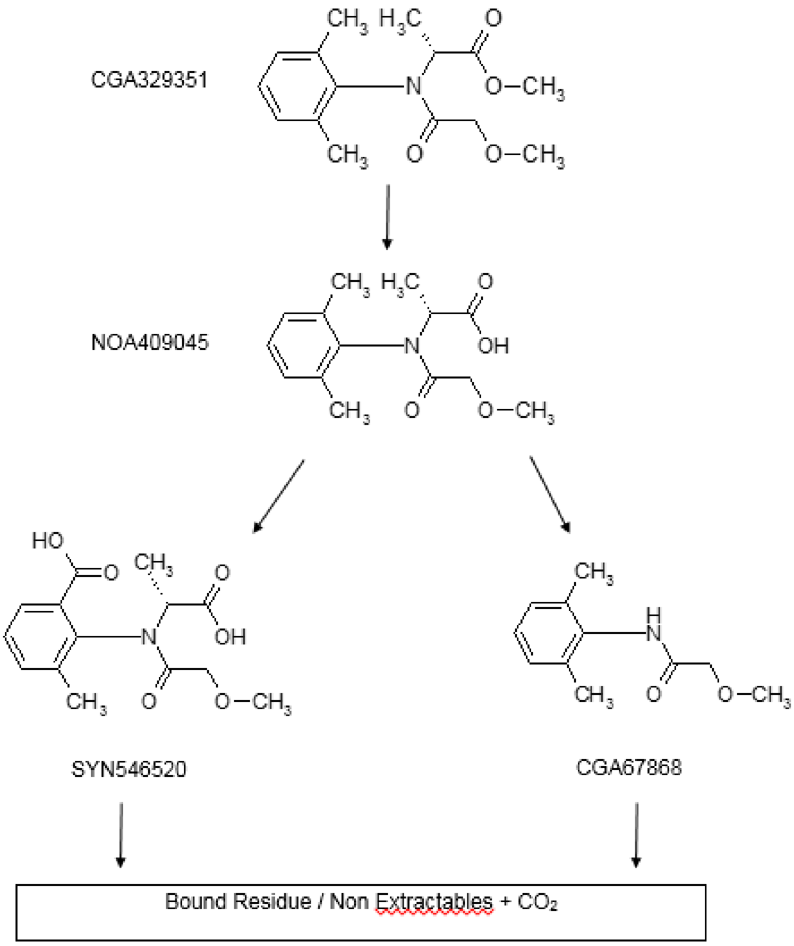


Figure 8.3-1: Proposed pathway of metalaxyl-M in soil

Oxathiapiprolin

As illustrated in the Figure 8.3-2 the major oxathiapiprolin metabolites in soil are IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72. All other metabolites shown in the degradation pathway of oxathiapiprolin in soil (Figure 8.3-2) are considered to be minor metabolites.

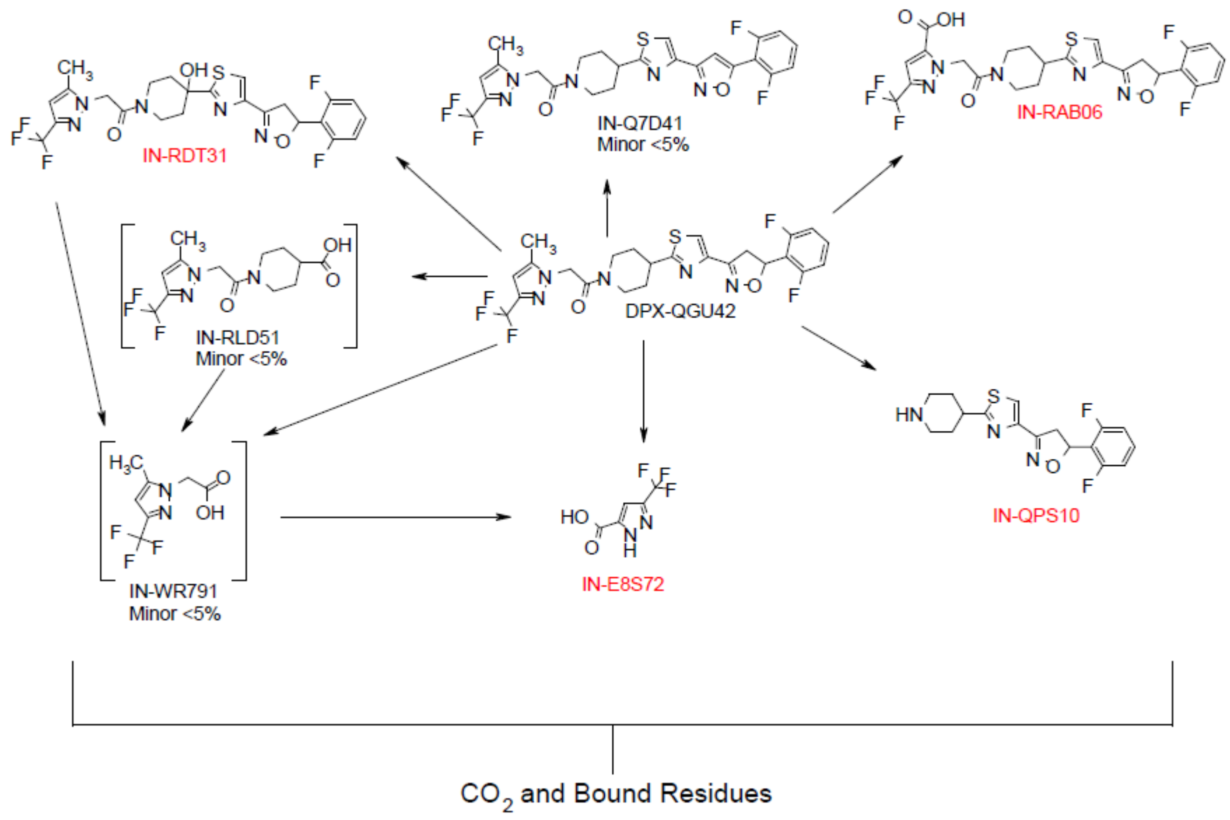


Figure 8.3-2: Proposed pathway of oxathiapiprolin in soil

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 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**).

A summary of the degradation rates is provided in Table 8.3-1 to Table 8.3-4.

Table 8.3-1: 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**	**Chi[2] (%)**	**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; Ellgehausen, 1996
Gartenacker	loam	7.25	20ºC	40%	5.73	19.0	3.75[a]	3.75	SFO	
Gartenacker	silt loam	7.6	20ºC	pF2	3.3	10.9	3.3	3.3	SFO	Yes / EFSA, 2015; Miner & Herczog, 2012
Les Evouettes	silt loam	7.3	20ºC	40%	3.90	13.0	2.38	7.31	SFO	Yes / EFSA, 2015; Ellgehausen, 1994
Collombey	loamy sand	7.4	20ºC	40%	8.13	27.0	6.28	1.38	SFO	Yes / EFSA, 2015; Ellgehausen, 1995
Birkenheide	sandy loam	5.6	20ºC	40%	26.4	87.6	22.5	2.70	SFO	Yes / EFSA, 2015; Dorn & Hein, 2003
Pappelacker	sandy loam	7.5	20ºC	40%	10.1	33.6	6.69	4.43	SFO	Yes / EFSA, 2015; Dorn & Möndel, 2003
Marsillargues	silty clay	8.0	20ºC	pF2	14.6	48.5	14.6	5.6	SFO	Yes / EFSA, 2015; Miner Herczog, 2012
Gardner	sandy loam	7.7	20ºC	pF2	8.2	27.3	8.2	6.5	SFO	
18 Acres	sandy clay loam	5.8	20°C	pF2	3.8	12.7	3.8	4.5	SFO	
San Miguel	sandy loam	7.4	20°C	pF2	73.1	243	73.1	2.3	SFO	
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 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 8.3-2: Summary of aerobic degradation rates for NOA409045 - laboratory studies

NOA409045, 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	loam	7.25	20ºC	40%	4.15	13.8	0.70	2.72[a]	9.04	SFO	Yes / EFSA, 2015; Ellgehausen, 1996
Gartenacker	loam	7.25	20ºC	40%	15.5	51.4	0.72	10.2[a]	9.80	SFO	
Gartenacker	silt loam	7.6	20°C	pF2	7.1	23.7	1	7.1	13.6	SFO	Yes / EFSA, 2015; Miner Herczog, 2012
Birkenheide	sandy loam	5.57	20ºC	40%	96.6	321	0.66	82.3[a]	2.61	SFO	Yes / EFSA, 2015; Dorn & Hein, 2003
Birkenheide	sandy loam	5.57	20ºC	40%	69.4	230	-	59.1[a]	2.18	SFO	
Pappelacker	sandy loam	7.5	20ºC	40%	7.88	26.2	0.83	5.22	10.3	SFO	Yes / EFSA, 2015; Dorn & Möndel, 2003
Marsillargues	silty clay	8.0	20°C	pF2	161	536	0.78	161	8.8	SFO	Yes / EFSA, 2015; Miner Herczog, 2012
Gardner	sandy loam	7.7	20°C	pF2	52.4	174	0.91	52.4	11.0	SFO	
18 Acres	sandy clay loam	5.8	20°C	pF2	32.3	107	0.81	32.3	12.8	SFO	
San Miguel	sandy loam	7.4	20°C	pF2	200	666	0.56	200	5.2	SFO	
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 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 8.3-3: 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; Miner Herczog, 2012
Gartenacker	silt loam	7.2	20°C	pF2	2.1	6.8	-	2.1[a]	9.1	SFO	Yes / EFSA, 2015; Miner & Hamilton, 2012
18 Acres	sandy loam	5.9	20°C	pF2	2.6	8.7	-	2.6	5.6	SFO	
Gardner	sandy loam	7.6	20°C	pF2	4.9	16.2	-	4.9	3.3	SFO	
Geometric mean/median (n=3)							-	2.9/2.6[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 of 2.9 days used as modelling endpoint, EFSA, 2015
[c] Kinetic formation fraction from NOA409045

Table 8.3-4: 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	0.47	42.1	5.5	SFO	Yes / EFSA, 2015; Miner Herczog, 2012
Marsillargues	silty clay	8.1	20°C	pF2	74.9	248.7	-	74.9	4.3	SFO	
18 Acres	sandy clay loam	6.2	20°C	pF2	287.9	956.5	-	287.9	1.9	SFO	
Geometric mean/median (n=3)							-	96.8/74.9[a]			
Formation fraction (from NOA409045)							0.47[b] / 0.1[c]	-			
pH-dependency:							No				

[a] Geometric mean DT_{50} 96.8 days used as modelling endpoint, 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 RMS Belgium for metalaxy-M has reviewed new kinetics data for deriving the formation fraction for SYN546520 (as this was an open point in the EFSA conclusion). The outcome of the review is included in the Article 7 updated dRAR (Amendmend of approval conditions for met-alaxy-M), in circulation for cMS/public commenting (May 2021) awaiting the completion of the EFSA conclusion at the time of preparation of this dossier.

The RMS Belgium concluded that 0.1 formation fraction for SYN546520 is the appropriate modelling endpoint based on available study data. If required, please find the new kinetics evaluations in Appendix A 3.1 to A 3.3.

For completeness and not relevant for the A23109A risk assessment, the Applicant would like to mention that a further CGA189096 (racemate of SYN546520) formation fraction modelling assessment on Pappelacker soil by Patterson D and Boardman M, 2020 was noted by RMS Belgium as complicated to follow in the on-going EU Article 7 review and hence was not included in this dossier, but is available upon request.

8.3.1.2 Oxathiapiprolin and its metabolites

Studies on the aerobic degradation rates of oxathiapiprolin and its metabolites IN-E8S72, IN-QPS10, IN-RDT31 and IN-E8S72 are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of oxathiapiprolin, **EFSA Journal 2016;14(7):4504.**

A summary of the persistence degradation rates is provided in Table 8.3-5 to Table 8.3-9. A summary of the modelling degradation rates is provided in Table 8.3-10 to Table 8.3-14.

Trigger endpoints

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

Oxathiapiprolin Laboratory studies, aerobic conditions									
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lleida	Clay Loam	7.9	20	50	59.4	197.2	7	SFO	Yes / EFSA 2016; Manjunatha, 2011
Nambsheim	Sandy Loam	7.6	20	50	134.8	640	2	DFOP (k_1 = 0.308, k_2 = 0.00319, g = 0.2)	
Speyer 2.2	Sand	6.1	20	50	116.3	386.3	7	SFO	
Tama	Silty clay loam	6.8	20	50	18.2	1224	4	FOMC (a = 0.4, ß = 3.907)	
Sassafras	Loamy sand	5.3	20	33.6	89.3	626.3	3	DFOP (k_1 = 0.071, k_2 = 0.00299, g = 0.3)	Yes / EFSA 2016; Cleland, 2013
Sassafras	Loamy sand	5.3	20	33.6	130.8	434.4	7	SFO	Yes / EFSA 2016; McCorquodale, 2013

* For FOMC kinetics DT_{50} = DT_{90}/3.32; For DFOP kinetics DT_{50} = ln(2)/k_2

Table 8.3-6: Summary of aerobic degradation rates for IN-RDT31 - laboratory studies

IN-RDT31, Laboratory studies, aerobic conditions									
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Nambsheim	Sandy Loam	7.4	20	50	46.3	235.2	5	DFOP (k_1 = 0.336, k_2 = 0.00852, g = 0.3)	Yes / EFSA, 2016; Sannappa, 2012
Tama	Silty clay loam	5.7	20	50	152	978.8	4	DFOP (k_1 = 0.084, k_2 = 0.00195, g = 0.3)	
Lleida	Clay	7.5	20	50	49.6	222.7	5	DFOP (k_1 = 0.152, k_2 = 0.009, g = 0.2)	
Speyer 2.2	Loamy sand	5.3	20	50	**736.4**	3652	2	DFOP (k_1 = 0.262, k_2 = 0.00055, g = 0.2)	
Sassafras	Sandy loam	5.1	20	50	216.2	1160	4	HS (k_1 = 0.057, k_2 = 0.00171, t_b = 5.9)	
Lleida	Clay loam	7.9	20	50	47.1	156.5	18	SFO-SFO	Yes / EFSA, 2016; Manjunatha, 2011

* For HS and DFOP kinetics DT_{50} = ln(2)/k_2
Values in bold were used for PEC soil calculation

Table 8.3-7: Summary of aerobic degradation rates for IN-RAB06 - laboratory studies

IN-RAB06, Laboratory studies, aerobic conditions									
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Speyer 2.2	Loamy sand	5.4	20	50	83.6	346.5	4	DFOP (k_1 = 0.083, k_2 = 0.006, g =0.2)	Yes / EFSA, 2016; Ravi, 2013
Lleida	Clay	7.7	20	50	51.7	258.2	5	FOMC (a = 2.194, ß = 139.09)	
Tama	Silty clay loam	6.2	20	50	74.6	247.9	4	SFO	
Nambsheim	Sandy loam	7.6	20	50	38.5	214.1	6	FOMC (a = 1.775, ß = 80.549)	
Cajon	Loam	7.3	20	50	68.1	226.4	4	SFO	
Tama	Silty Clay Loam	6.3	20	50	10.4	166.5	4	DFOP (k_1 = 0.245, k_2 = 0.0098, g = 0.5)	Yes / EFSA, 2016;

IN-RAB06, Laboratory studies, aerobic conditions									
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lleida	Clay	7.7	20	50	8.6	63.5	2	DFOP (k_1 = 0.628, k_2 = 0.029, g = 0.4)	Stenzel, Schaefer, 2012
Sassafras	Loam	5.1	20	50	100.5	603.9	3	DFOP (k_1 = 0.238, k_2 = 0.0032, g = 0.3)	
Nambsheim	Sandy Loam	7.7	20	50	3.5	58.6	4	DFOP (k_1 = 0.9, k_2 = 0.028, g = 0.5)	
Speyer	Loamy Sand	5.5	20	50	**170.2**	565.2	5	SFO	
Lleida	Clay loam	7.9	20	50	24.1	80.2	17	SFO-SFO	Yes, EFSA, 2016; Manjunatha, 2011
Sassafras	Loamy Sand	5.3	20	50	38.2	127	20	DFOP-SFO	Yes / EFSA, 2016; Cleland, 2013

* For FOMC kinetics $DT_{50} = DT_{90}/3.32$; For DFOP kinetics $DT_{50} = \ln(2)/k_2$
Value in bold was used for PEC soil calculation

Table 8.3-8: Summary of aerobic degradation rates for IN-E8S72 - laboratory studies

IN-E872, Laboratory studies, aerobic conditions									
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Speyer 2.2	Loamy sand	5.2	20	50	**477.4**	1585.8	2	SFO	Yes / EFSA, 2016; Ravi, 2013
Lleida	Clay	7.7	20	50	271.7	902.5	0.82	SFO	
Tama	Silty clay loam	6.4	20	50	216.2	718.2	3	SFO	
Nambsheim	Sandy Loam	7.6	20	50	328.4	1090.9	2	SFO	
Sassafras	Sandy loam	5.1	20	50	379.6	1260.9	1	SFO	

Value in bold used for PEC soil calculation

Table 8.3-9: Summary of aerobic degradation rates for IN-QPS10 - laboratory studies

IN-QPS10, Laboratory studies, aerobic conditions									
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**t. (°C)**	**MWHC (%)**	**DT_{50} (d)**	**DT_{90} (d)**	**Chi² (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Nambsheim	Sandy Loam	7.4	20	50	3	171.3	9	DFOP (k_1 = 0.645, k_2 = 0.00847, g = 0.6)	Yes / EFSA, 2016; Yogeesha, S., 2012
Lleida	Clay	7.5	20	50	19	192.8	4	DFOP (k_1 = 1.323, k_2 = 0.00926, g = 0.4)	
Sassafras	Sandy loam	5.3	20	50	**310.2**	2266.6	5	DFOP (k_1 = 0.811, k_2 = 0.00082, g = 0.4)	
Speyer 2.2	Loamy sand	5.1	20	50	301.4	1722.3	6	DFOP (k_1 = 5.827, k_2 = 0.00113, g = 0.3)	

*For DFOP kinetics DT_{50} = ln(2)/k_2
Values in bold were used for PEC soil calculation

Modelling endpoints

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

Oxathiapiprolin Laboratory studies, aerobic conditions						
Soil name	**Soil type (USDA)**	**pH (H_2O)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi² (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lleida	Clay Loam	7.9	59.4	7	SFO	Yes / EFSA 2016; Manjunatha, 2011
Nambsheim	Sandy Loam	7.6	217.3	2	HS (k_1 = 0.036, k_2 = 0.00319, t_b = 8.1)	
Speyer 2.2	Sand	6.1	116.3	7	SFO	
Tama	Silty clay loam	6.8	105.68	4	HS (k_1 = 0.051, k_2 = 0.00641, t_b = 14.7)	
Sassafras	Loamy sand	5.3	175	3	HS (k_1 = 0.02, k_2 = 0.00396, t_b = 19.9)	Yes / EFSA 2016; Cleland, 2013
Sassafras	Loamy sand	5.3	114.03	7	SFO	Yes / EFSA 2016; McCorquodale, 2013
Geometric mean (n=6)			121.2			
pH-dependency:			No			

* For HS kinetics DT_{50} = ln(2)/k_2

Table 8.3-11: Summary of aerobic degradation rates for IN-RDT31 - laboratory studies

IN-RDT31, Laboratory studies, aerobic conditions						
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Nambsheim	Sandy Loam	7.4	81.5	5	HS (k_1 = 0.092, k_2 = 0.00851, t_b = 3.6)	Yes / EFSA, 2016; Sannappa, 2012
Tama	Silty clay loam	5.7	177	5	HS (k_1 = 0.033, k_2 = 0.00361, t_b = 8.4)	
Lleida	Clay	7.5	62.6	5	HS (k_1 = 0.053, k_2 = 0.01043, t_b = 4)	
Speyer 2.2	Loamy sand	5.3	1260	2	DFOP (k_1 = 0.262, k_2 = 0.00055, g = 0.2)	
Sassafras	Sandy loam	5.1	313.4	4	HS (k_1 = 0.057, k_2 = 0.00171, t_b = 5.9)	Yes / EFSA, 2016; Manjunatha, 2011
Lleida	Clay loam	7.9	47.1	18	SFO-SFO	
Geometric mean (n=6)			160			
pH-dependency:			No			

* For HS and DFOP kinetics $DT_{50} = \ln(2)/k_2$

Table 8.3-12: Summary of aerobic degradation rates for IN-RAB06 - laboratory studies

IN-RAB06, Laboratory studies, aerobic conditions						
Soil name	**Soil type (USDA)**	**pH**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Speyer 2.2	Loamy sand	5.4	87.7	5	SFO	Yes / EFSA, 2016; Ravi, 2013
Lleida	Clay	7.7	53.5	5	SFO	
Tama	Silty clay loam	6.2	74.6	4	SFO	
Nambsheim	Sandy loam	7.6	44.4	7	SFO	
Cajon	Loam	7.3	66.1	4	SFO	
Tama	Silty Clay Loam	6.3	70.7	4	DFOP (k_1 = 0.245, k_2 = 0.0098, g = 0.5)	Yes / EFSA, 2016; Stenzel, Schaefer, 2012
Lleida	Clay	7.7	23.1	8	FOMC (a = 0.776, ß = 5.458)	
Sassafras	Loam	5.1	214.4	3	DFOP (k_1 = 0.238, k_2 = 0.0032, g = 0.3)	
Nambsheim	Sandy Loam	7.7	31.2	9	FOMC (a = 0.564, ß = 1.829)	
Speyer	Loamy Sand	5.5	231	4	HS (k_1 = 0.022, k_2 = 0.003, tb = 7.8)	
Lleida	Clay loam	7.9	24.1	17	SFO-SFO	Yes, EFSA, 2016; Manjunatha, 2011

IN-RAB06, Laboratory studies, aerobic conditions						
Soil name	**Soil type (USDA)**	**pH**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Sassafras	Loamy Sand	5.3	38.2	20	DFOP-SFO	Yes / EFSA, 2016; Cleland, 2013
Geometric mean (n=12)			60.5			
pH-dependency:			No			

* For FOMC kinetics $DT_{50} = DT_{90}/3.32$; For HS and DFOP kinetics $DT_{50} = \ln(2)/k_2$

Table 8.3-13: Summary of aerobic degradation rates for IN-E8S72 - laboratory studies

IN-E872, Laboratory studies, aerobic conditions						
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Speyer 2.2	Loamy sand	5.2	477.4	2	SFO	Yes / EFSA, 20 16; Ravi, 2013
Lleida	Clay	7.7	243	0.82	SFO	
Tama	Silty clay loam	6.4	213.9	3	SFO	
Nambsheim	Sandy Loam	7.6	328.4	2	SFO	
Sassafras	Sandy loam	5.1	352.3	1	SFO	
Geometric mean (n=5)			310.2			
pH-dependency:			No			

Table 8.3-14: Summary of aerobic degradation rates for IN-QPS10 - laboratory studies

IN-QPS10, Laboratory studies, aerobic conditions						
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Nambsheim	Sandy Loam	7.4	81.8	9	DFOP (k_1 = 0.645, k_2 = 0.00847, g = 0.6)	Yes / EFSA, 2016; Yogeesha, 2012
Lleida	Clay	7.5	70.5	4	DFOP (k_1 = 1.323, k_2 = 0.00926, g = 0.4)	
Sassafras	Sandy loam	5.3	520.3	7	HS (k_1 = 0.161, k_2 = 0.00103, t_b = 2.5)	
Speyer 2.2	Loamy sand	5.1	613.4	6	HS (k_1 = 0.353, k_2 = 0.00113, t_b = 1)	
Geometric mean acidic (n=2)			564.9			

IN-QPS10, Laboratory studies, aerobic conditions						
Soil name	**Soil type (USDA)**	**pH ($CaCl_2$)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi[2] (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Geometric mean alkaline (n=2)			75.9			
pH-dependency:			Yes			

* For HS and DFOP kinetics $DT_{50} = \ln(2)/k_2$

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Studies on anaerobic degradation rates are considered to be data provided in support of the active substance.

8.3.2.1 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.

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**).

8.3.2.2 Oxathiapiprolin

Studies on the anaerobic degradation rates of oxathiapiprolin are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of oxathiapiprolin, **EFSA Journal 2016;14(7):4504.**

Table 8.3-15: Summary of anaerobic degradation rates for oxathiapiprolin - laboratory studies

Oxathiapiprolin Laboratory studies, anaerobic 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**
Sassafras	Sandy loam	5.7	20	50	1505	4998	-	-	SFO	Yes / EFSA, 2016; Anderson & Wardrope, 2012

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 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**).

The resulting triggering endpoints for metalaxyl-M and NOA409045 are presented in Table 8.4-1 and Table 8.4-2 respectively.

Trigger endpoints

Table 8.4-1: Summary of aerobic degradation rates for metalaxyl-M - field studies: Triggering 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; Kühne, 1998
Silty clay loam	Marsillargues (FR)	7.4	0-30	13.5	44.7	26.5	SFO	Yes / EFSA, 2015; Kühne, 2000
Silty clay loam	Bastia di Rovolon (IT)	7.3	0-30	18.1	60.1	14.9	SFO	Yes / EFSA, 2015; Kühne, 2003
Loam	Vouvry (CH)	7.4	0-30	4.6	15.3	12.5	SFO	Yes / EFSA, 2015; Kühne, 2003
Silty clay	Vouvry (CH)	7.1	0-30	12.4	41.3	14.2	SFO	Yes / EFSA, 2015; Kühne, 2003
Loamy sand	Sevilla (SP)	7.8	0-30	15.3	50.9	9.02	SFO	Yes / EFSA, 2015; Kühne, 2003
Loam	Aimargues (FR)	7.4	0-30	30.9	102.6	11.4	SFO	Yes / EFSA, 2015; Kühne, 2003
Loamy sand	Middelfart (DK)	6.9	0-30	20.9	69.5	5.74	SFO	Yes / EFSA, 2015; Stolze, 2003
Loam	Sept Saux (FR)	7.8	0-30	9.3	30.7	14.8	SFO	Yes / EFSA, 2015; Lakachus & Gizler, 2008
Silty loam	Lower Saxony (DE)	6.0	0-30	19.7	65.4	11.6	SFO	Yes / EFSA, 2015; Simon, 2008

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**
Geometric mean/median (n=10)				14.1/14.4	46.7/47.8	-		
Maximum				30.9	102.6	-		

Table 8.4-2: Summary of aerobic degradation rates for NOA409045- field studies: Triggering 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; Kühne, 1998
Silty clay loam	Marsillargues (FR)	7.4	0-30	20.5	68.0	16.4	SFO	Yes / EFSA, 2015; Kühne, 2000
Silty clay loam	Bastia di Rovolon (IT)	7.3	0-30	14.9	49.6	59.0	SFO	Yes / EFSA, 2015; Kühne, 2003
Loam	Vouvry (CH)	7.4	0-30	5.8	19.2	25.7	SFO	Yes / EFSA, 2015; Kühne, 2003
Silty clay	Vouvry (CH)	7.1	0-30	8.3	27.7	44.7	SFO	Yes / EFSA, 2015; Kühne, 2003
Loamy sand	Sevilla (SP)	7.8	0-30	Uncertain[a]	Uncertain[a]	-	SFO	Yes / EFSA, 2015; Kühne, 2003
Loam	Aimargues (FR)	7.4	0-30	15.9	52.8	20.7	SFO	Yes / EFSA, 2015; Kühne, 2003
Loamy sand	Middelfart (DK)	6.9	0-30	39.8	132.2	20.9	SFO	Yes / EFSA, 2015; Stolze, 2003
Loam	Sept Saux (FR)	7.8	0-30	27.1	89.9	34.5	SFO	Yes / EFSA, 2015; Lakachus & Gizler, 2008
Silty loam	Lower Saxony (DE)	6.0	0-30	30.2	100	22.3	SFO	Yes / EFSA, 2015; Simon, 2008
Geometric mean/median (n=9)				17.1/16.0	56.6/53.3	-		

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**
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.

8.4.1.2 Oxathiapiprolin and its metabolites

Studies on the field dissipation rates of oxathiapiprolin are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of oxathiapiprolin, **EFSA Journal 2016;14(7):4504.**

The resulting triggering endpoints for oxathiapiprolin and IN-RDT31 are presented in Table 8.4-3 and Table 8.4-4, respectively. No reliable fits could be determined for IN-E8S72, IN-QPS10 and IN-RAB06.

The resulting modelling endpoints for oxathiapiprolin, IN-E8S72, IN-RDT31 and IN-RAB06 are presented in Table 8.4-5 to Table 8.4-8. No reliable fits could be determined for IN-QPS10.

Trigger endpoints

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

Oxathiapiprolin, Field studies – Trigger endpoints					
Location	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Chi[2] (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lucenay, France	5.5	178.5	8	DFOP (k_1 = 0.194, k_2 = 0.005, g = 0.8)	Yes / EFSA, 2016; Doig & Just, 2012
Lentzke, Germany	23.9	556.7	12	DFOP (k_1 = 0.055, k_2 = 0.002, g = 0.7)	Yes / EFSA, 2016; Doig & Just, 2012
Cambridgeshire, U.K.	101	524.5	6	DFOP (k_1 = 0.07, k_2 = 0.004, g = 0.3)	Yes / EFSA, 2016; Doig *et al.*, 2012
Sevilla, Spain	8.1	211.5	10	DFOP (k_1 = 0.239, k_2 = 0.007, g = 0.6)	Yes / EFSA, 2016; Doig *et al.*, 2012
North Rose, New York	3.9	208	19	DFOP (k_1 = 0.367, k_2 = 0.006, g = 0.6)	Yes / EFSA, 2016; Rice, 2012
Raymondville, Texas	9.8	75.8	13	FOMC (a = 1.155, ß = 11.956)	Yes / EFSA, 2016; Rice, 2012
Citra, Florida	34.6	270.3	9	FOMC (a = 1.14, ß = 41.333)	Yes / EFSA, 2016; Rice, 2012
Porterville, California	30	174.2	9	FOMC (a = 1.659, ß = 57.932)	Yes / EFSA, 2016; Rice, 2012

Oxathiapiprolin, Field studies – Trigger endpoints					
Location	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Manitoba, Canada	**205.3**	682	19	SFO	Yes / EFSA, 2016; Vincent, 2012
British Columbia, Canada	169.6	563.4	13	SFO	Yes / EFSA, 2016; Vincent, 2013

* For FOMC kinetics $DT_{50} = DT_{90}/3.32$; For HS and DFOP kinetics $DT_{50} = \ln(2)/k_2$
Figures in bold used for PEC soil calculation

Table 8.4-4: Summary of aerobic degradation rates for IN-RDT31- field studies: Trigger endpoints

IN-RDT31, Field studies – Trigger endpoints					
Location	**DT_{50} (d) Actual**	**DT_{90} (d) Actual**	**Chi^2 (%)**	**Kinetic model**	**Evaluated on EU level / Reference**
Lentzke, Germany	134.5	446.8	19	SFO	Yes / EFSA, 2016; Doig & Just, 2012
Cambridgeshire, U.K.	190.00	632.00	14	SFO	Yes / EFSA, 2016; Doig *et al.*, 2012

Modelling endpoints

Table 8.4-5: Summary of aerobic degradation rates for oxathiapiprolin - field studies: Modelling endpoints

Oxathiapiprolin, Field studies – Modelling endpoints					
Location	**pH**	**DT_{50} (d) Actual**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lucenay, France	6.9	31.5	11	FOMC (a = 0.567, ß = 1.843)	Yes / EFSA, 2016; Doig & Just, 2012
Lentzke, Germany	6	97.9	11	FOMC (a = 0.61, ß = 7.622)	Yes / EFSA, 2016; Doig & Just, 2012
Cambridgeshire, U.K.	7.4	68.4	9	SFO	Yes / EFSA, 2016; Doig *et al.*, 2012
Sevilla, Spain	8.1	104	13	FOMC (a = 0.468, ß = 2.544)	Yes / EFSA, 2016; Doig *et al.*, 2012
North Rose, New York	5.1	73.7	21	FOMC (a = 0.426, ß = 1.104)	Yes / EFSA, 2016; Rice, 2012
Raymondville, Texas	8.3	52.8	15	FOMC (a = 1.05, ß = 22.038)	Yes / EFSA, 2016; Rice, 2012
Citra, Florida	6.7	138.5	9	FOMC (a = 1.125, ß = 68.16)	Yes / EFSA, 2016; Rice, 2012
Porterville, California	8.5	56.5	8	FOMC (a = 0.828, ß = 12.369)	Yes / EFSA, 2016; Rice, 2012

Oxathiapiprolin, Field studies – Modelling endpoints					
Location	**pH**	**DT_{50} (d) Actual**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Manitoba, Canada	7.9	76.2	21	SFO	Yes / EFSA, 2016; Vincent, 2012
British Columbia, Canada	6.5	66.5	13	FOMC (a = 2.719, ß = 165.82)	Yes / EFSA, 2016; Vincent, 2013

* For FOMC kinetics $DT_{50} = DT_{90}/3.32$

Table 8.4-6: Summary of aerobic degradation rates for IN-E8S72- field studies: Modelling endpoints

IN-E8S72, Field studies – Modelling endpoints					
Location	**pH**	**DT_{50} (d) Actual**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lucenay, France	6.9	47.3	15	SFO	Yes / EFSA, 2016; Doig & Just, 2012
Cambridgeshire, U.K.	7.4	157.3	7	SFO	Yes / EFSA, 2016; Doig *et al.*, 2012
North Rose, New York	5.1	56.6	20	FOMC (a = 0.621, ß = 4.72)	Yes / EFSA, 2016; Rice, 2012
Raymondville, Texas	8.3	113.6	9	SFO	Yes / EFSA, 2016; Rice, 2012

* For FOMC kinetics $DT_{50} = DT_{90}/3.32$

Table 8.4-7: Summary of aerobic degradation rates for IN-RDT31- field studies: Modelling endpoints

IN-RDT31, Field studies – Modelling endpoints					
Location	**pH**	**DT_{50} (d) Actual**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lentzke, Germany	6	47.6	13	DFOP-SFO	Yes / EFSA, 2016; Doig & Just, 2012
Cambridgeshire, U.K.	7.4	53.6	15	SFO-SFO	Yes / EFSA, 2016; Doig *et al.*, 2012
Citra, Florida	6.7	111.7	20	FOMC-SFO	Yes / EFSA, 2016; Rice, 2012
British Columbia, Canada	6.5	105.1	7	FOMC-SFO	Yes / EFSA, 2016; Vincent, 2013

* Parent-metabolite

Table 8.4-8: Summary of aerobic degradation rates for IN-RAB06- field studies: Modelling endpoints

IN-RAB06, Field studies – Modelling endpoints					
Location	**pH**	**DT_{50} (d) Actual**	**Chi^2 (%)**	**Kinetic model***	**Evaluated on EU level / Reference**
Lucenay, France	6.9	77.1	12	SFO	Yes / EFSA, 2016; Doig & Just, 2012
North Rose, New York	5.1	34.2	20	FOMC (a = 0.616, ß = 2.77)	Yes / EFSA, 2016; Rice, 2012
Citra, Florida	6.7	167.6	21	SFO	Yes / EFSA, 2016; Rice, 2012
British Columbia, Canada	6.5	208.6	10	SFO	Yes / EFSA, 2016; Vincent, 2013

* For FOMC kinetics $DT_{50} = DT_{90}/3.32$

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

8.4.2.1 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 under-taken.

Given the maximum DT_{90} of SYN546520 is > 365 d, as shown in Section 8.3.1, the potential for accumulation has been assessed by calculation under Section 8.7.

8.4.2.2 Oxathiapiprolin and its metabolites

Given the maximum DT_{90} of oxathiapiprolin, IN-RDT31, IN-RAB06, IN-E8S72, IN-QPS10 is > 365 d, as shown in Section 8.3.1, the potential for accumulation has been assessed by calculation under Section 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 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.

The soil adsorption data for metalaxyl-M, NOA409045, CGA67868 and SYN546520 are presented Table 8.5-1 to Table 8.5-4.

Table 8.5-1: 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; Spare, 1987
Maryland	sand	0.53	6.5	0.157	29.6	0.795	
Mississippi	loam	0.71	7.6	1.41	199.8	1.31	
Collombey	sand	1.28	7.8	0.43	33.6	0.83	Yes / EFSA, 2015; Guth, 1978
Lakeland	sand	0.696	6.3	0.48	69.0	0.79	
Les Evouettes	loam	2.09	6.1	0.87	41.6	0.77	
Vetroz	sandy clay loam	3.25	6.7	1.40	43.1	0.83	
Mississippi	clay	1.33	7.0	7.61	570	1.45	Yes / EFSA, 2015; Spare, 1995
Maryland	sand	0.348	5.4	0.0700	20	0.892	
Washington	loam	1.51	7.0	1.30	86	1.05	
Borstel	loamy sand	1.2	5.0	0.480	40.0	0.923	Yes / EFSA, 2015; Phaff, 1999
Pappelacker	loamy sand	1.1	7.6	0.318	28.9	0.900	
Gartenacker	silt loam	2.08	7.3	0.644	31.0	0.908	
Vetroz	silt loam	4.7	7.2	1.67	35.5	0.928	
Illarsaz	silt loam	19.8	6.7	7.88	39.8	0.929	
Birkenheide	sandy loam	0.84	5.57	0.339	40.4	0.963	Yes / EFSA, 2015; Dorn & Hein, 2002
Pappelacker	sandy loam	1.56	7.47	0.480	30.8	0.956	
Gartenacker	silt loam	1.81	7.30	0.700	38.7	0.937	
Vetroz	silt loam	1.77	7.70	0.717	40.5	0.934	
Birkenheide	sandy loam	0.94	5.65	0.372	39.6	0.92	Yes / EFSA, 2015; Dorn, 2001
Gartenacker	silt loam	1.97	7.6	0.5	26	0.979	Yes / EFSA, 2015; Miner, 2012
18 Acres	sandy clay loam	3.19	5.8	0.9	29	0.910	
Marsillargues	silty clay	1.04	8	0.7	58	0.942	
Gardner	sandy loam	2.84	7.7	1.9	67	0.923	
Work Ranch	sandy loam	2.44	7.4	1.3	52	0.954	
Median (n=25)					40	0.93	
Geometric mean (n=25)					50.63	-	
Arithmetic Mean (n=25)					78.9	0.955	
pH-dependency:					No		

Note: K_{FOC} values were obtained on racemic and R-enantiomer for parent

Table 8.5-2: 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; Spare, 1996
Maryland	sand	0.348	5.4	0.124	36	0.927	
California	sandy loam	0.58	6.9	0.0175	3	0.867	
Washington	loam	1.28	7.0	0.105	8	0.909	
Arizona	clay loam	0.58	7.9	0.0992	17	0.929	
Les Evouettes	loam	1.4	5.5	0.3	22	0.91	Yes / EFSA, 2015; Heinis, 1994
Staffort	sandy loam	0.77	5.2	0.120	15.4	0.935	Yes / EFSA, 2015; Reischmann, 1998
Gartenacker	loam	2.40	7.2	0.210	8.88	0.960	
Vetroz	silt loam	4.39	7.1	0.440	9.94	0.956	
Birkenheide	sandy loam	0.84	5.57	0.131	15.6	0.907	Yes / EFSA, 2015; Dorn, 2001
Pappelacker	sandy loam	1.56	7.47	0.139	8.9	0.940	
Gartenacker	silt loam	1.81	7.30	0.205	11.3	0.918	
Vetroz	silt loam	1.77	7.70	0.173	9.8	0.930	
Birkenheide	sandy loam	0.94	5.65	0.122	12.9	0.956	Yes / EFSA, 2015; Dorn, 2001
Median (n=14)					12.1	-	
Geometric mean (n=14)					13.44	-	
Arithmetic Mean (n=14)					17.9	0.928	
pH-dependency:					No		

Table 8.5-3: 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; Miner, 2012
18 Acres	sandy clay loam	3.2	5.5	0.5	16	0.879	
Marsillargues	silty clay	1.2	7.8	0.2	20	0.794	
Gardner	sandy loam	2.8	7.3	0.5	19	0.816	
Madera	sandy loam	0.7	6.9	0.1	20	1.169	

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**
Geometric mean (n=15)					18.93	-	
Arithmetic Mean (n=5)					19.0	0.896	
pH-dependency:					No		

Table 8.5-4: 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; Miner, 2012
18 Acres	sandy clay loam	2.4	5.9	0.4	15	0.964	
Seven Springs	loamy sand	0.5	5.8	0.2	41	0.951	
Gardner	sandy loam	2.7	7.6	0.1	2	1.366	
Geometric Mean (n=4)					7.79	-	
Arithmetic Mean (n=4)					15.2	1.1	
pH-dependency:					No		

8.5.2 Oxathiapiprolin and its metabolites

Studies on the mobility of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, and IN-E8S72 in soil are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of oxathiapiprolin, **EFSA Journal 2016;14(7):4504**.

Table 8.5-5: Summary of soil adsorption for oxathiapiprolin

Oxathiapiprolin							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level/ Reference**
Drummer (USA) [a]	Clay loam	2.9	6.4	1322	45586	1.1207	Yes /EFSA, 2016; Manjunatha, 2010, Manjunatha, 2013
Gross Umstadt (Germany)	Loam	1.2	7.3	52.2	4350	0.9741	
Nambsheim (France)	Sandy loam	1.4	7.7	102	7286	1.0294	
Lleida (Spain)	Silty clay	1.8	7.6	100	5556	0.9833	
Sassafras (USA)	Sandy loam	1.2	5.7	87.4	7283	0.9851	
Porterville (USA)	Loam	1.3	7.4	53.9	6738	0.8877	
Geometric Mean (n=5)					6128	-	
Arithmetic mean (n=5)					6242.6	0.97	
pH-dependence					No		

[a] The values obtained from the Clay loam (Drummer) soil were significantly higher than the other soils. This was most likely due to experimental shortcomings described in the evaluation report. Therefore the Drummer values were excluded from the arithmetic mean calculation. The Drummer soil K_{FOC} value was used as a worst case scenario for acidic soils during the PEC_{SED} assessment.

Table 8.5-6: Summary of soil adsorption for IN-RDT31

IN-RDT31							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Nambsheim (France)	Sandy loam	1.7	7.6	14.2	835	0.8654	Yes /EFSA 2016; Sannappa, 2012
Tama (USA)	Silty clay loam	1.9	5.9	47.9	2521	0.9048	
Lleida (Spain)	Clay	2.0	7.5	12.6	630	0.8481	
Gross Umstadt (Germany)	Loam	1.2	7.0	14.1	1175	0.856	
Sassafras (USA)	Sandy loam	3.1	5.4	21.1	681	0.8814	
Geometric mean (n=5)					1012	-	
Arithmetic mean (n=5)					1168	0.87	
pH-dependence					No		

Table 8.5-7: Summary of soil adsorption of IN-RAB06

IN-RAB06							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Tama (USA)	Silty clay loam	1.9	6.3	9.98	521	0.7967	Yes /EFSA 2016; Schaefer & Ponizovsky, 2012
Sassafras (USA)	Loam	1.5	5.5	6.93	460	0.8767	
Lleida (Spain)	Clay	2.4	7.7	9.06	381	0.9614	
Gross Umstadt (Germany)	Loam	1.2	7.0	7.71	665	0.8865	
Nambsheim (France)	Sandy loam	1.7	7.7	7.59	451	0.9070	
Geometric mean (n=5)					487	-	
Arithmetic mean (n=5)					496	0.89	
pH-dependence					No		

Table 8.5-8: Summary of soil adsorption of IN-QPS10

IN-QPS10							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Nambsheim (France)	Sandy loam	1.7	7.6	39.2	2306	0.9034	Yes /EFSA 2016; Sannappa,. 2012
Tama (USA)	Silty clay loam	1.9	5.9	273	14368	0.9604	
Lleida (Spain)	Clay	2.0	7.5	51.4	2570	0.9127	
Gross Umstadt (Germany)	Loam	1.2	7.0	40.4	3367	0.8926	
Sassafras (USA)	Sandy loam	3.1	5.4	55.5	1790	0.9094	
Geometric mean (n=5)					3484	-	
Arithmetic mean (n=5)					4880.2	0.92	
pH-dependence					No		

Table 8.5-9: Summary of soil adsorption of IN-E8S72

IN-E8S72							
Soil name	**Soil type (USDA)**	**OC (%)**	**pH (H_2O)**	**K_F (mL/g)**	**K_{FOC} (mL/g)**	**1/n (-)**	**Evaluated on EU level / Reference**
Tama (USA)	Silty clay loam	2.2	6.6	0.135	6.14	1.07	Yes /EFSA 2016; Ravi, 2012
Lleida (Spain)	Clay	1.8	7.8	0.209	11	0.931	
Gross Umstadt (Germany)	Loam	1.1	6.8	0.116	9.67	1.12	
Nambsheim (France)	Sandy loam	1.5	7.8	0.075	5.01	0.928	
Sassafras (USA)	Sandy loam	1.1	5.4	0.058	4.83	1	
Geometric mean (n=5)					6.91	-	
Arithmetic mean (n=5)					7.33	1	
pH-dependence					No		

8.5.3 Column leaching (KCP 9.1.2.1)

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

Metalaxyl-M

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

Oxathiapiprolin

Column leaching studies were not conducted for oxathiapiprolin since reliable adsorption coefficient values were obtained from the adsorption/desorption studies reported for both active substances and their metabolites.

8.5.4 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies are considered to be data provided in support of the active substance.

Metalaxyl-M

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

Oxathiapiprolin

Where undertaken, lysimeter studies are considered to be data provided in support of the active substance. Based on the properties of oxathiapiprolin and the results of the ground water modelling (Section 8.8) lysimeter studies are not required.

8.5.5 Field leaching studies (KCP 9.1.2.3)

Field leaching studies are considered to be data provided in support of the active substance.

Metalaxyl-M

Where undertaken, field leaching studies are considered to be data provided in support of the active substance. Three field leaching studies have been performed, where 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**).

Oxathiapiprolin

Based on the properties of oxathiapiprolin and the results of the ground water modelling (Section 8.8) field leaching studies are not required.

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

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

8.6.1 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 8.6-1: 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	47.1	157	SFO	37.2	124	SFO	51.7	SFO	Yes / EFSA, 2015; Morgenroth 1994
Pond	8.2 / 6.9	21.9	72.7	SFO	16.6	55.2	SFO	19.6	SFO	
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	-	-

Table 8.6-2: Summary of observed metabolites of metalaxyl-M

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; Morgenroth 1994

8.6.2 Oxathiapiprolin and its metabolites

Studies on the mobility of oxathiapiprolin and are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of oxathiapiprolin, **EFSA Journal 2016;14(7):4504.**

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

Oxathiapiprolin, Distribution (Max.3.5% in water after 99 d. Max 43.27% in sed after 14 d)										
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**
Swiss Lake	5.8 / 6.3	44.9	-	SFO	13.6	-	SFO	112.7	SFO	Yes/ EFSA, 2016; Cleland, 2012
Calwich Abbey	6.7 / 7.5	110	-	HS	30.1	-	DFOP	249.2	SFO	
Geometric mean (n=2)		70.3	-	-	20.2	-	-	167.6	-	-

Table 8.6-4: Summary of observed metabolites

Metabolite (Water / sediment system)	Distribution in water / sediment system	Evaluated on EU level / Reference
IN-RAB06 (Water / sediment system)	Max. in water 4.2% after 28 d Max. in sediment 5.2% after 28 d Max. in total system: 9.5%	Yes/ EFSA, 2016; Cleland, 2012
IN-S2K66 (Water / sediment system)	Max. in water: not observed Max. in sediment 8.7% after 99 d	
IN-RSE01 (Water / sediment system)	Max. in water 3.8% after 60 d Max. in sediment 8.6% after 14 d Max in total system: 10.4% after 28 d	
IN-RYJ52 (Water / sediment system)	Max. in water 7.9% after 28-60 d (isomers combined) Max. in sediment 14.7% after 28-60 d (isomers combined) Max in total system: 16.0%[a]	
IN-Q7D41 (Water / sediment system)	Max. in water 1.5% after 99 d Max. in sediment 10.5% after 99 d Max. in total system: 11.8% after 99 d	

Metabolite (Water / sediment system)	Distribution in water / sediment system	Evaluated on EU level / Reference
IN-P3X26 (Aqueous photolysis)	Max. in water 14.0% after 15 d Max. in sediment: not observed	Yes/ EFSA, 2016; Wardrobe, 2011

[a] Maximum sum occurrence of two metabolites in the total system was observed for Calwich Abbey Lake system with thiazole label: isomer IN-RYJ52-A at 10.04% AR and isomer IN-RYJ52-B at 5.97% AR. Therefore, the sum of these two values of 16.0% AR was calculated

8.7 Predicted Environmental Concentrations in soil (PEC_S) (KCP 9.1.3)

Review Comments:

The PEC_{soil} calculations for metalaxyl-M, oxathiapiprolin and their metabolites and for formulation were provided by the Applicant and are considered acceptable. The EU agreed endpoints were used for PEC_{soil} calculations.

The PEC_{soil} reported below can be used for the risk assessment of the non-target organisms. Please refer to Section B9.

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of metalaxyl-M (**EFSA Journal 2015; 13(3):3999)** and oxathiapiprolin (**EFSA Journal 2016;14(7):4504** and **DAR, 2015).**

8.7.1 Justification for new endpoints

Only EU agreed endpoints were used for PEC_S calculations of metalaxyl-M and its metabolites and oxathiapiprolin and its metabolites.

8.7.2 Active substances and relevant metabolites

A23109A is foreseen for use on leafy vegetables in greenhouses. As a first tier, calculations were conducted as for field applications.

The following PEC_S calculations for metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 and oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 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.	PL-53 (CEU), FR-36 (SEU)
Crop	Lettuce
Application rate (g as/ha), parent compounds	Metalaxyl-M: 87.2 Oxathiapiprolin: 15
Number of applications/interval (d)	2 / 7[a]
Crop interception (%)	25

Use No.	**PL-53 (CEU), FR-36 (SEU)**
Maximum soil load (g a.s./ha)	Metalaxyl-M: 131 Oxathiapiprolin: 22.5
Pseudo application rate (g as/ha), metabolites[b]	**Metalaxyl-M:** NOA409045: 59.6 CGA67868: 3.6 SYN546520: 3.7 **Oxathiapiprolin:** IN-RDT31: 1.5 IN-RAB06: 2.1 IN-QPS10: 0.8 IN-E8S72: 0.5
Depth of soil layer (relevant for $PEC_{S,plateau}$) (cm)	5 ($PEC_{S,initial}$) / 20 ($PEC_{S,plateau}$)
Models used for calculation	ESCAPE v.2.0[c]

[a] Max. 2 appl. per year in same field

[b] Metabolites were treated as pseudo parent compounds. PEC soil for the metabolites was calculated based on the single maximum application rates of the parent compounds adjusted for the molar mass differences between metabolites and parents and maximum occurrence in soil

[c] It is acknowledged that the ESCAPE tool is not EU-agreed, however it was used in the EFSA conclusion (2016) as ESCAPE is "*capable of simulating various kinetic degradation models*". For consistency reasons ESCAPE was used in this evalaution

Table 8.7-2: Input parameter for active substances and relevant metabolites for PEC_S calculation

Compound	**Molar mass (g/mol)**	**Maximum occurrence (%)**	**DT_{50} (d)**	**Value in accordance to EU endpoint / Reference**
Metalaxyl-M	279.3	-	30.9 (SFO, maximum, field studies, n = 10, non-normalised)	Yes / EFSA, 2015
NOA409045	265.3	72.0	39.8 (SFO maximum, laboratory studies, n = 9,non-normalised)	Yes / EFSA, 2015
CGA67868	193.2	6.0	4.9 (SFO, maximum, laboratory studies, n = 3, non-normalised)	Yes / EFSA, 2015
SYN546520	295.3	4.0	287.9 (SFO, maximum, laboratory studies, n = 3, non-normalised)	Yes / EFSA, 2015
Oxathiapiprolin	539.53	-	205.3 (SFO, maximum, field studies, n = 10, non-normalised)	Yes / EFSA, 2016

Compound	Molar mass (g/mol)	Maximum occurrence (%)	DT_{50} (d)	Value in accordance to EU endpoint / Reference
IN-RDT31	555.53	9.4	736.4 (2.6 / 1260.3) (DFOP[a], maximum, field and lab studies, n = 7, non-normalised)	Yes / DAR, 2015
IN-RAB06	569.51	13.5	170.2 (SFO, maximum, lab studies, n = 12, non-normalised)	Yes / DAR, 2015
IN-QPS10	349.41	8.7	310.2 (0.855 / 845.3) (DFOP[b], maximum, lab studies, n = 4, non-normalised)	Yes / DAR, 2015
IN-E8S72	180.09	10.3	477.4 (SFO, maximum, lab studies, n = 5, non-normalised)	Yes / DAR, 2015

[a] DT_{50} 1 and DT_{50} 2, respectively, correspond to the maximum calculated half-life. Corresponding g = 0.2
[b] DT_{50} 1 and DT_{50} 2, respectively, correspond to the maximum calculated half-life. Corresponding g = 0.4

8.7.2.1 Metalaxyl-M and its metabolites

Table 8.7-3: PEC_S for metalaxyl-M[a] on lettuce, 2 × 87.2 g a.s./ha

PEC_S (mg/kg)		PL-53, FR-36, Lettuce, 2 × 87.2 g a.s./ha	
		Multiple applications	
		Actual	TWA
$PEC_{S,ini}$		0.1617	-
Short term	24h	0.1581	0.1599
	2d	0.1546	0.1582
	4d	0.1478	0.1547
Long term	7d	0.1382	0.1497
	14d	0.1181	0.1388
	21d	0.101	0.1298
	28d	0.0863	0.1212
	42d	0.063	0.1079
	50d	0.0527	0.1014
	100d	0.0172	0.0692
$PEC_{S,plateau}$ (20 cm) with tillage after many years		< 0.0001	-
$PEC_{S,accumulation}$ ($PEC_{S,ini}$ + $PEC_{S,plateau}$)		0.1617	-

[a] An example calculation is provided in the Appendix (A 3.1)

PEC_S of metabolites

Table 8.7-4: PEC_S for NOA409045[a]

Crop	PEC_S (mg/kg)	Multiple applications
PL-53, FR-36, Lettuce, 2 × 87.2 g a.s./ha[b]	$PEC_{S,ini}$	0.1124
	$PEC_{S,plateau}$ (20 cm) with tillage after may years	< 0.0001
	$PEC_{S,accumulation}$ ($PEC_{S,ini}$ + $PEC_{S,plateau}$)	0.1125

[a] An example calculation is provided in the Appendix (A 3.1)
[b] 'Pseudo application rate' of metabolite = parent total dose x MW correction factor x maximum formation

Table 8.7-5: PEC_S for CGA67868[a]

Crop	PEC_S (mg/kg)	Multiple applications
PL-53, FR-36, Lettuce, 2 × 87.2 g a.s./ha[b]	$PEC_{S,ini}$	0.0050
	$PEC_{S,plateau}$ (20 cm) with tillage after many years	< 0.0001
	$PEC_{S,accumulation}$ ($PEC_{S,ini}$ + $PEC_{S,plateau}$)	0.0050

[a] an example calculation is provided in the Appendix (A 3.1)
[b] 'Pseudo application rate' of metabolite = parent total dose x MW correction factor x maximum formation

Table 8.7-6: PEC_S for SYN546520[a]

Crop	PEC_S (mg/kg)	Multiple applications
PL-53, FR-36, Lettuce, 2 × 87.2 g a.s./ha[b]	$PEC_{S,ini}$	0.0073
	$PEC_{S,plateau}$ (20 cm) with tillage after many years	0.0013
	$PEC_{S,accumulation}$ ($PEC_{S,ini}$ + $PEC_{S,plateau}$)	0.0086

[a] an example calculation is provided in the Appendix (A 3.1)
[b] 'Pseudo application rate' of metabolite = parent total dose x MW correction factor x maximum formation

8.7.2.2 Oxathiapiprolin and its metabolites

Table 8.7-7: PEC_S for oxathiapiprolin[a] on lettuce, 2 × 15 g a.s./ha

PEC_S (mg/kg)		PL-53, FR-36, Lettuce, 2 × 15 g a.s./ha	
		Multiple applications	
		Actual	TWA
$PEC_{S,ini}$		0.0296	-
Short term	24h	0.0295	0.0296
	2d	0.0295	0.0295
	4d	0.0293	0.0295
Long term	7d	0.029	0.0293
	14d	0.0283	0.029
	21d	0.0276	0.0286
	28d	0.027	0.0283
	42d	0.0257	0.0276
	50d	0.025	0.0273
	100d	0.0212	0.0252
$PEC_{S,plateau}$ (20 cm) with tillage after many years		0.0031	-
$PEC_{S,accumulation}$ ($PEC_{S,accumulation} = PEC_{S,ini} + PEC_{S,plateau}$)		0.0327	-

[a] an example calculation is provided in the Appendix (A 3.5)

PEC_S of metabolites

Table 8.7-8: PEC_S for IN-RDT31[a]

Crop	PEC_S (mg/kg)	Multiple applications
PL-53, FR-36, Lettuce, 2 × 15 g a.s./ha a.s./ha[b]	$PEC_{S,ini}$	0.0027
	$PEC_{S,plateau}$ (20 cm) with tillage after many years	0.0026
	$PEC_{S,accumulation}$ ($PEC_{S,ini} + PEC_{S,plateau}$)	0.0053

[a] an example calculation is provided in the Appendix (A 3.5)
[b] 'Pseudo application rate' of metabolite = parent total dose x MW correction factor x maximum formation

Table 8.7-9: PEC$_S$ for IN-RAB06[a]

Crop	PEC$_S$ (mg/kg)	Multiple applications
PL-53, FR-36, Lettuce, 2 × 15 g a.s./ha a.s./ha[b]	PEC$_{S,ini}$	0.0042
	PEC$_{S,plateau}$ (20 cm) with tillage after many years	0.0003
	PEC$_{S,accumulation}$ (PEC$_{S,ini}$ + PEC$_{S,plateau}$)	0.0045

[a] an example calculation is provided in the Appendix (A 3.5)
[b] 'Pseudo application rate' of metabolite = parent total dose x MW correction factor x maximum formation

Table 8.7-10: PEC$_S$ for IN-QPS10[a]

Crop	PEC$_S$ (mg/kg)	Multiple applications
PL-53, FR-36, Lettuce, 2 × 15 g a.s./ha a.s./ha[b]	PEC$_{S,ini}$	0.0014
	PEC$_{S,plateau}$ (20 cm) with tillage after many years	0.0007
	PEC$_{S,accumulation}$ (PEC$_{S,ini}$ + PEC$_{S,plateau}$)	0.0021

[a] an example calculation is provided in the Appendix (A 3.5)
[b] 'Pseudo application rate' of metabolite = parent total dose x MW correction factor x maximum formation

Table 8.7-11: PEC$_S$ for IN-E8S72[a]

Crop	PEC$_S$ (mg/kg)	Multiple applications
PL-53, FR-36, Lettuce, 2 × 15 g a.s./ha a.s./ha[b]	PEC$_{S,ini}$	0.0010
	PEC$_{S,plateau}$ (20 cm) with tillage after many years	0.0004
	PEC$_{S,accumulation}$ (PEC$_{S,ini}$ + PEC$_{S,plateau}$)	0.0014

[a] an example calculation is provided in the Appendix (A 3.5)
[b] 'Pseudo application rate' of metabolite = parent total dose x MW correction factor x maximum formation

8.7.2.3 PEC$_S$ of A23109A

Table 8.7-12: PEC$_S$ for A23109A on lettuce

Formulation	**Crop**	**Maximum use rate (g A23109A /ha[a])**	**Crop interception (%)**	**PEC$_{S,ini}$ (mg A23109A/kg)[c]**
A23109A	Lettuce	537	25	0.537

[a] The formulation components are considered to dissipate rapidly after application, therefore only one application is taken into consideration. The rate of formulation was based on a specific density of 1.074 g/mL with a maximum application of 1 L/ha

[b] Rautmann drift values for one application (90th percentiles)

[c] Calculated as:

$$PEC_{S,ini}\,[mg/kg] = \frac{A \times (1 - I)}{z \times bd_{SOIL} \times 10}$$

Where:
A = application rate [g product/ha]
$PEC_{S,ini}$ = initial (maximum) concentration in soil [mg product/kg soil]
I = Interception [-]
z = soil mixing depth (5 cm) [m]
bd_{SOIL} = bulk density of the soil (1500 kg/m³) [kg soil/m³]

8.8 Predicted Environmental Concentrations in groundwater (PEC$_{GW}$) (KCP 9.2.4)

Review Comments:

The PEC$_{GW}$ calculations for metalaxyl-M, oxathiapiprolin and their metabolites were provided by the applicant and are considered acceptable.

The EU agreed endpoints, derived from the datasets presented in the EFSA Journal 2015; 13(3):3999 and EFSA Journal 2016;14(7):4504, were used. Furthermore, as Tier 2 for metalaxy-M, the new kinetics data for deriving the formation fraction for SYN546520 were provided. Additional active substance data submitted by the applicant were consider by izRMS as necessary for authorisation. Therefore, according to SANCO/10328/2004 – rev 9 (21.10.2021) point 4.3.1/2, izRMS used it for the groundwater risk assessment. It should be noted that a further laboratory study conducted (Crabtree, 2021) to derive a ff for a third soil (18 Acres, Vetroz and Gartenacker), which was kinetically evaluated in Patel (2021, amended 2022), was reviewed and accepted by EU RMS Belgium (please refer to metalaxyl-M RAR Vol. 3 CA B8 2022-7-22). Based on it, izRMS considered the Tier 2 PEC$_{GW}$ calculations as valid and suitable for the assessment of the relevance of metabolites in groundwater.

The results of FOCUS groundwater calculation for metalaxyl-M indicated that PEC$_{GW}$ values do not exceed the regulatory trigger of 0.1 µg/L at 1 m depth in any of the scenarios.

The PEC$_{GW}$ values for metabolites SYN546520 (Tier 2) and CGA67868 (worst case) are above 0.1 µg/L but below 10 µg/L for FOCUS scenarios. The PEC$_{GW}$ values for metabolite NOA409045 are above 0.1 µg/L for all FOCUS scenarios (max. PEC$_{GW}$ of 6.666 µg/L, FOCUS PEARL, application to cabbage, BBCH 12, Hamburg scenario CEU).

The relevance of metalaxyl-M metabolites in groundwater is assessed in Part B, Section 10. The assessment of metabolite NOA409045 is crucial for the authorisation process, therefore further refinement and is required. Please refer to Part B Section 10.

The results of FOCUS groundwater calculation for oxathiapiprolin, indicated that PEC$_{GW}$ values do not exceed the regulatory trigger of 0.1 µg/L at 1 m depth in any of the scenarios.

The maximum PEC$_{GW}$ of IN-RDT31, IN-RAB06 and IN-QPS10 were below 0.1 µg/L in all scenarios.

However, PEC_{GW} for metabolite IN-E8S72 exceed this threshold. The maximum PEC_{GW} was 1.939 µg/L (FOCUS PEARL, application to Cabbage, 2 × 15 g a.s./ha, BBCH 12, Hamburg scenario SEU).

Assessment of the relevance of these metabolites according to the stepwise procedure of the EC guidance document SANCO/221/2000 –rev.10 is presented in Section B10.

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of metalaxyl-M (**EFSA Journal 2015; 13(3):3999)** and oxathiapiprolin, (**EFSA Journal 2016;14(7):4504 and DAR, 2015).**

8.8.1 Justification for new endpoints

For uses that are relevant in the CEU zone, the PEC_{GW} values have been calculated based on EU agreed endpoints for metalaxyl-M, oxathiapiprolin and respective metabolites. The modelling reports for the CEU zone are listed in appendix 3 (A 3.6 for metalaxyl-M, A 3.7 for oxathiapiprolin).

For SEU uses, the endpoints used in modelling for metalaxyl-M, oxathiapiprolin and their respective metabolites were calculated based on the recommendation of the latest guideline (EFSA, 2014). The individual values from which the endpoint is calculated are those established in the EU review of metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999)** and oxathiapiprolin **(EFSA Journal 2016; 14(7):4504)**. The PEC_{GW} values for the CEU zone are listed in appendix 3 (A 3.8 for metalaxyl-M, A 3.9 for oxathiapiprolin).

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

A23109A is foreseen for use on leafy vegetables in greenhouses. As a first tier, calculations were conducted as for field applications with the FOCUS models.

The following PEC_{GW} modelling for metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 as well as oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 have not previously been reviewed and are 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.	PL-53 (CEU), FR-36 (SEU)	
Crop	Lettuce	
FOCUS GW crop	Cabbage[a]	
Application rate (g a.s./ha)	Metalaxyl-M: 87.2 Oxathiapiprolin: 15	
Number of applications / interval (d)	2 / 7	
BBCH growth stage	12	
Crop interception (%)[b]	25	
Frequency of application	Annual – 2 applications in 1 crop cycle[c]	Annual – 1 application in 2 crop cycles[c]
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO v5.5.4	

[a] Covering leafy vegetables
[b] Interception rates according to FOCUS, 2014
[c] Max. 2 appl. per year in same field

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

Crop	Rationale	Scenario	Application dates (absolute)	
			1st application	2nd application
PL-53 (CEU) FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha 7 days interval[a] First crop cycle	First application at BBCH 12 (AppDate 3.06)	Châteaudun	29 Apr	06 May
		Hamburg	29 Apr	06 May
		Jokioinen	11 Jun	18 Jun
		Kremsmünster	29 Apr	06 May
		Porto	16 Mar	23 Mar
		Sevilla	14 Mar	21 Mar
		Thiva	25 Aug	01 Sep
PL-53 (CEU) FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha 7 days interval[b] Second crop cycle	First application at BBCH 12 (AppDate 3.06)	Châteaudun	08 Aug	15 Aug
		Hamburg	08 Aug	15 Aug
		Kremsmünster	08 Aug	15 Aug
		Porto	07 Aug	14 Aug
		Sevilla	28 Jun	05 July
PL-53 (CEU) FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha 7 days interval[c]	First application at BBCH 12 (AppDate 3.06)	Châteaudun	29 Apr	08 Aug
		Hamburg	29 Apr	08 Aug
		Kremsmünster	29 Apr	08 Aug
		Porto	16 Mar	07 Aug
		Sevilla	14 Mar	28 Jun

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles – not all cabbage scenarios have 2 crop cycles (second crop cycle is not assessed in Jokioinen or Thiva scenario)
[cI] The 2nd application dates represent the BBCH 12 dates for the second crop cycle of cabbage in AppDate 3.06

8.8.2.1 Metalaxyl-M and its metabolites

Table 8.8-3: Input parameters related to active substance metalaxyl-M and metabolites 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[a]	265000[b]	Yes / EFSA, 2015
Saturated vapour pressure (Pa) (25°C)	0.0033	1×10^{-5}	1×10^{-5}	1×10^{-5}	Yes / EFSA, 2015
CEU uses: DT_{50} in soil (d) (normalised at 20°C and pF2)	6.5 Median n=10	30.5[c] Geometric mean n=8	2.9 Geometric mean n=3	96.8 Geometric mean n=3	Yes / EFSA (2015)

Compound	Metalaxyl-M	NOA409045	CGA67868	SYN546520	Value in accordance with EU endpoint / Reference
SEU uses: DT_{50} in soil (d) (normalised at 20°C and pF2)	-	30.5[c] Geometric mean n=8	2.9 Geometric mean n=3	96.8 Geometric mean n=3	Yes / EFSA (2015)
	7.74 Geometric mean n=10	-	-	-	No[d] / EFSA (2015)
CEU uses: K_{FOC} / K_{FOM} (mL/g)	40 / 23.2 Median n=25	12.1 / 7.02 Median n=14	19.0 / 11.0 Arithmetic mean n=5	15.2 / 8.82 Arithmetic mean n=4	Yes / EFSA (2015) K_{FOM} = K_{FOC} / 1.724
SEU uses: K_{FOC} / K_{FOM} (mL/g)	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) K_{FOM} = K_{FOC} / 1.724
1/n	0.955 Arithmetic mean n=25	0.928 Arithmetic mean n=14	0.896 Arithmetic mean n=5	1.1 Arithmetic mean n=4	Yes / EFSA (2015)
Plant uptake factor	0	0	0	0	Worst-case assumption
Formation fraction	-	0.783 from parent	0.53 from NOA409045	0.47 (**Tier 1**) / 0.1 (**Tier 2**) from NOA409045	Yes / EFSA (2015)
Conversion fraction	-	0.744 from parent	0.287 from parent	0.389 (**Tier 1**) / 0.083 (**Tier 2**)[e] from parent	-

[a] O'Connor & White (2012)
[b] Not available, value of NOA409045 used
[c] The overall DT_{50} value used in modelling has been re-calculated, as the geomean value of 31.3 days (EFSA, 2015) was incorrect
[d] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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
[e] For the metabolite SYN546520, as a tiered approach, the PEC_{GW} were calculated with two different formation fractions: 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2, derived from inverse modelling, EFSA 2015)

Table 8.8-4: PEC_{GW} for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 on various crops with FOCUS PEARL v5.5.5 for the CEU

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
PL-53 (CEU) Cabbage, BBCH 12 2 × 87.2 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	2.551	0.073	11.587	2.524
	Hamburg	0.001	4.746	0.143	14.396	3.182
	Kremsmünster	< 0.001	2.968	0.094	8.318	1.785
	Porto	< 0.001	1.020	0.022	5.706	1.225
PL-53 (CEU) Cabbage, BBCH 12 2 × 87.2 g a.s./ha[a] Second crop cycle	Châteaudun	0.001	4.830	0.143	12.529	2.717
	Hamburg	0.008	9.163	0.267	14.671	3.248
	Kremsmünster	0.002	4.583	0.141	8.830	1.899
	Porto	0.002	3.344	0.071	6.806	1.461

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
PL-53 (CEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[b]	Châteaudun	< 0.001	3.426	0.101	12.060	2.621
	Hamburg	0.004	6.666	0.194	14.494	3.222
	Kremsmünster	0.001	3.404	0.104	8.637	1.863
	Porto	0.001	2.084	0.045	6.280	1.350

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-5: PEC_{GW} for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 on various crops with FOCUS PELMO v6.6.4 for the CEU

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
PL-53 (CEU) Cabbage, BBCH 12 2 × 87.2 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	2.155	0.064	10.854	2.395
	Hamburg	< 0.001	3.941	0.111	12.602	2.732
	Kremsmünster	< 0.001	3.336	0.100	9.246	2.002
	Porto	< 0.001	1.414	0.030	5.099	1.101
PL-53 (CEU) Cabbage, BBCH 12 2 × 87.2 g a.s./ha[a] Second crop cycle	Châteaudun	0.001	4.332	0.127	11.598	2.522
	Hamburg	0.011	8.457	0.230	12.706	2.737
	Kremsmünster	0.003	5.132	0.147	9.532	2.021
	Porto	0.002	3.306	0.070	5.255	1.113
PL-53 (CEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[b]	Châteaudun	< 0.001	3.132	0.090	11.124	2.452
	Hamburg	0.004	6.080	0.166	12.708	2.747
	Kremsmünster	0.001	3.826	0.108	9.435	2.049
	Porto	0.001	2.115	0.045	5.099	1.085

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-6: PEC_{GW} for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 on various crops with FOCUS MACRO v5.5.4 for the CEU

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
PL-53 (CEU) Cabbage, BBCH 12 2 × 87.2 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	1.54	< 0.001	6.08	1.35
PL-53 (CEU) Cabbage, BBCH 12 2 × 87.2 g a.s./ha[a] Second crop cycle	Châteaudun	0.004	3.48	<0.001	7.81	1.71
PL-53 (CEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[b]	Châteaudun	0.001	2.36	< 0.001	6.77	1.49

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-7: PEC$_{GW}$ for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 on various crops with FOCUS PEARL v5.5.5 for the SEU

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	2.315	0.068	12.476	2.675
	Hamburg	0.001	4.398	0.134	15.951	3.428
	Jokioinen	< 0.001	5.124	0.120	19.099	4.149
	Kremsmünster	< 0.001	2.770	0.088	8.821	1.901
	Porto	< 0.001	0.892	0.021	5.846	1.245
	Sevilla	< 0.001	0.338	0.007	7.292	1.566
	Thiva	0.001	3.443	0.104	11.165	2.402
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[a] Second crop cycle	Châteaudun	<0.001	4.387	0.133	13.290	2.856
	Hamburg	0.005	8.397	0.252	16.278	3.501
	Kremsmünster	0.001	4.370	0.137	9.200	1.966
	Porto	0.003	3.111	0.072	7.060	1.507
	Sevilla	<0.001	0.880	0.020	9.970	2.145
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[b]	Châteaudun	< 0.001	3.125	0.094	12.915	2.778
	Hamburg	0.003	6.137	0.184	16.144	3.471
	Kremsmünster	0.001	3.245	0.101	9.065	1.941
	Porto	0.001	1.960	0.043	6.524	1.394
	Sevilla	< 0.001	0.576	0.013	8.531	1.834

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-8: PEC$_{GW}$ for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 on various crops with FOCUS PELMO v6.6.4 for the SEU

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	1.986	0.061	11.972	2.582
	Hamburg	< 0.001	3.751	0.107	13.543	2.909
	Jokioinen	< 0.001	4.940	0.101	16.504	3.573
	Kremsmünster	< 0.001	3.124	0.092	9.853	2.125
	Porto	< 0.001	1.263	0.028	5.253	1.118
	Sevilla	< 0.001	0.322	0.007	7.229	1.569
	Thiva	0.001	3.226	0.096	10.456	2.251
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[a] Second crop cycleC	Châteaudun	0.001	4.039	0.121	12.731	2.752
	Hamburg	0.007	7.753	0.222	13.460	2.901
	Kremsmünster	0.002	4.725	0.139	9.890	2.119
	Porto	0.004	3.085	0.070	5.287	1.123
	Sevilla	<0.001	0.743	0.015	8.816	1.915
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[b]	Châteaudun	< 0.001	2.890	0.085	12.396	2.669
	Hamburg	0.003	5.771	0.160	13.548	2.904
	Kremsmünster	0.001	3.574	0.106	10.153	2.183
	Porto	0.002	2.031	0.046	5.167	1.101
	Sevilla	< 0.001	0.508	0.010	7.943	1.724

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-9: PEC_{GW} for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 on various crops with FOCUS MACRO v5.5.4 for the SEU

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	1.45	<0.001	6.88	1.49
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[a] Second crop cycle	Châteaudun	0.004	3.25	0.001	8.56	1.84
FR-36 (SEU) Cabbage BBCH 12 2 × 87.2 g a.s./ha[b]	Châteaudun	0.001	2.20	<0.001	7.67	1.67

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-10: Summary of PEC_{GW} across all models for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 for the CEU

Substance		80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Metalaxyl-M		~~0.004~~ 0.011	Cabbage	2 × 87.2 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	~~PEARL v5.5.5 &~~ PELMO v6.6.4	Hamburg
NOA409045		~~6.666~~ 9.163	Cabbage	2 × 87.2 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	PEARL v5.5.5	Hamburg
CGA67868		~~0.194~~ 0.267	Cabbage	2 × 87.2 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	PEARL v5.5.5	Hamburg
SYN546520	Tier 1	~~14.494~~ 14.671	Cabbage	2 × 87.2 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	PEARL v5.5.5	Hamburg
	Tier 2	~~3.222~~ 3.248	Cabbage	2 × 87.2 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	PEARL v5.5.5	Hamburg

Table 8.8-11: Summary of PEC_{GW} across all models for metalaxyl-M and metabolites NOA409045, CGA67868 and SYN546520 for the SEU

Substance	80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Metalaxyl-M	~~0.004~~ 0.007	Cabbage	2 × 87.2 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	~~PEARL v5.5.5 &~~ PELMO v6.6.4	Hamburg
NOA409045	~~6.666~~ 8.397	Cabbage	2 × 87.2 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	PEARL v5.5.5	Hamburg
CGA67868	~~0.194~~ 0.252	Cabbage	2 × 87.2 g as/ha 1 app. in 2 crop cycles	PEARL v5.5.5	Hamburg

Substance		80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
SYN546520	Tier 1	19.099	Cabbage	2 × 87.2 g as/ha 2 app. in 1 crop cycle	PEARL v5.5.5	Jokioinen
	Tier 2	4.149	Cabbage	2 × 87.2 g as/ha 2 app. in 1 crop cycle	PEARL v5.5.5	Jokioinen

8.8.2.2 Oxathiapiprolin and its metabolites

Table 8.8-12: Summary of input parameters for oxathiapiprolin, IN-RDT31 and IN-RAB06 for PEC_{GW} calculations

Compound	Oxathiapiprolin	IN-RDT31	IN-RAB06	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	539.53	555.53*	569.51*	Yes / EFSA, 2016 *Yes / DAR, 2015
Water solubility (mg/L) (20°C)	0.1844	0.1844[a]	0.1844[a]	Yes / EFSA, 2016
Saturated vapour pressure (Pa) (20°C)	1.141×10^{-6}	0[b]	0[b]	Yes / EFSA, 2016
CEU and SEU uses: DT_{50} in soil (d) (normalised at 20°C and pF2)	121.2 Geometric mean[c] n= 6	160 Geometric mean[c] n= 6	60.5 Geometric mean[d] n=12	Yes / EFSA, 2016
CEU uses: K_{FOC} / K_{FOM} (mL/g)	6242.6 / 3621 (arithmetic mean, n = 5)	1168.4 / 677.7 (arithmetic mean, n = 5)	495.6 / 287.5 (arithmetic mean, n = 5)	Yes / EFSA, 2016
SEU uses: K_{FOC} / K_{FOM} (mL/g)	6128 / 3555 (geometric mean, n = 5)	1012 / 587 (geometric mean, n = 5)	487 / 282 (geometric mean, n = 5)	No[e] / EFSA, 2016
1/n	0.97 (arithmetic mean, n = 5)	0.87 (arithmetic mean, n = 5)	0.89 (arithmetic mean, n = 5)	Yes / EFSA, 2016
Plant uptake factor	0	0	0	Worst-case assumption
Formation fraction	-	0.7 from parent	0.4 from parent	Yes / EFSA, 2016
Conversion fraction	-	0.721 from parent	0.422 from parent	Calculated for MACRO; molar mass (metabolite) / molar mass (parent) x formation fraction

[a] Not available, value of parent used
[b] Worst-case assumption
[c] Of lab data
[d] Of lab and field data
[e] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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 oxathiapiprolin, EFSA Journal 2016; 14(7):4504

Table 8.8-13: Summary of input parameters for IN-QPS10 and IN-E8S72 for PEC_{GW} calculations

Compound	IN-QPS10	IN-E8S72	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	349.41	180.09	Yes / DAR, 2015
Water solubility (mg/L) (20°C)	0.1844	0.1844[a]	Yes / EFSA, 2016
Saturated vapour pressure (Pa) (20°C)	0[b]	0[b]	Yes / EFSA, 2016
CEU and SEU uses: DT_{50} in soil (d) (normalised at 20°C and pF2)	564.9 Geometric mean[c] n=2	310.2 Geometric mean[d] n=5	Yes / EFSA, 2016
CEU uses: K_{FOC} / K_{FOM} (mL/g)	4880.2 / 2830.7 (arithmetic mean, n = 5)	7.33 / 4.25 (arithmetic mean, n = 5)	Yes / EFSA, 2016
SEU uses: K_{FOC} / K_{FOM} (mL/g)	3484 / 2021 (geometric mean, n = 5)	6.91 / 4.01 (geometric mean, n = 5)	No[e] / EFSA, 2016
1/n	0.92 (arithmetic mean, n = 5)	1 (arithmetic mean, n = 5)	Yes / EFSA, 2016
Plant uptake factor	0	0	Worst-case assumption
Formation fraction	0.6 from parent 1.0 from IN-RAB06	0.3 from parent 0.4 from IN-RDT31	Yes / EFSA, 2016
Conversion fraction	0.648 from parent	0.194 from parent	Calculated for MACRO; molar mass (metabolite) / molar mass (parent) x formation fraction

[a] Not available, value of parent used
[b] Worst-case assumption
[c] Of acidic soils
[d] Of lab data
[e] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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 oxathiapiprolin, EFSA Journal 2016; 14(7):4504

Table 8.8-14: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 on various crops with FOCUS PEARL v5.5.5 for the CEU

Crop	Scenario	80[th] Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.654
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.927
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.318
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.756
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a]	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.650
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.931
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.086

Second crop cycle	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.751
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[b]	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.653
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.929
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.091
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.754

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-15: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 on various crops with FOCUS PELMO v6.6.4 for the CEU

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.593
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.584
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.243
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.612
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] Second crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.587
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.584
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.242
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.611
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[b]	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.590
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.582
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.243
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.611

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-16: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 on various crops with FOCUS MACRO v5.5.4 for the CEU

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.13
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] Second crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.17
PL-53 (CEU) Cabbage BBCH 12 2 × 15 g a.s./ha[b]	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.17

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-17: PEC$_{GW}$ for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 on various crops with FOCUS PEARL v5.5.5 for the SEU

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.670
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.937
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	1.812
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.324
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.758
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.904
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	1.358
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] Second crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.666
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.941
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.091
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.752
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.914
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[b]	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.669
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.939
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.094
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.755
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.909

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-18: PEC$_{GW}$ for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 on various crops with FOCUS PELMO v6.6.4 for the SEU

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.599
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.587
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	1.708
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.245
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.612
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.591
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	1.267
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] Second crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.593
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.587
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.244
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.611
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.594
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[b]	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.596
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.585
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.245
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.611
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.592

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-19: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 on various crops with FOCUS MACRO v5.5.4 for the SEU

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] First crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.14
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[a] Second crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.17
FR-36 (SEU) Cabbage BBCH 12 2 × 15 g a.s./ha[b]	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.17

[a] 2 applications in 1 crop cycle
[b] 1 applciation in 2 crop cycles

Table 8.8-20: Summary of maximum PEC_{GW} across all models for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 for CEU

Substance	80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Oxathiapiprolin	< 0.001	All crops	All applications	All models	All scenarios
IN-RDT31	< 0.001	All crops	All applications	All models	All scenarios
IN-RAB06	< 0.001	All crops	All applications	All models	All scenarios
IN-QPS10	< 0.001	All crops	All applications	All models	All scenarios
IN-E8S72	~~1.929~~ 1.931	Cabbage	2 × 15 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	PEARL v5.5.5	Hamburg

Table 8.8-21: Summary of maximum PEC_{GW} across all models for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 for SEU

Substance	80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Oxathiapiprolin	< 0.001	All crops	All applications	All models	All scenarios
IN-RDT31	< 0.001	All crops	All applications	All models	All scenarios
IN-RAB06	< 0.001	All crops	All applications	All models	All scenarios
IN-QPS10	< 0.001	All crops	All applications	All models	All scenarios
IN-E8S72	~~1.939~~ 1.941	Cabbage	2 × 15 g as/ha ~~1 app. in 2 crop cycles~~ Second crop cycle	PEARL v5.5.5	Hamburg

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

Review Comments:

The $PECS_{SW/SED}$ calculations for metalaxyl-M, oxathiapiprolin and their metabolites were provided by the Applicant and are considered acceptable.

For active substances and relevant metabolites PEC_{SW} calculations were performed with FOCUS STEPS 1-2 (both active substances and metabolites).

The EU agreed endpoints, derived from the datasets presented in the EFSA Journal 2016;14(7):4504 and EFSA Journal 2015; 13(3):3999, were used.

The PEC_{sw} reported below can be used for the risk assessment for aquatic organisms. Please refer to section 9.

Unless otherwise stated, EU agreed endpoints refer to those stated in the EU review of metalaxyl-M (**EFSA Journal 2015; 13(3):3999)** and oxathiapiprolin (**EFSA Journal 2016;14(7):4504** and **DAR, 2015).**

8.9.1 Justification for new endpoints

For uses that are relevant in the CEU zone, the PEC_{SW} and PEC_{SED} values have been calculated based on EU agreed endpoints for metalaxyl-M, oxathiapiprolin and respective metabolites. The modelling reports for the CEU zone are listed in Appendix 3 (A 3.10 for metalaxyl-M, A 3.11 for oxathiapiprolin).

For SEU uses, the endpoints used in modelling for metalaxyl-M, oxathiapiprolin and their respective metabolites were calculated based on the recommendation of the latest guideline (EFSA, 2014). The individual values from which the endpoint is calculated are those established in the EU review of metalaxyl-M (**Metalaxyl-M, EFSA Journal 2015; 13(3):3999)** and oxathiapiprolin **(EFSA Journal 2016; 14(7):4504)**. The PEC_{SW} and PEC_{SED} values for the SEU zone are listed in Appendix 3 (A 3.12 for metalaxyl-M, A 3.13 for oxathiapiprolin).

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

A23109A is foreseen for use on leafy vegetables in greenhouses. As a first tier, calculations were conducted as for field applications with the FOCUS models.

PEC_{SW} and PEC_{SED} of metalaxyl-M and its metabolite NOA409045, as well as oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41, and IN-P3X26 have been assessed with the FOCUS surface water models, i.e. FOCUS STEPS 1-2 (Step 1 and 2 simulations). The input parameters relevant for the calculation are summarised in Table 8.9-1.

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

Use No.	**PL-53 (CEU), FR-36 (SEU)**
Crop	Lettuce
FOCUS SW crop	Leafy vegetables
Application rate (g as/ha)	Metalaxyl-M: 87.2 Oxathiapiprolin: 15
Number of applications/interval (d)	2/7
BBCH growth stage	12
Crop interception	Minimal crop cover
Season of application	Mar. – May
Models used for calculation	FOCUS STEPS 1-2 v3.2

8.9.2.1 Metalaxyl-M and its metabolites

Table 8.9-2: Input parameters related to active substance a metalaxyl-M and metabolite NOA409045, for $PEC_{SW/SED}$ calculations STEPS 1/2

Compound	**Metalaxyl-M**	**NOA409045**	**Value in accordance with EU endpoint / Reference**
Molar mass (g/mol)	279.3	265.3	Yes / EFSA (2015)
Water solubility (mg/L)	26000	265000	Yes / EFSA (2015)
CEU uses: K_{FOC} (mL/g)	40 Median n=25	12.1 Median n=14	Yes / EFSA (2015)
SEU uses: K_{FOC} (mL/g)	50.63 Geometric mean n=25	13.44 Geometric mean n=14	No[a] / EFSA (2015)
CEU uses: $DT_{50,soil}$ (d) (normalised at 20°C and pF2)	6.5 Median n=10	30.5[b] Geometric mean n=8	Yes / EFSA (2015)
SEU uses: $DT_{50,soil}$ (d) (normalised at 20°C and pF2)	-	30.5[b] Geometric mean n=8	Yes / EFSA (2015)
	7.74 Geometric mean n=10	-	No[a] / EFSA (2015)
$DT_{50,water}$ (d)	47.1 Whole system value	1000	Yes / EFSA (2015)
$DT_{50,sed}$ (d)	47.1 Whole system value	1000	Yes / EFSA (2015)
$DT_{50,whole\ system}$ (d)	47.1 Maximum n=2	1000	Yes / EFSA (2015)

Compound	Metalaxyl-M	NOA409045	Value in accordance with EU endpoint / Reference
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 72 Total system: 88	Yes / EFSA (2015)

[a] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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

[b] The overall DT_{50} value used in modelling has been re-calculated, as the geomean value of 31.3 days (EFSA, 2015) was incorrect

$PEC_{SW/SED}$

Table 8.9-3: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for metalaxyl-M for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 87.2 g a.s./ha	1	-	-	56.79	48.79	22.35
	2	North Europe	Mar. – May	5.21	4.46	2.05
		South Europe	Mar. – May	9.19	7.89	3.62

Table 8.9-4: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for metalaxyl-M for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 87.2 g a.s./ha	1	-	-	56.06	48.14	27.92
	2	North Europe	Mar. – May	5.60	4.79	2.78
		South Europe	Mar. – May	9.98	8.56	4.96

Metabolites of metalaxyl-M

Table 8.9-5: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for NOA409045 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 87.2 g a.s./ha	1	-	-	88.29	87.63	10.67
	2	North Europe	Mar. – May	9.58	9.51	1.16
		South Europe	Mar. – May	18.00	17.86	2.18

Table 8.9-6: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for NOA409045 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 87.2 g a.s./ha	1	-	-	88.14	87.48	11.83
	2	North Europe	Mar. – May	9.96	9.88	1.34
		South Europe	Mar. – May	18.76	18.61	2.52

8.9.2.2 Oxathiapiprolin and its metabolites

Table 8.9-7: Input parameters related to active substance oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 for $PEC_{SW/SED}$ calculations STEPS 1/2

Compound	Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	539.53	555.53	569.51	349.41	180.09	Yes / EFSA (2016)
Water solubility (mg/L)	0.1844	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
CEU uses: K_{foc} (mL/g)	6242.6[b] / 45586[c] Arithmetic mean / worst-case n=5	1168.4 Arithmetic mean n=5	495.6 Arithmetic mean n=5	4880.2 Arithmetic mean n=5	7.33 Arithmetic mean n=5	Yes / EFSA (2016)
SEU uses: K_{foc} (mL/g)	6128[b] / 45586[c] Geometric mean / worst-case n=5	1012 Geometric mean n=5	487 Geometric mean n=5	3484 Geometric mean n=5	6.91 Geometric mean n=5	No[d] / EFSA (2016)
CEU and SEU uses: $DT_{50,soil}$ (d) (normalised at 20°C and pF2)	121.2 Geometric mean[e] n= 6	160 Geometric mean[e] n= 6	60.5 Geometric mean[f] n=12	564.9 Geometric mean[g] n=2	310.2 Geometric mean[e] n=5	Yes / EFSA (2016)
$DT_{50,water}$ (d)	70.3 Whole system value	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,sed}$ (d)	70.3 Whole system value	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,whole\ system}$ (d)	70.3 Geometric mean n=2	1000	1000	1000	1000	Yes / EFSA (2016)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 9.4 Total system: 0	Soil: 13.5 Total system: 9.5	Soil: 8.7 Total system: 0	Soil: 10.3 Total system: 0	Yes / EFSA (2016)

[a] Not available, value of parent used
[b] Used for PEC_{sw}
[c] Used for PEC_{sed}
[d] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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 oxathiapiprolin, EFSA Journal 2016; 14(7):4504
[e] Of lab data

[f] Of lab and field data
[g] Of acidic lab data

Table 8.9-8: Input parameters related to metabolites of oxathiapiprolin IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41, and IN-P3X26 for $PEC_{SW/SED}$ calculations STEPs 1/2

Compound	IN-S2K66	IN-RSE01	IN-RYJ52	IN-Q7D41	IN-P3X26	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	528.54	542.53	544.54	537.51	402.4	Yes / EFSA (2016)
Water solubility (mg/L)	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
K_{foc} (mL/g)	10[b] / 10000[c]	10[b] / 10000[c]	10[b] / 10000[c]	10[b] / 10000[c]	0.1[b] / 10000[c]	Yes / EFSA (2016)
$DT_{50,soil}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,water}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,sed}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,whole\ system}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 0 Total system: 8.7	Soil: 0 Total system: 10.4	Soil: 0 Total system: 16	Soil: 0 Total system: 11.8	Soil: 0 Total system: 14[d]	Yes / EFSA (2016)

[a] Not available, value of parent used
[b] Used for PEC_{sw}
[c] Used for PEC_{sed}
[d] Aqueous photolysis

$PEC_{SW/SED}$

Table 8.9-9: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for oxathiapiprolin for CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-36 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.35	1.00	75.08
	2	North Europe	Mar. – May	0.19	0.16	12.25
		South Europe	Mar. – May	0.34	0.30	22.86

Table 8.9-10: FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} for oxathiapiprolin for SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.37	1.02	75.08
	2	North Europe	Mar. – May	0.19	0.16	12.25
		South Europe	Mar. – May	0.35	0.31	22.86

Metabolites of oxathiapiprolin

Table 8.9-11: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RDT31 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.38	0.38	4.42
	2	North Europe	Mar. – May	0.05	0.05	0.64
		South Europe	Mar. – May	0.11	0.11	1.28

Table 8.9-12: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RAB06 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.49	1.47	7.32
	2	North Europe	Mar. – May	0.22	0.22	1.09
		South Europe	Mar. – May	0.43	0.42	2.10

Table 8.9-13: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-QPS10 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.08	0.07	3.66
	2	North Europe	Mar. – May	0.01	0.01	0.54
		South Europe	Mar. – May	0.02	0.02	1.09

Table 8.9-14: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-E8S72 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.34	0.34	0.02
	2	North Europe	Mar. – May	0.05	0.05	< 0.01
		South Europe	Mar. – May	0.10	0.10	0.01

Table 8.9-15: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-S2K66 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.86	0.86	6.11
	2	North Europe	Mar. – May	0.14	0.14	1.00
		South Europe	Mar. – May	0.26	0.26	1.85

Table 8.9-16: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RSE01 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.06	1.05	7.49
	2	North Europe	Mar. – May	0.17	0.17	1.22
		South Europe	Mar. – May	0.32	0.32	2.27

Table 8.9-17: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RYJ52 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.64	1.63	11.57
	2	North Europe	Mar. – May	0.27	0.27	1.89
		South Europe	Mar. – May	0.50	0.49	3.51

Table 8.9-18: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-Q7D41 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.19	1.18	8.42
	2	North Europe	Mar. – May	0.20	0.19	1.38
		South Europe	Mar. – May	0.36	0.36	2.55

Table 8.9-19: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-P3X26 for the CEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
PL-53 (CEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.07	1.07	7.48
	2	North Europe	Mar. – May	0.18	0.17	1.22
		South Europe	Mar. – May	0.33	0.32	2.27

Table 8.9-20: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RDT31 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.41	0.41	4.17
	2	North Europe	Mar. – May	0.06	0.06	0.61
		South Europe	Mar. – May	0.12	0.12	1.21

Table 8.9-21: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RAB06 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.50	1.48	7.25
	2	North Europe	Mar. – May	0.22	0.22	1.08
		South Europe	Mar. – May	0.43	0.42	2.08

Table 8.9-22: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-QPS10 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.10	0.10	3.48
	2	North Europe	Mar. – May	0.01	0.01	0.52
		South Europe	Mar. – May	0.03	0.03	1.03

Table 8.9-23: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-E8S72 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.34	0.34	0.02
	2	North Europe	Mar. – May	0.05	0.05	< 0.01
		South Europe	Mar. – May	0.10	0.10	0.01

Table 8.9-24: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-S2K66 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	0.86	0.86	6.11
	2	North Europe	Mar. – May	0.14	0.14	1.00
		South Europe	Mar. – May	0.26	0.26	1.85

Table 8.9-25: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RSE01 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.06	1.05	7.49
	2	North Europe	Mar. – May	0.17	0.17	1.22
		South Europe	Mar. – May	0.32	0.32	2.27

Table 8.9-26: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-RYJ52 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.64	1.63	11.57
	2	North Europe	Mar. – May	0.27	0.27	1.89
		South Europe	Mar. – May	0.50	0.49	3.51

Table 8.9-27: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-Q7D41 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.19	1.18	8.42
	2	North Europe	Mar. – May	0.20	0.19	1.38
		South Europe	Mar. – May	0.36	0.36	2.55

Table 8.9-28: Maximum FOCUS Step 1 and 2 $PEC_{SW/SED}$ for IN-P3X26 for the SEU

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
FR-36 (SEU) Leafy vegetables, BBCH 12 2 × 15 g a.s./ha	1	-	-	1.07	1.07	7.48
	2	North Europe	Mar. – May	0.18	0.17	1.22
		South Europe	Mar. – May	0.33	0.32	2.27

8.9.2.3 PEC_{SW} of A23109A

PEC_{SW} for the formulation was calculated for drift only, based on the percentage drift data from Rautmann (2001)[1]. The formulation components are expected to dissipate rapidly after application; therefore, only one application and drift entry are taken into consideration.

The maximum PEC_{SW} immediately after a single application is calculated as follows:

[1] . Rautmann, M. Streloke, M. Winkler (2001). New basic drift values in the authorisation procedure for plant protection products. In: R. Forster, M. Streloke: Workshop on Risk Assessment and Risk Mitigation Measures in the Context of the Authorization of Plant Protection Products (WORMM). Mitt. Biol. Bundesanst. Land-Forstwirtsch, Berlin-Dahlem, Heft 381

$$PEC_{SW}\ (\mu g/L) = \frac{\%\ drift \times application\ rate\ (g/ha)}{water\ depth\ (30\ cm) \times 10}$$

Time-dependent PEC_{SW} values, PEC_{SW} from drainage and run-off, and PEC_{Sed} values were not calculated since they are not appropriate for the formulation as it separates into its constituent components by transport and dissipation process over time in the environment.

Table 8.9-29: Maximum PEC_{SW} for the A23109A formulation

Formulation	Crop	Appl. timing	Max. rate per appl. (L A23109A/ha)	Max. rate per appl. (L A23109A/ha)[a]	Spray drift[b]	Max. PEC_{SW} (µg A23109A/L)
A23109A	Field crops	BBCH 12	0.5	537	2.77	4.958

[a] The rate of the formulation was based on a specific density of 1.074 g/mL
[b] Rautmann drift values for one application (90[th] percentiles)

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

Review Comments:

The data on atmospheric degradation and behaviour in air for metalaxyl-M and oxathiapiprolin provided by the Applicant are considered acceptable. The justification for non-assessment via volatilization is accepted. Exposure of adjacent surface waters and terrestrial ecosystems by metalaxyl-M and oxathiapiprolin due to volatilization with subsequent deposition is not expected.

8.10.1 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 8.10-1: 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 12 h dark/12 h light
Volatilisation	from plant surfaces: 35% volatilization (after 24 h, glasshouse 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 x 10^{-3} (at 25°C) Henry's Law Constant (Pa.m^3/mol): 3.5 x 10^{-5} (at 25°C)
Metabolites[a]	-

[a] Data not currently 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 compared to other routes (spray drift and drainage). Thus, PEC air is deemed not required for metalaxyl-M.

8.10.2 Oxathiapiprolin

The fate and behaviour of oxathiapiprolin in air are considered to be data provided in support of the active substance. All relevant detailed experimental information has been submitted for EU review of oxathiapiprolin, (**EFSA Journal 2016;14(7):4504.**.

Table 8.10-2: Summary of atmospheric degradation and behaviour

Compound	**Oxathiapiprolin**
Direct photolysis in air	Not required as oxathiapiprolin is not volatile
Quantum yield of direct phototransformation	Not required as oxathiapiprolin is not volatile
Photochemical oxidative degradation in air	DT_{50} (h): 3.307 derived by the Atkinson model OH (12h) concentration assumed = 1.5×10^6 cm^{-3}
Volatilisation	Not required as oxathiapiprolin is not volatile.
Metabolites	Metabolites of oxathiapiprolin are not anticipated to be volatile so no additional work was performed.

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

Appendix 1 Lists of data considered in support of the evaluation

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	Crabtree, G.	20/04/2021	Formation Fraction of SYN546520 from CGA329351 Degradation in Aerobic Soils Report No. 3202751 Document No. VV-899796 Test Facility Smithers (ERS), Ltd. GLP Unpublished	N	SYN
KCP 9.1.1	Patel, M.	01/03/2022	Metalaxyl-M – FOCUS Kinetics Evaluation of Three Laboratory Soils to Derive Formation Fraction of SYN546520 from NOA409045 Report No. RAJ1429B Document No. VV-902577 Test Facility Syngenta Limited Not GLP Unpublished	N	SYN
KCP 9.1.1	Patel, M.	16/12/2021	CGA108906 – Kinetic evaluation of Formation Fraction with EFSA endpoints Report No. RAJ1447B Document No. VV-933662 Test Facility Syngenta Limited Not GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Cooke, J.	04/03/2022	Metalaxyl-M - A Leaching Assessment for Parent and Metabolites NOA409045, CGA67868 and SYN546520 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Central Zone Report No. 0608830-GW3 Document No. VV-942658 Test Facility ERM Not GLP Unpublished	N	SYN
KCP 9.2.4	Cooke, J.	04/03/2022	Metalaxyl-M - A Leaching Assessment for Parent and Metabolites NOA409045, CGA67868 and SYN546520 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Southern Zone Report No. 0608830-GW1 Document No. VV-942649) Test Facility ERM Not GLP Unpublished	N	SYN
KCP 9.2.5	Cooke, J.	04/03/2022	Metalaxyl-M – An Environmental Fate Assessment for Parent and Metabolite NOA409045 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Central Zone Report No. 0608830-SW3 Document No. VV-942673 Test Facility ERM Not GLP Unpublished	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.5	Cooke, J.	04/03/2022	Metalaxyl-M – An Environmental Fate Assessment for Parent and Metabolite NOA409045 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Southern Zone Report No. 0608830-SW1 Document No. VV-942666) Test Facility ERM Not GLP Unpublished	N	SYN

List of data submitted by the applicant and relied on - Oxathiapiprolin

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4	Cooke, J.	04/03/2022	Oxathiapiprolin - A Leaching Assessment for Parent and Metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Central Zone Report No. 0608830-GW4 Document No. VV-942664 Test Facility ERM Not GLP Unpublished	N	SYN

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 9.2.4	Cooke, J.	04/03/2022	Oxathiapiprolin - A Leaching Assessment for Parent and Metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Southern Zone Report No. 0608830-GW2 Document No. VV-942656) Test Facility ERM Not GLP Unpublished	N	SYN
KCP 9.2.5	Cooke, J.	04/03/2022	Oxathiapiprolin – An Environmental Fate Assessment for Parent and Metabolite IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Central Zone Report No. 0608830-SW4 Document No. VV-942675 Test Facility ERM Not GLP Unpublished	N	SYN
KCA 9.2.5	Cooke, J.	04/03/2022	Oxathiapiprolin – An Environmental Fate Assessment for Parent and Metabolite IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Southern Zone Report No. 0608830-SW2 Document No. VV-942670) Test Facility ERM Not GLP Unpublished	N	SYN

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

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

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

List of data relied on not submitted by the applicant but necessary for evaluation

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

Appendix 2 Detailed evaluation of the new Annex II studies

No studies provided.

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

A 3.1 KCP 9.1.1: Crabtree, G., 2021, Metalaxyl-M – Formation Fraction of SYN546520 from CGA329351 Degradation in Aerobic Soils

Comments of izRMS:	The study is necessary for authorization of A23109A. Therefore was evaluated and accepted by izRMS. Moreover, this study was reviewed and accepted by EU RMS-BE in RAR 2022.

Reference:	KCP 9.1.1
Report	Metalaxyl-M – Formation Fraction of SYN546520 from CGA329351 Degradation in Aerobic Soils Crabtree, G. 2021 Report Number 3202751 Smithers ERS Limited, 108 Woodfield Drive, Harrogate, North Yorkshire, HG1 4LS, UK. Syngenta file No. VV-899796
Guideline(s):	OECD 307. Aerobic and Anaerobic Transformation in Soil; EPA OPPTS 835.4100 . Aerobic Soil Metabolism
Deviations:	No
GLP:	Yes
Acceptability:	Yes

The degradation of CGA329351, and the metabolite formation and decline of NOA409045 and SYN546520 were investigated in three different soils: 18 Acres (sandy loam), Vetroz (loam) and Gartenacker (loam).Three further soils were investigated in a preliminary-study, Gardner (sandy clay loam), Marsillargues (silty clay) and Capay (clay) together with 18 Acres, Vetroz and Gartenacker. All soils were known from previous studies for their potential to degrade metalaxyl-M. In the preliminary study SYN546520 was not detected in early time sampling points for Gardner, Marsillargues and Capay soils. The three soils which demonstrated formation of NOA409045 and SYN546520 in measurable concentrations necessary to track formation and degradation of the metabolites, and hence to derive SYN546520 formation fraction were selected for use in the definitive study. Although the selected soils had been previously investigated, a high metalaxyl-M dose rate was applied to ensure significant measurable concentration of all analytes, which was not previously the case. Whilst Gartenacker and Vetroz have the same USDA soil classification, Gartenacker is closer to a clay loam classification.

CGA329351 was applied at a rate of 0.857 mg/kg dry weight equivalent of soil, which is equivalent to a single field application rate of 643.0 g ai/ha (assuming an incorporation depth of 5 cm and a bulk density of 1.5 g/cm^3). The soils were incubated under aerobic conditions at 20 ± 2°C in the dark and maintained at a soil moisture of pF 2 for up to 120 days. Duplicate samples were taken from each soil for analysis at 0, 1, 3, 7, 14, 21, 30, 43, 59, 90 and 120 Days After Treatment (DAT).

Each soil sample was shaken for 2 hours with 50:50 v/v methanol:tetraborate buffer (pH 10). A sub-sample of the extract slurry was centrifuged and supernatant removed. An aliquot of the supernatant (0.2 mL) was diluted with water (0.8 mL) and analysed by LC-MS/MS. The amounts of CGA329351 and the degradation products NOA409045 and SYN546520 present in each extract were quantified by LC-MS/MS analysis using external calibration curves.

The specificity and efficiency of the analytical method was tested at each sampling interval by the inclusion of control (untreated) and recovery samples (fortified after sampling with a known amount of CGA329351, NOA409045 and SYN546520), which were processed in the same way as the test samples.

The method was validated with regards to accuracy, precision, linearity, specificity, and the lowest fortification levels. The Limit of Detection (LOD) was calculated. Matrix effects were assessed.

Mean recoveries from the validation samples were within the acceptable range of 70-110% at each concentration for each soil. Precision (% RSD) was within the acceptable limit of ≤ 20% at each concentration for each soil. Matrix effects were insignificant (< 20% difference from non-matrix standards), therefore non-matrix matched calibration standards were used. Based on peak to background noise ratio of 3, LODs were calculated to be as low as 0.26, 0.43, and 0.36 µg/kg for CGA329351, NOA409045 and SYN546520, respectively.

Control (untreated) soil extracts were free from components that interfered with the analysis of CGA329351, NOA409045 and SYN546520 and therefore, the analytical procedure was considered specific for CGA329351, NOA409045 and SYN546520.

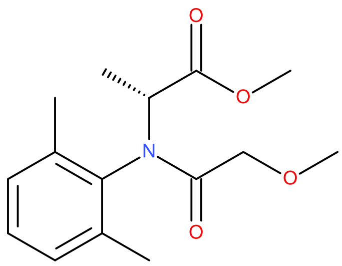
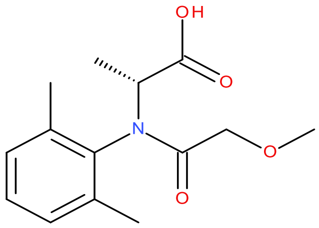
The procedural recoveries in fortified control soils for CGA329351, NOA409045 and SYN546520 were mainly distributed within the range of 70-110%. On occasions recoveries were outside the acceptable limits (70-110%). For example, at initial sampling intervals some procedural recoveries in fortified samples for SYN546520 were < 70%, but this had no impact as the degradation product had not had time to form. On all other occasions, the data from the study sample extracts were assessed and found to be in line with expected concentration values from previous and later sampling intervals. As a result no correction was made for procedural recoveries in the test samples.

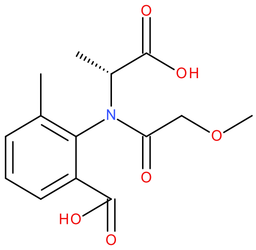
CGA329351 concentrations in treated samples declined rapidly over the course of the experiment from mean values of 84.07 – 90.55% of the applied at 0 DAT to 2.31 to 4.15% by 21 DAT and 0 to 0.08% by 90 DAT.

Whilst CGA329351 degraded quickly, NOA409045 began to form and its concentration, expressed as parent equivalent % of the applied, increased rapidly to mean values of 24.20 to 35.50% by 3 DAT, before increasing to maximum values of 55.03% and 53.25% at 14 DAT in 18 Acres and Vetroz, respectively and to 54.24% at 7 DAT in Gartenacker. NOA409045 further degraded then declined to the mean values of 1.13, 1.63 and 0.20% in 18 Acres, Vetroz and Gartenacker, respectively at the end of the incubation period.

With the formation and degradation of NOA409045, SYN546520 began to form and its concentration, expressed as parent equivalent % of the applied, increased to mean values of 0.22 to 0.36% by 14 DAT, before increasing to maximum values of 0.47% at 59 DAT in 18 Acres and 0.64% and 0.45% at 43 DAT in Vetroz and Gartenacker, respectively. SYN546520 further degraded and then declined to mean values of 0.24, 0.32 and 0.13% in 18 Acres, Vetroz and Gartenacker, respectively at the end of the incubation period.

Materials

Test Material:	**CGA329351**
	
Isomer ratio:	NA
Lot/Batch #:	AMS 758/5
Certified chemical purity:	99.3%
Date of certification:	19 Sep 2017
Expiry date:	30 Sep 2023
Supplier:	Syngenta
Description of supplied material:	Colourless viscous liquid
Application solvent/vehicle:	Water
Concentration of application solution:	362 µg/mL
Solubility of application solution:	The application solution remained soluble and homogeneous throughout the application with a coefficient of variation (CV) of 11.7% in aliquots taken at the beginning and end of the application procedure.
Stability of application solution:	Stable, determined within study
Storage conditions:	Refrigerated (2 to 8°C)
Test Material:	**NOA409045**
	
Lot/Batch #:	DAH-XXXIV-69
Certified chemical purity:	98.9%
Date of certification:	30 Apr 2020
Expiry date:	30 Apr 2022
Supplier:	Syngenta
Description of supplied material:	White Powder
Test Material:	**SYN546520**



Lot/Batch #:	DAH-XXXIV-83
Certified chemical purity:	87.3%
Date of certification:	30 Apr 2020
Expiry date:	30 Apr 2022
Supplier:	Syngenta
Description of supplied material:	Off White Powder

Soils: Three soils were used in the study. The soils were chosen to represent a range of arable farming conditions in respect of soil texture, organic carbon content and pH.

Name	**18 Acres**	**Vetroz**	**Gartenacker**
Sampling location	Nuptown Road, Warfield, Bracknell, UK	Vetroz 1963, Switzerland	Vouvry 1896, Valais, Switzerland
GPS co-ordinates	51° 27'16.2828"N 0° 42'14.9232"W	N 46.217411 E 7.287322	N 46.33270 E 6.92506
Date of collection	21 Sep 2020	15 Sep 2020	15 Sep 2020
Syngenta batch reference	S20/18A/044	S20/VET/047	S20/GAR/046
Pesticide History	No pesticide use in last 5 years	No pesticide use in last 5 years	No pesticide use in last 5 years
Sampling depth (cm)	5 to 25 cm	5 to 20 cm	5 to 20 cm
Collection procedures	Excavation	Shovel	Shovel
Storage conditions	4 ± 2ºC, in loosely tied plastic bags	4 ± 2ºC, in loosely tied plastic bags	4 ± 2ºC, in loosely tied plastic bags
Duration of storage	43 days	49 days	49 days
Duration of acclimation	7 days	7 days	7 days
Soil preparation	Soils were thoroughly mixed and passed through a 2 mm mesh sieve, with the minimum of air drying. Soils were adjusted to just below the water holding capacity at pF 2.0 by the addition of reverse osmosis water		
Particle size (% w/w):			
Sand (2000-50 µm)	53	35	41
Silt (50-2 µm)	30	42	48
Clay (<2 µm)	17	23	11
Texture (USDA)	Sandy Loam	Loam	Loam
USA Taxonomy (order and sub-order)			
pH (1:1 w/v soil:water)	5.8	7.8	7.5
pH (1:2 w/v soil:0.01M $CaCl_2$)	5.6	7.6	7.2
Organic matter[1] (%)	4.3	4.1	3.5
Organic carbon[1] (%)	2.5	2.4	2.0
CEC[2] (meq/100 g soil)	15.5	11.9	8.4
Moisture content at pF 2.0 (0.1bar, % w/w)	24.2	42.8	46.0
Moisture content at pF 2.5[3] (0.33 bar, % w/w)	16.7	28.1	24.5
Moisture content at 15 bar[3] (% w/w)	11.5	10.9	6.1
Moisture content on arrival (% w/w)	13.5	21.6	26.1
Moisture content used in study (% w/w)	23.8	39.7	45.0
Initial biomass (start of study) in: a) mg carbon/100 g soil b) % OC	579 µg C/g 2.3% OC	784 µg C/g 3.3% OC	583 µg C/g 2.9% OC
Final biomass (end of study) in: mg carbon/100 g soil % OC	503 µg C/g 2.0 % OC	573 µg C/g 2.4 % OC	536 µg C/g 2.7 % OC

Organic carbon (OC) % = organic matter (OM) %/1.724.
CEC = cation exchange capacity.
Measured in 2 mm soil

Experimental design

Parameter		Description
Duration between soil collection and dosing		43 to 49 days
Soil storage conditions prior to pre-incubation		Stored in the dark in plastic bags with free access to air at *ca*. 4°C.
Soil condition and preparation		Fresh soil, passed through 2 mm sieve prior to use
Soil sample weight		100 g (dry weight) per replicate
Pre-incubation	Duration of pre-incubation	7 days
	Temperature (°C)	20 ± 2
	Moisture content	Equivalent to pF 2
	Moisture maintenance method	Vessel weighed 7 days prior to application and any weight loss re-adjusted by the addition of water.
	Continuous darkness:	Yes
Test concentration *		0.875 mg ai/kg of soil (dry weight), equivalent to 643 g ai/ha
Control conditions		Not applicable
Number of replicates	Treated soil samples	2
	Control soil samples	1
	Recovery soil samples	1
Test apparatus		Glass incubation vessels (*ca* 7 cm diameter) plugged with pre dampened bungs.
Test material application	Identity of solvent in application solution	Dosed in water
	Volume of application solution used/treatment	0.276 mL
	% of co-solvent per sample (mL/g X 100%)	0.276 %
	Application method	Positive displacement pipette
	Evaporation of application solvent	No
	Biomass samples	Received an equivalent amount of solvent only (without the test item).
Experimental conditions	Duration of the test	120 days
	Temperature (°C)	20 ± 2
	Moisture content	Equivalent to pF 2
	Moisture maintenance method	Vessels weighed every 8 days and any weight loss relative to Day 0 attributed to water loss. Water added to restore original system.
	Continuous darkness:	Yes

Sampling

Parameter		Description
Sampling intervals	Treated soil samples	Duplicate samples from all three soils: 0, 1, 3, 7, 14, 21, 30, 43, 59, 90 and 120 DAT.
	Control soil samples	Single samples from all three soils: 0, 1, 3, 7, 14, 21, 30, 43, 59, 90 and 120 DAT.

	Recovery soil samples	Single samples from all three soils: 0, 1, 3, 7, 14, 21, 30, 43, 59, 90 and 120 DAT
	Untreated soils for biomass	0 and 120 DAT from all three soils
Soil sampling procedures		Complete test systems were removed at each sampling time and extracted as detailed below.
Sample storage before analysis		All samples were extracted on the day of sampling and analysed by LC-MS-MS within 4 days.

Description of analytical procedures

Each treated soil sample was transferred to a plastic pot and extracted with the following extraction solution:

Extract 1: 50:50 v/v CH_3OH/buffer (tetraborate, pH10), once

During each extraction step, the soil was shaken on a flat-bed shaker with 1000 mL of extraction solution for 2 hours at room temperature. The extract was separated from the soil by centrifugation (3500 rpm for 5 mins). The resulting supernatant was decanted .

A sub-sample (0.2 mL) was added to water (0.8 mL), prior to LC-MS-MS analysis. Injected samples were quantified by peak area with reference to an external calibration curve. The latter was obtained by correlation of the peak area of the calibration standards (made up in 20:80 v/v methanol:water) with the corresponding concentrations of the test item.

At each sampling interval, control (untreated) samples and recovery samples (fortified after sampling with a known amount of CGA329351, NOA4090456 and SYN546520) were processed in the same way as the treated soil samples to determine the specificity and efficiency of the analytical method.

Details of analytical techniques used in the study are given below:

Instrument Description

Pump	:	Shimadzu LC-30AD
Degasser	:	Shimadzu DGU-20A5
Column Oven	:	Shimadzu CTO-20AC
Detector	:	ABSciex API Q-Jet 5000
Autosampler	:	Shimadzu LC-30AD

Chromatography Conditions for CGA329351

Column	:	Waters Acquity BEH phenyl 2.1×50mm 1.7 µm
Column Oven Temperature	:	40°C
Injection volume	:	10 µL
Run Time	:	4.5 minutes

Injection protocol	:	Inject the full calibration line during the sample sequence, injecting a standard at the start and end of the sequence and the remainder interspersed throughout
Mobile phase	:	A: 0.1% Formic acid in water

Mobile Phase Composition

Time (mins)	Mobile phase A	Mobile phase B	Flow rate
0	95	5	0.5
0.5	95	5	0.5
3.0	10	90	0.5
3.5	10	90	0.5
3.6	95	5	0.5
4.5	95	5	0.5

Valve Switching programme

Time (mins)	Position
0	To waste
0.5	To mass spectrometer
4.0	To waste

Under these conditions the retention time of CGA329351 was *ca* 2.6 minutes, the retention time of NOA409045 was *ca* 2.4 minutes and the retention time of SYN546520 was *ca* 2.2 minutes.

Mass Spectrometer Conditions for CGA329351

Interface	:	ElectroSpray
Polarity	:	Positive
Curtain gas (CUR)	:	Nitrogen set at 20 (arbitrary units)
Temperature (TEM)	:	500°C
Ionspray voltage	:	5000 V
Collision gas setting (CAD)	:	Nitrogen set at 5 (arbitrary units)
Gas 1 (GS1)	:	Air set at 60 (arbitrary units)
Gas 2 (GS2)	:	Air set at 60 (arbitrary units)
Interface heater (ihe)	:	On
Scan type	:	MRM

MRM Conditions		**CGA329351 primary**	**CGA329351 confirmatory**	**NOA409045 primary**	**NOA409045 confirmatory**
Q1 Da	:	280	280	266	266
Q3 Da	:	220	192	220	192
Dwell time	:	100 ms	100 ms	100 ms	100 ms
Resolution Q1	:	Unit	Unit	Unit	Unit
Resolution Q3	:	Unit	Unit	Unit	Unit
Declustering potential (DP)	:	46 V	46 V	56 V	56 V
Entrance potential (EP)	:	10 V	10 V	10 V	10 V
Collision energy (CE)	:	21 V	27 V	19 V	22 V
Collision cell exit potential (CXP)	:	13 V	13 V	13 V	13 V

MRM Conditions		SYN546520 primary transition	SYN546520 confirmatory
Q1 Da	:	296	296
Q3 Da	:	160	91
Dwell time	:	100 ms	100 ms
Resolution Q1	:	Unit	Unit
Resolution Q3	:	Unit	Unit
Declustering potential (DP)	:	40 V	40 V
Entrance potential (EP)	:	10 V	10 V
Collision energy (CE)	:	35 V	65 V
Collision cell exit potential (CXP)	:	13 V	13 V

Results and Discussion

Suitability of the Analytical Method

Specificity of the method:	Control (blank) soil extracts were free from components that interfered with the analysis of CGA329351, NOA409045 and SYN546520. Therefore, the analytical procedure was considered specific for CGA329351, NOA409045 and SYN546520.
Detector linearity:	The LC-MS/MS detector response for CGA329351, NOA409045 and SYN546520 was found to be linear in the range of 0.05 ng to 40 ng injected on column, which is equivalent to 0.0005 ng/mL to 0.40 ng/mL in solution when using an injection volume of 10 µL. The correlation coefficients (r^2) for calibration curves were ≥0.99.
Matrix effects:	No significant matrix effects were observed in the soil types tested and therefore non-matrix matched standards were used for quantification of CGA329351, NOA409045 and SYN546520.
LOD/LOQ:	The LOD of the test item was estimated based on the lowest analyte concentration that would be detectable at three times the background noise. This corresponded to a concentration of 0.26 to 0.42 µg/L, 0.43 to 1.37 µg/L and 0.36 to 1.48 µg/L for CGA329351, NOA409045 and SYN546520, respectively. Taking into consideration a typical extract volume of 1000 mL, this is equivalent to 0.26 to 0.42 µg/kg, 0.43 to 1.37 µg/kg and 0.36 to 1.48 µg/kg for CGA329351, NOA409045 and SYN546520, respectively in dry soil of the applied amount.
Standard storage stability	After storage for 84 days at 2-8°C, CGA329351 primary stock solution and treatment solution in water was found to be stable with the difference between stocks being ≤ 5%.
Sample storage stability	Soil extracts were analysed within 4 days of extraction.

Recovery of CGA329351, NOA409045 and SYN546520 in Fortified Samples

The procedural recoveries in fortified samples for 18 Acres, Vetroz and Gartenacker are shown in Table A 1 to .Table A 9, respectively.

The procedural recoveries in fortified control soils for CGA329351, NOA409045 and SYN546520 were mainly distributed within the range of 70-110%. On occasions recoveries were outside the acceptable limits (70-110%). For example, at initial sampling intervals some procedural recoveries in fortified samples for SYN546520 were < 70%, but this had no impact as the degradation product had not had time to form. On all other occasions, the data from the study sample extracts were assessed and found to be in line with expected concentration values from previous and later sampling intervals. As a result no correction was made for procedural recoveries in the test samples.

Rate of Degradation of Parent Material

The concentrations of CGA329351, NOA409045 and SYN546520 in treated samples are shown in Table A 10 to Table A 12.

CGA329351 concentrations in treated samples declined rapidly over the course of the experiment from mean values of 84.07 – 90.55% of the applied at 0 DAT to 2.31 – 4.15% by 21 DAT and 0 – 0.08% by 90 DAT.

Whilst CGA329351 degraded quickly, NOA409045 began to form and its concentration, expressed as parent equivalent % of the applied, increased rapidly to mean values of 24.20 to 35.50% by 3 DAT, before increasing to maximum values of 55.03% and 53.25% at 14 DAT in 18 Acres and Vetroz, respectively and to 54.24% at 7 DAT in Gartenacker. NOA409045 further degraded and then declined to mean values of 1.13, 1.63 and 0.20% in 18 Acres, Vetroz and Gartenacker, respectively at the end of the incubation period.

With the formation and degradation of NOA409045, SYN546520 began to form and its concentration, expressed as parent equivalent % of the applied, increased to mean values of 0.22 to 0.36% by 14 DAT, before increasing to maximum mean values of 0.47% at 59 DAT in 18 Acres, 0.64% at 43 DAT in Vetroz and 0.51% at 21 DAT in Gartenacker, respectively. SYN546520 further degraded and then declined to mean values of 0.24, 0.32 and 0.13% in 18 Acres, Vetroz and Gartenacker, respectively at the end of the incubation period.

Table A 1: Procedural Recoveries of CGA329351 in Recovery Samples: 18 Acres

DAT	Fortification level[a] (mg/kg)	Expected concn in soil (mg/kg)	Measured CGA329351 concn in soil (mg/kg)	CGA329351 Procedural recovery (%)
1	0.01	0.01	0.0103	103
	1.1	1.1	1.100	99.8
3	0.01	0.01	0.0101	101
	1.1	1.1	1.070	97.0
7	0.01	0.01	0.00994	99.4
	1.1	1.1	1.080	97.8
14	0.01	0.01	0.00911	91.1
	1.1	1.1	1.100	100
21	0.01	0.01	0.00981	98.1
	1.1	1.1	1.070	97.1
30	0.01	0.01	0.00921	92.1
	1.1	1.1	1.070	97.6
43	0.01	0.01	0.0103	103
	1.1	1.1	1.090	98.7
59	0.01	0.01	0.00939	93.9
	1.1	1.1	1.110	101
90	0.01	0.01	0.00936	93.6
	1.1	1.1	1.160	105

[a] Based on a nominal application rate of 750 g ai/ha.

Table A 2: Procedural Recoveries of CGA329351 in Recovery Samples: Vetroz

DAT	Fortification level[a] (mg/kg)	Expected concn in soil (mg/kg)	Measured CGA329351 concn in soil (mg/kg)	CGA329351 Procedural recovery (%)
1	0.01	0.01	0.00924	92.4
	1.1	1.1	1.070	97.0
3	0.01	0.01	0.00872	87.2
	1.1	1.1	1.060	96.3
7	0.01	0.01	0.00986	98.6
	1.1	1.1	1.080	98.2
14	0.01	0.01	0.0105	105
	1.1	1.1	1.180	107
21	0.01	0.01	0.00995	99.5
	1.1	1.1	1.160	106
30	0.01	0.01	0.00986	98.6
	1.1	1.1	1.060	96.4
43	0.01	0.01	0.00823	82.3
	1.1	1.1	1.040	94.3
59	0.01	0.01	0.00865	86.5
	1.1	1.1	1.010	91.4
90	0.01	0.01	0.00850	85.0
	1.1	1.1	1.080	98.3

[a] Based on a nominal application rate of 750 g ai/ha.

Table A 3: Procedural Recoveries of CGA329351 in Recovery Samples: Gartenacker

DAT	Fortification level[a] (mg/kg)	Expected conc^n in soil (mg/kg)	Measured CGA329351 conc^n in soil (mg/kg)	CGA329351 Procedural recovery (%)
1	0.01	0.01	0.0103	103
	1.1	1.1	0.771	70.1
3	0.01	0.01	0.00588	58.8[1]
	1.1	1.1	0.703	63.9[1]
7	0.01	0.01	0.00696	69.6[1]
	1.1	1.1	0.731	66.4[1]
14	0.01	0.01	0.00981	98.1
	1.1	1.1	1.090	98.9
21	0.01	0.01	0.00985	98.5
	1.1	1.1	1.170	107
30	0.01	0.01	0.00939	93.9
	1.1	1.1	0.993	90.3
43	0.01	0.01	0.00973	97.3
	1.1	1.1	1.100	100
59	0.01	0.01	0.00985	98.5
	1.1	1.1	1.080	98.4
90	0.01	0.01	0.00892	89.2
	1.1	1.1	1.160	106

[a] Based on a nominal application rate of 750 g ai/ha.
[1] Low procedural recoveries in fortified samples. Assay of CGA329351 correlates well with the other sampling intervals, so no impact on assayed results

Table A 4: Procedural Recoveries of NOA409045 in Recovery Samples: 18 Acres

DAT	Fortification level[a] (mg/kg)	Expected conc^n in soil (mg/kg)	Measured NOA409045 conc^n in soil (mg/kg)	NOA409045 Procedural recovery (%)
1	0.01	0.01	0.0100	100
	1.1	1.1	1.080	98.5
3	0.01	0.01	0.0104	104
	1.1	1.1	1.110	101
7	0.01	0.01	0.0104	104
	1.1	1.1	1.130	103
14	0.01	0.01	0.0997	99.7
	1.1	1.1	1.130	103
21	0.01	0.01	0.0110	110
	1.1	1.1	1.100	100
30	0.01	0.01	0.00933	93.3
	1.1	1.1	1.100	100
43	0.01	0.01	0.0113	113
	1.1	1.1	1.070	96.8
59	0.01	0.01	0.00908	90.8
	1.1	1.1	1.110	101
90	0.01	0.01	0.00424	42.4[1]
	1.1	1.1	1.140	104
120	0.01	0.01	0.00969	96.9
	1.1	1.1	1.150	105

[a] Based on a nominal application rate of 750 g ai/ha.
[1] Low procedural recovery at 90 DAT. As this occurred in all three soils suspect samples not fortified at the correct concentration. Concentration level in quantified soils < LOD but 120 DAT samples analysed as a result

Table A 5: Procedural Recoveries of NOA409045 in Recovery Samples: Vetroz

DAT	Fortification level[a] (mg/kg)	Expected concn in soil (mg/kg)	Measured NOA409045 concn in soil (mg/kg)	NOA409045 Procedural recovery (%)
1	0.01	0.01	0.00858	85.8
	1.1	1.1	1.040	94.4
3	0.01	0.01	0.00827	82.7
	1.1	1.1	1.050	95.9
7	0.01	0.01	0.00945	94.5
	1.1	1.1	1.130	102
14	0.01	0.01	0.0107	107
	1.1	1.1	1.170	106
21	0.01	0.01	0.0103	103
	1.1	1.1	1.140	104
30	0.01	0.01	0.00878	87.8
	1.1	1.1	1.040	94.6
43	0.01	0.01	0.00828	82.8
	1.1	1.1	1.070	97.5
59	0.01	0.01	0.00957	95.7
	1.1	1.1	1.010	91.9
90	0.01	0.01	0.00341	34.1[1]
	1.1	1.1	1.050	95.4
120	0.01	0.01	0.0111	111
	1.1	1.1	1.150	104

[a] Based on a nominal application rate of 750 g ai/ha.
[1] Low procedural recovery at 90 DAT. As this occurred in all three soils suspect samples not fortified at the correct concentration. Concentration level in quantified soils < LOQ but 120 DAT samples analysed as a result

Table A 6: Procedural Recoveries of NOA409045 in Recovery Samples: Gartenacker

DAT	Fortification level[a] (mg/kg)	Expected concn in soil (mg/kg)	Measured NOA409045 concn in soil (mg/kg)	NOA409045 Procedural recovery (%)
1	0.01	0.01	0.00955	95.5
	1.1	1.1	0.766	69.6
3	0.01	0.01	0.00548	54.8[1]
	1.1	1.1	0.791	71.9
7	0.01	0.01	0.00689	68.9[1]
	1.1	1.1	0.620	56.4[1]
14	0.01	0.01	0.00987	98.7
	1.1	1.1	1.110	101
21	0.01	0.01	0.0104	104
	1.1	1.1	1.170	106
30	0.01	0.01	0.00822	82.2
	1.1	1.1	1.030	93.2
43	0.01	0.01	0.00877	87.7
	1.1	1.1	1.090	99.0
59	0.01	0.01	0.00945	94.5
	1.1	1.1	1.110	101
90	0.01	0.01	0.00384	38.4[2]
	1.1	1.1	1.140	104
120	0.01	0.01	0.0107	107
	1.1	1.1	1.120	102

[a] Based on a nominal application rate of 750 g ai/ha.
[1] Low procedural recoveries in fortified samples. Assay of NOA409045 correlates well with the other sampling intervals , so no impact on assayed results.
[2] Low procedural recovery at 90 DAT. As this occurred in all three soils suspect samples not fortified at the correct

concentration. Concentration level in quantified soils < LOQ but 120 DAT samples analysed as a result.

Table A 7: Procedural Recoveries of SYN546520 in Recovery Samples: 18 Acres

DAT	Fortification level[a] (mg/kg)	Expected conc^{n} in soil (mg/kg)	Measured SYN546520 conc^{n} in soil (mg/kg)	SYN546520 Procedural recovery (%)
1	0.005	0.005	0.00503	101
	1.1	1.1	1.060	96.1
3	0.005	0.005	0.00380	75.9
	1.1	1.1	1.050	95.4
7	0.005	0.005	0.00451	90.2
	1.1	1.1	1.050	95.2
14	0.005	0.005	0.00410	81.9
	1.1	1.1	1.110	101
21	0.005	0.005	0.00484	96.8
	1.1	1.1	1.060	96.5
30	0.005	0.005	0.00317	63.5[1]
	1.1	1.1	1.020	92.9
43	0.005	0.005	0.00548	110
	1.1	1.1	1.090	99.3
59	0.005	0.005	0.00442	88.4
	1.1	1.1	1.090	99.0
90	0.005	0.005	0.00444	88.9
	1.1	1.1	1.120	102
120	0.005	0.005	0.00456	91.2
	1.1	1.1	1.070	97.5

[a] Based on a nominal application rate of 750 g ai/ha.
[1] Low procedural recovery, levels of SYN546520 in samples in line with levels expected, so no effect on the assayed result.

Table A 8: Procedural Recoveries of SYN546520 in Recovery Samples: Vetroz

DAT	Fortification level[a] (mg/kg)	Expected conc[n] in soil (mg/kg)	Measured SYN546520 conc[n] in soil (mg/kg)	SYN546520 Procedural recovery (%)
1	0.005	0.005	0.00383	76.7
	1.1	1.1	1.010	91.5
3	0.005	0.005	0.00308	61.6[1]
	1.1	1.1	997	90.6
7	0.005	0.005	0.00497	99.5
	1.1	1.1	1.070	96.9
14	0.005	0.005	0.00488	97.5
	1.1	1.1	1.130	102
21	0.005	0.005	0.00495	98.9
	1.1	1.1	1.090	99.2
30	0.005	0.005	0.00400	80.1
	1.1	1.1	0.996	90.5
43	0.005	0.005	0.00316	63.2[1]
	1.1	1.1	1.040	94.7
59	0.005	0.005	0.00423	84.5
	1.1	1.1	0.974	88.6
90	0.005	0.005	0.00326	65.3[1]
	1.1	1.1	1.030	93.8
120	0.005	0.005	0.00449	89.8
	1.1	1.1	1.150	104

[a] Based on a nominal application rate of 750 g ai/ha.
[1] Low procedural recovery in 1 fortification level, levels of SYN546520 in samples in line with levels expected, so no effect on the assayed result.

Table A 9: Procedural Recoveries of SYN546520 in Recovery Samples: Gartenacker

DAT	Fortification level[a] (mg/kg)	Expected conc[n] in soil (mg/kg)	Measured SYN546520 conc[n] in soil (mg/kg)	SYN546520 Procedural recovery (%)
1	0.005	0.005	0.00456	91.1
	1.1	1.1	0.670	60.9[1]
3	0.005	0.005	0.00205	41.0[1]
	1.1	1.1	0.649	59.0[1]
7	0.005	0.005	0.00294	58.7[1]
	1.1	1.1	0.549	49.9[1]
14	0.005	0.005	0.00499	99.9
	1.1	1.1	1.100	99.6
21	0.005	0.005	0.00470	94.0
	1.1	1.1	1.100	99.7
30	0.005	0.005	0.00368	73.6
	1.1	1.1	1.010	91.6
43	0.005	0.005	0.00434	86.8
	1.1	1.1	1.110	101
59	0.005	0.005	0.00458	91.7
	1.1	1.1	1.010	91.4
90	0.005	0.005	0.00398	79.5
	1.1	1.1	1.130	103
120	0.005	0.005	0.00487	97.5
	1.1	1.1	1.180	107

[a] Based on a nominal application rate of 750 g ai/ha.
[1] Low procedural recoveries. As no SYN546520 detected in sample extracts there is no impact on the assayed results.

Table A 10: Concentration of CGA329351 in soil (values as % of applied)

Soil	Replicate	% of the Applied at Time (DAT)									
		0	1	3	7	14	21	30	43	59	90
18 Acres	A	86.11	71.30	58.81	30.34	15.05	4.19	1.66	0.76	0.42	0.13
	B	82.03	72.81	59.04	29.99	12.02	4.11	2.22	0.78	0.42	0.04
	Mean	**84.07**	**72.05**	**58.93**	**30.16**	**13.54**	**4.15**	**1.94**	**0.77**	**0.42**	**0.08**
Vetroz	A	88.80	59.16	46.32	20.07	6.04	2.79	1.60	0.59	0.37	0.06
	B	92.30	61.26	48.31	20.65	6.43	2.98	1.56	0.65	0.35	0.03
	Mean	**90.55**	**60.21**	**47.32**	**20.36**	**6.24**	**2.88**	**1.58**	**0.62**	**0.36**	**0.04**
Gartenacker	A	89.15	57.53	52.98	22.40	5.68	2.25	1.12	0.30	0.16	ND
	B	90.20	66.16	51.81	25.90	5.37	2.37	1.23	0.54	0.16	ND
	Mean	**89.67**	**61.84**	**52.39**	**24.15**	**5.53**	**2.31**	**1.17**	**0.42**	**0.16**	**ND**

ND = Not Detected

Table A 11: Concentration of NOA409045 in soil (values as equivalent % of applied)

Soil	Replicate	Parent Equivalent % of the Applied at Time (DAT)										
		0	1	3	7	14	21	30	43	59	90	120
18 Acres	A	0.25	8.44	25.43	45.58	55.53	47.79	40.54	20.27	11.45	4.55	0.82
	B	0.22	8.30	22.97	44.10	54.54	49.75	42.38	23.09	14.13	2.27	1.44
	Mean	**0.24**	**8.37**	**24.20**	**44.84**	**55.03**	**48.77**	**41.46**	**21.68**	**12.79**	**3.41**	**1.13**
Vetroz	A	0.43	9.18	34.15	51.84	51.84	42.26	30.59	15.85	5.75	1.28	2.42
	B	0.40	9.23	34.89	52.45	54.67	43.73	30.71	16.83	6.47	1.70	0.84
	Mean	**0.41**	**9.20**	**34.52**	**52.15**	**53.25**	**43.00**	**30.65**	**16.34**	**6.11**	**1.49**	**1.63**
Gartenacker	A	0.33	9.31	35.13	53.93	42.75	13.14	2.78	0.23	1.24	ND	0.31
	B	0.29	9.91	35.87	54.54	43.61	14.62	3.78	1.70	0.41	0.72	0.10
	Mean	**0.31**	**9.61**	**35.50**	**54.24**	**43.18**	**13.88**	**3.28**	**0.96**	**0.82**	**0.36**	**0.20**

ND = Not Detected

Table A 12: Concentration of SYN546520 in soil (values as equivalent % of applied)

Soil	Replicate	Parent Equivalent % of the Applied at Time (DAT)										
		0	**1**	**3**	**7**	**14**	**21**	**30**	**43**	**59**	**90**	**120**
18 Acres	A	ND	0.02	ND	0.09	0.26	0.38	0.41	0.45	0.56	0.45	0.23
	B	ND	ND	ND	0.06	0.19	0.36	0.36	0.36	0.39	0.27	0.24
	Mean	**ND**	**0.01**	**ND**	**0.07**	**0.22**	**0.37**	**0.38**	**0.41**	**0.47**	**0.36**	**0.24**
Vetroz	A	ND	ND	ND	0.11	0.36	0.55	0.56	0.69	0.55	0.24	0.49
	B	ND	ND	ND	0.11	0.29	0.55	0.57	0.59	0.52	0.30	0.16
	Mean	**ND**	**ND**	**ND**	**0.11**	**0.33**	**0.55**	**0.57**	**0.64**	**0.53**	**0.27**	**0.32**
Gartenacker	A	ND	ND	ND	0.14	0.36	0.51	0.45	0.39	0.40	0.20	0.12
	B	ND	ND	ND	0.09	0.37	0.51	0.48	0.52	0.36	0.20	0.14
	Mean	**ND**	**ND**	**ND**	**0.12**	**0.36**	**0.51**	**0.46**	**0.45**	**0.38**	**0.20**	**0.13**

ND = Not Detected

Conclusion:

The degradation of CGA329351 and the metabolite formation and degradation of SYN546520 and NOA409045 were investigated in three different soils. CGA329351 degraded rapidly over the incubation period and metabolite concentration levels of SYN546520 and NOA409405 increased before declining.

CGA329351 concentrations in treated samples declined rapidly over the course of the experiment from mean values of 84.07 – 90.55% of applied at 0 DAT to 2.31 to 4.15% by 21 DAT and 0 to 0.08% by 90 DAT.

Parent equivalent levels of NOA409045 increased rapidly and reached maximum values of 55.03%, 53.25% and 54.24% of the applied before declining to 1.13, 1.63 and 0.20% in 18 Acres, Vetroz, and Gartenacker, respectively at the end of the incubation period.

Parent equivalent levels of SYN546520 increased to maximum values of 0.47%, 0.64% and 0.45% of the applied, before declining to 0.24, 0.32 and 0.13% in 18 Acres, Vetroz, and Gartenacker, respec tively, at the end of the incubation period.

A 3.2 KCP 9.1.1: Patel, M., 2022, Metalaxyl-M: FOCUS kinetics evaluation of three laboratory soils to derive formation fraction of SYN546520 from NOA409045

Comments of izRMS:	The determined DT_{50} and formation fraction values of SYN546520 (CGA108906) were accepted by izRMS (and EU RMS-BE – RAR 2022).

Reference:	KCP 9.1.1
Report	Metalaxyl-M: FOCUS kinetics evaluation of three laboratory soils to derive formation fraction of SYN546520 from NOA409045, Modelling Assessment Amendment 1. Patel M., 2022 Report Number RAJ1429B Syngenta, Jealott's Hill Int. Research Centre, Bracknell, RG42 6EY, UK. Syngenta file No. VV-902577 Supporting Data VV-902578
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

Summary

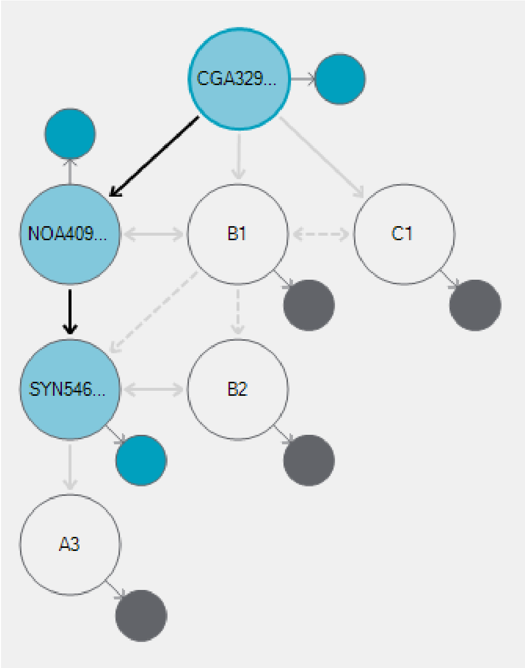
This kinetic assessment has been conducted based on the aerobic degradation of metalaxyl-M (R enantiomer) studied in the laboratory on three soils, 18 Acres (sandy loam), Vetroz (loam) and Gartenacker (loam) (Crabtree, 2021, VV-899796).

Methods

This report presents the calculations to determine modelling DT_{50} and DT_{90} values as well as the respective formation fractions for active substance metalaxyl-M (CGA329351) and its metabolites NOA409045 and the di-acid metabolite SYN546520. The di-acid metabolite formed from the racemic (R/S) compound metalaxyl is also a racemic mixture and is known as CGA108906.

The original data from the study was used to calculate the rate of degradation of metalaxyl-M and metabolites NOA409045 and SYN546520 in soil and their formation fractions, following the guidance in FOCUS Kinetics (2006, 2014). The degradation scheme for metalaxyl-M in soil is shown in Figure A 1. The pathway implemented for kinetic modelling is presented in Figure A 2.

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



Kinetic modelling following the appropriate FOCUS Kinetics (2006, 2014) flowchart for the derivation of parent or metabolite modelling endpoints was carried out using CAKE v3.4 (2020).

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). The χ^2 error % parameter has also been used to determine the goodness of fit.

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, 2014). 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.

For SFO and DFOP 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 χ2 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.

Metabolites:

Metabolites have been fitted in the step-wise procedure indicated by the guidance (FOCUS, 2006, 2014). 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.

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). The χ2 error % parameter has also been used to determine the goodness of fit. The outputs from the final step only are given in Appendix 4-7 of the corresponding report.

Data Manipulation,

Input data were generated according to the data handling recommendations made in the FOCUS guidance for degradation kinetics (FOCUS, 2006, 2014). True replicates were included individually in the optimisations. No samples were reported with measured residues below the level of detection in any soils

18 Acres

Day 0 metabolite concentration (%) were added to parent metalaxyl-M and metabolite Day 0 values were set to zero. Preceding values of zero were set to ½ LOD (0.01%) for metabolite SYN546520 for Day 1 replicate b, replicates 3a and b. Residues used in the kinetic analysis.

Vetroz

Day 0 metabolite concentration (%) were added to parent metalaxyl-M and metabolite Day 0 values were set to zero. Preceding values of zero were set to ½ LOD (0.01%) for metabolite SYN546520 for Day 3 replicate a and b. Day 1 concentrations for SYN546520 were omitted.

Gartenacker

Day 0 metabolite concentration (%) were added to parent metalaxyl-M and metabolite day 0 values were set to zero. Preceding values of zero were set to ½ LOD (0.01%) for metabolite SYN546520 for Day 3 replicate a and b. Day 1 concentrations for SYN546520 were omitted. ½ LOD was also added to parent at Day 90 (replicate) and NOA409045, Day 90 replicate a only residue was used in the kinetic analysis.

Normalisation to 20ºC and pF2

These studies were performed at standard conditions. Therefore, normalisation was not required

Results

The DT_{50}, DT_{90}, χ2 error% values as well as formation fractions are summarised in Table A 13 to Table A 15. Detailed summary of endpoints and kinetics fits are summarised in Table A 16 to Table A 18.

Table A 13: Summary of modelling endpoints DT_{50} and DT_{90} for metalaxyl-M

Soil name	Soil Origin	Kinetic model	χ2 error (%)	DT_{50} (days)	DT_{90} (days)
18 Acres	Warfield, Bracknell, UK	SFO	4.15	5.13	17.0
Vetroz	Vetroz 1963, Switzerland	SFO	12.8	3.59	11.9
Gartenacker	Vouvry 1896, Valais, Switzerland	SFO	12.2	3.46	11.5
			Geomean	**3.99**	**13.3**

Table A 14: Summary of modelling endpoints DT_{50} and DT_{90} for metalaxyl-M metabolite NOA409045

Soil name	Soil Origin	Kinetic model	χ2 error (%)	DT_{50} (days)	DT_{90} (days)	Formation fraction from parent
18 Acres	Warfield, Bracknell, UK	SFO	6.51	19.7	65.5	1
Vetroz	Vetroz 1963, Switzerland	SFO	7.98	19.9	66.2	0.921
Gartenacker	Vouvry 1896, Valais, Switzerland	SFO	26.4	7.79	25.9	1
			Geomean	**14.5**	**48.2**	**-**
			Arithmetic mean			**0.974**

Table A 15: Summary of modelling endpoints DT_{50} and DT_{90} for metalaxyl-M metabolite SYN546520

Soil name	Soil Origin	Kinetic model	χ2 error (%)	DT_{50} (days)	DT_{90} (days)	Formation fraction from NOA409045
18 Acres	Warfield, Bracknell, UK	SFO	9.65	39.9	132	0.0113
Vetroz	Vetroz 1963, Switzerland	SFO	12.4	28.5	94.5	0.0189
Gartenacker	Vouvry 1896, Valais, Switzerland	SFO	8.00	40.0	133	0.00867
			Geomean	**35.7**	**118.4**	
			Arithmetic mean			**0.0130**

Table A 16: Detailed summary of endpoints for 18 Acres soil

Soil	18 Acres (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
Model	SFO	SFO	SFO
Visual Fit	Good	Good	Good
Residuals	Good	Acceptable	Good
χ2 error (%)	4.15	6.51	9.65
Optimised M0	84.58	-	-
Optimised rate parameter/ t-test probability	k: 0.1352 $p < 0.01$	k: 0.03514 $p < 0.01$	k: 0.01738 $p < 0.01$

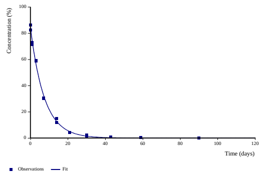
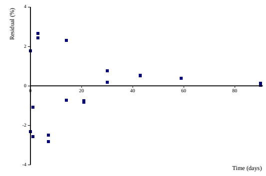
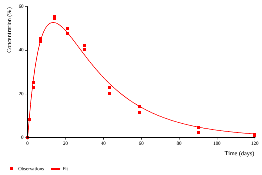
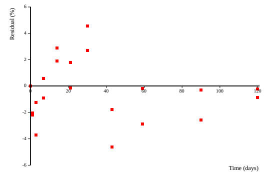
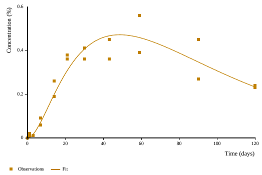
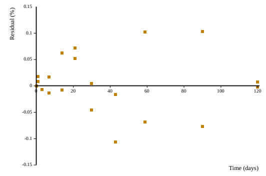
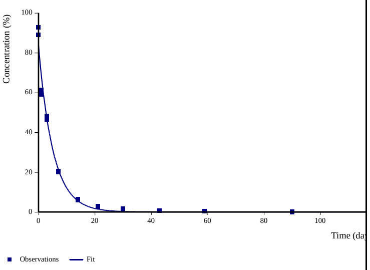
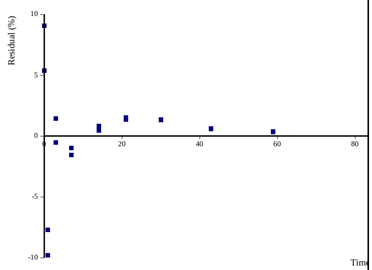
Soil	18 Acres (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
DT_{50}	5.13	19.7	39.9
DT_{90}	17.0	65.5	132
Formation fraction from parent	-	1	-
Formation fraction from NOA409045	-	-	0.01133
FOCUS decision step (Modelling endpoints)	Fit is acceptable	Fit is acceptable	Fit is acceptable
Metalaxyl-M			
NOA409045			
SYN546520			

Table A 17: Detailed summary of endpoints for Vetroz soil

Soil	Vetroz (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
Model	SFO	SFO	SFO
Visual Fit	Good	Good	Acceptable
Residuals	Good	Acceptable	Acceptable
χ^2 error (%)	12.8	7.98	12.4
Optimised M0	83.66	-	-
Optimised rate parameter/ t-test probability	k: 0.1931 $p < 0.01$	k: 0.03477 $p < 0.01$	k: 0.02436 $p < 0.01$
DT_{50}	3.59	19.9	28.5
DT_{90}	11.9	66.2	94.5
Formation fraction from parent	-	0.9208	-
Formation fraction from NOA409045	-	-	0.01885
FOCUS decision step (Modelling endpoints)	Fit is acceptable	Fit is acceptable	Fit is acceptable
Metalaxyl-M			

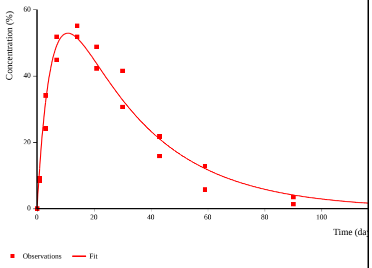
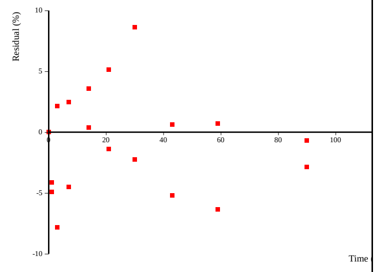
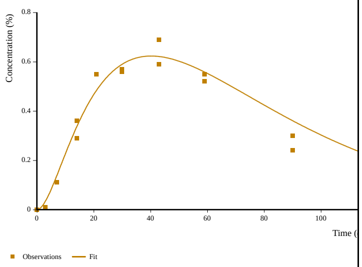
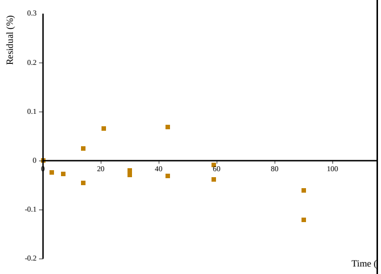
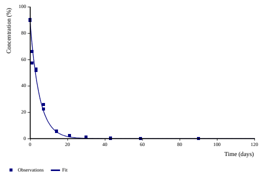
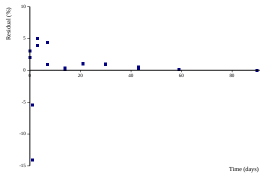
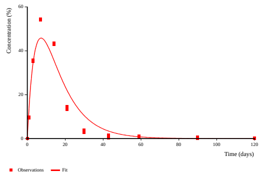
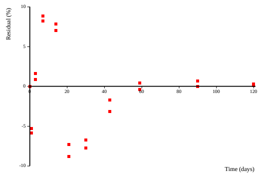
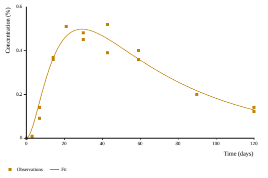
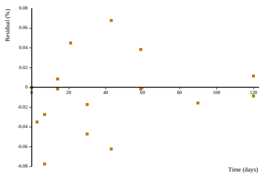
Soil	Vetroz (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
NOA409045			
SYN546520			

Table A 18: Detailed summary of endpoints for Gartenacker soil

Soil	Gartenacker (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
Model	SFO	SFO	SFO
Visual Fit	Good	Acceptable	Good
Residuals	Acceptable	Acceptable	Good
$\chi 2$ error (%)	12.2	26.4	8.00
Optimised M0	87.49	-	-
Optimised rate parameter/ t-test probability	k: 0.2005 $p < 0.01$	k: 0.08901 $p < 0.01$	k: 0.01733 $p < 0.01$
DT_{50}	3.46	7.79	40.0
DT_{90}	11.5	25.9	133
Formation fraction from parent	-	1	-
Formation fraction from NOA409045	-	-	0.008669
FOCUS decision step (Modelling endpoints)	Fit is acceptable	Fit is acceptable	Fit is acceptable
Metalaxyl-M			
NOA409045			

Soil	Gartenacker (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
SYN546520			

High χ2 error was observed for NOA409045. It should be noted that under certain circumstances that statistical quality criteria expected for parent kinetics may not always be achieved for metabolites.

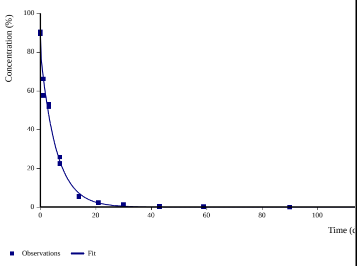
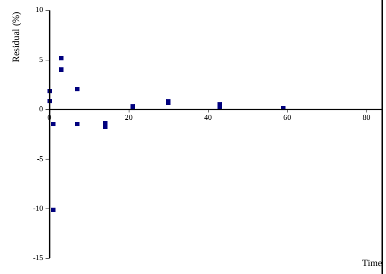
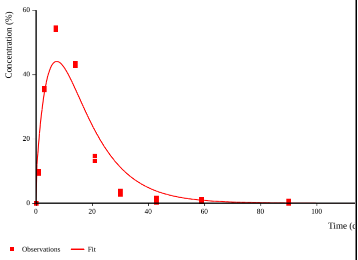
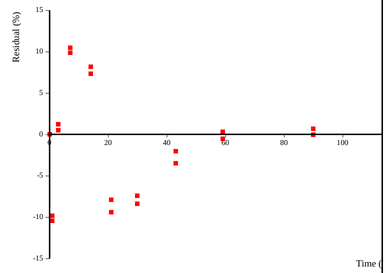
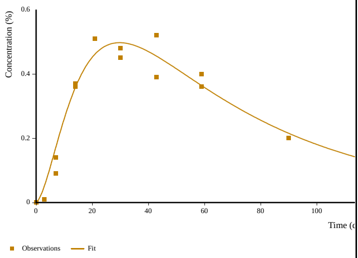
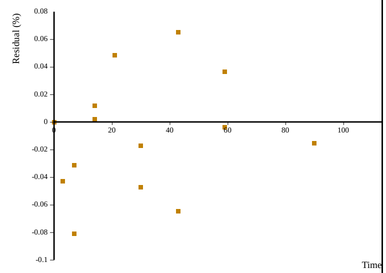
Nevertheless, five different approaches to improve the Gartenacker soil kinetics were attempted, and presented as follows.

1: To test biphasic model for the metabolite (NOA409045).

Metalaxyl-M (parent) was modelled using DFOP kinetics and the subsequent metabolite, analysed using SFO (Table A 19). Due to limitation in CAKE 3.4, only parent biphasic pathway is possible.

Table A 19: Summary of kinetic evaluation for Gartenacker soil using parent (metalaxyl-M) with DFOP fit

Soil	Gartenacker (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
Model	DFOP	SFO	SFO
Visual Fit	Good	Acceptable	Acceptable
Residuals	Acceptable	Acceptable	Acceptable
χ2 error (%)	9.16	31.8	8.62
Optimised M0	88.65	-	-
Optimised rate parameter/ t-test probability	k1 = 258.7 k1 p: n.d k2 = 0.01737 k2 p: <0.01 g= 0.09222	k: 0.08863 p < 0.01	k: 0.01767 p < 0.01
DT_{50}	3.43	7.82	39.2
DT_{90}	12.7	26.0	130
Modelling DT_{50}	3.99	7.82	39.2
Formation fraction from parent	-	1	-
Formation fraction from NOA409045	-	-	0.008668
FOCUS decision step (Modelling endpoints)	Visual and statistical acceptable fit to the data but high χ2 error (%) for NOA409045. Worse χ2 error than SFO pathway		

Soil	Gartenacker (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
Metalaxyl-M			
NOA409045			
SYN546520			

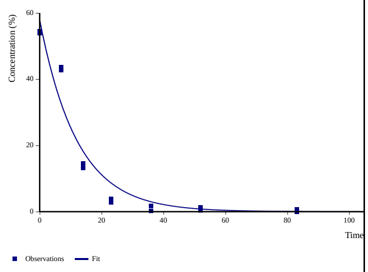
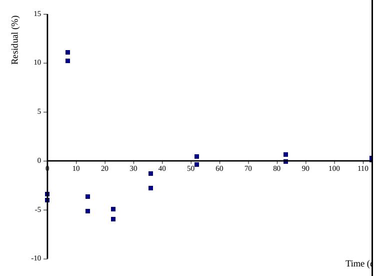
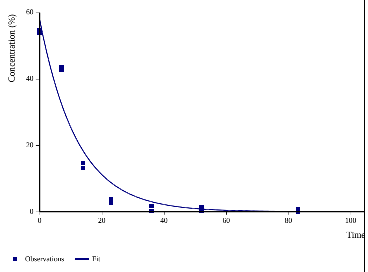
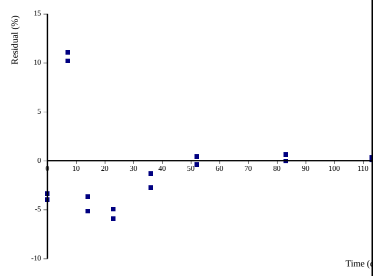
Conclusion: Slight improvement in the χ2 error (%) for the parent (metalaxyl-M) over SFO kinetics (9.16 compared to 12.2) when using DFOP but worse for NOA409045 (31.8 vs 26.4) and SYN546520 (8.62 vs 8.00), in sequence.

SFO kinetic analysis provides acceptable fits visually, despite the slightly high χ2 error observed for NOA409045. Using SFO kinetics for metalaxyl-M is still acceptable within the guidance tolerance for χ2 error (12.2 %) and with the formation fraction of 1, (the formation of N0A409045 cannot be greater) is described as best in the main the report based on the study data.

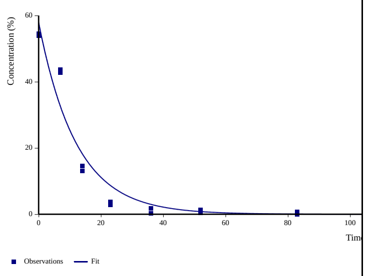
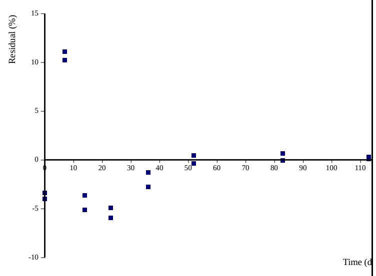
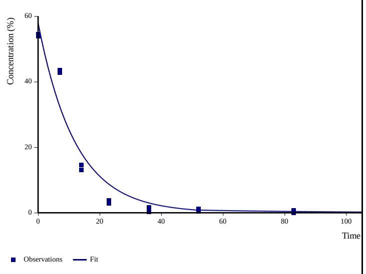
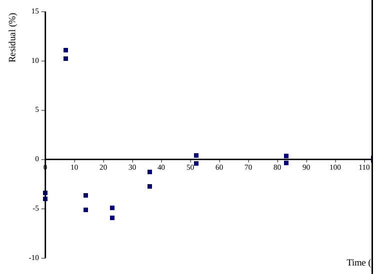
2: Consider NOA409045 as parent and test with SFO/ biphasic models.

The decline curve (from the maximum occurrence) of NOA409045 was fitted below using SFO, FOMC, DFOP and HS to see which kinetic model best described the dissipation (Table A 20). Additionally, using this approach gives no fitting to SYN546520 metabolite, hence no formation fraction.

Table A 20: Summary of kinetic evaluation for Gartenacker soil, using the decline phase for parent (NOA409045)

Soil	Gartenacker (Crabtree, 2021)	
Compartment	NOA409045	
Model	SFO	FOMC
CAKE output location (report page)	57	60
Visual Fit	Acceptable	Acceptable
Residuals	Acceptable	Acceptable
$\chi 2$ error (%)	25.9	27.6
Optimised M0	57.91	57.91
Optimised rate parameter/ t-test probability	k: 0.08239 $p < 0.01$	$\alpha = 2190$ α: n.d. $\beta = 26500$ β: n.d.
DT_{50}	8.41	8.41
DT_{90}	28.0	28.0
Modelling DT_{50}	8.41	8.42
FOCUS decision step (Modelling endpoints)	Acceptable visual but poor statistical fit to the data with high $\chi 2$ error (%).	Acceptable visual but poor statistical fit to the data with no confidence in α and β parameters. Also, high $\chi 2$ error (%)
SFO		
FOMC		

n.d. Not determined

Soil	Gartenacker (Crabtree, 2021)	
Compartment	NOA409045	
Model	DFOP	HS
CAKE output location (report page)	63	66
Visual Fit	Acceptable	Acceptable
Residuals	Acceptable	Acceptable
$\chi2$ error (%)	29.8	29.8
Optimised M0	57.91	57.91
Optimised rate parameter/ t-test probability	k1 = 0.08239 k1 p: 0.5 k2 = 0.08239 k2 p: 0.5 g= 0.6814	k1 = 0.0824 k1 p: <0.01 k2 = 0.02444 k2 p: 0.4644 t_b= 51.53
DT_{50}	8.41	8.41
DT_{90}	28.0	27.9
Modelling DT_{50}	8.41	28.4
FOCUS decision step (Modelling endpoints)	Acceptable visual but poor statistical fit to the data with no confidence in k1 and k2 parameters. Also, high $\chi2$ error (%)	Acceptable visual but poor statistical fit to the data with no confidence in k2 parameter. Also, high $\chi2$ error (%)
DFOP		
HS		

Conclusion: SFO provides the best modelling fit to the data compared to FOMC, DFOP and HS, with over estimation in the DT_{50} (8.41 days) and an acceptable k (<0.01) probability but still high $\chi2$ error (25.9%).

3: Perform a decline fit with NOA409045 and SYN546520 to calculate an optimal DT_{50} value

The decline curve (from the maximum occurrence) of NOA409045 and formation and degradation of

SYN546520 was fitted below using SFO, FOMC, DFOP and HS (for NOA409045) and SFO only for SYN546520 (Table A 21 - Table A 24), to see which kinetic model best describes the dissipation of NOA409045 and subsequent formation and degradation of SYN546520 giving optimal DT_{50}'s. Also with this pathway, a formation fraction from parent (NOA409045) to SYN546520 can be yielded.

Table A 21: Summary of kinetic evaluation for Gartenacker soil, using the decline phase for parent (NOA409045) SFO degrading to SYN546520 (SFO)

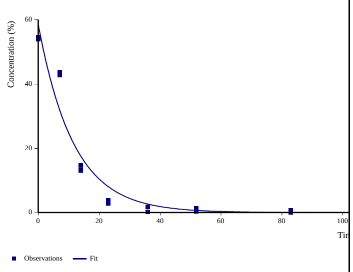
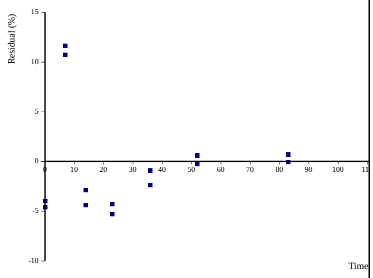
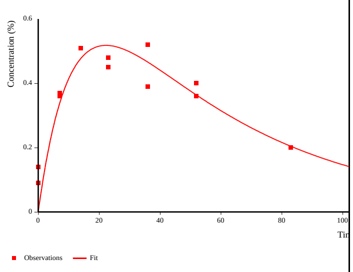
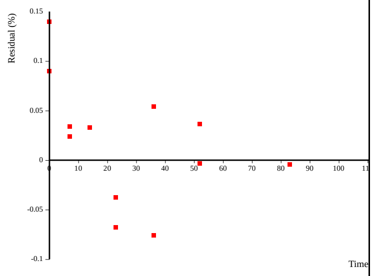
Soil	Gartenacker (Crabtree, 2021)	
Compartment	NOA409045	SYN546520
Model	SFO	SFO
Visual Fit	Acceptable	Acceptable
Residuals	Acceptable	Acceptable
χ2 error (%)	26.0	6.13
Optimised M0	58.52	-
Optimised rate parameter/ t-test probability	k: 0.08617 $p < 0.01$	k: 0.01949 $p < 0.01$
DT_{50}	8.04	35.6
DT_{90}	26.7	118
Modelling DT_{50}	8.04	35.6
Formation fraction from parent (NOA409045)	0.01366	-
FOCUS decision step (Modelling endpoints)	Fit is not acceptable due to high χ2 error (%) for NOA409045. Try FOMC	
NOA409045		
SYN546520		

Table A 22: Summary of kinetic evaluation for Gartenacker soil, using the decline phase for parent (NOA409045) FOMC degrading to SYN546520 (SFO)

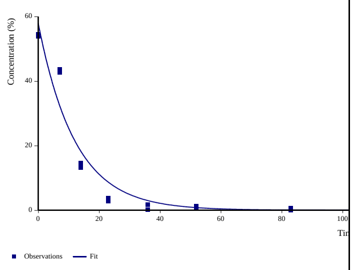
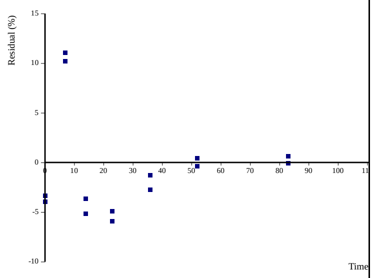
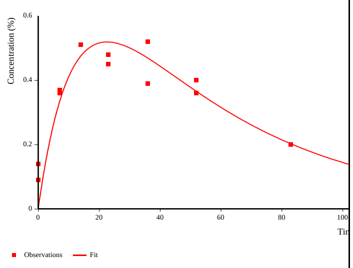
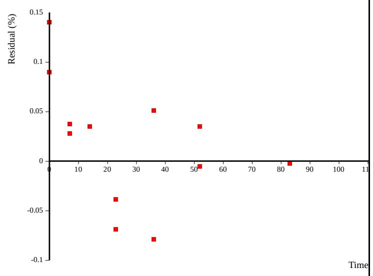
Soil	Gartenacker (Crabtree, 2021)	
Compartment	NOA409045	SYN546520
Model	FOMC	SFO
Visual Fit	Acceptable	Acceptable
Residuals	Acceptable	Acceptable
χ2 error (%)	27.6	6.47
Optimised M0	57.91	-
Optimised rate parameter/ t-test probability	α = 2190 α: 95th centile CI does not contain 0 β = 26500 β: 95th centile CI does not contain 0	k: 0.02015 $p < 0.01$
DT_{50}	8.41	34.4
DT_{90}	28.0	114
Modelling DT_{50}	8.43	34.4
Formation fraction from parent (NOA409045)	0.01414	-
FOCUS decision step (Modelling endpoints)	Fit is not acceptable due to high χ2 error (%) for NOA409045. Try DFOP	
NOA409045		
SYN546520		

Table A 23: **Summary of kinetic evaluation for Gartenacker soil, using the decline phase for parent (NOA409045) DFOP degrading to SYN546520 (SFO)**

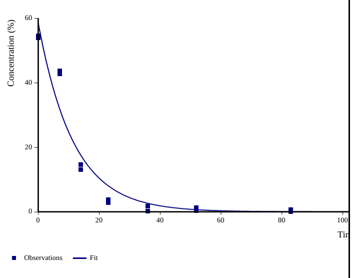
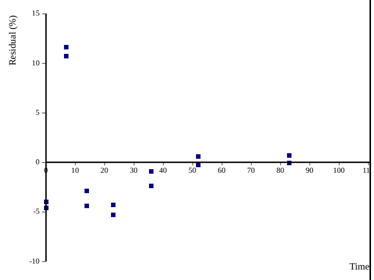
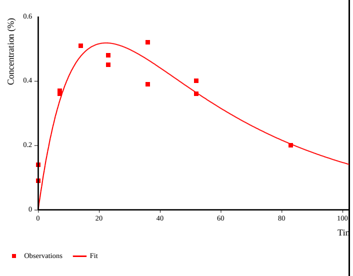
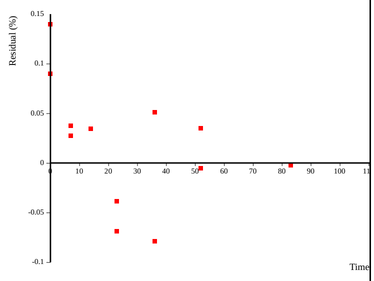
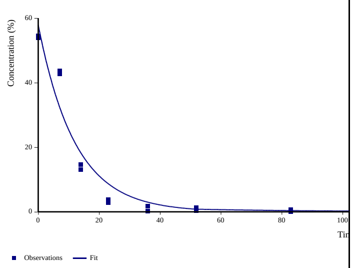
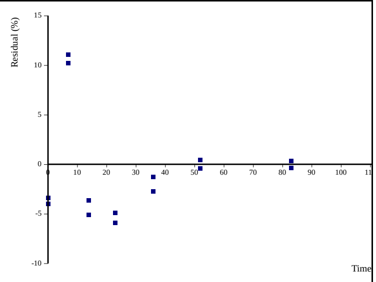
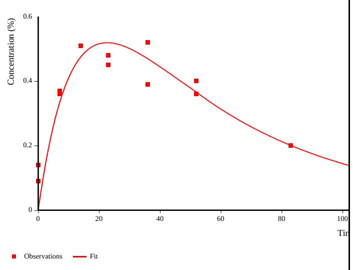
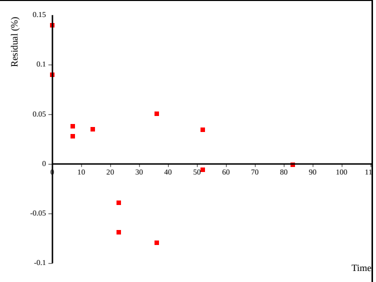
Soil	Gartenacker (Crabtree, 2021)	
Compartment	NOA409045	SYN546520
Model	DFOP	SFO
Visual Fit	Acceptable	Acceptable
Residuals	Acceptable	Acceptable
χ^2 error (%)	30.0	6.13
Optimised M0	58.52	-
Optimised rate parameter/ t-test probability	k1 = 0.08617 k1 p: <0.01 k2 = 0.08617 k2 p: <0.01 g= 0.7017	k: 0.01949 p < 0.01
DT_{50}	8.05	35.6
DT_{90}	26.7	118
Modelling DT_{50}	8.04	35.6
Formation fraction from parent (NOA409045)	0.01366	-
FOCUS decision step (Modelling endpoints)	Fit is not acceptable due to high χ^2 error (%) for NOA409045. Try HS	
NOA409045		
SYN546520		

Table A 24: Summary of kinetic evaluation for Gartenacker soil, using the decline phase for parent (NOA409045) HS degrading to SYN546520 (SFO)

Soil	Gartenacker (Crabtree, 2021)	
Compartment	NOA409045	SYN546520
Model	HS	SFO
Visual Fit	Acceptable	Acceptable
Residuals	Acceptable	Acceptable
$\chi 2$ error (%)	30.0	6.12
Optimised M0	58.52	-
Optimised rate parameter/ t-test probability	k1 = 0.08615 k1 p: <0.01 k2 = 0.02852 k2 p: 0.4783 t_b= 52.3	k: 0.01944 p < 0.01
DT_{50}	8.05	35.7
DT_{90}	26.7	118
Modelling DT_{50}	24.3	35.7
Formation fraction from parent (NOA409045)	0.01366	-
FOCUS decision step (Modelling endpoints)	Fit is not acceptable due to high $\chi 2$ error (%) for NOA409045	
NOA409045		
SYN546520		

FFM = 1 (from metalaxyl-M) to NOA409045

Conclusion: SFO pathway provides the best modelling fit to the data compared to FOMC, DFOP and HS, with an over estimation in the DT_{50} (8.04 days) and an acceptable k probability (<0.01) but a high $\chi 2$ error (26.0) for NOA409045 and DT_{50} of 35.6 days, probability of <0.01 and $\chi 2$ error 6.13 for

SYN546520 using SFO.
FFM = 0.01366 (from NOA409045 to SYN546520)

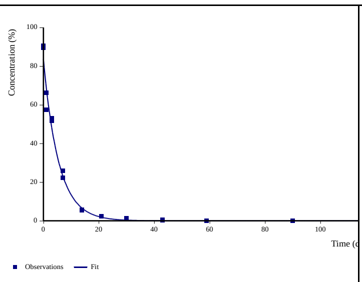
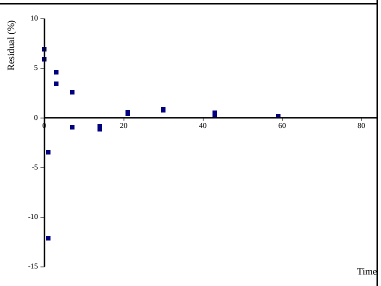
4: Conservative estimate of NOA409045 DT_{50} and degradation

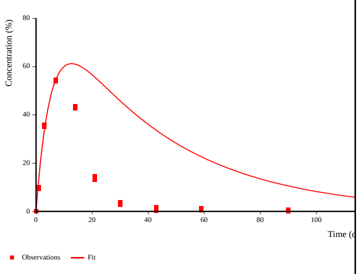
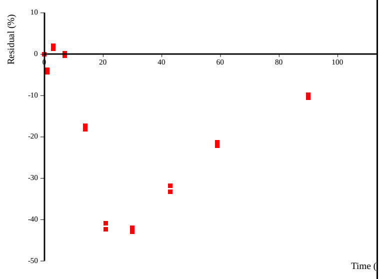
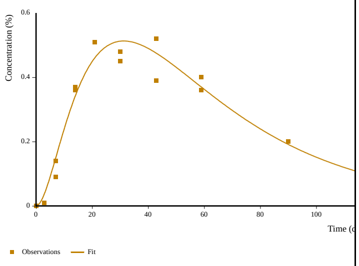
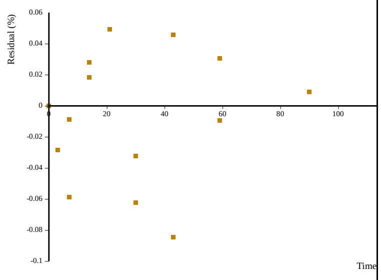
Parameters Fixed: FFM from Metalaxyl-M to NOA409045 of 1.

DT_{50} of NOA409045 to 26.25 days (calculated based on based geomean of 12 soils, 10 soils taken from EFSA conclusion and 2 soils from this study (VV-899796).

Kinetic model – SFO for parent (metalaxyl-M) and its metabolites (NOA409045 and SYN546520) (Table A 25).

Table A 25: Summary of kinetic evaluation for Gartenacker soil, using the proposed pathway for parent (metalaxyl-M) (SFO) degrading to NOA409045 (SFO) and in turn SYN546520 (SFO)

Soil	Gartenacker (Crabtree, 2021)		
Compartment	Metalaxyl-M	NOA409045	SYN546520
Model	SFO	SFO	SFO
Visual Fit	Acceptable	Acceptable	Acceptable
Residuals	Acceptable	Acceptable	Acceptable
χ^2 error (%)	11.7	102	9.01
Optimised M0	83.58	-	-
Optimised rate parameter/ t-test probability	k: 0.1823 $p < 0.01$	k: 0.02641 (fixed)	k: 0.0582 $p < 0.01$
DT_{50}	3.78	26.2	11.9
DT_{90}	12.6	87.2	39.6
Modelling DT_{50}	3.78	26.2	11.9
Formation fraction from parent	-	1 (fixed)	-
Formation fraction from NOA409045	-	-	0.0269
FOCUS decision step (Modelling endpoints)	Visual and statistical acceptable fit to the data but high χ^2 error (%) for NOA409045 as k is fixed providing a conservative estimation of the degradation. Worse χ^2 error for NOA409045 than SFO (unbound)		
Metalaxyl			

NOA409045		
SYN546520		

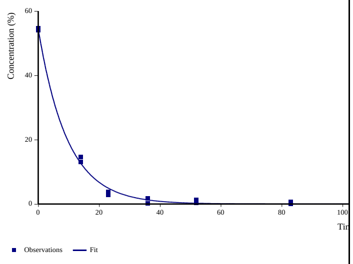
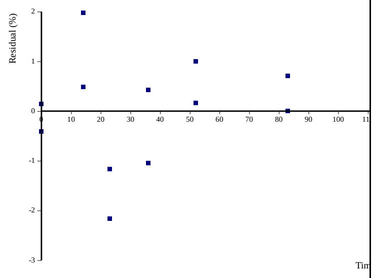
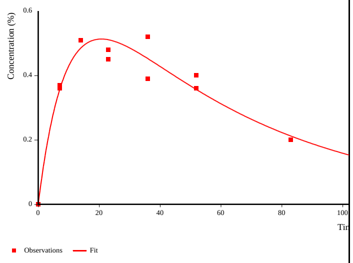
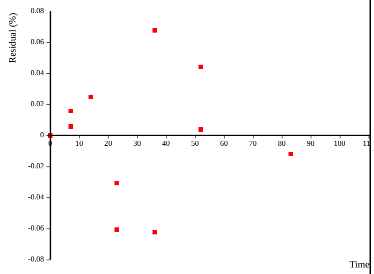
Conclusion: The overall fit to the data using a fixed formation fraction of 1 and a fixed DT_{50} of 26.2 days for NOA409045 shows a very conservative formation and decline of NOA409045. However, this yields a $\chi2$ error of 107% and in turn also provides a conservative formation fraction of 0.0269 from NOA409045 to SYN546520.

5: Consideration of an outlier in the NOA409045 dataset

Treating NOA409045 as parent and evaluating data points which visually appear to impact statistical quality, Day 14 was considered as an outlier from the original dataset (or Day 7 for decline from NOA409045 maximum) and was removed. NOA409045 was initiated from the maximum occurrence (decline) as well as the formation/ decline of SYN546520. (Table A 26).

Table A 26: Summary of kinetic evaluation for Gartenacker soil, using the decline phase for parent (NOA409045) as SFO omitting Day 14 and degrading to SYN546520 (SFO)

Soil	Gartenacker (Crabtree, 2021)	
Compartment	NOA409045	SYN546520
Model	SFO	SFO
Visual Fit	Good	Acceptable
Residuals	Acceptable	Acceptable
$\chi2$ error (%)	6.32	5.01
Optimised M0	54.48	-
Optimised rate parameter/ t-test probability	k: 0.1043 $p < 0.01$	k: 0.01705 $p < 0.01$
DT_{50}	6.65	40.6
DT_{90}	22.1	135
Modelling DT_{50}	6.65	40.6

Formation fraction from parent (NOA409045)	0.01341	-
NOA409045		
SYN546520		

Conclusion Visual fit improved as well as χ2 error (%) and DT_{50} for both NOA049045 and SYN546520 in comparison to point 3 (SFO).

The conclusion drawn after thorough examination of five alternative Gartenacker kinetics techniques evaluated, was that the original SFO kinetics derive the most appropriate description of degradation, albeit with slightly high NOA409045 χ2 error.

Conclusions

Geomean DT_{50} values for metalaxyl-M, NOA409045 and SYN546520 were determined as 3.99, 14.5 and 35.7 days, respectively, in three soils.

An arithmetic mean formation fraction value of 0.0130 for SYN546520 from NOA409045 was determined in three soils.

A 3.3 KCP 9.1.1: Patel, M., 2021, Kinetic evaluation of Formation Fraction with EFSA endpoints

Comments of izRMS:	The proposition of SYN546520 (CGA108906) formation fraction of 0.1 is acceptable to be used in the PEC_{gw} calculations by izRMS (and EU RMS-BE – RAR 2022).

Reference:	KCP 9.1.1
Report	Kinetic evaluation of Formation Fraction with EFSA endpoints Patel, M. 2021 Report Number RAJ1447B Syngenta Ltd, Jealott's Hill International Research Centre, Bracknell, Berkshire, RG42 6EY UK Syngenta File No. VV-933662 and excel file VV-933663
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

Materials and methods

This report demonstrates how the formation fraction of 0.47 for SYN546520 (metabolite of metalaxyl-M) from the EFSA List of Endpoints 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 Jones, 2012, and Ford 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 IIA 7.2.3-3.

The route and rate of degradation of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520/CGA108906 was studied in 3 laboratory studies (Miner and Herczog, 2012a and b and Crabtree, 2021) and in 2 lysimeter studies (Kubiak, 1995 and 1996). The data from these studies was used to calculate the rate of degradation of metalaxyl-M and its metabolites in soil or water/ sediment, following the guidance in FOCUS Kinetics (2006). Details of the study data values used in the evaluation are presented in Jones, 2012, Ford, 2013 and Patel, 2021b. From these studies, DT_{50}s and formation fractions (ff) for each compound were derived.

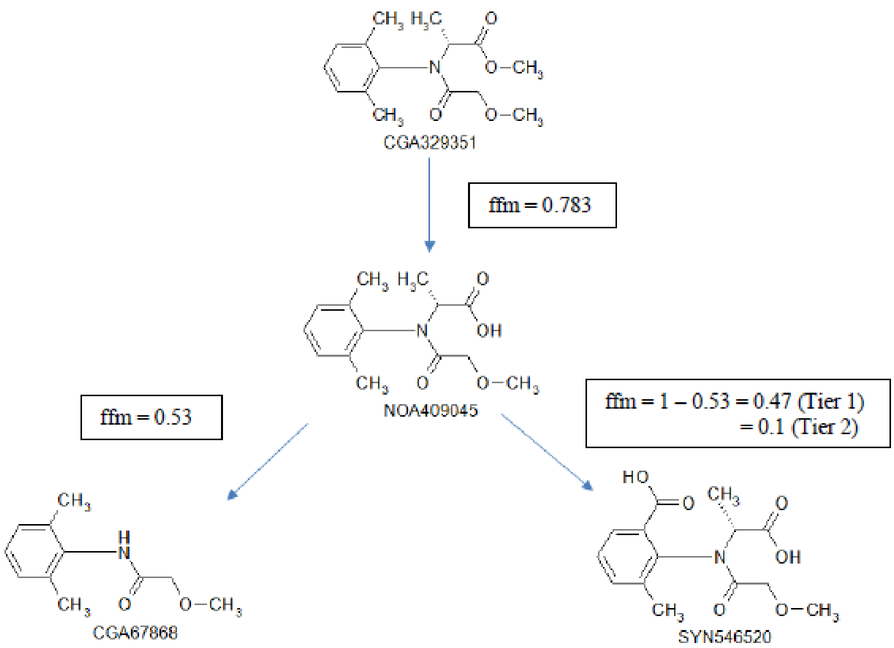
Whilst CGA108906 was observed in the lysimeter studies (Kubiak, 1995 and 1996), it did not exceed

5% of application rate in the soil laboratory studies (Miner and Herczog, 2012a and b and Crabtree, 2021). However, based on parallel metabolite CGA67868 ff = 0.53 in Gartenacker soil only (Miner and Herczog, 2012; Jones, 2012), RMS Belgium proposed a conservative ff = 0.47 (derived from 1 - 0.53) for CGA108906 forming from NOA409045. It should be noted that CGA108906 was not observed in this study and the maximum unidentified radioactive component was <2.3% applied radioactive residue (ARR).

During Annex 1 Renewal evaluation CGA108906 ff was available for two soils (Gartenacker and Borstel). An EFSA Expert meeting concluded that an arithmetic mean could not be calculated when information was available on fewer than three soils. Therefore, EFSA specified the highest 0.47 ff in the RAR List of Endpoints as the modelling endpoint until further soil data were available.

Subsequently, a further laboratory study was conducted Crabtree 2021, to derive a ff for a third soil (18 Acres, Vetroz and Gartenacker), which was kinetically evaluated in Patel, 2021, amended 2022.
From the kinetic studies of Jones, 2012, and Ford 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.

Figure A 2: Proposed degradation pathway and formation fractions for metalaxyl-M and its metabolites in soil



Data from Miner and Herczog, 2012a on a Gartenacker soil was re-evaluated to establish hypothetical CGA108906 concentrations expected from a ff of 0.47 and estimate a ff using the maximum unidentified component concentration, as CGA108906 was not observed (<2.3%).
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 27.

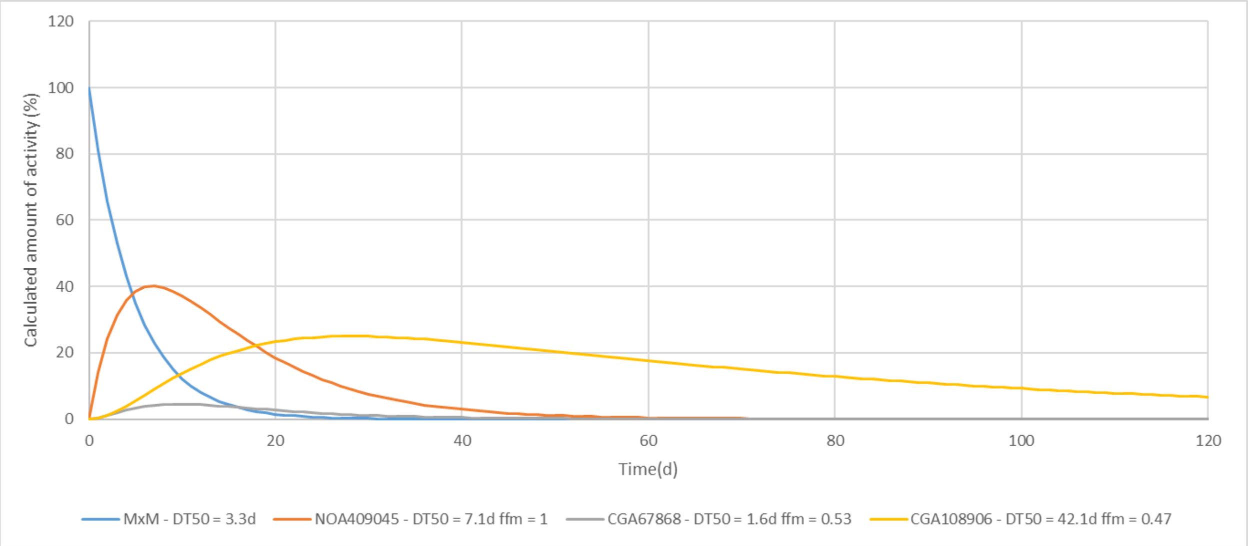
Table A 27: Half-life and formation fraction values for metalaxyl-M and its metabolites in Gartenacker soil from Miner & Herczog, 2012b and Jones, 2012.

Compound	DegT50 (d)	Formation Fraction (ff)	Evaluation Status
Metalaxyl-M	3.3	-	Annex I Renewal Review Assessment Report, 2015
Acid metabolite NOA409045	7.1	0.783 (from parent)	
Amide CGA67868	1.6	0.53	
Diacid metabolite SYN546520 (CGA108906)	42.1	Tier I Belgium RMS proposed conservative 0.47 (1 - 0.53) (from NOA409045)	
		Tier II 0.1	

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 ff were inputted into the SFO model spreadsheet and the outputs of the model are presented in Figure A 3 and Figure A 4, respectively.

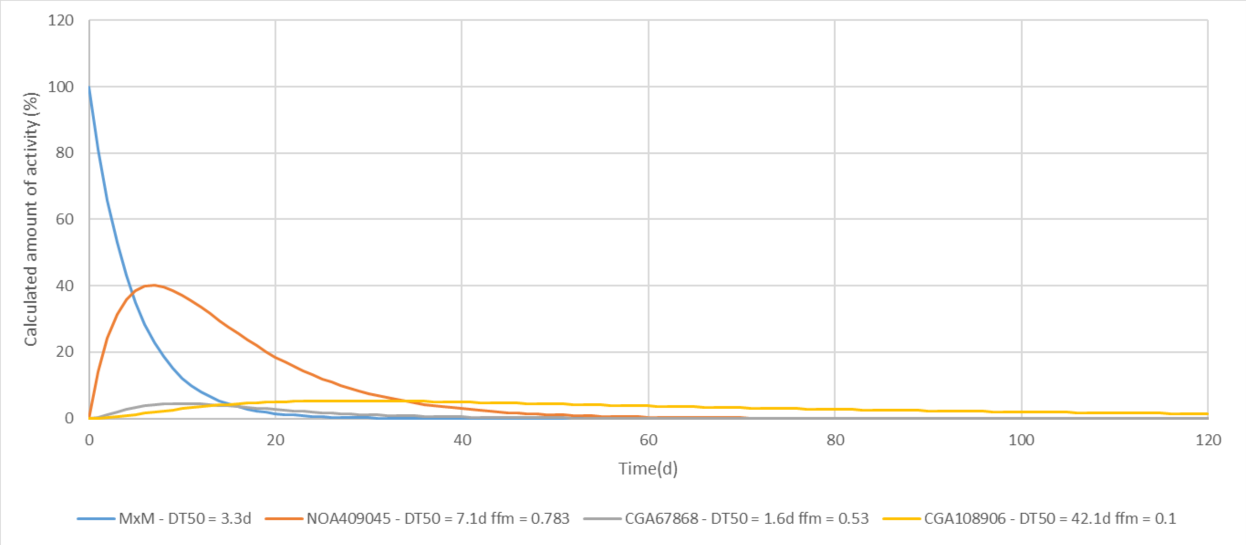
Figure A 3: Formation and decay curves of metalaxyl-M and its metabolites using CGA108906 0.47 Tier 1 ff based on EFSA 2015 Gartenacker endpoints.



Max of NOA409045 predicted = 40.24%
Max of CGA67868 predicted = 4.49%
Max of CGA108906 predicted = 25.01% (overly conservative), CGA108906 was not observed >2.3%

From Figure IIA 7.2.3-4, a CGA108906 ff value of 0.47 leads to a maximum predicted value of CGA108906 of 25.01%. Whereas from Figure IIA 7.2.3-5 a CGA108906 ff value of 0.1 leads to a maximum predicted value of CGA108906 of 5.32%. Since CGA108906 was not observed in the Gartenacker soil and the maximum unidentified radioactive component was <2.3%, both ff values are therefore very conservative.

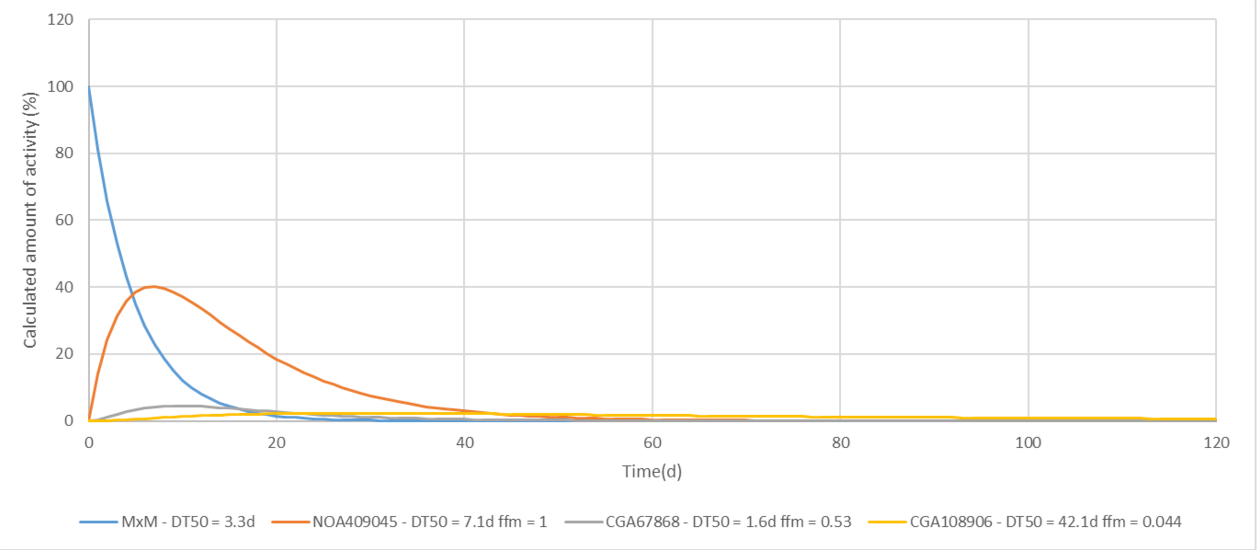
Figure A 4: Formation and decay curves of metalaxyl-M and its metabolites using CGA108906 0.1 Tier 2 ff based on EFSA 2015 Gartenacker endpoints.



Max of NOA409045 predicted = 40.24%
Max of CGA67868 predicted = 4.49%
Max of CGA108906 predicted = 5.32% (still very conservative), CGA108906 was not observed >2.3%

Values of ff were then tested to determine the maximum CGA108906 ff that does not lead to an exceedance of 2.3%. Figure A 5 demonstrates that a CGA108906 ff of 0.044 leads to a maximum predicted value of CGA108906 of 2.3%.

Figure A 5: Formation and decay curves of metalaxyl-M and its metabolites using estimated CGA108906 0.044 ff based on EFSA 2015 Gartenacker endpoints.

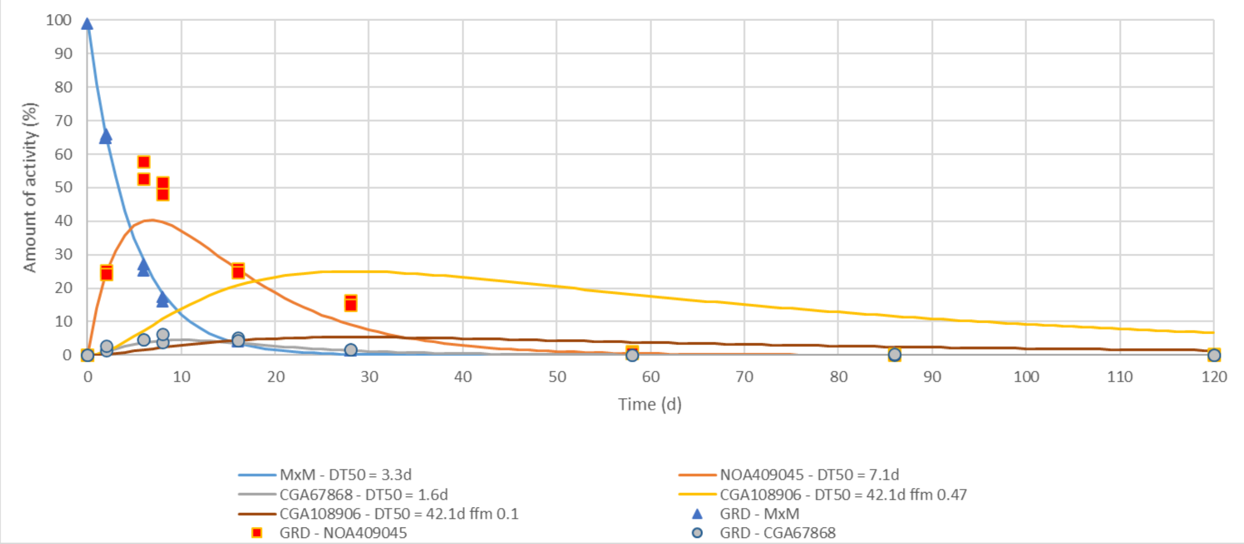


Max of NOA409045 predicted = 40.24 %
Max of CGA67868 predicted = 4.49%
Max of CGA108906 predicted = 2.33%, maximum unidentified component

The CGA108906 formation fraction of 0.044 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 Miner and Herczog, 2012a, study, that is CGA108906 was < 2.3% ARR.

Figure A 6 shows the residue data from the Gartenacker soil superimposed onto the predicted data for metalaxyl-M and its metabolites, and 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 0.044 and not 0.47 as proposed by Belgium RMS at Tier I.

Figure A 6: Formation and decay curves of metalaxyl-M and its metabolites using estimated CGA108906 0.044 ff based on EFSA 2015 Gartenacker endpoints.



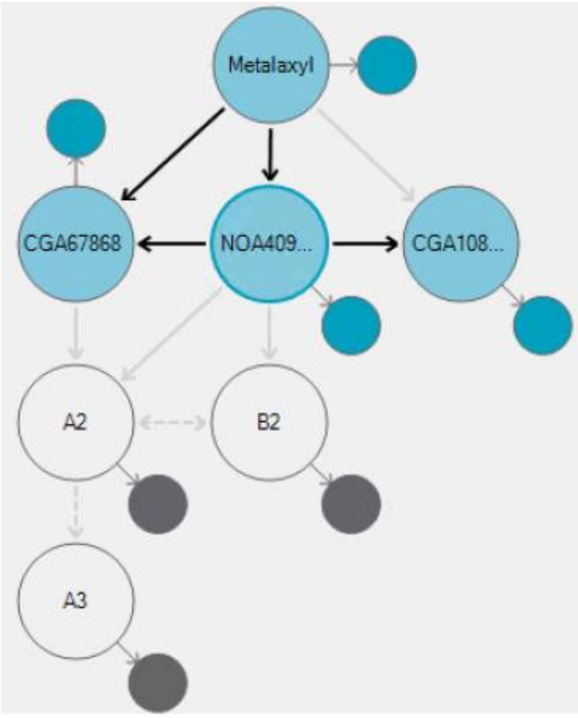
GRD = Gartenacker Residue Data

Additionally, an alternative degradation pathway proposed by Patterson and Boardman, 2021, was further evaluated. The only difference from this new pathway and that presented in Figure A 7, is the availability of a direct degradation pathway from parent to CGA67868 which was considered chemically viable.

Therefore, this schematic pathway was kinetically assessed using the input parameters in Table A 27 as well as the ff of CGA67868 as described below.

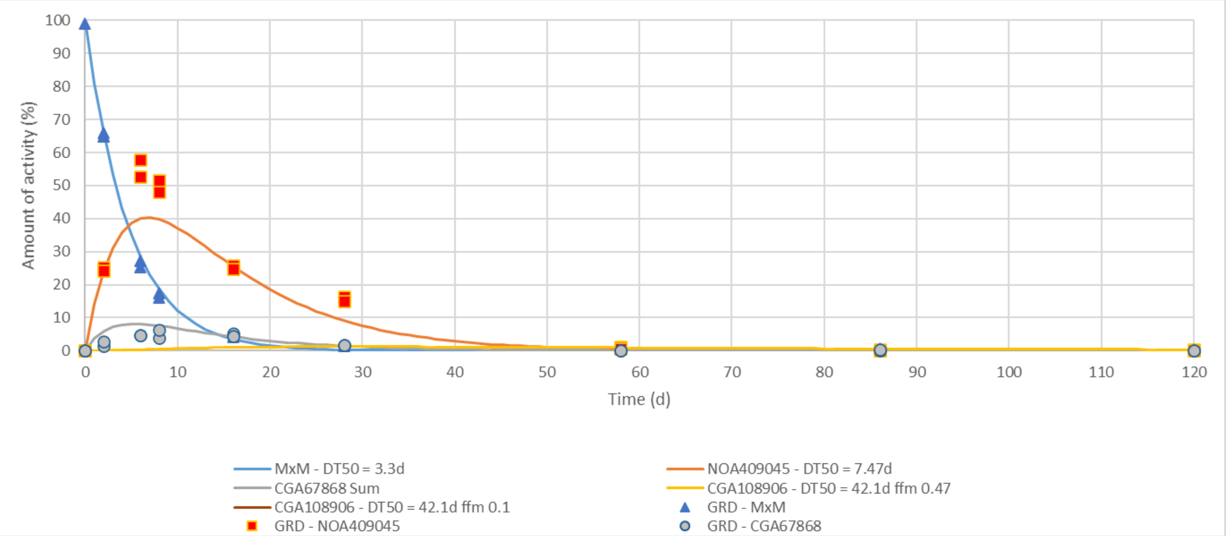
A revised CGA67868 formation fraction was derived from 1-0.783 (parent to NOA409045 ff), that is 0.217 direct from parent, plus 0.53 formation fraction from NOA409045. The combined CGA67868 formation fraction derived was 0.747.

Figure A 7: Alternative degradation pathway and formation fractions for metalaxyl-M and its metabolites in soil by Patterson and Boardman, 2021



From this hypothesis, the revised fits of metalaxyl-M and its metabolites are displayed in Figure A 8. The fit for CGA67868 overestimates the CGA67868 datapoints, compared to a better CGA67868 fit seen in Figure A 8, indicating that addition of a direct sink from parent to amide metabolite reduces the acceptability of the visual fit and therefore does not add validity to the hypothesis.

Figure A 8: Formation and decay curves of metalaxyl-M and its metabolites incorporating direct parent to amide sink (Patterson and Boardman, 2021).



Conclusions

Re-evaluation of the Gartenacker soil data (Miner, and Herczog, 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 have been 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, SYN546520 (CGA10896) would be anticipated to be observed at >10% applied radioactive residue (ARR) at seven time points in the Miner and Herczog 2012a study, reaching a maximum of 25% of ARR. Whereas, in the soil study, CGA108906 was not 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 fails to consider other possible sink routes, e.g., to carbon dioxide.

This report has also shown that assuming the maximum 2.3% unidentified component to be CGA108906, this would result in a SYN546520 (CGA108906) formation fraction of 0.044 in Gartenacker soil. The CGA108906 formation fraction of 0.044 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 Miner and Herczog, 2012a study, that is CGA108906 was < 2.3% ARR. The Crabtree 2021 study (and associated Kinetics report, Patel 2021a) which derived a FF of 0.009 for Gartenacker soil confirm this conservatism.

In addition, the formation fraction of 0.044 derived in this report for Gartenacker soil is consistent with formation fractions in other soils

- - 0.035 in Borstel soil (Ford 2013),
- - 0.011, 0.019, 0.009 in 18 Acres, Vetroz and Gartenacker, respectively (Patel 2021, Amended 2022)

In conclusion and to introduce a further degree of conservatism and considering ff <0.05 in four soils, this study therefore proposes that a CGA108906 formation fraction of 0.1 is appropriate to be used as a modelling endpoint.

The analysis of an alternative pathway with inclusion of a direct “parent to CGA67868” formation worsened the CGA67868 kinetic fit.

A 3.4 KCP 9.1.3: Metalaxyl-M - PECs following application to lettuce

Comments of izRMS:	All input parameters for metalaxyl-M and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{soil} calculations acceptable for the parent and its metabolites.

Simulation of $PEC_{S,ini}$, short-term and long-term PEC_S values as well as $PEC_{S,plateau}$ and $PEC_{S,accumulation}$ were carried out using the tool ESCAPE (v.2). ESCAPE output files for metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 are presented below.

Metalaxyl-M, lettuce, 2 x 87.2 g/ha, BBCH 12

ESCAPE

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 13:47:33
Calculation problem: Mefenoxam

PROGRAM SETTINGS

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

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: MFX, Lettuce, BBCH 12
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications :	2
1st Application date:	1 May
Application rate (g/ha):	87.2
Time between two applications (d):	7
Crop interception (%):	25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for Mefenoxam:	Single First order (SFO)
DT50 (d):	30.9
Rate constant (1/d):	0.0224
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Mefenoxam

Calculations over one year

Maximum annual total soil concentration for Mefenoxam over 5 cm(mg/kg): 0.1617
occurring on day 7

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

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1581	0.1599	7	8
2	0.1546	0.1582	7	9
4	0.1478	0.1547	7	11
7	0.1382	0.1497	7	14
14	0.1181	0.1388	7	21
21	0.1010	0.1298	6	27
28	0.0863	0.1212	6	34
42	0.0630	0.1079	0	42

50	0.0527	0.1014	0	50
100	0.0172	0.0692	0	100

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

Calculation of background concentrations after many years

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

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

Reduction factor to account for crop rotation: 1

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

Calculations of concentrations considering accumulation after many years of application

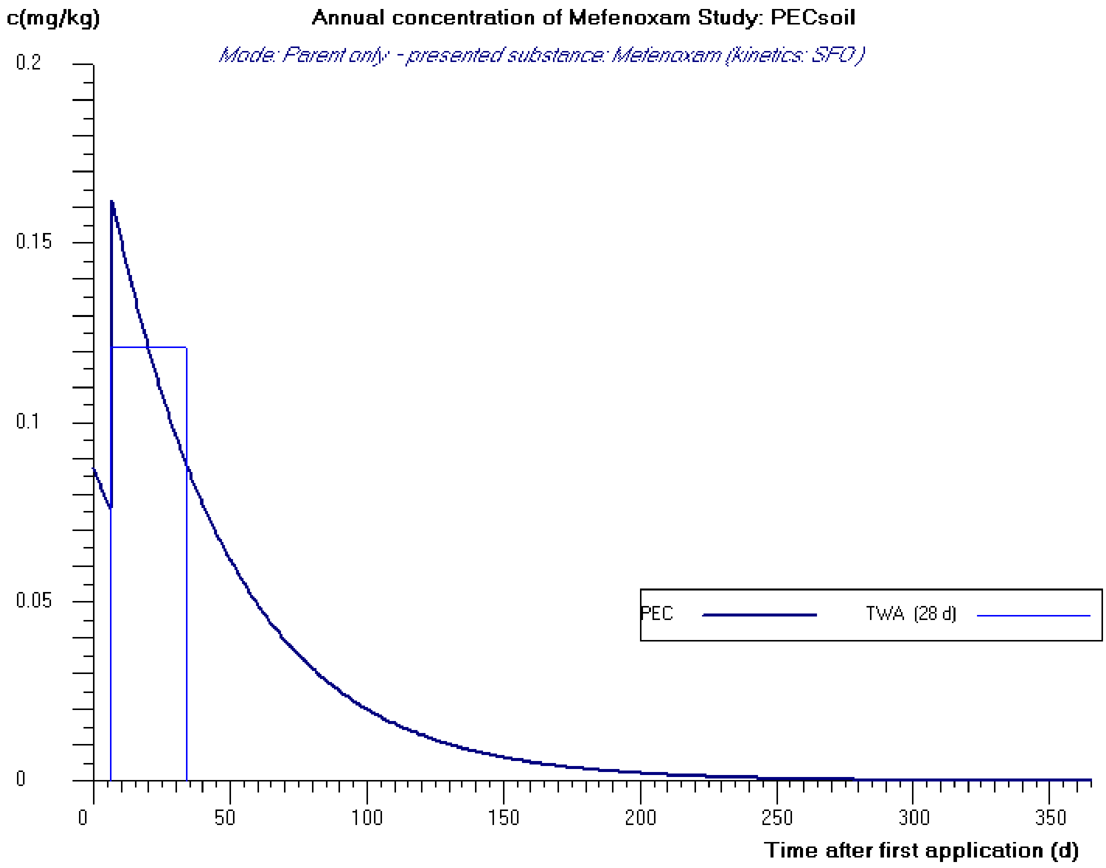
Maximum total soil concentration for Mefenoxam over 5 cm considering accumulation* (mg/kg) 0.1617
(* a tillage depth of 20 cm was considered for calculating the background concentration)

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

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1582	0.1599	7	8
2	0.1546	0.1582	7	9
4	0.1479	0.1547	7	11
7	0.1382	0.1497	7	14
14	0.1182	0.1388	7	21
21	0.1010	0.1298	6	27
28	0.0863	0.1212	6	34
42	0.0631	0.1079	0	42
50	0.0527	0.1014	0	50
100	0.0172	0.0692	0	100

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

GRAPHIC REPRESENTATION OF THE CALCULATION



NOA409045, lettuce, 1 x 87.2 g/ha, BBCH 12

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 13:56:12
Calculation problem: NOA409045

PROGRAM SETTINGS

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

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario:	NOA409045, Lettuce, BBCH 12
Name of the soil:	Borstel
Soil density (kg/L):	1.5
Soil depth (cm):	5
Tillage depth (cm)*:	20
Organic carbon content (%):	1.5
Field capacity (Vol%):	29.2
Wilting point (Vol%):	6.4
Climatic conditions:	20 °C constant

(* for calculation of background concentrations)

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications :	2
1st Application date:	1 May
Application rate (g/ha):	59.637
Time between two applications (d):	7
Crop interception (%):	25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for NOA409045:	Single First order (SFO)
DT50 (d):	39.8
Rate constant (1/d):	0.0174
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: NOA409045

Calculations over one year

Maximum annual total soil concentration for NOA409045 over 5 cm(mg/kg): 0.1124
occurring on day 7

Calculated time dependent total soil concentrations over 5 cm for NOA409045 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1105	0.1115	7	8
2	0.1086	0.1105	7	9
4	0.1049	0.1086	7	11
7	0.0995	0.1058	7	14
14	0.0881	0.0998	7	21
21	0.0780	0.0944	6	27
28	0.0690	0.0895	6	34
42	0.0541	0.0804	6	48
50	0.0471	0.0765	0	50
100	0.0197	0.0560	0	100

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

Calculation of background concentrations after many years

Final Background concentration in total soil for NOA409045 over 20 cm(mg/kg): <0.0001**

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

Reduction factor to account for crop rotation: 1

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

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for NOA409045 over 5 cm considering accumulation* (mg/kg) 0.1125
(* a tillage depth of 20 cm was considered for calculating the background concentration)

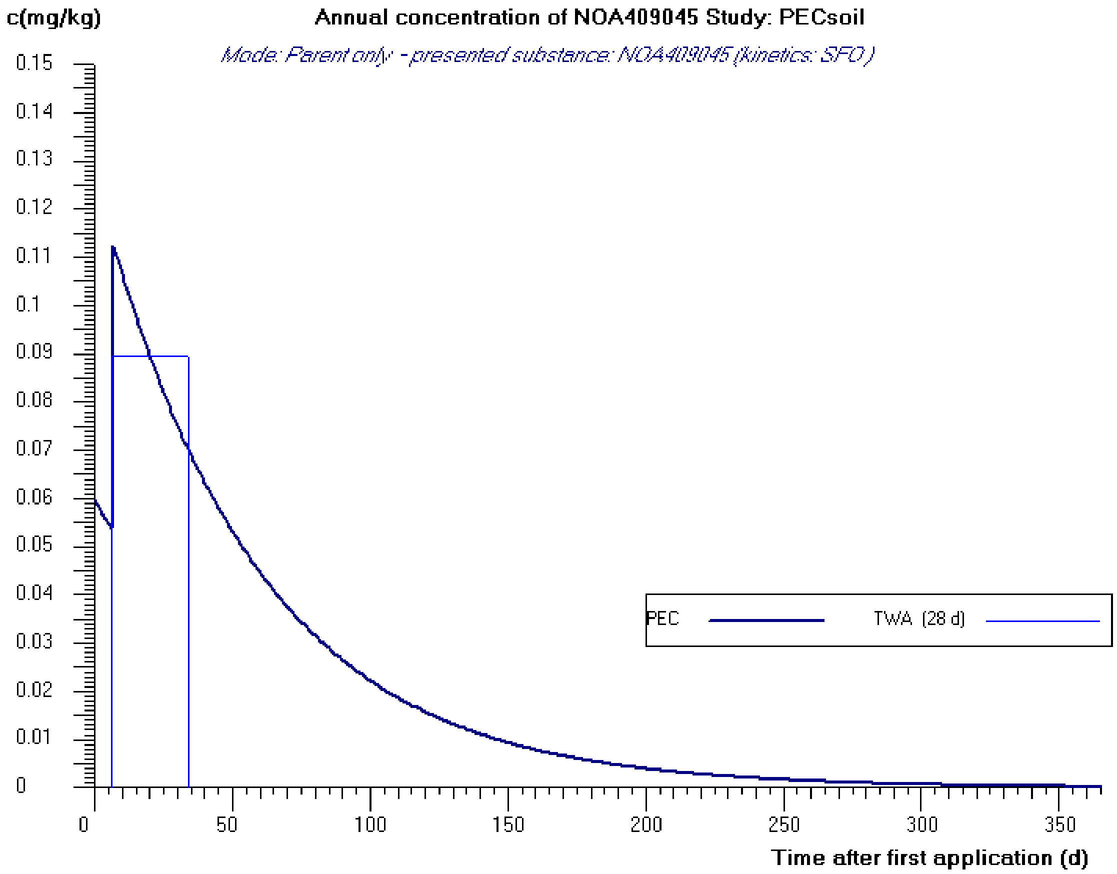
Calculated time dependent total soil concentrations over 5 cm for NOA409045(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.1105	0.1115	7	8
2	0.1086	0.1105	7	9

4	0.1049	0.1087	7	11
7	0.0996	0.1059	7	14
14	0.0882	0.0998	7	21
21	0.0780	0.0944	6	27
28	0.0691	0.0895	6	34
42	0.0542	0.0805	6	48
50	0.0471	0.0766	0	50
100	0.0198	0.0561	0	100

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

GRAPHIC REPRESENTATION OF THE CALCULATION



CGA67868, lettuce, 2 x 15 g a.s./ha, BBCH 12

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 13:59:19
Calculation problem: CGA67868

PROGRAM SETTINGS

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

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: CGA67868, Lettuce, BBCH 12
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications : 2
1st Application date: 1 May
Application rate (g/ha): 3.619
Time between two applications (d): 7
Crop interception (%): 25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for CGA67868:	Single First order (SFO)
DT50 (d):	4.9
Rate constant (1/d):	0.1415
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: CGA67868

Calculations over one year

Maximum annual total soil concentration for CGA67868 over 5 cm(mg/kg): 0.0050
occurring on day 7

Calculated time dependent total soil concentrations over 5 cm for CGA67868 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0043	0.0046	7	8
2	0.0037	0.0043	7	9
4	0.0028	0.0039	6	10
7	0.0018	0.0033	6	13
14	0.0007	0.0029	0	14
21	0.0003	0.0023	0	21
28	0.0001	0.0018	0	28
42	<0.0001	0.0013	0	42
50	<0.0001	0.0011	0	50
100	<0.0001	0.0005	0	100

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

Calculation of background concentrations after many years

Final Background concentration in total soil for CGA67868 over 20 cm(mg/kg): <0.0001**

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

Reduction factor to account for crop rotation: 1

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

Calculations of concentrations considering accumulation after many years of application

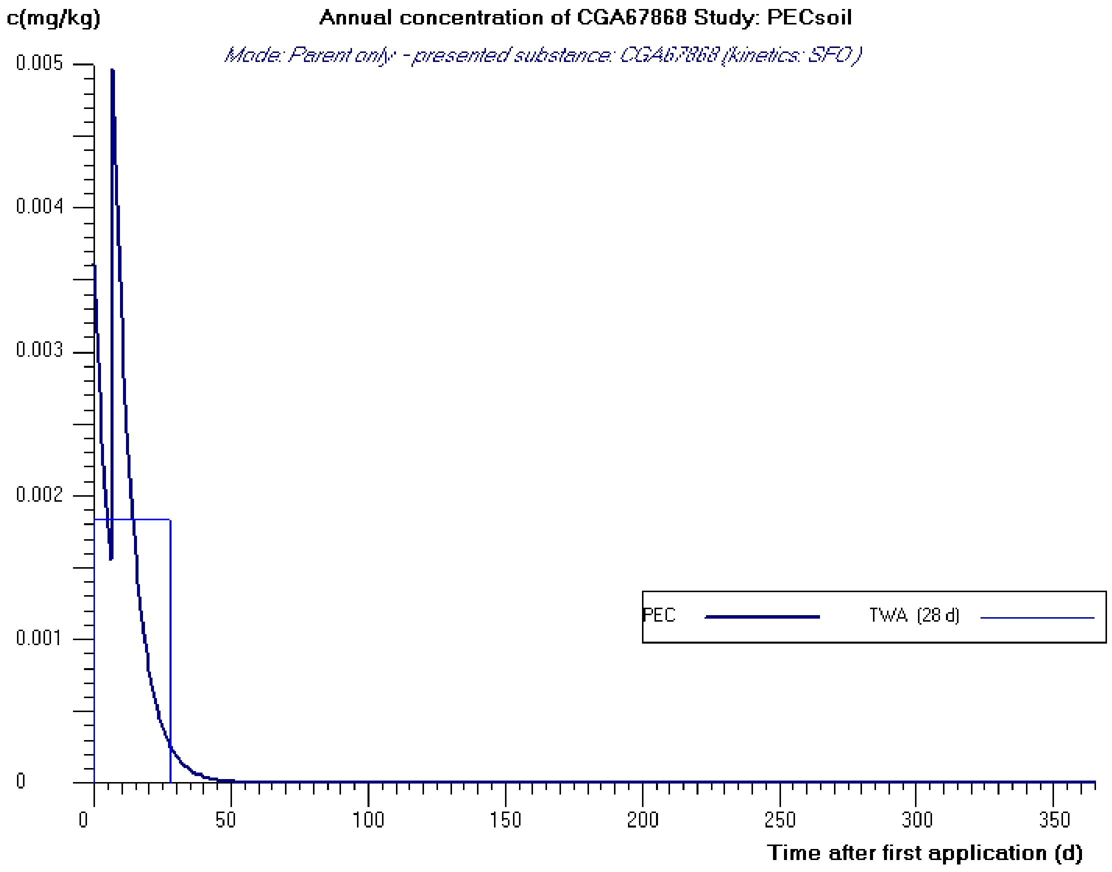
Maximum total soil concentration for CGA67868 over 5 cm considering accumulation* (mg/kg)
0.0050
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for CGA67868(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0043	0.0046	7	8
2	0.0037	0.0043	7	9
4	0.0028	0.0039	6	10
7	0.0018	0.0033	6	13
14	0.0007	0.0029	0	14
21	0.0003	0.0023	0	21
28	0.0001	0.0018	0	28
42	<0.0001	0.0013	0	42
50	<0.0001	0.0011	0	50
100	<0.0001	0.0005	0	100

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

GRAPHIC REPRESENTATION OF THE CALCULATION



SYN546520, lettuce, 2 x 87.2 g a.s./ha, BBCH 12

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 14:03:20
Calculation problem: SYN54620

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Iteration of annual application pattern over 10 years

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario:	SYN54620, Lettuce, BBCH 12
Name of the soil:	Borstel
Soil density (kg/L):	1.5
Soil depth (cm):	5
Tillage depth (cm)*:	20
Organic carbon content (%):	1.5
Field capacity (Vol%):	29.2
Wilting point (Vol%):	6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications :	2
1st Application date:	1 May
Application rate (g/ha):	3.688
Time between two applications (d):	7
Crop interception (%):	25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for SYN54620:	Single First order (SFO)
DT50 (d):	287.9
Rate constant (1/d):	0.0024
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: SYN54620

Calculations over one year

Maximum annual total soil concentration for SYN54620 over 5 cm(mg/kg): 0.0073
occurring on day 7

Calculated time dependent total soil concentrations over 5 cm for SYN54620 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0073	0.0073	7	8
2	0.0073	0.0073	7	9
4	0.0072	0.0073	7	11
7	0.0072	0.0073	7	14
14	0.0071	0.0072	7	21
21	0.0070	0.0071	7	28
28	0.0068	0.0071	7	35
42	0.0066	0.0070	7	49
50	0.0065	0.0069	7	57
100	0.0057	0.0065	7	107

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

Calculation of background concentrations after many years

Final Background concentration in total soil for SYN54620 over 20 cm(mg/kg): 0.0013**

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

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0013

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for SYN54620 over 5 cm considering accumulation* (mg/kg) 0.0086
(* a tillage depth of 20 cm was considered for calculating the background concentration)

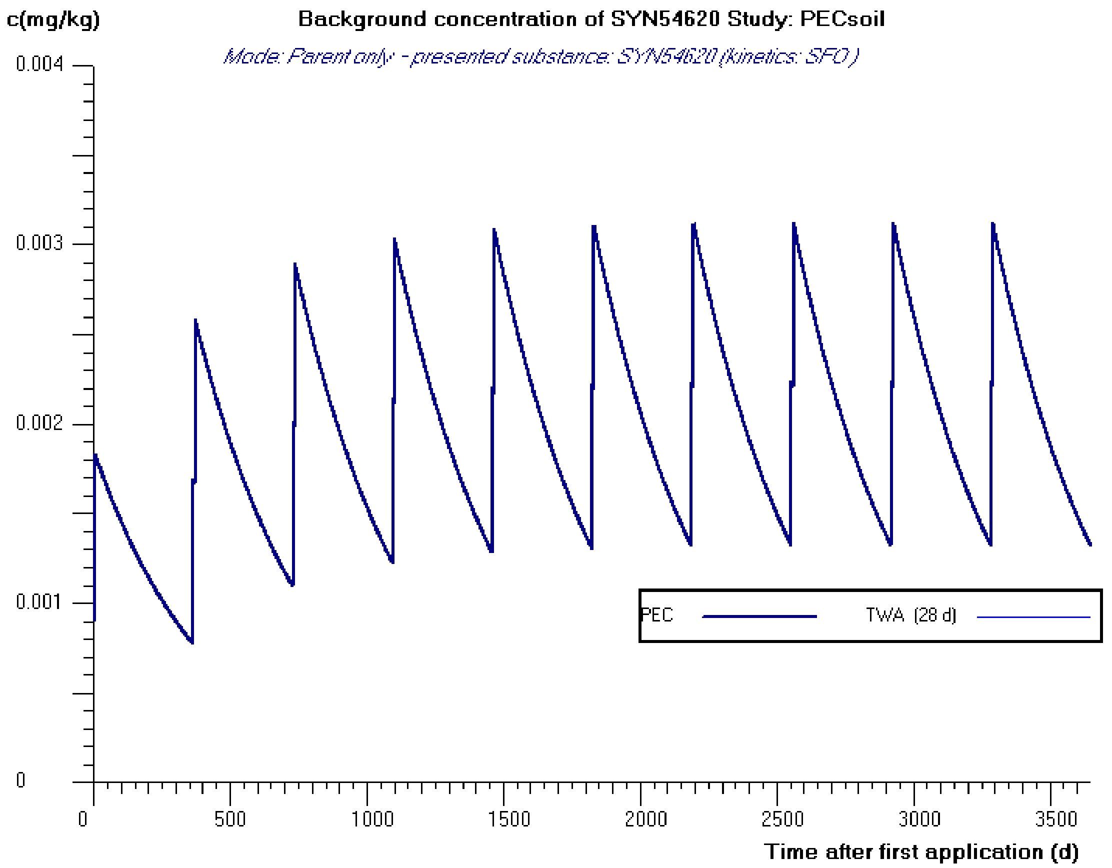
Calculated time dependent total soil concentrations over 5 cm for SYN54620(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0086	0.0086	7	8
2	0.0086	0.0086	7	9
4	0.0085	0.0086	7	11
7	0.0085	0.0086	7	14
14	0.0084	0.0085	7	21

21	0.0083	0.0084	7	28
28	0.0081	0.0084	7	35
42	0.0079	0.0083	7	49
50	0.0078	0.0082	7	57
100	0.0070	0.0078	7	107

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

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.5 KCP 9.1.3: Oxathiapiprolin - PEC_S following application to lettuce

Comments of izRMS:	All input parameters for oxathiapiprolin and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{soil} calculations acceptable for the parent and its metabolites.

Simulation of $PEC_{S,ini}$, short-term and long-term PEC_S values as well as $PEC_{S,plateau}$ and $PEC_{S,accumulation}$ were carried out using the tool ESCAPE (v.2). ESCAPE output files for oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 are presented below.

Oxathiapiprolin, lettuce, 2 x 15 g/ha, BBCH 12

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 14:16:34
Calculation problem: Oxathiapiprolin

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Iteration of annual application pattern over 10 years

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: OXTP, Lettuce, BBCH12
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications : 2

1st Application date:	1 May
Application rate (g/ha):	15
Time between two applications (d):	7
Crop interception (%):	25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for Oxathiapiprolin:	Single First order (SFO)
DT50 (d):	205.3
Rate constant (1/d):	0.0034
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: Oxathiapiprolin

Calculations over one year

Maximum annual total soil concentration for Oxathiapiprolin over 5 cm(mg/kg): 0.0296 occurring on day 7

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

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0295	0.0296	7	8
2	0.0295	0.0295	7	9
4	0.0293	0.0295	7	11
7	0.0290	0.0293	7	14
14	0.0283	0.0290	7	21
21	0.0276	0.0286	7	28
28	0.0270	0.0283	7	35
42	0.0257	0.0276	7	49
50	0.0250	0.0273	7	57

100	0.0212	0.0252	6	106

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

Calculation of background concentrations after many years

Final Background concentration in total soil for Oxathiapiprolin over 20 cm(mg/kg): 0.0031**

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

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0031

Calculations of concentrations considering accumulation after many years of application

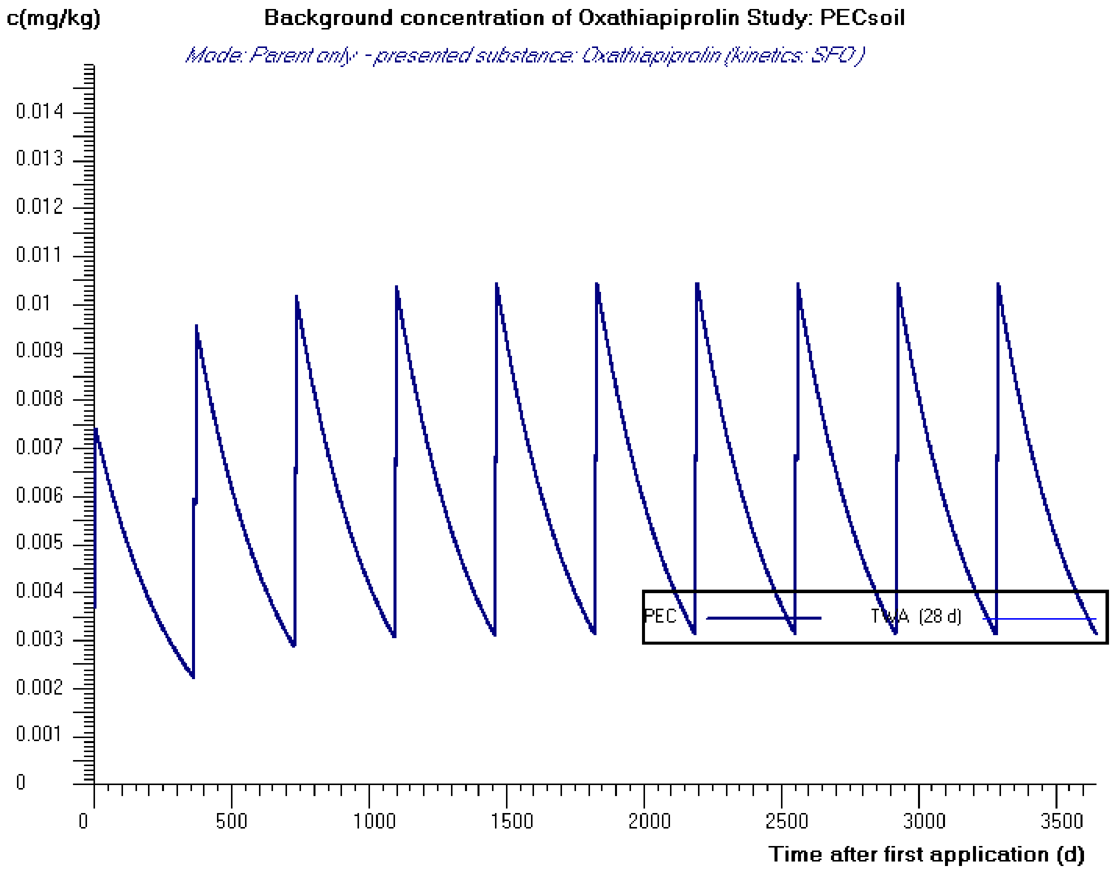
Maximum total soil concentration for Oxathiapiprolin over 5 cm considering accumulation* (mg/kg) 0.0327
(* a tillage depth of 20 cm was considered for calculating the background concentration)

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

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0326	0.0327	7	8
2	0.0325	0.0326	7	9
4	0.0323	0.0325	7	11
7	0.0320	0.0324	7	14
14	0.0313	0.0320	7	21
21	0.0307	0.0317	7	28
28	0.0300	0.0313	7	35
42	0.0288	0.0307	7	49
50	0.0281	0.0303	7	57
100	0.0242	0.0282	6	106

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

GRAPHIC REPRESENTATION OF THE CALCULATION



IN-RDT31, lettuce, 1 x 15 g a.s./ha, BBCH 12

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 14:18:32
Calculation problem: IN-RDT31

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Iteration of annual application pattern over 10 years

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario:	IN-RDT31, Lettuce, BBCH12
Name of the soil:	Borstel
Soil density (kg/L):	1.5
Soil depth (cm):	5
Tillage depth (cm)*:	20
Organic carbon content (%):	1.5
Field capacity (Vol%):	29.2
Wilting point (Vol%):	6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications :	2
1st Application date:	1 May
Application rate (g/ha):	1.452
Time between two applications (d):	7
Crop interception (%):	25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for IN-RDT31:	Double First Order in Parallel (DFOP)
DT50 1(d):	2.6
DT50 2(d):	1260.3
Rate constant 1 (1/d):	0.2666
Rate constant 2 (1/d):	0.0005
Parameter g:	0.2
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: IN-RDT31

Calculations over one year

Maximum annual total soil concentration for IN-RDT31 over 5 cm(mg/kg): 0.0027
occurring on day 7

Calculated time dependent total soil concentrations over 5 cm for IN-RDT31 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0026	0.0026	7	8
2	0.0025	0.0026	7	9
4	0.0024	0.0025	7	11
7	0.0024	0.0025	7	14
14	0.0023	0.0024	7	21
21	0.0023	0.0024	7	28
28	0.0023	0.0023	7	35
42	0.0023	0.0023	7	49
50	0.0023	0.0023	7	57
100	0.0022	0.0023	7	107

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

Calculation of background concentrations after many years

Final Background concentration in total soil for IN-RDT31 over 20 cm(mg/kg):
0.0026**

(** according to the estimation 84% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0026

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for IN-RDT31 over 5 cm considering accumulation* (mg/kg)
0.0053
(* a tillage depth of 20 cm was considered for calculating the background concentration)

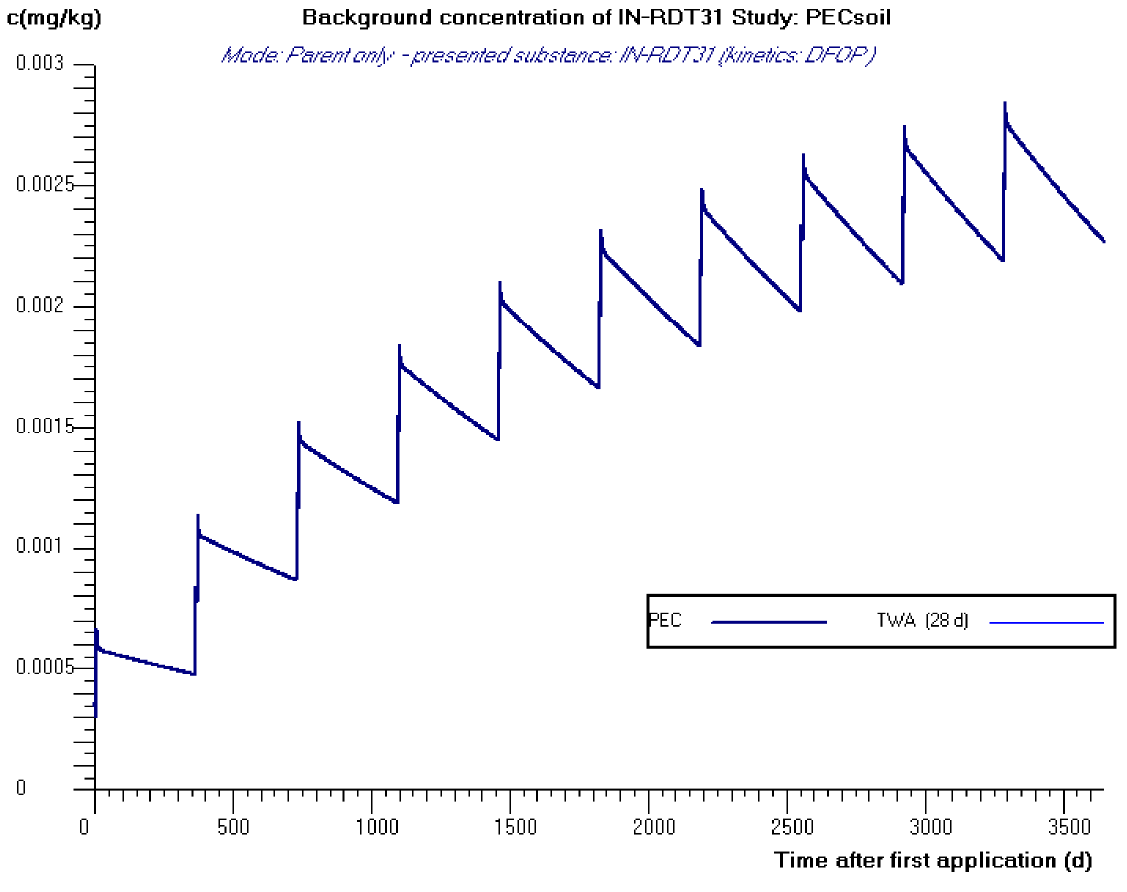
Calculated time dependent total soil concentrations over 5 cm for IN-RDT31(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0052	0.0052	7	8
2	0.0051	0.0052	7	9

4	0.0050	0.0051	7	11
7	0.0050	0.0051	7	14
14	0.0049	0.0050	7	21
21	0.0049	0.0050	7	28
28	0.0049	0.0049	7	35
42	0.0049	0.0049	7	49
50	0.0049	0.0049	7	57
100	0.0048	0.0049	7	107

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

GRAPHIC REPRESENTATION OF THE CALCULATION



IN-RAB06, lettuce, 1 x 15 g a.s./ha, BBCH 12

E S C A P E

Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 14:21:22
Calculation problem: IN-RAB06

PROGRAM SETTINGS

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

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: IN-RAB06, Lettuce, BBCH12
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications : 2
1st Application date: 1 May
Application rate (g/ha): 2.136
Time between two applications (d): 7
Crop interception (%): 25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for IN-RAB06:	Single First order (SFO)
DT50 (d):	170.2
Rate constant (1/d):	0.0041
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: IN-RAB06

Calculations over one year

Maximum annual total soil concentration for IN-RAB06 over 5 cm(mg/kg): 0.0042
occurring on day 7

Calculated time dependent total soil concentrations over 5 cm for IN-RAB06 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0042	0.0042	7	8
2	0.0042	0.0042	7	9
4	0.0041	0.0042	7	11
7	0.0041	0.0042	7	14
14	0.0040	0.0041	7	21
21	0.0039	0.0040	7	28
28	0.0038	0.0040	7	35
42	0.0035	0.0039	7	49
50	0.0034	0.0038	7	57
100	0.0028	0.0035	6	106

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

Calculation of background concentrations after many years

Final Background concentration in total soil for IN-RAB06 over 20 cm(mg/kg): 0.0003**

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

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0003

Calculations of concentrations considering accumulation after many years of application

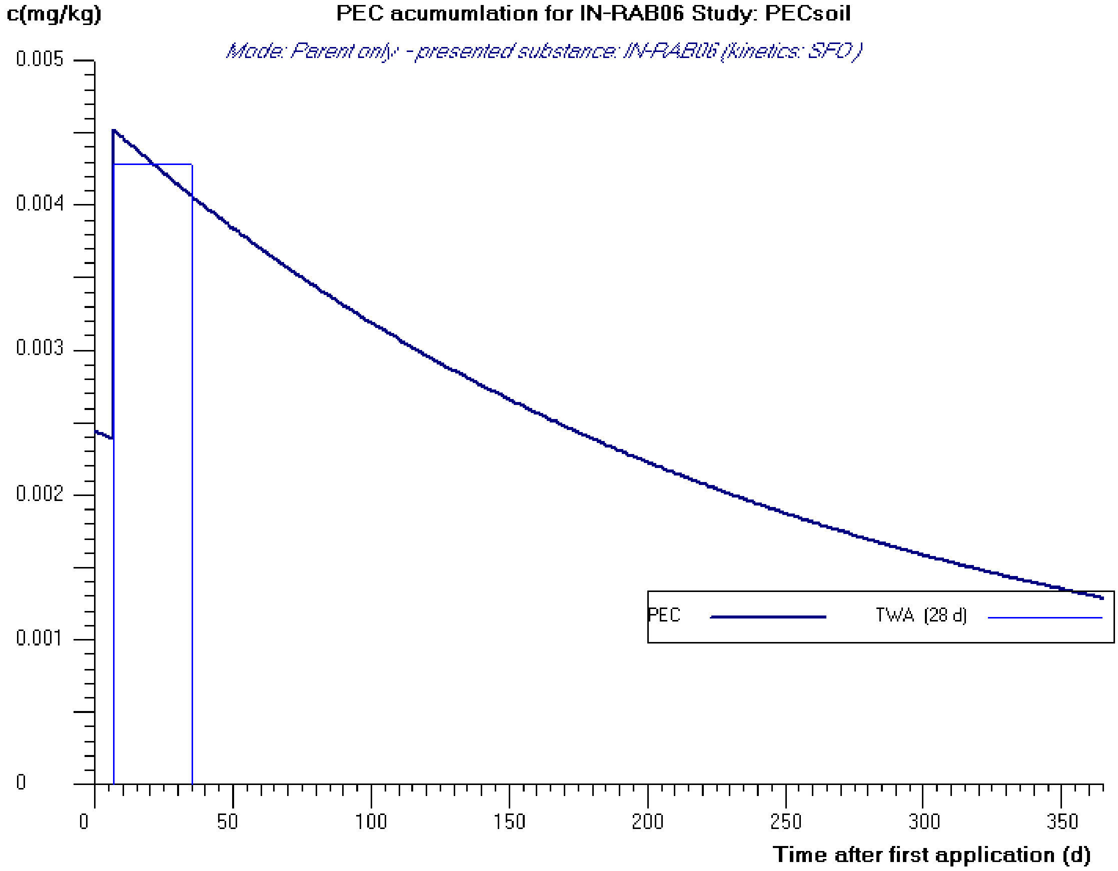
Maximum total soil concentration for IN-RAB06 over 5 cm considering accumulation* (mg/kg)
0.0045
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for IN-RAB06(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0045	0.0045	7	8
2	0.0045	0.0045	7	9
4	0.0045	0.0045	7	11
7	0.0044	0.0045	7	14
14	0.0043	0.0044	7	21
21	0.0042	0.0043	7	28
28	0.0041	0.0043	7	35
42	0.0039	0.0042	7	49
50	0.0037	0.0041	7	57
100	0.0031	0.0038	6	106

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

GRAPHIC REPRESENTATION OF THE CALCULATION



IN-QPS10, lettuce, 1 x 15 g a.s./ha, BBCH 12

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

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 14:23:31
Calculation problem: IN-QPS10

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Iteration of annual application pattern over 10 years

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario:	IN-QPS10, Lettuce, BBCH12
Name of the soil:	Borstel
Soil density (kg/L):	1.5
Soil depth (cm):	5
Tillage depth (cm)*:	20
Organic carbon content (%):	1.5
Field capacity (Vol%):	29.2
Wilting point (Vol%):	6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications :	2
1st Application date:	1 May
Application rate (g/ha):	0.845
Time between two applications (d):	7
Crop interception (%):	25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for IN-QPS10:	Double First Order in Parallel (DFOP)
DT50 1(d):	0.855
DT50 2(d):	845.3
Rate constant 1 (1/d):	0.8107
Rate constant 2 (1/d):	0.0008
Parameter g:	0.4
Q10-factor:	2.2
Walker-exponent:	0.7
Ref. temperature (°C):	20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: IN-QPS10

Calculations over one year

Maximum annual total soil concentration for IN-QPS10 over 5 cm(mg/kg): 0.0014
occurring on day 7

Calculated time dependent total soil concentrations over 5 cm for IN-QPS10 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0012	0.0013	7	8
2	0.0011	0.0012	7	9
4	0.0010	0.0011	7	11
7	0.0010	0.0011	7	14
14	0.0010	0.0010	7	21
21	0.0010	0.0010	7	28
28	0.0010	0.0010	7	35
42	0.0010	0.0010	7	49
50	0.0010	0.0010	7	57
100	0.0009	0.0010	7	107

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

Calculation of background concentrations after many years

Final Background concentration in total soil for IN-QPS10 over 20 cm(mg/kg):
0.0007**

(** according to the estimation 94% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0007

Calculations of concentrations considering accumulation after many years of application

Maximum total soil concentration for IN-QPS10 over 5 cm considering accumulation* (mg/kg)
0.0021
(* a tillage depth of 20 cm was considered for calculating the background concentration)

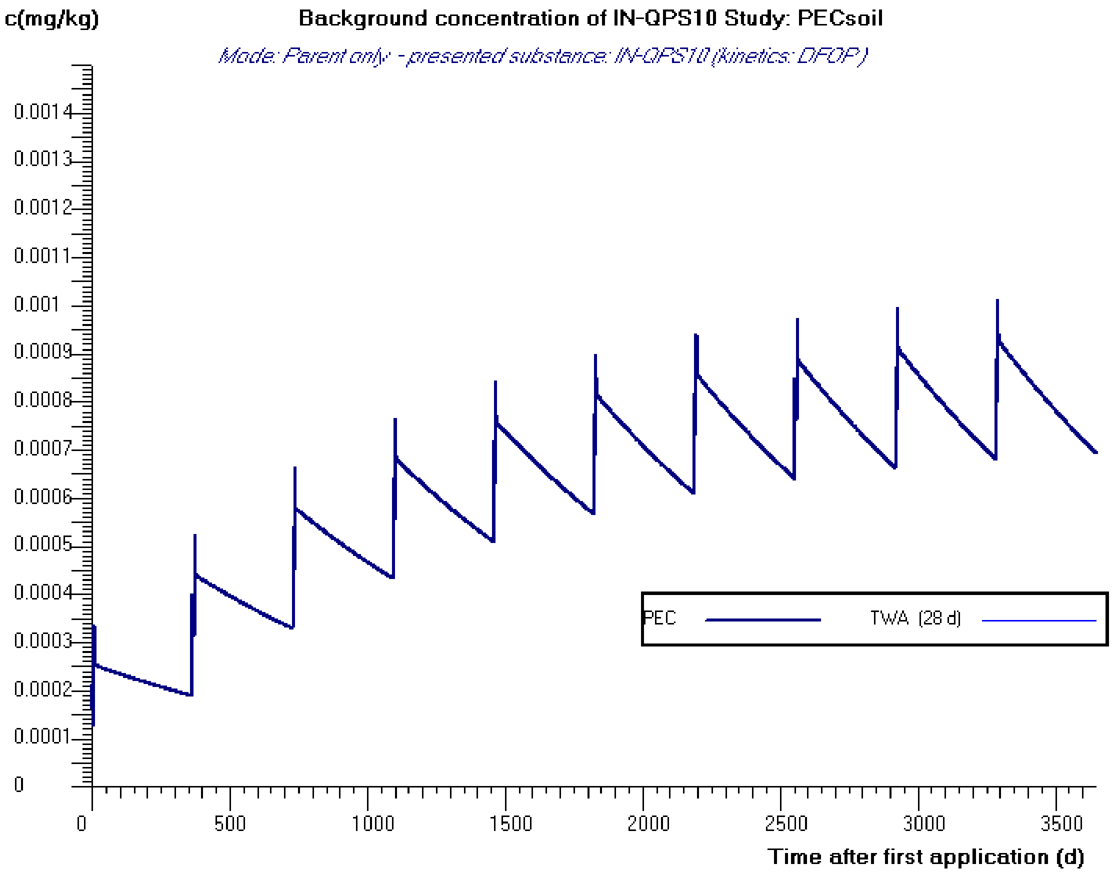
Calculated time dependent total soil concentrations over 5 cm for IN-QPS10(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0019	0.0020	7	8

2	0.0018	0.0019	7	9
4	0.0017	0.0018	7	11
7	0.0017	0.0018	7	14
14	0.0017	0.0018	7	21
21	0.0017	0.0017	7	28
28	0.0017	0.0017	7	35
42	0.0017	0.0017	7	49
50	0.0017	0.0017	7	57
100	0.0017	0.0017	7	107

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

GRAPHIC REPRESENTATION OF THE CALCULATION



IN-E8S72, lettuce, 1 x 15 g a.s./ha, BBCH 12

ESCAPE
Estimation of Soil Concentrations After PEsticide Applications

developed by Michael Klein

Program version: 2.0 (26 November 2019)
Date of this simulation: 04/04/2022, 14:24:49
Calculation problem: IN-E8S72

PROGRAM SETTINGS

Calculation mode: Residues from different applications are considered separately over one year
Application mode: Iteration of annual application pattern over 10 years

SCENARIO DATA USED IN THE CALCULATION

Name of the scenario: IN-E8S72, Lettuce, BBCH12
Name of the soil: Borstel
Soil density (kg/L): 1.5
Soil depth (cm): 5
Tillage depth (cm)*: 20
Organic carbon content (%): 1.5
Field capacity (Vol%): 29.2
Wilting point (Vol%): 6.4

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

APPLICATION PATTERN USED IN THE CALCULATION

Crop rotation: every year

Number of Applications : 2
1st Application date: 1 May
Application rate (g/ha): 0.516
Time between two applications (d): 7
Crop interception (%): 25

COMPOUNDS CONSIDERED IN THE CALCULATION

Metabolism scheme: Parent compound without metabolites

DEGRADATION KINETICS PARAMETERS CONSIDERED FOR THE CALCULATION

Soil study: PECsoil

Metabolism scheme: Parent compound without metabolites

Kinetics for IN-E8S72: Single First order (SFO)

DT50 (d): 477.4
Rate constant (1/d): 0.0015
Q10-factor: 2.2
Walker-exponent: 0.7
Ref. temperature (°C): 20

RESULTS OF THE CALCULATION

Metabolism scheme: Parent compound without metabolites

RESULTS FOR: IN-E8S72

Calculations over one year

Maximum annual total soil concentration for IN-E8S72 over 5 cm(mg/kg): 0.0010
occurring on day 7

Calculated time dependent total soil concentrations over 5 cm for IN-E8S72 after one year (mg/kg)

Time(d)	PECact*	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0010	0.0010	7	8
2	0.0010	0.0010	7	9
4	0.0010	0.0010	7	11
7	0.0010	0.0010	7	14
14	0.0010	0.0010	7	21
21	0.0010	0.0010	7	28
28	0.0010	0.0010	7	35
42	0.0010	0.0010	7	49
50	0.0010	0.0010	7	57
100	0.0009	0.0010	7	107

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

Calculation of background concentrations after many years

Final Background concentration in total soil for IN-E8S72 over 20 cm(mg/kg): 0.0004**

(** according to the estimation 99% of the final plateau was reached after 10 years without crop rotation)

Reduction factor to account for crop rotation: 1

Final Background concentration in total soil including crop rotation(mg/kg): 0.0004

Calculations of concentrations considering accumulation after many years of application

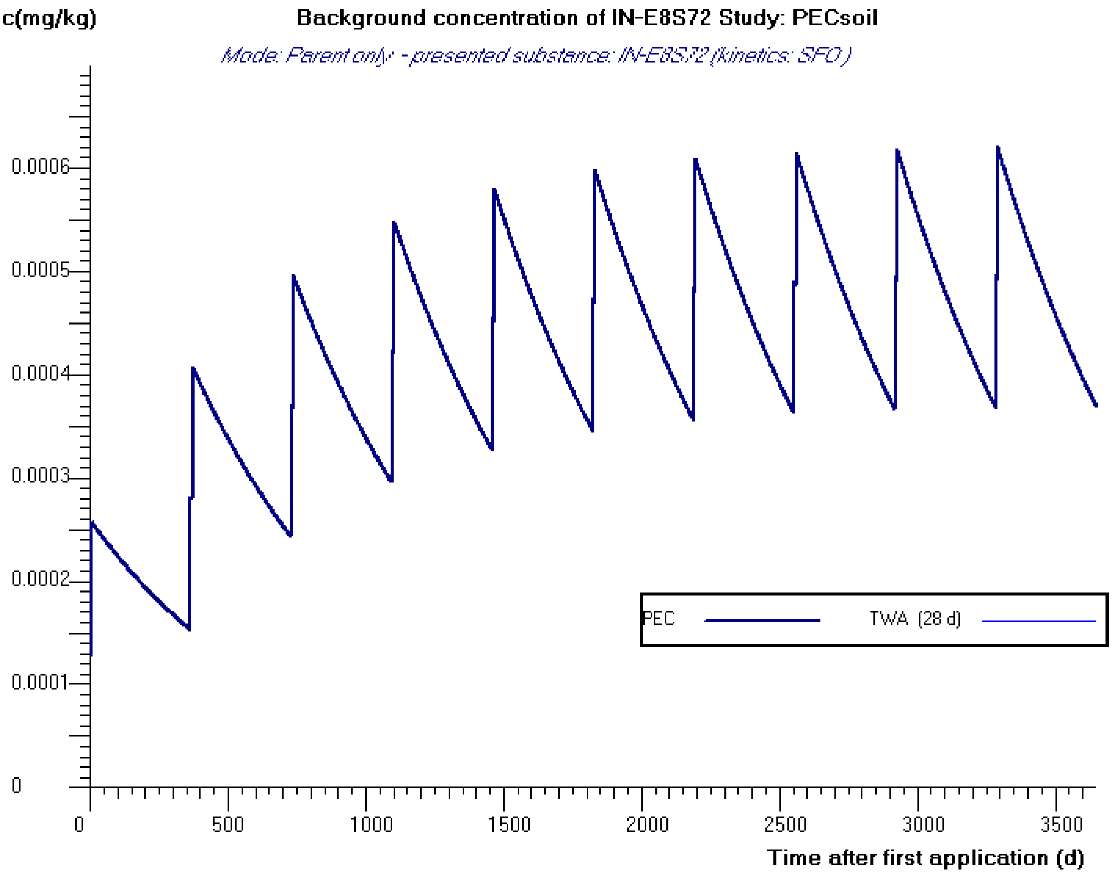
Maximum total soil concentration for IN-E8S72 over 5 cm considering accumulation* (mg/kg)
0.0014
(* a tillage depth of 20 cm was considered for calculating the background concentration)

Calculated time dependent total soil concentrations over 5 cm for IN-E8S72(mg/kg) considering accumulation*

Time(d)	PECact**	PECtwa	Begin TWAframe(d)	End TWAframe(d)
1	0.0014	0.0014	7	8
2	0.0014	0.0014	7	9
4	0.0014	0.0014	7	11
7	0.0014	0.0014	7	14
14	0.0014	0.0014	7	21
21	0.0014	0.0014	7	28
28	0.0014	0.0014	7	35
42	0.0013	0.0014	7	49
50	0.0013	0.0014	7	57
100	0.0013	0.0013	7	107

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

GRAPHIC REPRESENTATION OF THE CALCULATION



A 3.6 KCP 9.2.4: Cooke, J., 2022, Metalaxyl-M PEC_{GW} following application to various crops - Arithmetic Mean Endpoints

Comments of izRMS:	All input parameters for matalaxyl-M and its metabolites were considered acceptable as they followed the EFSA conclusion/RAR 2022, LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{gw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.4.
Report	Metalaxyl-M - A Leaching Assessment for Parent and Metabolites NOA409045, CGA67868 and SYN546520 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Central Zone Cooke, J. 2022 Report No. 0608830-GW3 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No. VV-942658)
Guideline(s):	European Commission (2014). Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS ground water work group, EC document reference SANCO/13144/2010 version 3, 613 pp. EC (2014). Assessing potential for movement of active substances and their metabolites to groundwater in the EU. Report of the FOCUS Groundwater Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp 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 (2021). Generic guidance for Tier 1 FOCUS ground water assessments, version 2.3. FOCUS groundwater scenarios working group. June 2021.
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 for metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 to reach groundwater following application to onions and cabbage. The FOCUS simulation models FOCUS PEARL (v5.5.5), FOCUS PELMO (v6.6.4) and MACRO (v5.5.4) were used in the modelling study.

Single and twofold foliar applications each at a rate of 87.2 g a.s./ha, from approximately BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 28: Application patterns of metalaxyl-M to various crops used in the modelling

Use No.	PL-31	PL-3	PL-29
Crop	Onion[a]	Broccoli[b]	Lettuce[c]
FOCUS GW crop	Onions	Cabbage	Cabbage
Application rate (g as/ha)	87.2	87.2	87.2
Number of applications/interval (d)	2/7	2/7	2/-
Relative application date/BBCH growth stage	-/12	-/12	-/12
Crop interception (%)	10	25	25
Frequency of application	annual	annual – 2 applications in 1 crop cycle[d]	annual – 1 application in 2 crop cycles[e]
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO v5.5.4		

[a] Covering bulbs
[b] Covering brassicas
[c] covering leafy veg.
[d] Only 1 crop cycle per year is common practice for brassicas
[e] Max. 2 applications per year in same field)

Applications were considered for the FOCUS scenarios in PEARL and PELMO Châteaudun, Hamburg, Kremsmünster and Porto (EU Central Zone required). For MACRO, only the scenario Châteaudun is defined. The dates were selected with the tool AppDate (v3.06). Simulations were carried out using the FOCUS standard crops onions and cabbage in FOCUS PEARL and PELMO as well as onions and cabbage in FOCUS-MACRO. Simulations were carried out over 26 years, as proposed by FOCUS for pesticides that are applied annually. 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. Application dates are presented in following table.

Table A 29: Application dates of metalaxyl-M to onions and cabbage used in modelling

Crop	Scenario	Application dates (absolute)	
		1st Application	2nd Application
Onions Use No. PL-31	Châteaudun	09 May	16 May
	Hamburg	09 May	16 May
	Kremsmünster	09 May	16 May
	Porto	16 Mar	24 Mar
Cabbage – 2 app. in 1 crop cycle Use No. PL-3	Châteaudun	29 Apr	06 May
	Hamburg	29 Apr	06 May
	Kremsmünster	29 Apr	06 May
	Porto	16 Mar	23 Mar

Crop	**Scenario**	**Application dates (absolute)**	
		1st Application	**2nd Application**
Cabbage – 1 app. in 2 crop cycles Use No. PL-29	Châteaudun	29 Apr	08 Aug
	Hamburg	29 Apr	08 Aug
	Kremsmünster	29 Apr	08 Aug
	Porto	16 Mar	07 Aug

The input parameters of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 used in modelling are shown in the following table. All other input values were set at the default values unless otherwise stated. A schematic diagram of the modelled route of degradation of metalaxyl-M in soil is shown in Figure A 1. Since the complex degradation scheme of metalaxyl-M cannot be implemented in the GUI of MACRO, all metabolites were assumed to form directly from metalaxyl-M. For this purpose, the formation fraction of secondary metabolites was corrected for the formation of preceding metabolites, e.g.:

$FF(tot)_{P \rightarrow met\ 2} = FF_{P \rightarrow met\ 1} \times FF_{met\ 1 \rightarrow met\ 2}$

Additionally, molar based formation fractions have to be corrected for molar mass differences between metabolite and parent to get conversion fractions for MACRO.

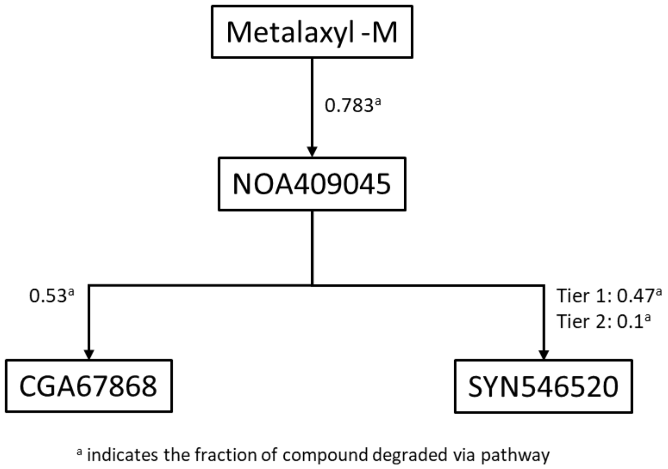
Table A 30: Summary of input parameters for metalaxyl-M, NOA409045, CGA67868 and SYN546520 for PEC_{GW} calculations

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[a]	265000[b]	Yes / EFSA (2015)
Saturated vapour pressure (Pa) (25°C)	0.0033	1×10^{-5}	1×10^{-5}	1×10^{-5}	Yes / EFSA (2015)
DT_{50} in soil (d) (normalised at 20°C and pF2)	6.5 Median n=10	30.5[c] Geometric mean n=8	2.9 Geometric mean n=3	96.8 Geometric mean n=3	Yes / EFSA (2015)
Formation fraction	-	0.783 from parent	0.53 from NOA409045	0.47 (**Tier 1**) / 0.1 (**Tier 2**) from NOA409045	Yes / EFSA (2015)
Conversion fraction (MACRO)	-	0.744 from parent	0.287 from parent	0.389 (**Tier 1**) / 0.083 (**Tier 2**)[d] from parent	-
K_{foc} / K_{fom} (mL/g)	40 / 23.2 Median n=25	12.1 / 7.02 Median n=14	19.0 / 11.0 Arithmetic mean n=5	15.2 / 8.82 Arithmetic mean n=4	Yes / 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 Arithmetic mean n=5	1.1 Arithmetic mean n=4	Yes / EFSA (2015)
Plant uptake factor	0	0	0	0	Worst-case assumption

[a] O'Connor & White (2012)
[b] Not available, value of NOA409045 used
[c] The overall DT_{50} value used in modelling has been re-calculated, as the geomean value of 31.3 days (EFSA, 2015) was incorrect
[d] For the metabolite SYN546520, as a tiered approach, the PEC_{GW} were calculated with two different formation fractions: 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2, derived from inverse modelling, EFSA 2015)

Figure A 9: Schematic diagram of the modelled route of degradation of metalaxyl-M



A 3.6.2 Results and discussions

Predicted environmental concentrations for metalaxyl-M and its metabolites in groundwater (PEC_{GW}) were calculated for the use of metalaxyl-M on onions and cabbage in the EU Central Zone in accordance with FOCUS guidelines (FOCUS, 2000, 2014, 2021).

The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS PEARL, FOCUS PELMO and MACRO simulations are given in Table A 31 to Table A 33. The overall maximum 80th percentile PEC_{GW} values are given in Table A 34.

Table A 31: PEC$_{GW}$ for metalaxyl-M, NOA409045, CGA67868 and SYN546520 (with FOCUS PEARL v5.5.5)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
Onions	Châteaudun	< 0.001	2.612	0.077	13.823	3.032
	Hamburg	0.001	6.016	0.185	15.462	3.489
	Kremsmünster	< 0.001	3.528	0.112	9.467	2.046
	Porto	< 0.001	1.031	0.026	6.118	1.346
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	2.551	0.073	11.587	2.524
	Hamburg	0.001	4.746	0.143	14.396	3.182
	Kremsmünster	< 0.001	2.968	0.094	8.318	1.785
	Porto	< 0.001	1.020	0.022	5.706	1.225
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	3.426	0.101	12.060	2.621
	Hamburg	0.004	6.666	0.194	14.494	3.222
	Kremsmünster	0.001	3.404	0.104	8.637	1.863
	Porto	0.001	2.084	0.045	6.280	1.350

Table A 32: PEC$_{GW}$ for metalaxyl-M, NOA409045, CGA67868 and SYN546520 (with FOCUS PELMO v6.6.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
Onions	Châteaudun	< 0.001	2.576	0.076	12.888	2.843
	Hamburg	0.001	5.028	0.140	15.134	3.281
	Kremsmünster	< 0.001	4.071	0.123	11.014	2.386
	Porto	< 0.001	1.720	0.037	6.110	1.320
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	2.155	0.064	10.854	2.395
	Hamburg	< 0.001	3.941	0.111	12.602	2.732
	Kremsmünster	< 0.001	3.336	0.100	9.246	2.002
	Porto	< 0.001	1.414	0.030	5.099	1.101
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	3.132	0.090	11.124	2.452
	Hamburg	0.004	6.080	0.166	12.708	2.747
	Kremsmünster	0.001	3.826	0.108	9.435	2.049
	Porto	0.001	2.115	0.045	5.099	1.085

Table A 33: PEC$_{GW}$ for metalaxyl-M, NOA409045, CGA67868 and SYN546520 (with MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
Onions	Châteaudun	< 0.001	1.68	< 0.001	8.41	1.84
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	1.54	< 0.001	6.08	1.35
Cabbage – 1 app. in 2 crop cycles	Châteaudun	0.001	2.36	< 0.001	6.77	1.49

Table A 34: Summary of maximum PEC$_{GW}$ across all models for metalaxyl-M, NOA409045, CGA67868 and SYN546520

Substance		80th Percentile PEC$_{GW}$ (µg/L)	Crop	Application	Model and Version Number	Scenario
Metalaxyl-M		0.004	Cabbage	2 × 87.2 g as/ha 1 app. in 2 crop cycles	PEARL v5.5.5 & PELMO v6.6.4	Hamburg
NOA409045		6.666	Cabbage	2 × 87.2 g as/ha 1 app. in 2 crop cycles	PEARL v5.5.5	Hamburg
CGA67868		0.194	Cabbage	2 × 87.2 g as/ha 1 app. in 2 crop cycles	PEARL v5.5.5	Hamburg
SYN546520	Tier 1	15.462	Onions	2 × 87.2 g as/ha	PEARL v5.5.5	Hamburg
	Tier 2	3.489	Onions	2 × 87.2 g as/ha	PEARL v5.5.5	Hamburg

A 3.7 KCP 9.2.4: Cooke, J. , 2022, Oxathiapiprolin PEC_{GW} following application to various crops - Arithmetic Mean Endpoints

Comments of izRMS:	All input parameters for oxathiapiprolin and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{gw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.4.
Report	Oxathiapiprolin - A Leaching Assessment for Parent and Metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Central Zone Cooke, J. 2022 Report No. 0608830-GW4 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No VV-942664
Guideline(s):	European Commission (2014). Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS ground water work group, EC document reference SANCO/13144/2010 version 3, 613 pp. EC (2014). Assessing potential for movement of active substances and their metabolites to groundwater in the EU. Report of the FOCUS Groundwater Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp 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 (2021). Generic guidance for Tier 1 FOCUS ground water assessments, version 2.3. FOCUS groundwater scenarios working group. June 2021..
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 for oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 to reach groundwater following application to onions and cabbage. The FOCUS simulation models FOCUS PEARL (v5.5.5), FOCUS PELMO (v6.6.4) and MACRO (v5.5.4) were used in the modelling study.

Single and twofold foliar applications each at a rate of 15 g a.s./ha, from approximately BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 35: Application patterns of oxathiapiprolin to various crops used in the modelling

Use No.	**PL-31**	**PL-3**	**PL-29**
Crop	Onion[a]	Broccoli[b]	Lettuce[c]
FOCUS GW crop	Onions	Cabbage	Cabbage
Application rate (g as/ha)	15	15	15
Number of applications/interval (d)	2/7	2/7	2/-
Relative application date/BBCH growth stage	-/12	-/12	-/12
Crop interception (%)	10	25	25
Frequency of application	annual	annual – 2 applications in 1 crop cycle[d]	annual – 1 application in 2 crop cycles[e]
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO v5.5.4		

[a] Covering bulbs
[b] Covering brassicas
[c] Covering leafy veg.
[d] Only 1 crop cycle per year is common practice for brassicas
[e] Max. 2 applications per year in same field

Applications were considered for the FOCUS scenarios in PEARL and PELMO Châteaudun, Hamburg, Kremsmünster and Porto (EU Central Zone required). For MACRO, only the scenario Châteaudun is defined. Application dates are presented in Table A 36, below. The dates were selected with the tool AppDate (v3.06). Simulations were carried out using the FOCUS standard crops onions and cabbage in FOCUS PEARL and PELMO as well as onions and cabbage in FOCUS-MACRO. Simulations were carried out over 26 years, as proposed by FOCUS for pesticides that are applied annually. 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. Application dates are presented in the following table.

Table A 36: Application dates of oxathiapiprolin to onions and cabbage used in modelling

Crop	**Scenario**	**Application dates (absolute)**	
		1st Application	**2nd Application**
Onions Use No. PL-31	Châteaudun	09 May	16 May
	Hamburg	09 May	16 May
	Kremsmünster	09 May	16 May
	Porto	16 Mar	24 Mar
Cabbage – 2 app. in 1 crop cycle Use No.	Châteaudun	29 Apr	06 May
	Hamburg	29 Apr	06 May
	Kremsmünster	29 Apr	06 May

Crop	**Scenario**	**Application dates (absolute)**	
		1st Application	**2nd Application**
PL-3	Porto	16 Mar	23 Mar
Cabbage – 1 app. in 2 crop cycles Use No. PL-29	Châteaudun	29 Apr	08 Aug
	Hamburg	29 Apr	08 Aug
	Kremsmünster	29 Apr	08 Aug
	Porto	16 Mar	07 Aug

The input parameters of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 used in modelling are shown in Table A 37, below. All other input values were set at the default values unless otherwise stated. A schematic diagram of the proposed pathway of oxathiapiprolin in soil is shown in Figure 1. Since the complex degradation scheme of oxathiapiprolin cannot be implemented in the GUI of MACRO, all metabolites were assumed to form directly from oxathiapiprolin. For this purpose, the formation fraction of secondary metabolites was corrected for the formation of preceding metabolites, e.g.:

$FF(tot)_{P\rightarrow met\ 2} = FF_{P\rightarrow met\ 1} \times FF_{met\ 1\rightarrow met\ 2}$

Additionally, molar based formation fractions have to be corrected for molar mass differences between metabolite and parent to get conversion fractions for MACRO.

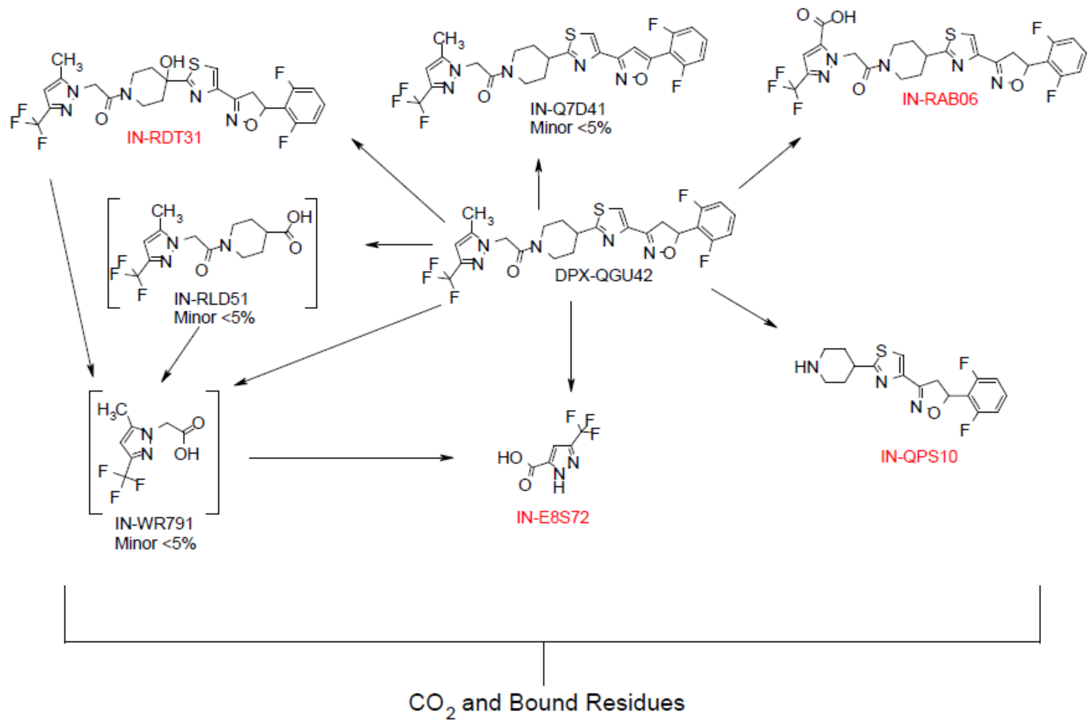
Table A 37: Summary of input parameters for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 for PEC_{GW} calculations

Compound	**Oxathia-piprolin**	**IN-RDT31**	**IN-RAB06**	**IN-QPS10**	**IN-E8S72**	**Value in accordance with EU endpoint / Reference**
Molar mass (g/mol)	539.53	555.53	569.51	349.41	180.09	Yes / EFSA (2016)
Water solubility (mg/L) (20°C)	0.1844	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
Saturated vapour pressure (Pa) (20°C)	1.141×10^{-6}	0[b]	0[b]	0[b]	0[b]	Yes / EFSA (2016)
DT_{50} in soil (d) (normalised at 20°C and pF2)	121.2 Geometric mean[c] n= 6	160 Geometric mean[c] n= 6	60.5 Geometric mean[d] n=12	564.9 Geometric mean[e] n=2	310.2 Geometric mean[c] n=5	Yes / EFSA (2016)
Formation fraction	-	0.7 from parent	0.4 from parent	0.6 from parent 1.0 from IN-RAB06	0.3 from parent 0.4 from IN-RDT31	Yes / EFSA (2016)
Conversion fraction (MACRO)	-	0.721 from parent	0.422 from parent	0.648 from parent	0.194 from parent	-

Compound	Oxathia-piprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72	Value in accordance with EU endpoint / Reference
K_{foc} / K_{fom} (mL/g)	6242.6 / 3621 Arithmetic mean n=5	1168.4 / 677.7 Arithmetic mean n=5	495.6 / 287.5 Arithmetic mean n=5	4880.2 / 2830.7 Arithmetic mean n=5	7.33 / 4.25 Arithmetic mean n=5	Yes / EFSA (2016)
1/n	0.97 Arithmetic mean n=5	0.87 Arithmetic mean n=5	0.89 Arithmetic mean n=5	0.92 Arithmetic mean n=5	1 Arithmetic mean n=5	Yes / EFSA (2016)
Plant uptake factor	0	0	0	0	0	Worst-case assumption

[a] Not available, value of parent used
[b] Worst-case assumption
[c] Of lab data
[d] Of lab and field data
[e] Of acidic lab data

Figure A 10: Schematic diagram of the modelled route of degradation of oxathiapiprolin in soil



A 3.7.2 Results and discussions

Predicted environmental concentrations for oxathiapiprolin and its metabolites in groundwater (PEC_{GW}) were calculated for the use of oxathiapiprolin on onions and cabbage in the EU Central Zone in accordance with FOCUS guidelines (FOCUS, 2000, 2014, 2021).

The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS PEARL, FOCUS PELMO and MACRO simulations in are given in Table A 38 to Table A 40. The overall maximum 80th percentile PEC_{GW} values are given in Table A 41.

Table A 38: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 (with FOCUS PEARL v5.5.5)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	**IN-RDT31**	**IN-RAB06**	**IN-QPS10**	**IN-E8S72**
Onions	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	2.238
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	2.130
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.254
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.878
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.654
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.927
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.318
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.756
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.653
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.929
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.091
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.754

Table A 39: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 (with FOCUS PELMO v6.6.4)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	**IN-RDT31**	**IN-RAB06**	**IN-QPS10**	**IN-E8S72**
Onions	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	2.010
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.792
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.372
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.964
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.593
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.584
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.243
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.612
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.590
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.582
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.243
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.611

Table A 40: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 (with FOCUS MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	**IN-RDT31**	**IN-RAB06**	**IN-QPS10**	**IN-E8S72**
Onions	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.33
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.13
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.17

Table A 41: Summary of maximum PEC_{GW} across all models for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72

Substance	80th Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Oxathiapiprolin	< 0.001	All crops	All applications	All models	All scenarios
IN-RDT31	< 0.001	All crops	All applications	All models	All scenarios
IN-RAB06	< 0.001	All crops	All applications	All models	All scenarios
IN-QPS10	< 0.001	All crops	All applications	All models	All scenarios
IN-E8S72	2.238	Onions	2 × 15 g as/ha	PEARL v5.5.5	Châteaudun

A 3.8 KCP 9.2.4: Cooke, J., 2022, Metalaxyl-M PEC_{GW} following application to various crops Using Geometric Mean Sorption Endpoints

Comments of izRMS:	All input parameters for matalaxyl-M and its metabolites were considered acceptable as they followed the EFSA conclusion/RAR 2022, LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{gw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.4.
Report	Metalaxyl-M - A Leaching Assessment for Parent and Metabolites NOA409045, CGA67868 and SYN546520 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Southern Zone Cooke, J. 2022 Report No. 0608830-GW1 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No. VV-942649
Guideline(s):	European Commission (2014). Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS ground water work group, EC document reference SANCO/13144/2010 version 3, 613 pp. EC (2014). Assessing potential for movement of active substances and their metabolites to groundwater in the EU. Report of the FOCUS Groundwater Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp 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 (2021). Generic guidance for Tier 1 FOCUS ground water assessments, version 2.3. FOCUS groundwater scenarios working group. June 2021.
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 for metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 to reach groundwater following application to onions and cabbage. The FOCUS simulation models FOCUS PEARL (v5.5.5), FOCUS PELMO (v6.6.4) and MACRO (v5.5.4) were used in the modelling study.

Single and twofold foliar applications each at a rate of 87.2 g a.s./ha, from approximately BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 42: Application patterns of metalaxyl-M to various crops used in modelling

Use No.	FR-22	FR-3	FR-21
Crop	Onion[a]	Broccoli[b]	Lettuce[c]
FOCUS GW crop	Onions	Cabbage	Cabbage
Application rate (g as/ha)	87.2	87.2	87.2
Number of applications/interval (d)	2/7	2/7	2/-
Relative application date/BBCH growth stage	-/12	-/12	-/12
Crop interception (%)	10	25	25
Frequency of application	annual	annual – 2 applications in 1 crop cycle[d]	annual – 1 application in 2 crop cycles[e]
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO v5.5.4		

[a] Covering bulbs
[b] Covering brassicas
[c] Covering leafy veg.
[d] Only 1 crop cycle per year is common practice for brassicas
[e] Max. 2 applications per year in same field

Applications were considered for the FOCUS scenarios in PEARL and PELMO Châteaudun, Hamburg, Kremsmünster and Porto (EU Central Zone required). For MACRO, only the scenario Châteaudun is defined. The dates were selected with the tool AppDate (v3.06). Simulations were carried out using the FOCUS standard crops onions and cabbage in FOCUS PEARL and PELMO as well as onions and cabbage in FOCUS-MACRO. Simulations were carried out over 26 years, as proposed by FOCUS for pesticides that are applied annually. 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. Application dates are presented in following table.

Table A 43: Application dates metalaxyl-M to onions and cabbage used in modelling

Crop	Scenario	Application dates (absolute)	
		1st Application	2nd Application
Onions Use No. PL-31	Châteaudun	09 May	16 May
	Hamburg	09 May	16 May
	Kremsmünster	09 May	16 May
	Porto	16 Mar	24 Mar
Cabbage – 2 app. in 1 crop cycle Use No. PL-3	Châteaudun	29 Apr	06 May
	Hamburg	29 Apr	06 May
	Kremsmünster	29 Apr	06 May
	Porto	16 Mar	23 Mar
Cabbage –	Châteaudun	29 Apr	08 Aug

Crop	**Scenario**	**Application dates (absolute)**	
		1st Application	**2nd Application**
1 app. in 2 crop cycles Use No. PL-29	Hamburg	29 Apr	08 Aug
	Kremsmünster	29 Apr	08 Aug
	Porto	16 Mar	07 Aug

The input parameters of metalaxyl-M and its metabolites NOA409045, CGA67868 and SYN546520 used in modelling are shown in the following table. All other input values were set at the default values unless otherwise stated. A schematic diagram of the modelled route of degradation of metalaxyl-M in soil is shown in Figure A 1. Since the complex degradation scheme of metalaxyl-M cannot be implemented in the GUI of MACRO, all metabolites were assumed to form directly from metalaxyl-M. For this purpose, the formation fraction of secondary metabolites was corrected for the formation of preceding metabolites, e.g.:

$FF(tot)_{P \rightarrow met\ 2} = FF_{P \rightarrow met\ 1} \times FF_{met\ 1 \rightarrow met\ 2}$

Additionally, molar based formation fractions have to be corrected for molar mass differences between metabolite and parent to get conversion fractions for MACRO.

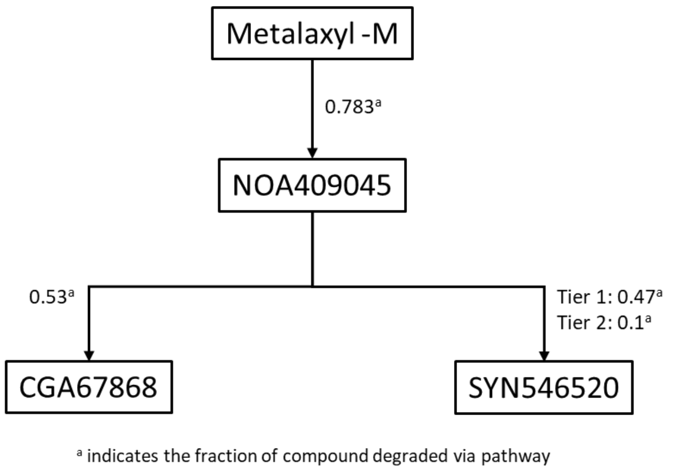
Table A 44: Summary of input parameters for metalaxyl-M, NOA409045, CGA67868 and SYN546520 for PEC_{GW} calculations

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[a]	265000[b]	Yes / EFSA (2015)
Saturated vapour pressure (Pa) (25°C)	0.0033	1×10^{-5}	1×10^{-5}	1×10^{-5}	Yes / EFSA (2015)
DT_{50} in soil (d) (normalised at 20°C and pF2)	-	30.5[c] Geometric mean n=8	2.9 Geometric mean n=3	96.8 Geometric mean n=3	Yes / EFSA (2015)
	7.74 Geometric mean n=10	-	-	-	No[d] / EFSA (2015)
Formation fraction	-	0.783 from parent	0.53 from NOA409045	0.47 (**Tier 1**) / 0.1 (**Tier 2**) from NOA409045	Yes / EFSA (2015)
Conversion fraction (MACRO)	-	0.744 from parent	0.287 from parent	0.389 (**Tier 1**) / 0.083 (**Tier 2**)[e] from parent	-
K_{foc} / K_{fom} (mL/g)	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[c] / 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 Arithmetic mean n=5	1.1 Arithmetic mean n=4	Yes / EFSA (2015)
Plant uptake factor	0	0	0	0	Worst-case assumption

[a] O'Connor & White (2012)[2]
[b] Not available, value of NOA409045 used
[c] The overall DT_{50} value used in modelling has been re-calculated, as the geomean value of 31.3 days (EFSA, 2015) was incorrect
[d] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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
[e] For the metabolite SYN546520, as a tiered approach, the PEC_{GW} were calculated with two different formation fractions: 0.47 (Tier 1, EFSA 2015) and 0.1 (Tier 2, derived from inverse modelling, EFSA 2015)

Figure A 11: Schematic diagram of the modelled route of degradation of metalaxyl-M



A 3.8.2 Results and discussions

Predicted environmental concentrations for metalaxyl-M and its metabolites in groundwater (PEC_{GW}) were calculated for the use of metalaxyl-M on onions and cabbage in the EU Southern Zone in accordance with FOCUS guidelines (FOCUS, 2000, 2014, 2021).

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 are given in Table A 45 to Table A 47. The overall maximum 80th percentile PEC_{GW} values are given in Table A 48.

[2] O'Connor, B. J., White, D. F. (2012). CGA92370 (alternative codename for CGA67868) Determination of water solubility. Final Report. Harlan Laboratories Ltd., Shardlow, UK. Report Number: 41201474. [Syngenta File No. CGA092370_10001

Table A 45: PEC$_{GW}$ for metalaxyl-M, NOA409045, CGA67868 and SYN546520 (with FOCUS PEARL v5.5.5)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
Onions	Châteaudun	< 0.001	2.415	0.072	15.463	3.370
	Hamburg	0.001	5.573	0.174	17.798	3.840
	Jokioinen	< 0.001	5.159	0.117	19.056	4.158
	Kremsmünster	< 0.001	3.346	0.107	10.028	2.151
	Porto	< 0.001	0.917	0.024	6.587	1.412
	Thiva	< 0.001	0.449	0.013	8.393	1.822
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	2.315	0.068	12.476	2.675
	Hamburg	0.001	4.398	0.134	15.951	3.428
	Jokioinen	< 0.001	5.124	0.120	19.099	4.149
	Kremsmünster	< 0.001	2.770	0.088	8.821	1.901
	Porto	< 0.001	0.892	0.021	5.846	1.245
	Sevilla	< 0.001	0.338	0.007	7.292	1.566
	Thiva	0.001	3.443	0.104	11.165	2.402
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	3.125	0.094	12.915	2.778
	Hamburg	0.003	6.137	0.184	16.144	3.471
	Kremsmünster	0.001	3.245	0.101	9.065	1.941
	Porto	0.001	1.960	0.043	6.524	1.394
	Sevilla	< 0.001	0.576	0.013	8.531	1.834

Table A 46: PEC$_{GW}$ for metalaxyl-M, NOA409045, CGA67868 and SYN546520 (with FOCUS PELMO v6.6.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
Onions	Châteaudun	< 0.001	2.186	0.063	14.186	3.048
	Hamburg	0.001	4.500	0.131	15.413	3.305
	Jokioinen	< 0.001	4.671	0.099	16.530	3.635
	Kremsmünster	0.001	3.789	0.117	11.159	2.390
	Porto	< 0.001	1.261	0.028	7.517	1.609
	Thiva	< 0.001	0.466	0.012	7.678	1.657
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	1.986	0.061	11.972	2.582
	Hamburg	< 0.001	3.751	0.107	13.543	2.909
	Jokioinen	< 0.001	4.940	0.101	16.504	3.573
	Kremsmünster	< 0.001	3.124	0.092	9.853	2.125
	Porto	< 0.001	1.263	0.028	5.253	1.118
	Sevilla	< 0.001	0.322	0.007	7.229	1.569
	Thiva	0.001	3.226	0.096	10.456	2.251
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	2.890	0.085	12.396	2.669
	Hamburg	0.003	5.771	0.160	13.548	2.904
	Kremsmünster	0.001	3.574	0.106	10.153	2.183
	Porto	0.002	2.031	0.046	5.167	1.101
	Sevilla	< 0.001	0.508	0.010	7.943	1.724

Table A 47: PEC$_{GW}$ for metalaxyl-M, NOA409045, CGA67868 and SYN546520 (with MACRO v5.5.4)

Crop	Scenario	80th Percentile PEC$_{GW}$ at 1 m Soil Depth (µg/L)				
		Metalaxyl-M	NOA409045	CGA67868	SYN546520	
					Tier 1	Tier 2
Onions	Châteaudun	< 0.001	1.54	< 0.001	9.55	2.09
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	1.45	< 0.001	6.88	1.49
Cabbage – 1 app. in 2 crop cycles	Châteaudun	0.001	2.20	< 0.001	7.67	1.67

Table A 48: Summary of maximum PEC$_{GW}$ across all models for metalaxyl-M, NOA409045, CGA67868 and SYN546520

Substance		80th Percentile PEC$_{GW}$ (µg/L)	Crop	Application	Model and Version Number	Scenario
Metalaxyl-M		0.003	Cabbage	2 × 87.2 g as/ha 1 app. in 2 crop cycles	PEARL v5.5.5 & PELMO v6.6.4	Hamburg
NOA409045		6.137	Cabbage	2 × 87.2 g as/ha 1 app. in 2 crop cycles	PEARL v5.5.5	Hamburg
CGA67868		0.184	Cabbage	2 × 87.2 g as/ha 1 app. in 2 crop cycles	PEARL v5.5.5	Hamburg
SYN546520	Tier 1	19.099	Cabbage	2 × 87.2 g as/ha 2 app. in 1 crop cycle	PEARL v5.5.5	Jokioinen
	Tier 2	4.158	Onions	2 × 87.2 g as/ha	PEARL v5.5.5	Jokioinen

A 3.9 KCP 9.2.4: Cooke, J. , 2022, Oxathiapiprolin PEC_{GW} following application to various crops Using Geometric Mean Sorption Endpoints

Comments of izRMS:	All input parameters for oxathiapiprolin and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{gw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.4.
Report	Oxathiapiprolin - A Leaching Assessment for Parent and Metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 Using the PEARL 5.5.5, PELMO 6.6.4 and MACRO 5.5.4 Groundwater Models Following Spray Application to Various Crops in the EU Southern Zone Cooke, J. 2022 Report No. 0608830-GW2 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No VV-942656
Guideline(s):	European Commission (2014). Assessing potential for movement of active substances and their metabolites to ground water in the EU. Report of the FOCUS ground water work group, EC document reference SANCO/13144/2010 version 3, 613 pp. EC (2014). Assessing potential for movement of active substances and their metabolites to groundwater in the EU. Report of the FOCUS Groundwater Work Group, EC Document Reference Sanco/13144/2010 version 3, 613 pp 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 (2021). Generic guidance for Tier 1 FOCUS ground water assessments, version 2.3. FOCUS groundwater scenarios working group. June 2021..
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.9.1 Materials and methods

This report describes a FOCUS groundwater modelling study that examined the potential for oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 to reach groundwater following application to onions and cabbage. The FOCUS simulation models FOCUS PEARL (v5.5.5), FOCUS PELMO (v6.6.4) and MACRO (v5.5.4) were used in the modelling study.

Single and twofold foliar applications each at a rate of 15 g a.s./ha, from approximately BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 49: Application patterns of o oxathiapiprolin to various crops used in modelling

Use No.	PL-31	PL-3	PL-29
Crop	Onion[a]	Broccoli[b]	Lettuce[c]
FOCUS GW crop	Onions	Cabbage	Cabbage
Application rate (g as/ha)	15	15	15
Number of applications/interval (d)	2/7	2/7	2/-
Relative application date/BBCH growth stage	-/12	-/12	-/12
Crop interception (%)	10	25	25
Frequency of application	annual	annual – 2 applications in 1 crop cycle[d]	annual – 1 application in 2 crop cycles[e]
Models used for calculation	FOCUS PEARL v5.5.5, FOCUS PELMO v6.6.4, MACRO v5.5.4		

[a] Covering bulbs
[b] Covering brassicas
[c] Covering leafy veg.
[d] Only 1 crop cycle per year is common practice for brassicas
[e] Max. 2 applications per year in same field

Applications were considered for the FOCUS scenarios in PEARL and PELMO Châteaudun, Hamburg, Kremsmünster and Porto (EU Central Zone required). For MACRO, only the scenario Châteaudun is defined. Application dates are presented in Table A 50, below. The dates were selected with the tool AppDate (v3.06). Simulations were carried out using the FOCUS standard crops onions and cabbage in FOCUS PEARL and PELMO as well as onions and cabbage in FOCUS-MACRO. Simulations were carried out over 26 years, as proposed by FOCUS for pesticides that are applied annually. 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. Application dates are presented in the following table.

Table A 50: Application dates of o oxathiapiprolin to onions and cabbage used in modelling

Crop	Scenario	Application dates (absolute)	
		1st Application	2nd Application
Onions Use No. PL-31	Châteaudun	09 May	16 May
	Hamburg	09 May	16 May
	Kremsmünster	09 May	16 May
	Porto	16 Mar	24 Mar
Cabbage – 2 app. in 1 crop cycle Use No.	Châteaudun	29 Apr	06 May
	Hamburg	29 Apr	06 May
	Kremsmünster	29 Apr	06 May

Crop	Scenario	Application dates (absolute)	
		1st Application	2nd Application
PL-3	Porto	16 Mar	23 Mar
Cabbage – 1 app. in 2 crop cycles Use No. PL-29	Châteaudun	29 Apr	08 Aug
	Hamburg	29 Apr	08 Aug
	Kremsmünster	29 Apr	08 Aug
	Porto	16 Mar	07 Aug

The input parameters of oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 used in modelling are shown in Table A 51, below. All other input values were set at the default values unless otherwise stated. A schematic diagram of the proposed pathway of oxathiapiprolin in soil is shown in Figure 1. Since the complex degradation scheme of oxathiapiprolin cannot be implemented in the GUI of MACRO, all metabolites were assumed to form directly from oxathiapiprolin. For this purpose, the formation fraction of secondary metabolites was corrected for the formation of preceding metabolites, e.g.:

$FF(tot)_{P \rightarrow met\ 2} = FF_{P \rightarrow met\ 1} \times FF_{met\ 1 \rightarrow met\ 2}$

Additionally, molar based formation fractions have to be corrected for molar mass differences between metabolite and parent to get conversion fractions for MACRO.

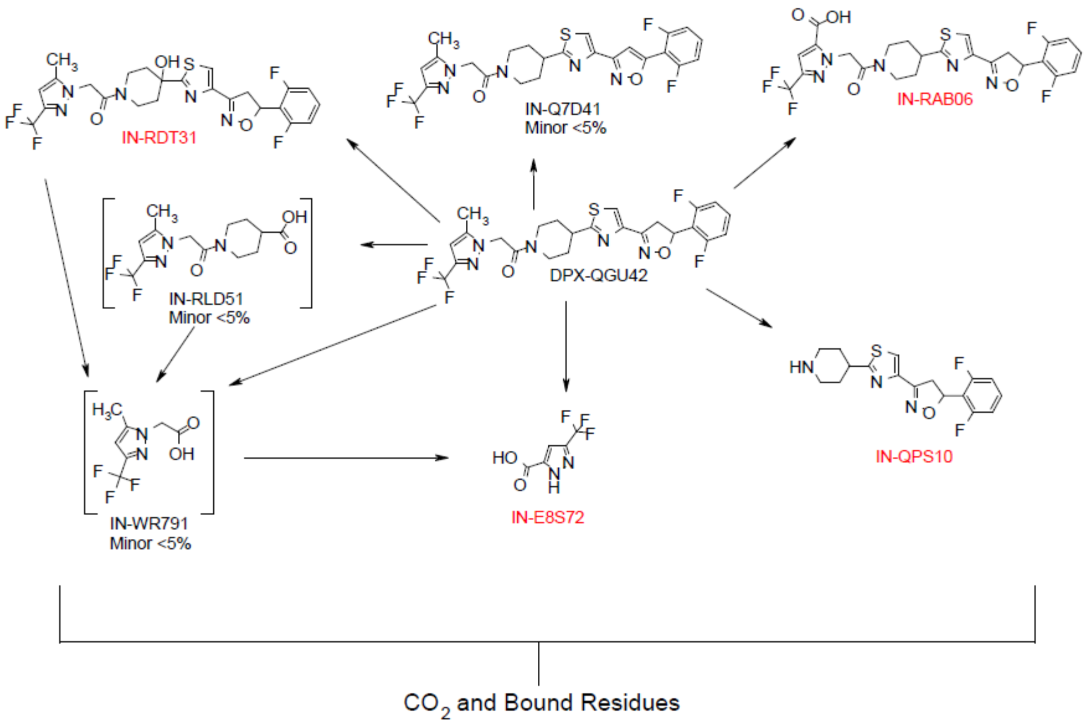
Table A 51: Summary of input parameters for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 for PEC_{GW} calculations

Compound	Oxathia-piprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	539.53	555.53	569.51	349.41	180.09	Yes / EFSA (2016)
Water solubility (mg/L) (20°C)	0.1844	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
Saturated vapour pressure (Pa) (20°C)	1.141×10^{-6}	0[b]	0[b]	0[b]	0[b]	Yes / EFSA (2016)
DT_{50} in soil (d) (normalised at 20°C and pF2)	121.2 Geometric mean[c] n= 6	160 Geometric mean[c] n= 6	60.5 Geometric mean[d] n=12	564.9 Geometric mean[e] n=2	310.2 Geometric mean[c] n=5	Yes / EFSA (2016)
Formation fraction	-	0.7 from parent	0.4 from parent	0.6 from parent 1.0 from IN-RAB06	0.3 from parent 0.4 from IN-RDT31	Yes / EFSA (2016)
Conversion fraction (MACRO)	-	0.721 from parent	0.422 from parent	0.648 from parent	0.194 from parent	-

Compound	Oxathia-piprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72	Value in accordance with EU endpoint / Reference
K_{foc} / K_{fom} (mL/g)	6128 / 3555 Geometric mean n=5	1012 / 587 Geometric mean n=5	487 / 282 Geometric mean n=5	3484 / 2021 Geometric mean n=5	6.91 / 4.01 Geometric mean n=5	No[f] / EFSA (2016)
1/n	0.97 Arithmetic mean n=5	0.87 Arithmetic mean n=5	0.89 Arithmetic mean n=5	0.92 Arithmetic mean n=5	1 Arithmetic mean n=5	Yes / EFSA (2016)
Plant uptake factor	0	0	0	0	0	Worst-case assumption

[a] Not available, value of parent used
[b] Worst-case assumption
[c] Of lab data
[d] Of lab and field data
[e] Of acidic lab data
[f] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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 oxathiapiprolin, EFSA Journal 2016; 14(7):4504

Figure A 12: Schematic diagram of the modelled route of degradation of oxathiapiprolin in soil



A 3.9.2 Results and discussions

Predicted environmental concentrations for oxathiapiprolin and its metabolites in groundwater (PEC_{GW}) were calculated for the use of oxathiapiprolin on onions and cabbage in the EU Southern Zone in accordance with FOCUS guidelines (FOCUS, 2000, 2014, 2021).

The 80th percentile (at 1 m soil depth) PEC_{GW} values generated by the FOCUS PEARL, FOCUS PELMO and MACRO simulations are given in are given in Table A 52 to Table A 54. The overall maximum 80th percentile PEC_{GW} values are given in Table A 55.

Table A 52: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 (with FOCUS PEARL v5.5.5)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
Onions	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	2.246
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	2.142
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	1.753
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.262
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.884
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	2.012
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.670
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.937
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	1.812
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.324
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.758
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.904
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	1.358
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.669
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.939
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.094
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.755
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.909

Table A 53: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 (with FOCUS PELMO v6.6.4)

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
Onions	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	2.017
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.796
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	1.808
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.373
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.965
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	1.736
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.599
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.587
	Jokioinen	< 0.001	< 0.001	< 0.001	< 0.001	1.708
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.245
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.612
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.591

Crop	Scenario	80th Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
	Thiva	< 0.001	< 0.001	< 0.001	< 0.001	1.267
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.596
	Hamburg	< 0.001	< 0.001	< 0.001	< 0.001	1.585
	Kremsmünster	< 0.001	< 0.001	< 0.001	< 0.001	1.245
	Porto	< 0.001	< 0.001	< 0.001	< 0.001	0.611
	Sevilla	< 0.001	< 0.001	< 0.001	< 0.001	1.592

Table A 54: PEC_{GW} for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 (with MACRO v5.5.4)

Crop	Scenario	80^{th} Percentile PEC_{GW} at 1 m Soil Depth (µg/L)				
		Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72
Onions	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.72
Cabbage – 2 app. in 1 crop cycle	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.14
Cabbage – 1 app. in 2 crop cycles	Châteaudun	< 0.001	< 0.001	< 0.001	< 0.001	1.17

Table A 55: Summary of maximum PEC_{GW} across all models for oxathiapiprolin, IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72

Substance	80^{th} Percentile PEC_{GW} (µg/L)	Crop	Application	Model and Version Number	Scenario
Oxathiapiprolin	< 0.001	All crops	All applications	All models	All scenarios
IN-RDT31	< 0.001	All crops	All applications	All models	All scenarios
IN-RAB06	< 0.001	All crops	All applications	All models	All scenarios
IN-QPS10	< 0.001	All crops	All applications	All models	All scenarios
IN-E8S72	2.246	Onions	2 × 15 g as/ha	PEARL v5.5.5	Châteaudun

A 3.10 KCP 9.2.5: Cooke, J., 2022, Metalaxyl-M - FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} Using Arithmetic Mean Endpoints

Comments of izRMS:	All input parameters for metalaxyl-M and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{sw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.5
Report	Metalaxyl-M – An Environmental Fate Assessment for Parent and Metabolite NOA409045 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Central Zone Cooke, J. 2022 Report No. 0608830-SW3 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No VV-942673
Guideline(s):	FOCUS (2001). FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 rev. 2. FOCUS (2015). Generic Guidance for FOCUS Surface Water Scenarios, version 1.4.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.10.1 Materials and methods

This report describes a FOCUS modelling study that examined the potential for metalaxyl-M and its metabolite NOA409045 to reach surface water following foliar application to bulb vegetables and leafy vegetables. The FOCUS tool Steps 1-2 in FOCUS (v 3.2) was used in the modelling study.

Twofold foliar applications each at a rate of 87.2 g a.s./ha, from approximately growth stage BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 56: Input parameters related to application for $PEC_{SW/SED}$ calculations

Use No.	PL-31	PL-3	PL-29
Crop	Onion	Broccoli	Lettuce
FOCUS SW crop	Bulb vegetables	Leafy vegetables	
Application rate (g as/ha)	87.2	87.2	
Number of applications/interval (d)	2/7	2/7	
BBCH growth stage	12	12	
Crop interception	Minimal crop cover	Minimal crop cover	
Season of application	Mar. – May	Mar. – May	
Models used for calculation	FOCUS STEPS 1-2 v3.2		

Applications were considered for the FOCUS scenarios North Europe and South Europe.

The input parameters for metalaxyl-M and its metabolite NOA409045 as used in the modelling are shown in the following table.

Table A 57: Input parameters related to active substance metalaxyl-M and NOA409045 for $PEC_{SW/SED}$ calculations

Compound	Metalaxyl-M	NOA409045	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	279.3	265.3	Yes / EFSA (2015)
Water solubility (mg/L)	26000	265000	Yes / EFSA (2015)
K_{foc} (mL/g)	40 Median n=25	12.1 Median n=14	Yes / EFSA (2015)
$DT_{50,soil}$ (d)	6.5 Median n=10	30.5[a] Geometric mean n=8	Yes / EFSA (2015)
$DT_{50,water}$ (d)	47.1 Whole system value	1000	Yes / EFSA (2015)
$DT_{50,sed}$ (d)	47.1 Whole system value	1000	Yes / EFSA (2015)
$DT_{50,whole\ system}$ (d)	47.1 Maximum n=2	1000	Yes / EFSA (2015)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 72 Total system: 88	Yes / EFSA (2015)

[a] The overall DT_{50} value used in modelling has been re-calculated, as the geomean value of 31.3 days (EFSA, 2015) was incorrect

A 3.10.2 Results and discussions

Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) were calculated for the use of metalaxyl-M and its metabolite NOA409045 on bulb vegetables and leafy vegetables in the EU Central Zone in accordance with FOCUS guidelines. The PEC_{SW} and PEC_{SED} values are given in Table A 58 and Table A 59.

Table A 58: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for metalaxyl-M

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	56.79	48.79	22.35
	2	North Europe	Mar. – May	6.01	5.15	2.36
		South Europe	Mar. – May	10.79	9.26	4.24
Leafy vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	56.79	48.79	22.35
	2	North Europe	Mar. – May	5.21	4.46	2.05
		South Europe	Mar. – May	9.19	7.89	3.62

Table A 59: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for NOA409045

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	88.29	87.63	10.67
	2	North Europe	Mar. – May	11.27	11.18	1.36
		South Europe	Mar. – May	21.36	21.20	2.58
Leafy vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	88.29	87.63	10.67
	2	North Europe	Mar. – May	9.58	9.51	1.16
		South Europe	Mar. – May	18.00	17.86	2.18

A 3.11 KCP 9.2.5: Cooke, J., 2022, Oxathiapiprolin - FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} Using Arithmetic Mean Endpoints

Comments of izRMS:	All input parameters for oxathiapiprolin and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{sw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.5
Report	Oxathiapiprolin – An Environmental Fate Assessment for Parent and Metabolite IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Central Zone Cooke, J. 2022 Report No. 0608830-SW4 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No VV-942676
Guideline(s):	FOCUS (2001). FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 rev. 2. FOCUS (2015). Generic Guidance for FOCUS Surface Water Scenarios, version 1.4.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.11.1 Materials and methods

This report describes a FOCUS modelling study that examined the potential for oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 to reach surface water following foliar application to bulb vegetables and leafy vegetables. The FOCUS tool Steps 1-2 in FOCUS (v 3.2) was used in the modelling study.

Twofold foliar applications each at a rate of 15 g a.s./ha, from approximately growth stage BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 60: Input parameters related to application for $PEC_{SW/SED}$ calculations

Use No.	PL-31	PL-3	PL-29
Crop	Onion	Broccoli	Lettuce
FOCUS SW crop	Bulb vegetables	Leafy vegetables	
Application rate (g as/ha)	15	15	
Number of applications/interval (d)	2/7	2/7	
BBCH growth stage	12	12	
Crop interception	Minimal crop cover	Minimal crop cover	
Season of application	Mar. – May	Mar. – May	
Models used for calculation	FOCUS STEPS 1-2 v3.2		

Applications were considered for the FOCUS scenarios North Europe and South Europe.

The input parameters for oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 as used in the modelling are shown in the following tables.

Table A 61: Input parameters related to active substance oxathiapiprolin and IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 for $PEC_{SW/SED}$ calculations

Compound	Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	539.53	555.53	569.51	349.41	180.09	Yes / EFSA (2016)
Water solubility (mg/L)	0.1844	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
K_{foc} (mL/g)	6242.6[b] / 45586[c] Arithmetic mean / worst-case n=5	1168.4 Arithmetic mean n=5	495.6 Arithmetic mean n=5	4880.2 Arithmetic mean n=5	7.33 Arithmetic mean n=5	Yes / EFSA (2016)
$DT_{50,soil}$ (d) (normalised at 20°C and pF2)	121.2 Geometric mean[d] n= 6	160 Geometric mean[d] n= 6	60.5 Geometric mean[e] n=12	564.9 Geometric mean[f] n=2	310.2 Geometric mean[d] n=5	Yes / EFSA (2016)

Compound	**Oxathiapiprolin**	**IN-RDT31**	**IN-RAB06**	**IN-QPS10**	**IN-E8S72**	**Value in accordance with EU endpoint / Reference**
$DT_{50,water}$ (d)	70.3 Whole system value	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,sed}$ (d)	70.3 Whole system value	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,whole\ system}$ (d)	70.3 Geometric mean n=2	1000	1000	1000	1000	Yes / EFSA (2016)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 9.4 Total system: 0	Soil: 13.5 Total system: 9.5	Soil: 8.7 Total system: 0	Soil: 10.3 Total system: 0	Yes / EFSA (2016)

[a] Not available, value of parent used
[b] Used for PEC_{SW}
[c] Used for PEC_{SED}
[d] Of lab data
[e] Of lab and field data
[f] Of acidic lab data

Table A 62: Input parameters related to active substance IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 for $PEC_{SW/SED}$ calculations

Compound	**IN-S2K66**	**IN-RSE01**	**IN-RYJ52**	**IN-Q7D41**	**IN-P3X26**	**Value in accordance with EU endpoint / Reference**
Molar mass (g/mol)	528.54	542.53	544.54	537.51	402.4	Yes / EFSA (2016)
Water solubility (mg/L)	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
K_{foc} (mL/g)	10[b] / 10000[c]	10[b] / 10000[c]	10[b] / 10000[c]	10[b] / 10000[c]	0.1[b] / 10000[c]	Yes / EFSA (2016)
$DT_{50,soil}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,water}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,sed}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)

Compound	IN-S2K66	IN-RSE01	IN-RYJ52	IN-Q7D41	IN-P3X26	Value in accordance with EU endpoint / Reference
$DT_{50,whole\ system}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 0 Total system: 8.7	Soil: 0 Total system: 10.4	Soil: 0 Total system: 16	Soil: 0 Total system: 11.8	Soil: 0 Total system: 14[d]	Yes / EFSA (2016)

[a] Not available, value of parent used
[b] Used for PEC_{SW}
[c] Used for PEC_{SED}
[d] Aqueous photolysis

A 3.11.2 Results and discussions

Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) were calculated for the use of oxathiapiprolin and its metabolites on bulb vegetables and leafy vegetables in the EU Central Zone in accordance with FOCUS guidelines. The PEC_{SW} and PEC_{SED} values are given in Table A 63 to Table A 72.

Table A 63: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for oxathiapiprolin

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.35	1.00	75.08
	2	North Europe	Mar. – May	0.22	0.19	14.37
		South Europe	Mar. – May	0.41	0.36	27.10
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.35	1.00	75.08
	2	North Europe	Mar. – May	0.19	0.16	12.25
		South Europe	Mar. – May	0.34	0.30	22.86

Table A 64: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RDT31

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.38	0.38	4.42
	2	North Europe	Mar. – May	0.07	0.07	0.77
		South Europe	Mar. – May	0.13	0.13	1.54
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.38	0.38	4.42
	2	North Europe	Mar. – May	0.05	0.05	0.64
		South Europe	Mar. – May	0.11	0.11	1.28

Table A 65: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RAB06

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.49	1.47	7.32
	2	North Europe	Mar. – May	0.26	0.26	1.29
		South Europe	Mar. – May	0.51	0.50	2.51
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.49	1.47	7.32
	2	North Europe	Mar. – May	0.22	0.22	1.09
		South Europe	Mar. – May	0.43	0.42	2.10

Table A 66: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-QPS10

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.08	0.07	3.66
	2	North Europe	Mar. – May	0.01	0.01	0.65
		South Europe	Mar. – May	0.03	0.03	1.31
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.08	0.07	3.66
	2	North Europe	Mar. – May	0.01	0.01	0.54
		South Europe	Mar. – May	0.02	0.02	1.09

Table A 67: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-E8S72

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.34	0.34	0.02
	2	North Europe	Mar. – May	0.06	0.06	< 0.01
		South Europe	Mar. – May	0.12	0.12	0.01
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.34	0.34	0.02
	2	North Europe	Mar. – May	0.05	0.05	< 0.01
		South Europe	Mar. – May	0.10	0.10	0.01

Table A 68: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-S2K66

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.86	0.86	6.11
	2	North Europe	Mar. – May	0.17	0.16	1.17
		South Europe	Mar. – May	0.31	0.31	2.19
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.86	0.86	6.11
	2	North Europe	Mar. – May	0.14	0.14	1.00
		South Europe	Mar. – May	0.26	0.26	1.85

Table A 69: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RSE01

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.06	1.05	7.49
	2	North Europe	Mar. – May	0.20	0.20	1.43
		South Europe	Mar. – May	0.38	0.38	2.69
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.06	1.05	7.49
	2	North Europe	Mar. – May	0.17	0.17	1.22
		South Europe	Mar. – May	0.32	0.32	2.27

Table A 70: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RYJ52

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.64	1.63	11.57
	2	North Europe	Mar. – May	0.31	0.31	2.21
		South Europe	Mar. – May	0.59	0.58	4.16
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.64	1.63	11.57
	2	North Europe	Mar. – May	0.27	0.27	1.89
		South Europe	Mar. – May	0.50	0.49	3.51

Table A 71: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-Q7D41

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.19	1.18	8.42
	2	North Europe	Mar. – May	0.23	0.23	1.61
		South Europe	Mar. – May	0.43	0.43	3.03
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.19	1.18	8.42
	2	North Europe	Mar. – May	0.20	0.19	1.38
		South Europe	Mar. – May	0.36	0.36	2.55

Table A 72: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-P3X26

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.07	1.07	7.48
	2	North Europe	Mar. – May	0.21	0.20	1.43
		South Europe	Mar. – May	0.39	0.38	2.69
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.07	1.07	7.48
	2	North Europe	Mar. – May	0.18	0.17	1.22
		South Europe	Mar. – May	0.33	0.32	2.27

A 3.12 KCP 9.2.5: Cooke, J., 2022, Metalaxyl-M - FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} Using Geometric Mean Endpoints

Comments of izRMS:	All input parameters for metalaxyl-M and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{sw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.5
Report	Metalaxyl-M – An Environmental Fate Assessment for Parent and Metabolite NOA409045 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Southern Zone Cooke, J. 2022 Report No. 0608830-SW1 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No VV-942666
Guideline(s):	FOCUS (2001). FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 rev. 2. FOCUS (2015). Generic Guidance for FOCUS Surface Water Scenarios, version 1.4.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.12.1 Materials and methods

This report describes a FOCUS modelling study that examined the potential for metalaxyl-M and its metabolite NOA409045 to reach surface water following foliar application to bulb vegetables and leafy vegetables. The FOCUS tool Steps 1-2 in FOCUS (v 3.2) was used in the modelling study.

Twofold foliar applications each at a rate of 87.2 g a.s./ha, from approximately growth stage BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 73: Input parameters related to application for $PEC_{SW/SED}$ calculations

Use No.	**FR-22**	**FR-3**	**FR-21**
Crop	Onion	Broccoli	Lettuce
FOCUS SW crop	Bulb vegetables	Leafy vegetables	
Application rate (g as/ha)	87.2	87.2	
Number of applications/interval (d)	2/7	2/7	
BBCH growth stage	12	12	
Crop interception	Minimal crop cover	Minimal crop cover	
Season of application	Mar. – May	Mar. – May	
Models used for calculation	FOCUS STEPS 1-2 v3.2		

Applications were considered for the FOCUS scenarios North Europe and South Europe.

The input parameters for metalaxyl-M and its metabolite NOA409045 as used in the modelling are shown in the following table.

Table A 74: Input parameters related to active substance metalaxyl-M and NOA409045 for $PEC_{SW/SED}$ calculations

Compound	**Metalaxyl-M**	**NOA409045**	**Value in accordance with EU endpoint / Reference**
Molar mass (g/mol)	279.3	265.3	Yes / EFSA (2015)
Water solubility (mg/L)	26000	265000	Yes / EFSA (2015)
K_{foc} (mL/g)	50.63 Geometric mean n=25	13.44 Geometric mean n=14	No[a] / EFSA (2015)
$DT_{50,soil}$ (d)	7.74 Geometric mean n=10	30.5[a] Geometric mean n=8	No[a] / EFSA (2015)
$DT_{50,water}$ (d)	47.1 Whole system value	1000	Yes / EFSA (2015)
$DT_{50,sed}$ (d)	47.1 Whole system value	1000	Yes / EFSA (2015)
$DT_{50,whole\ system}$ (d)	47.1 Maximum n=2	1000	Yes / EFSA (2015)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 72 Total system: 88	Yes / EFSA (2015)

[a] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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
[b] The overall DT_{50} value used in modelling has been re-calculated, as the geomean value of 31.3 days (EFSA, 2015) was incorrect

A 3.12.2 Results and discussions

Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) were calculated for the use of metalaxyl-M on bulb vegetables and leafy vegetables in the EU Southern Zone in accordance with FOCUS guidelines. The PEC_{SW} and PEC_{SED} values are given in Table A 75 and Table A 76.

Table A 75: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for metalaxyl-M

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	56.06	48.14	27.92
	2	North Europe	Mar. – May	6.47	5.55	3.22
		South Europe	Mar. – May	11.73	10.07	5.84
Leafy vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	56.06	48.14	27.92
	2	North Europe	Mar. – May	5.60	4.79	2.78
		South Europe	Mar. – May	9.98	8.56	4.96

Table A 76: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for NOA409045

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	88.14	87.48	11.83
	2	North Europe	Mar. – May	11.72	11.63	1.57
		South Europe	Mar. – May	22.27	22.11	2.99
Leafy vegetables 2 × 87.2 g a.s./ha BBCH 12	1	-	-	88.14	87.48	11.83
	2	North Europe	Mar. – May	9.96	9.88	1.34
		South Europe	Mar. – May	18.76	18.61	2.52

A 3.13 KCP 9.2.5: Cooke, J., 2022, Oxathiapiprolin - FOCUS Step 1 and 2 PEC_{SW} and PEC_{SED} Using Geometric Mean Endpoints

Comments of izRMS:	All input parameters for oxathiapiprolin and its metabolites were considered acceptable as they followed the EFSA conclusion and LoEP or corresponded to standard default values. Thus, the izRMS considers the presented PEC_{sw} calculations acceptable for the parent and its metabolites.

Reference:	KCP 9.2.5
Report	Oxathiapiprolin – An Environmental Fate Assessment for Parent and Metabolite IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 Using the FOCUS Surface Water Models at Steps 1 to 2 Following Spray Application to Various Crops in the EU Southern Zone Cooke, J. 2022 Report No. 0608830-SW2 ERM, The Exchange, Station Parade, Harrogate, North Yorkshire, HG1 1TS, United Kingdom Syngenta File No VV-942670
Guideline(s):	FOCUS (2001). FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 rev. 2. FOCUS (2015). Generic Guidance for FOCUS Surface Water Scenarios, version 1.4.
Deviations:	No
GLP:	Not applicable
Acceptability:	Yes

A 3.13.1 Materials and methods

This report describes a FOCUS modelling study that examined the potential for oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 to reach surface water following foliar application to bulb vegetables and leafy vegetables. The FOCUS tool Steps 1-2 in FOCUS (v 3.2) was used in the modelling study.

Twofold foliar applications each at a rate of 15 g a.s./ha, from approximately growth stage BBCH 12 and with an interval of 7 days were considered. The input parameters relating to application are shown in the following table.

Table A 77: Input parameters related to application for $PEC_{SW/SED}$ calculations

Use No.	FR-22	FR-3	FR-21
Crop	Onion	Broccoli	Lettuce
FOCUS SW crop	Bulb vegetables	Leafy vegetables	
Application rate (g as/ha)	15	15	
Number of applications/interval (d)	2/7	2/7	
BBCH growth stage	12	12	
Crop interception	Minimal crop cover	Minimal crop cover	
Season of application	Mar. – May	Mar. – May	
Models used for calculation	FOCUS STEPS 1-2 v3.2		

Applications were considered for the FOCUS scenarios North Europe and South Europe.

The input parameters for oxathiapiprolin and its metabolites IN-RDT31, IN-RAB06, IN-QPS10, IN-E8S72, IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 as used in the modelling are shown in the following tables.

Table A 78: Input parameters related to active substance oxathiapiprolin and IN-RDT31, IN-RAB06, IN-QPS10 and IN-E8S72 for $PEC_{SW/SED}$ calculations

Compound	Oxathiapiprolin	IN-RDT31	IN-RAB06	IN-QPS10	IN-E8S72	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	539.53	555.53	569.51	349.41	180.09	Yes / EFSA (2016)
Water solubility (mg/L)	0.1844	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
K_{foc} (mL/g)	6128[b] / 45586[c] Geometric mean / worst-case n=5	1012 Geometric mean n=5	487 Geometric mean n=5	3484 Geometric mean n=5	6.91 Geometric mean n=5	No[d] / EFSA (2016)
$DT_{50,soil}$ (d) (normalised at 20°C and pF2)	121.2 Geometric mean[e] n= 6	160 Geometric mean[e] n= 6	60.5 Geometric mean[f] n=12	564.9 Geometric mean[g] n=2	310.2 Geometric mean[e] n=5	Yes / EFSA (2016)

Compound	**Oxathiapiprolin**	**IN-RDT31**	**IN-RAB06**	**IN-QPS10**	**IN-E8S72**	**Value in accordance with EU endpoint / Reference**
$DT_{50,water}$ (d)	70.3 Whole system value	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,sed}$ (d)	70.3 Whole system value	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,whole\ system}$ (d)	70.3 Geometric mean n=2	1000	1000	1000	1000	Yes / EFSA (2016)
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 9.4 Total system: 0	Soil: 13.5 Total system: 9.5	Soil: 8.7 Total system: 0	Soil: 10.3 Total system: 0	Yes / EFSA (2016)

[a] Not available, value of parent used
[b] Used for PEC_{SW}
[c] Used for PEC_{SED}
[g] Differs from the EFSA conclusion as the latest guideline (EFSA Journal 2014;12(5):3662) 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 oxathiapiprolin, EFSA Journal 2016; 14(7):4504
[e] Of lab data
[f] Of lab and field data
[g] Of acidic lab data

Table A 79: Input parameters related to active substance IN-S2K66, IN-RSE01, IN-RYJ52, IN-Q7D41 and IN-P3X26 for $PEC_{SW/SED}$ calculations

Compound	**IN-S2K66**	**IN-RSE01**	**IN-RYJ52**	**IN-Q7D41**	**IN-P3X26**	**Value in accordance with EU endpoint / Reference**
Molar mass (g/mol)	528.54	542.53	544.54	537.51	402.4	Yes / EFSA (2016)
Water solubility (mg/L)	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	0.1844[a]	Yes / EFSA (2016)
K_{foc} (mL/g)	10[b] / 10000[c]	10[b] / 10000[c]	10[b] / 10000[c]	10[b] / 10000[c]	0.1[b] / 10000[c]	Yes / EFSA (2016)
$DT_{50,soil}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,water}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)

Compound	**IN-S2K66**	**IN-RSE01**	**IN-RYJ52**	**IN-Q7D41**	**IN-P3X26**	**Value in accordance with EU endpoint / Reference**
$DT_{50,sed}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
$DT_{50,whole\ system}$ (d)	1000	1000	1000	1000	1000	Yes / EFSA (2016)
Maximum occurrence observed (% molar basis with respect to the parent)	Soil: 0 Total system: 8.7	Soil: 0 Total system: 10.4	Soil: 0 Total system: 16	Soil: 0 Total system: 11.8	Soil: 0 Total system: 14[d]	Yes / EFSA (2016)

[a] Not available, value of parent used
[b] Used for PEC_{SW}
[c] Used for PEC_{SED}
[d] Aqueous photolysis

A 3.13.2 Results and discussions

Predicted environmental concentrations in surface water (PEC_{SW}) and sediment (PEC_{SED}) were calculated for the use of oxathiapiprolin and its metabolites on bulb vegetables and leafy vegetables in the EU Southern Zone in accordance with FOCUS guidelines. The PEC_{SW} and PEC_{SED} values are given in Table A 80 to Table A 89.

Table A 80: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for oxathiapiprolin

Application scenario	**Step**	**Region**	**Season**	**Max PEC_{SW} (µg/L)**	**21-d $PEC_{SW,twa}$ (µg/L)**	**Max PEC_{SED} (µg/kg)**
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.37	1.02	75.08
	2	North Europe	Mar. – May	0.22	0.19	14.37
		South Europe	Mar. – May	0.41	0.36	27.10
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.37	1.02	75.08
	2	North Europe	Mar. – May	0.19	0.16	12.25
		South Europe	Mar. – May	0.35	0.31	22.86

Table A 81: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RDT31

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.41	0.41	4.17
	2	North Europe	Mar. – May	0.07	0.07	0.73
		South Europe	Mar. – May	0.14	0.14	1.45
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.41	0.41	4.17
	2	North Europe	Mar. – May	0.06	0.06	0.61
		South Europe	Mar. – May	0.12	0.12	1.21

Table A 82: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RAB06

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.50	1.48	7.25
	2	North Europe	Mar. – May	0.26	0.26	1.28
		South Europe	Mar. – May	0.51	0.51	2.48
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.50	1.48	7.25
	2	North Europe	Mar. – May	0.22	0.22	1.08
		South Europe	Mar. – May	0.43	0.42	2.08

Table A 83: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-QPS10

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.10	0.10	3.48
	2	North Europe	Mar. – May	0.02	0.02	0.62
		South Europe	Mar. – May	0.04	0.04	1.24
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.10	0.10	3.48
	2	North Europe	Mar. – May	0.01	0.01	0.52
		South Europe	Mar. – May	0.03	0.03	1.03

Table A 84: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-E8S72

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.34	0.34	0.02
	2	North Europe	Mar. – May	0.06	0.06	< 0.01
		South Europe	Mar. – May	0.12	0.12	0.01
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.34	0.34	0.02
	2	North Europe	Mar. – May	0.05	0.05	< 0.01
		South Europe	Mar. – May	0.10	0.10	0.01

Table A 85: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-S2K66

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.86	0.86	6.11
	2	North Europe	Mar. – May	0.17	0.16	1.17
		South Europe	Mar. – May	0.31	0.31	2.19
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	0.86	0.86	6.11
	2	North Europe	Mar. – May	0.14	0.14	1.00
		South Europe	Mar. – May	0.26	0.26	1.85

Table A 86: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RSE01

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.06	1.05	7.49
	2	North Europe	Mar. – May	0.20	0.20	1.43
		South Europe	Mar. – May	0.38	0.38	2.69
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.06	1.05	7.49
	2	North Europe	Mar. – May	0.17	0.17	1.22
		South Europe	Mar. – May	0.32	0.32	2.27

Table A 87: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-RYJ52

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.64	1.63	11.57
	2	North Europe	Mar. – May	0.31	0.31	2.21
		South Europe	Mar. – May	0.59	0.58	4.16
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.64	1.63	11.57
	2	North Europe	Mar. – May	0.27	0.27	1.89
		South Europe	Mar. – May	0.50	0.49	3.51

Table A 88: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-Q7D41

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.19	1.18	8.42
	2	North Europe	Mar. – May	0.23	0.23	1.61
		South Europe	Mar. – May	0.43	0.43	3.03
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.19	1.18	8.42
	2	North Europe	Mar. – May	0.20	0.19	1.38
		South Europe	Mar. – May	0.36	0.36	2.55

Table A 89: FOCUS Step 1 and Step 2 PEC_{SW} and PEC_{SED} for IN-P3X26

Application scenario	Step	Region	Season	Max PEC_{SW} (µg/L)	21-d $PEC_{SW,twa}$ (µg/L)	Max PEC_{SED} (µg/kg)
Bulb vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.07	1.07	7.48
	2	North Europe	Mar. – May	0.21	0.20	1.43
		South Europe	Mar. – May	0.39	0.38	2.69
Leafy vegetables 2 × 15 g a.s./ha BBCH 12	1	-	-	1.07	1.07	7.48
	2	North Europe	Mar. – May	0.18	0.17	1.22
		South Europe	Mar. – May	0.33	0.32	2.27