REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: ADM.09050.H.1.A

Product name(s): **STEMPER**

Chemical active substances:

Trinexapac-ethyl, 175 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: **ADAMA**

Submission date: May 2022

Evaluation date: March 2023

Version history

When	What
January 2021	dRR version 1 submitted by applicant
May 2022	dRR submitted by applicant to the Polish Ministry of Agriculture and Rural Development
September 2022	Submission to the evaluation unit
March 2023	zRMS finalized dRR evaluation

DATA PROTECTION CLAIM

Under Article 59, Regulation 1107/2009/EC, on behalf of the Sponsor Company the applicant claims data protection for these studies. The data protection status and corresponding justification as valid for the respective country will be confirmed in the respective PART A

STATEMENT FOR OWNERSHIP

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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 ADM.09050.H.1.A, an emulsifiable concentrate containing 175 g/L trinexapac-ethyl for use in cereals and grass for seeds.

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.

This document reviews the fate and behaviour in the environment for the product ADM.09050.H.1.

ADM.09050.H.1.A is an emulsion concentrate containing 175 g/L trinexapac-ethyl for use as a plant growth regulator in field crops.

Trinexapac was included in Annex I of Council Directive 91/414/EEC (Commission Directive 2006/64/EC of 18 July 2006). This active substance is an approved active substance under Regulation (EC) 1107/2009 (repealing Commission Directive 91/414/EEC) as specified in Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011. Trinexapac-ethyl is a variant of the active substance trinexapac, and all data relied on are for the variant unless it is otherwise specified.

Where appropriate this document refers to the Commission Implementing Regulation (EU) No. 540/2011 for trinexapac and to the EFSA Scientific Report for trinexapac (EFSA Scientific Report (2018 16(3):5229), and in particular the endpoints provided in Appendix I.

This document covers data and risk assessments which are necessary to reflect changes:

- In requirements under Commission Regulation (EU) No 284/2013, and the associated Annex, which repeals Commission Regulation (EU) No 545/2011 which, under Regulation (EC) 1107/2009, replaced the requirements of Annex III to Directive 91/414/EEC
- In scientific and technical knowledge since the approval or last renewal of the approval
- To representative uses

Concentrations of trinexapac-ethyl and ADM.09050.H.1.A in various environmental compartments are predicted following the proposed use pattern. The predicted environmental concentrations (PEC) in soil, surface water, sediment and groundwater are provided. The long-term concentrations are based on results obtained for the active substance contained in the formulation.
The critical uses for the risk assessment of trinexapac-ethyl in ADM.09050.H.1.A in this section are summarised in Table 8-1.

8.1 Critical GAP and overall conclusions

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

Critical GAP

Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	Application				Application rate			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Winter barley (HORVW)	F	Prevention of lodging	Foliar spray	BBCH 25-49	a) 1 b) 1	n/a	a) 0.8 L/ha b) 0.8 L/ha	a) 200 g/ha b) 200 g/ha	100-400	n/a	
2	EU	Spring barley (HORVS)	F	Prevention of lodging	Foliar spray	BBCH 25-37	a) 1 b) 1	n/a	a) 0.6 L/ha b) 0.6 L/ha	a) 150 g/ha b) 150 g/ha	100-400	n/a	
3	EU	Winter wheat (TRZAW)	F	Prevention of lodging	Foliar spray	BBCH 25-49	a) 1 b) 1	n/a	a) 0.5 L/ha b) 0.5 L/ha	a) 125 g/ha b) 125 g/ha	100-400	n/a	

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha	**Conclusion**
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			Groundwater
Zonal uses (field or outdoor uses, certain types of protected crops)														
7	BE	Spring barley (HORVS)	F	Growth regulator (YHALM) Lodging control (YELDU)	Foliar, spraying, overall	-/ BBCH 29-32	a) 1 b) 1	n/a	a) 0.6 L/ha b) 0.6 L/ha	a) 105 g/ha b) 105 g/ha	200-400	n/a		
14	CZ	Winter barley (HORVW)	F	Growth regulator (YHALM)	Foliar, spraying, overall	-/ BBCH 31-35	a) 1 b) 1	n/a	a) 1.2 L/ha b) 1.2 L/ha	a) 210 g/ha b) 210 g/ha	200-400	n/a		
25	NL	Grass for seed; festuces (FESSS) and ryegrass (LOLSS)	F	Growth regulator (YHALM) lodging control (YELDU)	foliar, spraying, overall	-/ BBCH 30-37	a) 1 b) 1	n/a	a) 0.8 L/ha b) 0.8 L/ha	a) 140 b) 140	200-400	n/a		

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

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

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

The representative use pattern proposed for EU review of trinexapac is summarised below in Table 8.1-2

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

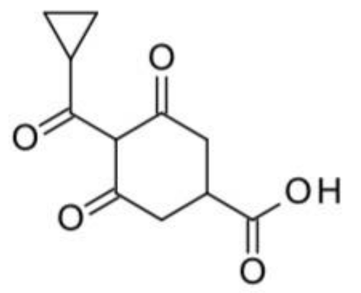
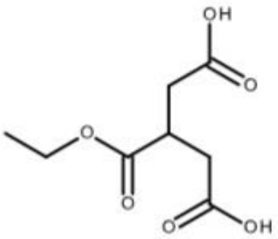
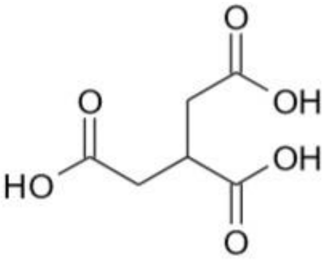
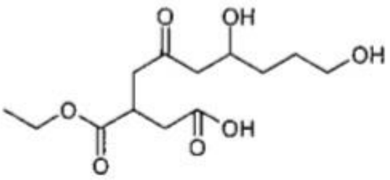
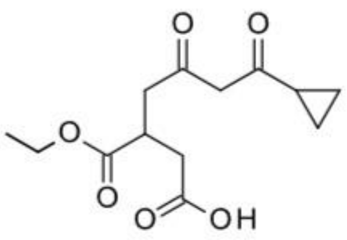
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use-No. *	Member state(s)	Crop and/or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn or I **	Pests or Group of pests controlled (additionally: developmental stages of the pest or pest group)	**Application**				**Application rate**			PHI (days)	Remarks: e.g. g safener/ synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	kg or L product/ha a) max. rate per appl. b) max. total rate per crop/season	g or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Winter barley (HORVW)	F	Prevention of lodging	Foliar spray	BBCH 25-49	a) 1 b) 1	n/a	a) 0.8 L/ha b) 0.8 L/ha	a) 200 g/ha b) 200 g/ha	100-400	n/a	
2	EU	Spring barley (HORVS)	F	Prevention of lodging	Foliar spray	BBCH 25-37	a) 1 b) 1	n/a	a) 0.6 L/ha b) 0.6 L/ha	a) 150 g/ha b) 150 g/ha	100-400	n/a	
3	EU	Winter wheat (TRZAW)	F	Prevention of lodging	Foliar spray	BBCH 25-49	a) 1 b) 1	n/a	a) 0.5 L/ha b) 0.5 L/ha	a) 125 g/ha b) 125 g/ha	100-400	n/a	

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

The impact of formulants is limited to short-term effects such as formation of stable spray dispersions or to facilitate uptake by target organisms, while their influence on long-term processes, such as degradation and distribution is negligible. Therefore, for the purposes of this risk assessment, it is assumed that formulations do not influence the fate and behaviour of an active substance in the environment and are not considered further.

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass	Chemical structure	Maximum observed occurence in compartements	Exposue assessment required due to
CGA179500	224.2		Soil: 93.1% AR Water: 64% AR Sediment: 6.9% AR Water/Sediment: 70.9%	PEC_{gw}: leaching potential to groundwater PEC_{soil}: >10% of a.s $PEC_{sw/sed}$: >10% of a.s
CGA300405	204.1		Soil (photolysis): 12.5% AR Water (photolysis): 41% AR	PEC_{gw}: leaching potential to groundwater PEC_{soil}: >10% of a.s $PEC_{sw/sed}$: >10% of a.s
CGA275537	176.1		Soil (photolysis): 10.8% AR	PEC_{gw}: leaching potential to groundwater PEC_{soil}: >10% of a.s $PEC_{sw/sed}$: >10% of a.s
M2	290.3		Water (direct photolysis): 17.9% AR	$PEC_{sw/sed}$: >10% of a.s
M3 (WaterM3 Photolysis)	252.3		Water (direct photolysis) : 16.9% AR	$PEC_{sw/sed}$: >10% of a.s

The degradation pathway of trinexapac-ethyl is presented in the diagram below.

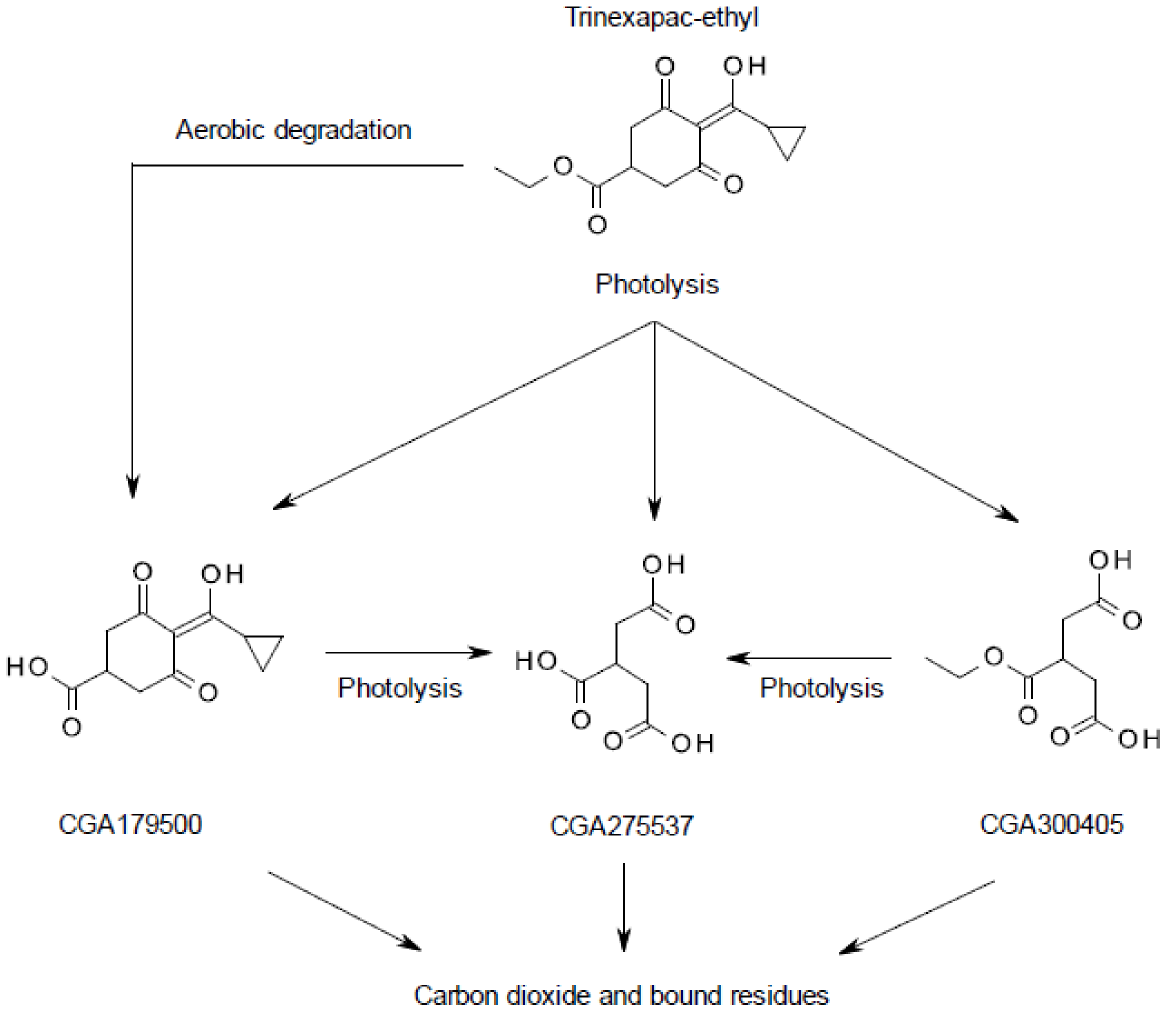


Figure 1. Degradation pathway of trinexapac-ethyl in soil

8.3 Rate of degradation in soil (KCP 9.1.1)

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

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

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

Trinexapac-ethyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T.ºC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Vouvry I	Loam	7.1	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	Y EFSA 2018; 16(3):5229
Vouvry II	Sandy loam	7.2	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Borstel	Loamy sand	6.4	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Gartenacker	Loam	7.26	20.6	pF 2	0.04	0.15	0.046	4.8	SFO	
18 Acres	Sandy clay loam	6.47	20.6	pF 2	[a]	[a]	[a]	[a]	[a]	
Capay	Clay loam	6.6	20.6	pF 2	0.72	2.4	0.72	2	SFO	
Sarpy	Silt loam	6.7	20.6	pF 2	[a]	[a]	[a]	[a]	[a]	
East Anglia	Sandy loam	6.9	20.6	pF 2	0.013	0.22	0.045[b]	19.7	FOMC	
Filsis	Silt loam	7.3	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Speyer 2.3	Sandy loam	6.4	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Borstel	Loamy sand	6.7	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Maryland I	Sandy loam	7.2	25	75% FC of 1/3 bar	0.14	0.71	0.19	12.7	SFO	
Geometric mean/Median (n=4)							**0.13**			
pH-dependency: y/n							No			

*Values in **bold** considered reliable for modelling*
All pH measurements in calcium chloride solution apart from Maryland I (no medium specified)
All DT_{50} values normalized to 20°C, pF2/10kPa using a Q10 of 2.58 and a Walker equation coefficient of 0.7 (unless otherwise stated)
[a] – due to high percentage of bound residues DT_{50} values based on extractable trinexapac-ethyl were considered unreliable
[b] – $\alpha = 0.6894$, $\beta = 0.0055$, back-calculate DT_{50} from DT_{90} for FOMC ($DT_{50} = DT_{90} / 3.32$)

Table 8.3-2: Summary of aerobic degradation rates for CGA179500 - laboratory studies

CGA179500, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T.ºC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Vouvry I	Loam	7.1	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	Y EFSA 2018; 16(3):5229
Vouvry II	Sandy loam	7.2	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Borstel	Loamy sand	6.4	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Gartenacker	Loam	7.26	20.6	pF 2	1.7	5.7	2.7	11.4	SFO-SFO	
18 Acres	Sandy clay loam	6.47	20.6	pF 2	[a]	[a]	[a]	[a]	[a]	
Capay	Clay loam	6.6	20.6	pF 2	7.7	25.6	7.7	21.7	SFO-SFO	
Sarpy	Silt loam	6.7	20.6	pF 2	[a]	[a]	[a]	[a]	[a]	
East Anglia	Sandy loam	6.9	20.6	pF 2	1.0	3.33	1.0	5.7	FOMC-SFO	
Filsis	Silt loam	7.3	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Speyer 2.3	Sandy loam	6.4	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Borstel	Loamy sand	6.7	20	pF 2.0-2.5	[a]	[a]	[a]	[a]	[a]	
Maryland I	Sandy loam	7.2	25	75% FC of 1/3 bar	32	106	39.5[b]	11.8	SFO-SFO	
Geometric mean/Median (n=4)							**5.4**			
pH-dependency: y/n							No			

*Values in **bold** considered reliable for modelling*
All pH measurements in calcium chloride solution apart from Maryland I (no medium specified)
All DT_{50} values normalized to 20°C, pF2/10kPa using a Q10 of 2.58 and a Walker equation coefficient of 0.7 (unless otherwise stated)
[a] – due to high percentage of bound residues DT_{50} values based on extractable trinexapac-ethyl were considered unreliable
[b] - Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-3: Summary of aerobic degradation rates for CGA300405 - laboratory studies

CGA300405, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
18 Acres	Clay loam	6.1	20	pF 2	0.08	1.71	0.52[a]	7.9	FOMC	Y EFSA 2018; 16(3):5229
East Anglia	Sandy loam	7.0	20	pF 2	0.03	0.37	0.11 [ab]	6.0	FOMC	
Gartenacker	Loam	7.0	20	pF 2	0.06	0.45	0.21[c]	10.7	HS	
Geometric mean/Median (n=3)							**0.23**			
pH-dependency: y/n							No			

*Values in **bold** considered reliable for modelling*
All pH measurements in calcium chloride solution apart from Maryland I (no medium specified)
All DT_{50} values normalized to 20°C, pF2/10kPa using a Q10 of 2.58 and a Walker equation coefficient of 0.7 (unless otherwise stated)
[a] – back-calculate DT_{50} from DT_{90} for FOMC (DT_{50} = DT_{90} / 3.32)
[b] - α = 0.818, β = 0.5676
[c] – DT_{50} for HS kinetics = ln2/k2 where k2 is the rate constant of the slow phase

Table 8.3-4: Summary of aerobic degradation rates for CGA275537 - laboratory studies

CGA275537, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH**	**T.ºC**	**MWHC %**	**DT50 (d)**	**DT90 (d)**	**DT50 (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
18 Acres	Sandy clay loam	6.6	20	pF 2	0.27	0.91	0.27	4.29	SFO	Y EFSA 2018; 16(3):5229
East Anglia	Sandy loam	7.1	20	pF 2	0.21	0.7	0.21	6.92	SFO	
Gartenacker	Loam	7.2	20	pF 2	0.17	0.56	0.17	4.2	SFO	
Geometric mean/Median (n=3)							**0.21**			
pH-dependency: y/n							No			

*Values in **bold** considered reliable for modelling*
All pH measurements in calcium chloride solution apart from Maryland I (no medium specified)
All DT_{50} values normalized to 20°C, pF2/10kPa using a Q10 of 2.58 and a Walker equation coefficient of 0.7 (unless otherwise stated)

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Table 8.3-5: Summary of anaerobic degradation rates for trinexapac-ethyl - laboratory studies

Trinexapac-ethyl, Laboratory studies, anaerobic conditions										
Soil name	**Soil type**	**pH**	**T.ºC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Loam	7.3	20.9	pF 2	0.3	1.0	[a]	15.6	SFO	Y EFSA 2018; 16(3):5229
18 Acres	Sandy clay loam	6.0	20.9	pF 2	0.7	2.4	[a]	14.3	SFO	
Capay	Clay loam	6.6	20.9	pF 2	2.0	6.7	[a]	9.2	SFO	
Sarpy	Silt loam	6.7	20.9	pF 2	0.6	2.1	[a]	10.6	SFO	
Geometric mean/Median (n=4)							[a]			
pH-dependency: y/n							[a]			

[a] Due to study deficiencies degradation rate should not be used for risk assessments but for indicative value only

Soil Photolysis

The photolysis of trinexapac-ethyl in soil was evaluated during the active substance renewal assessment, EFSA Journal 2018;16(3):5229. The degradation rates are summarised in the table below.

Table 8.3-6: Summary of photolysis rates for trinexapac-ethyl - laboratory studies

Trinexapac-ethyl, Laboratory studies, aerobic conditions										
Soil name	**Soil type**	**pH ($CaCl_2$)**	**T.ºC**	**MWHC %**	**DT_{50} (d)**	**DT_{90} (d)**	**DT_{50} (d) 20°C pF2/10kPa[a]**	**Chi2 (%)**	**Kinetic model**	**Evaluated on EU level y/n/ Reference**
Gartenacker	Loam	7.2	20	Dry	5.7	19.0	[a]	17.2	SFO	Y EFSA 2018; 16(3):5229
Gartenacker	Loam	7.2	20	Moist	0.7	2.2	[a]	3.9	SFO	

[a] – Degradation rates provided as indicative values only

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)

As trinexapac-ethyl and its metabolite CGA179500 do not trigger the need for field data, no new studies were performed.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

Soil accumulation testing was not triggered.

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.

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

Trinexapac-ethyl							
Soil name	**Soil type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
n/a	Clay	2.8	5.9	17.77	629	0.92	Y EFSA 2018; 16(3):5229
n/a	Sand	0.5	6.5	1.50	289	1.01	
n/a	Loam	0.5	6.7	0.67	143	0.92	
n/a	Sandy loam	1.1	7.5	0.66	60	0.92	
Worst-case					**60**		
Associated with worst-case Kfoc						**0.92**	
pH-dependency y/n					yes		

*Values in **bold** considered reliable for modelling*
n/a – not available

Table 8.5-2: Summary of soil adsorption/desorption for CGA179500

CGA179500							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
n/a	Clay	2.8	5.9	16.4	581	0.92	Y EFSA 2018; 16(3):5229
n/a	Sand	0.5	6.5	3.22	609	0.85	
n/a	Loam	0.5	6.7	1.54	328	0.90	
n/a	Sandy loam	1.1	7.5	1.61	145	0.90	
Worst-case					**145**		
Associated with worst-case Kfoc						**0.90**	
pH-dependency y/n					yes		

*Values in **bold** considered reliable for modelling*
n/a – not available

A study was provided in the active substance dossier to determine adsorption/desorption of metabolite CGA300405. However, reliable mobility data could not be generated due to high instability of this metabolite in soil:water systems. Therefore, the Kfoc was determined using the QSPR method (using KOCWIN^{TM}) = 1 mL/g.

Table 8.5-3: Summary of soil adsorption/desorption for CGA275537

CGA275537							
Soil Name	**Soil Type**	**OC (%)**	**pH (-)**	**Kf (mL/g)**	**Kfoc (mL/g)**	**1/n (-)**	**Evaluated on EU level y/n Reference**
Gartenacker	Loam	2.0	7.2	0.07	4.35	0.71	Y EFSA 2018; 16(3):5229
18 Acres	Sandy clay loam	25	5.9	1.32	52.8	0.68	
East Anglia	Sandy loam	1.9	7.1	0.7	14.0	0.83	
Sarpy	Loamy sand	2.3	6.5	0.47	20.4	0.83	
Seven Spring	Silt loam	0.54	5.2	6.7	1241	0.76	
				Worst-case	**4.35**		
				Associated with worst-case Kfoc		**0.71**	
				pH-dependency y/n	yes		

*Values in **bold** considered reliable for modelling*
pH values were measured in calcium chloride solution

8.5.1 Column leaching (KCP 9.1.2.1)

Column leaching studies were not required.

8.5.2 Lysimeter studies (KCP 9.1.2.2)

Lysimeter studies were evaluated during the active substance renewal assessment (please refer to EFSA Journal 2018;16(3):5229). Due to some technical deficiencies and low use rate used, results were not used for the risk assessment.

8.5.3 Field leaching studies (KCP 9.1.2.3)

Filed leaching studies were 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.

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

Trinexapac-ethyl, Distribution (max. sediment 6% after 1day in River, 4.4% after 3 days in Pond)											
Water/ sediment system	**pH water**	**pH sediment**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**χ^2**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**χ^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n Reference**
River (sand)	7.7/8.5	7.6	3.7	12.3	3.8	3.3	11	4.6	-	SFO	Y EFSA 2018; 16(3):5229
Pond (loam)	7.3/8.3	7.3	5.1	17	6.4	4.9	16.2	5.0	-	SFO	
Geometric mean (n=2)			**4.4**	14.5		4.0	13.3		-		

*Values in **bold** considered reliable for modelling*
pH in water phase measured at test start and end
pH in sediment measure in calcium chloride solution
Geometric mean normalized using Q10 of 2.58

Table 8.6-2: Summary of degradation in water/sediment of CGA179500

CGA179500, Distribution (max. water 64% after 14 days, max. in sediment 6.9% after 14 days, max. in total system 70.9% AR after 14 days) Kinetic formation fraction (k_f/k_{dp}): not available											
Water/ sediment system	**pH water**	**pH sediment**	**$DegT_{50}$ whole syst. (d)**	**$DegT_{90}$ whole syst. (d)**	**χ^2**	**$DissT_{50}$ water (d)**	**$DissT_{90}$ water (d)**	**χ^2**	**$DissT_{50}$ sed. (d)**	**Kinetic, Fit**	**Evaluated on EU level y/n Reference**
River (sand)	7.7/8.5	7.6	14	46.6	17.1	-	-	-	-	SFO-SFO	Y EFSA 2018; 16(3):5229
Pond (loam)	7.3/8.3	7.3	18	60.9	16.5	-	-	-	-	SFO-SFO	
Geometric mean (n=2)			**16**	53.3		-	--				

*Values in **bold** considered reliable for modelling*
pH in water phase measured at test start and end
pH in sediment measured in calcium chloride solution
Geometric mean normalized using Q10 of 2.58

Table 8.6-3: Summary of mineralisation and non-extractable residues in water/sediment of trinexapac-ethyl

Water/ sediment system	pH water	pH sediment	Mineralisation (x% after n days)	Non-extractable residues in sediment (max. x% after n days)	Non-extractable residues in sediment (x%) at study end	Evaluated on EU level y/n Reference
River (sand)	7.7/8.5	7.6	69% after 111 d	26% after 55 d	16% after 111 d	Y EFSA 2018; 16(3):5229
Pond (loam)	7.3/8.3	7.3	59% after 111 d	39% after 55 d	27% after 111 d	

pH in water phase measured at test start and end
pH in sediment measure in calcium chloride solution

Hydrolysis, phototransformation and ready biodegradability

The hydrolysis, phototransformation in water and ready biodegradability of trinexapac-ethyl were evaluated during the active substance renewal assessment, EFSA Journal 2018;16(3):5229. The endpoints are summarised in the table below.

Table 8.6-4: Hydrolysis, Phototransformation and Ready Biodegradability of Trinexapac-ethyl and metabolites

Parameter	Endpoint	Evaluated on EU level y/n Reference
Hydrolytic degradation of trinexapac-ethyl and metabolites >10%	pH 4: Trinexapac DT_{50} = 188.3 d at 24.5 ºC (1st order χ^2 = 1.9) SYN549299: 23% AR at 24.7 ºC (64 d)	Y EFSA 2018; 16(3):5229
	pH 5: Trinexapac DT_{50} = 221 d at 25 ºC (1st order χ^2 = 2.05) DT_{50} = 514 d at 25 ºC (1st order χ^2 = 0.75) CGA179500: 18% AR at 25 ºC (179 d) Mono-ethyl ester of tricarboxylic acid: 12.5% AR at 25 ºC (179 d)	
	pH 7: Trinexapac DT_{50} = 432 d at 25 ºC (1st order χ^2 = 3.2) DT_{50} = 782 d at 25 ºC (1st order χ^2 = 1.11) Hydrolytically stable CGA179500: 16% AR at 25 ºC (179 d)	
	pH 9: Trinexapac DT_{50} = 7.2 d at 25 ºC (1st order χ^2 = 3.05) DT_{50} = 11.3 d at 24. 7ºC (1st order χ^2 = 2.7) CGA179500: 88.2% AR at 25 ºC (30 d) CGA179500: 85.6% AR at 24.7 ºC (30 d)	
Hydrolytic degradation of CGA179500 and metabolites >10%	pH 4: CGA179500 DT_{50} = 81.6 d at 20 ºC (1st order χ^2 = 1.53) DT_{50} = 76.5 d at 24.9 ºC (1st order χ^2 = 3.3) DT_{50} = 72.7 d at 20 ºC (1st order χ^2 = 9.49) CGA313458: 31% AR at 20 ºC (91 d) Unknown (proposed as CGA224439): 25% AR at 20 ºC (9 1d) CGA313458: 36.8% AR at 24.9 ºC (91 d) CGA113745: 18.6% AR at 24.9 ºC (91 d) CGA313458: 12% AR at 20 ºC (91 d)	
	pH 5:	

Parameter	**Endpoint**	**Evaluated on EU level y/n Reference**
	CGA179500 DT_{50} = 80 d at 20 ºC (1st order χ^2 = 1.72) DT_{50} = 71.3 d at 20 ºC (1st order χ^2 = 8.48) CGA313458: 22% AR at 20 ºC (91 d) Unknown (proposed as CGA224439): 35% AR at 20 ºC (91 d)	
	pH 7: stable	
	pH 9: stable	
Photolytic degradation of the active substance and metabolites above 10% - Direct photolysis	Trinexapac-ethyl: DT_{50}: 2.8 d, Natural light, 50°N; DT_{50} 5.4 days CGA300405: 41% AR (15 d) Continuously formed during the study, DT_{50} was not determined M2: 17.9% AR (5 d) Estimated DT_{50} at 50°N 34.4 days WaterM3Photolysis: 16.9% AR (5 d) Estimated DT_{50} at 50°N 27.5 days	
Photolytic degradation of the active substance and metabolites above 10% - Indirect photolysis	Trinexapac-ethyl: DT_{50}: 2.6 d, Natural light, 35°N; DT_{50} 15.3 days (SFO) CGA300405: 83% AR (7 d) Continuously formed during the study, DT_{50} was not determined	
Quantum yield of direct phototransformation in water at ∑ > 290 nm	Not calculated	
Readily biodegradable (y/n)	No	

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

8.7.1 Justification for new endpoints

Review Comments:

The PEC_{soil} calculations for trinexapac-ethyl, its 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.

The EU agreed endpoints were used for PEC_{Soil} calculations of trinexapac-ethyl and its metabolites. Reference is made to EFSA Journal 2018;16(3):5229.

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

PEC_{soil} of ADM.09050.H.1.A are calculated below in accordance with FOCUS Guidance (SANCO/10058/2005 v.2.0, 2006) considering the worst-case application pattern of all intended GAP uses as given in Appendix 1 of part B0. Note that EFSA Guidance for predicting environmental concentrations in soil (EFSA Journal 2017;15(10):4982) is not yet noted and the modeling tool PERSAM is not intended for regulatory use in support of 1107/2009, according to the Joint Research Centre, European Soil Data Centre website. PEC_{Soil} were calculated for a standard soil according to the EU guideline FOCUS (1997)[1] considering a dry soil bulk density of 1.5 g/cm^3 and a 5 cm soil depth following application to the soil surface.

Table 8.7-1: Input parameters related to application for PEC$_{soil}$ calculations

Use No.	7	14	25
Crop	Spring barley	Winter barley	Grass for seed
Application rate (g as/ha)	105	210	140
Number of applications/interval	1/not applicable	1/not applicable	1/not applicable
Crop interception (%)	20	80	60
Depth of soil layer (relevant for plateau concentration) (cm)	Not applicable	Not applicable	Not applicable

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

Compound	Molecular weight (g/mol)	Max. occurrence (%)	DT$_{50}$ (days)	Value in accordance to EU endpoint y/n/ Reference
Trinexapac-ethyl	252.3	-	0.72 d (SFO Kinetics, Maximum, laboratory study)	Y EFSA Journal 2018;16(3):5229
CGA179500	224.2	93.1	53 d (SFO Kinetics, Maximum, laboratory study)	
CGA300405	204.1	12.5	0.52 d (FOMC Kinetics, Maximum, laboratory study)	
CGA275537	176.1	10.8	0.27 d (SFO Kinetics, Maximum, laboratory study)	

[1] FOCUS (1997): Soil Persistence Models and EU Registration - The final report of the work of the Soil Modelling Work group of FOCUS (FOrum for the Co-ordination of pesticide fate models and their Use). 29.02.97, 77 pp.

Table 8.7-3: PEC_{soil} for Trinexapac-ethyl on spring barley

PEC_{soil} (mg/kg)		Spring barley	
		Single application	
		Actual	TWA
Initial		0.112	-
Short term	24h	0.043	0.072
	2d	0.016	0.050
	4d	0.002	0.028
Long term	7d	<0.001	0.017
	14d	<0.001	0.008
	21d	<0.001	0.006
	28d	<0.001	0.004
	50d	<0.001	0.002
	100d	<0.001	0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not applicable	

Table 8.7-4: PEC_{soil} for Trinexapac-ethyl on winter barley

PEC_{soil} (mg/kg)		Winter barley	
		Single application	
		Actual	TWA
Initial		0.056	-
Short term	24h	0.021	0.036
	2d	0.008	0.025
	4d	0.001	0.014
Long term	7d	<0.001	0.008
	14d	<0.001	0.004
	21d	<0.001	0.003
	28d	<0.001	0.002
	50d	<0.001	0.001
	100d	<0.001	0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not applicable	

Table 8.7-5: PEC$_{soil}$ for Trinexapac-ethyl on grass for seed

PEC$_{soil}$ (mg/kg)		Grass for seed	
		Single application	
		Actual	TWA
Initial		0.075	-
Short term	24h	0.029	0.048
	2d	0.011	0.033
	4d	0.002	0.019
Long term	7d	<0.001	0.011
	14d	<0.001	0.006
	21d	<0.001	0.004
	28d	<0.001	0.003
	50d	<0.001	0.002
	100d	<0.001	0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

PEC$_{soil}$ of metabolites

Table 8.7-6: PEC$_{soil}$ for CGA179500 on spring barley

PEC$_{soil}$ (mg/kg)		Spring barley	
		Single application	
		Actual	TWA
Initial		0.093	-
Short term	24h	0.091	0.092
	2d	0.090	0.091
	4d	0.088	0.090
Long term	7d	0.085	0.09
	14d	0.077	0.085
	21d	0.070	0.081
	28d	0.064	0.078
	50d	0.048	0.068
	100d	0.025	0.052
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

Table 8.7-7: PEC$_{soil}$ for CGA179500 on winter barley

PEC$_{soil}$ (mg/kg)		Winter barley	
		Single application	
		Actual	TWA
Initial		0.046	-
Short term	24h	0.046	0.046
	2d	0.045	0.046
	4d	0.044	0.045
Long term	7d	0.042	0.044
	14d	0.039	0.042
	21d	0.035	0.041
	28d	0.032	0.039
	50d	0.024	0.034
	100d	0.013	0.026
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

Table 8.7-8: PEC$_{soil}$ for CGA179500 on grass for seed

PEC$_{soil}$ (mg/kg)		Grass for seed	
		Single application	
		Actual	TWA
Initial		0.062	-
Short term	24h	0.061	0.061
	2d	0.060	0.061
	4d	0.059	0.060
Long term	7d	0.056	0.059
	14d	0.051	0.056
	21d	0.047	0.054
	28d	0.043	0.052
	50d	0.032	0.045
	100d	0.017	0.034
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

Table 8.7-9: PEC$_{soil}$ for CGA300405 on spring barley

PEC$_{soil}$ (mg/kg)		Spring barley	
		Single application	
		Actual	TWA
Initial		0.011	-
Short term	24h	0.003	0.006
	2d	0.001	0.004
	4d	<0.001	0.002
Long term	7d	<0.001	0.001
	14d	<0.001	0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

Table 8.7-10: PEC$_{soil}$ for CGA300405 on winter barley

PEC$_{soil}$ (mg/kg)		Winter barley	
		Single application	
		Actual	TWA
Initial		0.006	-
Short term	24h	0.001	0.003
	2d	<0.001	0.002
	4d	<0.001	0.001
Long term	7d	<0.001	0.001
	14d	<0.001	<0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

Table 8.7-11: PEC_{soil} for CGA300405 on grass for seed

PEC_{soil} (mg/kg)		Grass for seed	
		Single application	
		Actual	TWA
Initial		0.006	-
Short term	24h	0.001	0.003
	2d	<0.001	0.002
	4d	<0.001	0.001
Long term	7d	<0.001	0.001
	14d	<0.001	<0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not applicable	

Table 8.7-12: PEC_{soil} for CGA275527 on spring barley

PEC_{soil} (mg/kg)		Spring barley	
		Single application	
		Actual	TWA
Initial		0.008	-
Short term	24h	0.001	0.003
	2d	<0.001	0.002
	4d	<0.001	0.001
Long term	7d	<0.001	<0.001
	14d	<0.001	<0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
$PEC_{accumulation}$ (PEC_{act} +$PEC_{soil\ plateau}$)		Not applicable	

Table 8.7-13: PEC$_{soil}$ for CGA275527 on winter barley

PEC$_{soil}$ (mg/kg)		Winter barley	
		Single application	
		Actual	TWA
Initial		0.004	-
Short term	24h	<0.001	0.002
	2d	<0.001	0.001
	4d	<0.001	<0.001
Long term	7d	<0.001	<0.001
	14d	<0.001	<0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

Table 8.7-14: PEC$_{soil}$ for CGA275527 on grass for seed

PEC$_{soil}$ (mg/kg)		Grass for seed	
		Single application	
		Actual	TWA
Initial		0.006	-
Short term	24h	<0.001	0.002
	2d	<0.001	0.001
	4d	<0.001	0.001
Long term	7d	<0.001	<0.001
	14d	<0.001	<0.001
	21d	<0.001	<0.001
	28d	<0.001	<0.001
	50d	<0.001	<0.001
	100d	<0.001	<0.001
Plateau concentration (5/20 cm) after year x		Not applicable	-
PEC$_{accumulation}$ (PEC$_{act}$ +PEC$_{soil\ plateau}$)		Not applicable	

8.7.2.1 PEC$_{soil}$ of ADM.09050.H.1.A

The initial PECsoil values for the formulation ADM.09050.H.1.A have been calculated using the relevant application rates for each critical GAP and the formulation density of 0.997 g/mL. The worst-case crop interception have been used for each critical GAP.

Table 8.7-15: PEC$_{soil}$ for ADM.09050.H.1.A

GAP No.	Crop	Application rate (g/ha)	Crop interception (%)	PEC$_{act}$ (mg/kg)	PEC$_{twa}$21 d (mg/kg)	Tillage depth (cm)	PEC$_{soil,plateau}$ (mg/kg)	PEC$_{accu}$ = PEC$_{act}$ + PEC$_{soil,plateau}$ (mg/kg)
7	Spring barley	598.2	20	0.638	n/r	n/r	n/r	n/r
14	Winter barley	1196.4	80	0.319	n/r	n/r	n/r	n/r
25	Grass	797.6	60	0.425	n/r	n/r	n/r	n/r

n/r not relevant

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

8.8.1 Justification for new endpoints

Review Comments:

According FOCUS DG SANTE for active substances and their relevant metabolites PEC$_{GW}$ calculations after 1 January 2022 should be performed with new versions of models: FOCUS PEARL 5.5.5 and FOCUS PELMO 6.6.4. Nevertheless, as PECgw values for the active substance and its metabolites are extremely low (<0.001 µg/L in all scenarios of three models), thus the calculation performed with FOCUS MACRO 5.5.4, FOCUS PEARL 4.4.4 and FOCUS PELMO 5.5.3 were accepted (KCP 9.2.4-01, Hicks 2020, TXP-EFA-01CEU).

The EU agreed endpoints, derived from the datasets presented in the Journal 2018;16(3):5229, were used.

The PEC$_{GW}$ of trinexapac-ethyl (80th percentile) at 1 m depth following uses on cereals and grasses, were less than 0.001 µg/L in all scenarios. The potential for the metabolites CGA179500, CGA300405 and CGA275537 to leach to ground water has been assessed using the same approach. The PEC$_{GW}$ for those metabolites were less than 0.001 µg/L in all scenarios.

In conclusion, the results demonstrate that ADM.09050.H.1.A (Stemper) can be applied safely according to the recommended use patterns without risk of trinexapac-ethyl and its metabolites exceeding acceptable levels in groundwater.

Reference is made to EFSA Journal 2018;16(3):5229

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

In accordance with the active substance renewal assessment, EFSA Journal 2018;16(3):5229, the soil metabolites of trinexapac-ethyl are formed by different processes, therefore different PECgw calculations are required. Metabolite CGA179500 is formed by microbial degradation in aerobic soil. Metabolites CGA179500, CGA300405 and CGA275537 are formed by photolytic degradation in the soil.

For microbial degradation, PECgw values for CGA179500 were calculated as a metabolite of trinexapac-ethyl.

For photolytic degradation, each substance was calculated separately as if it was a parent substance. Pseudo application rates were calculated for the metabolites as follows:

$$\frac{\text{MW metabolite}}{\text{MW parent}} \times \frac{\text{Max. observed}}{100} \times \text{parent app. rate} = \text{pseudo app. Rate}$$

Details of PECgw calculations can be found in report Hicks J., 2020a, TXP/EFA/01 submitted as KCP 9.2.4-01.

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

Use No.	7	14	25
Crop	Spring cereals	Winter cereals	Grass
Application rate (g as/ha)	105	210	140
Pseudo application rates (g met/ha)	CGA179500 57.4 CGA300405 10.6 CGA275537 7.9	CGA179500 114.8 CGA300405 21.2 CGA275537 15.8	CGA179500 76.5 CGA300405 14.2 CGA275537 10.6
Number of applications/interval (d)	1/not applicable	1/not applicable	1/not applicable
Relative application date	Absolute dates used	Absolute dates used	Absolute dates used
Crop interception (%)	20	80	60
Frequency of application	annual	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v~~5.5.3~~ 5.5.4	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v~~5.5.3~~ 5.5.4	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v~~5.5.3~~ 5.5.4

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

Scenario	**Application dates (absolute)**		
Crop	**Spring cereals**	**Winter cereals**	**Grass**
Châteaudun	2nd Apr	13th Feb	23rd Mar
Hamburg	21st Apr	15th Feb	25th Mar
Jokioinen	31st May	15th Oct	25th Apr
Kremsmünster	21st Apr	15th Feb	25th Mar
Okehampton	17th Apr	5th Feb	15th Mar

Scenario	Application dates (absolute)		
Crop	**Spring cereals**	**Winter cereals**	**Grass**
Piacenza	Not applicable	20th Feb	30th Mar
Porto	7th Apr	15th Feb	25th Mar
Sevilla	Not applicable	28th Dec	4th Feb
Thiva	Not applicable	27th Jan	6th Mar

Application dates are taken from EFSA Journal 2018;16(3):5229. These dates were selected using AppDate v2.0b.

Table 8.8-3: Input parameters related to active substance trinexapac-ethyl and metabolite(s) for PEC_{gw} calculations

Compound	Trinexapac-ethyl	CGA179500	CGA300405	CGA275537	Value in accordance with EU endpoint y/n/ Reference
Molecular weight (g/mol)	252.3	224.2	204.1	176.1	Y EFSA 2018; 16(3):5229
Water solubility (mg/L):	21100	200000	21100	200000	Y EFSA 2018; 16(3):5229
Saturated vapour pressure (Pa):	0	0	0	0	Y EFSA 2018; 16(3):5229
DT_{50} in soil (d)	0.13 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =4)	5.4 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =4)	0.23 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =3)	0.21 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =3)	Y EFSA 2018; 16(3):5229
Transformation rate	5.332	0.128	3.014	3.301	Calculated in PELMO
K_{foc} (mL/g)/K_{fom}	60/34.9 (worst-case)	145/84.3 (worst-case)	1/0.58 (calculated using KOCWIN™)	4.35/2.53 (worst-case)	Y EFSA 2018; 16(3):5229
1/n	0.92 (associated with worst-case Kf_{oc})	0.9 (associated with worst-case Kf_{oc})	1 (calculated using KOCWIN™)	0.71 (associated with worst-case Kf_{oc})	Y EFSA 2018; 16(3):5229
Plant uptake factor	0	0	0	0	Y EFSA 2018;

Compound	Trinexapac-ethyl	CGA179500	CGA300405	CGA275537	Value in accordance with EU endpoint y/n/ Reference
					16(3):5229
Formation fraction	Not applicable	1 from parent	Not applicable	Not applicable	Y EFSA 2018; 16(3):5229

* Delete row in case of no pH dependency

Table 8.8-4: PEC$_{gw}$ for trinexapac-ethyl and metabolites on spring cereals, winter cereals and grass formed by aerobic soil degradation (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)	
		Trinexapac-ethyl	CGA179500
Spring cereals	Châteaudun	<0.001/<0.001	<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001
	Porto	<0.001/<0.001	<0.001/<0.001
Winter cereals	Châteaudun	<0.001/<0.001	<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001
	Piacenza	<0.001/<0.001	<0.001/<0.001
	Porto	<0.001/<0.001	<0.001/<0.001
Grass	Châteaudun	<0.001/<0.001	<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001
	Piacenza	<0.001/<0.001	<0.001/<0.001
	Porto	<0.001/<0.001	<0.001/<0.001

Table 8.8-5: PEC$_{gw}$ for trinexapac-ethyl and metabolites on spring cereals, winter cereals and grass formed by photolytic degradation (with FOCUS PEARL 4.4.4/PELMO 5.5.3)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Trinexapac-ethyl	**CGA179500**	**CGA300405**	**CGA275537**
Spring cereals	Châteaudun	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Porto	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
Winter cereals	Châteaudun	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Piacenza	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Porto	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
Grass	Châteaudun	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Hamburg	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Kremsmünster	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Okehampton	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Piacenza	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001
	Porto	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001	<0.001/<0.001

Table 8.8-6: PEC$_{gw}$ for trinexapac-ethyl and metabolites on spring cereals, winter cereals and grass formed by aerobic soil degradation / photolytic degradation (with MACRO 5.5.4)

Crop	Scenario	80th Percentile PEC$_{gw}$ at 1 m Soil Depth (µg/L)			
		Trinexapac-ethyl	**CGA179500**	**CGA300405**	**CGA275537**
Spring cereals	Châteaudun	<0.001/<0.001	<0.001/<0.001	n/a/<0.001	n/a/<0.001
Winter cereals	Châteaudun	<0.001/<0.001	<0.001/<0.001	n/a/<0.001	n/a/<0.001
Grass	Châteaudun	<0.001/<0.001	<0.001/<0.001	n/a/<0.001	n/a/<0.001

n/a not applicable

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

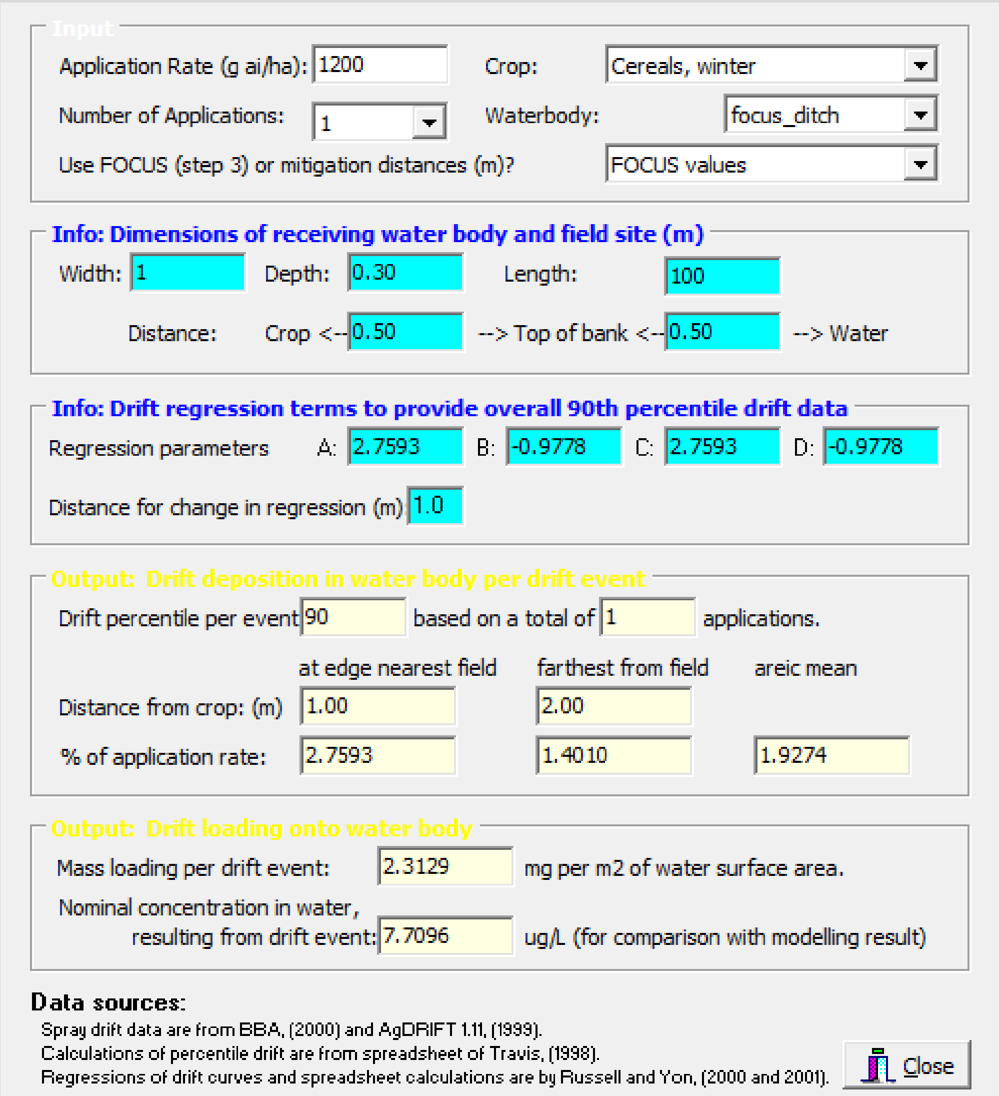
Review Comments:

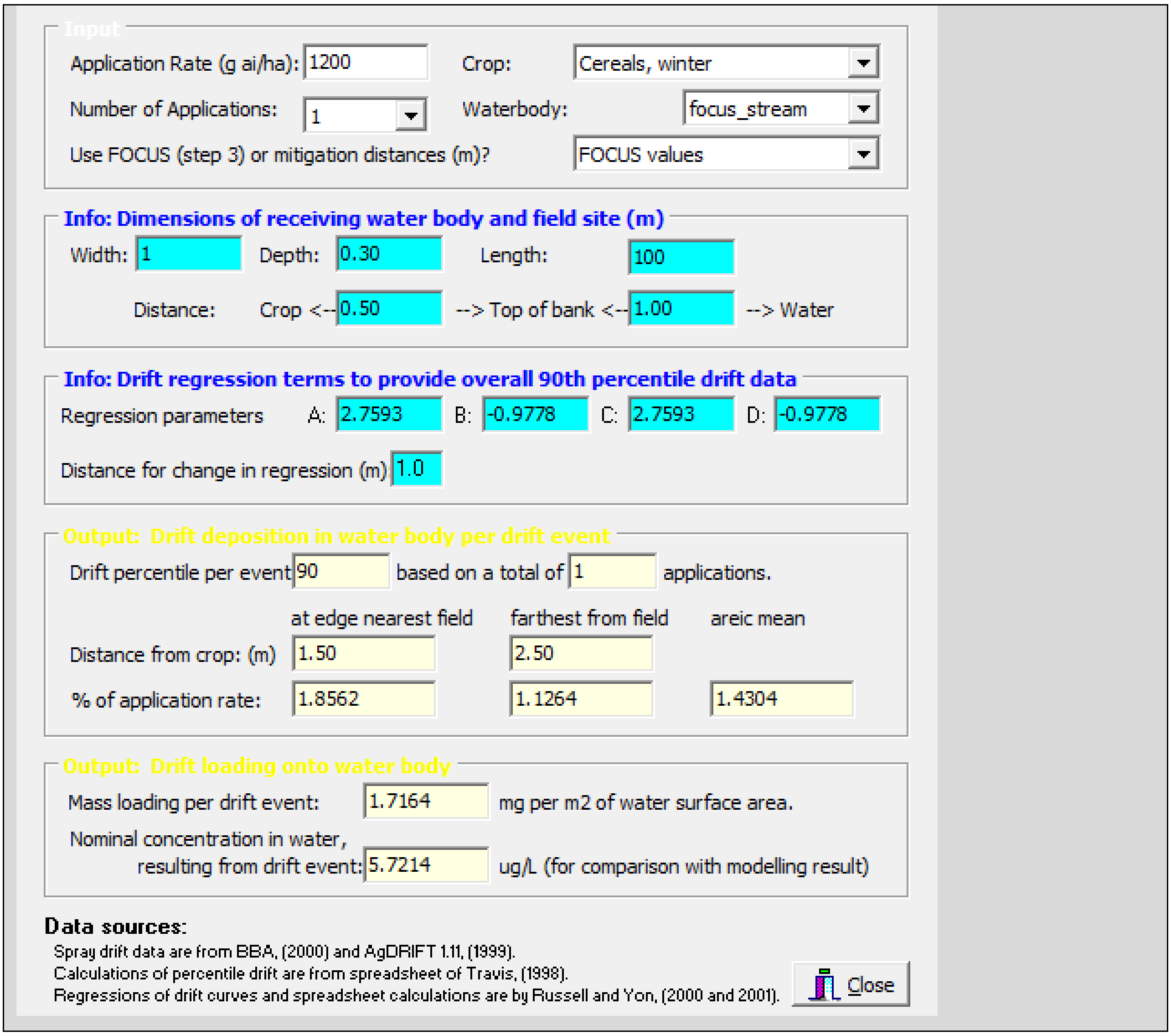
The $PECS_{SW/SED}$ calculations for trinexapac-ethyl and its relevant metabolites were provided by the Applicant and are considered acceptable.

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

The EU agreed endpoints, derived from the datasets presented in the EFSA Journal 2018;16(3):5229, were used.

Additional calculations for the formulation were performed by zRMS (the risk envelope approach). The initial PECsw values for the formulation ADM.09050.H.1.A have been calculated using the application rates of 1.2L/ha and the formulation density of 1 g/mL.





Input

Application Rate (g ai/ha): 1200 Crop: Cereals, winter

Number of Applications: 1 Waterbody: focus_stream

Use FOCUS (step 3) or mitigation distances (m)? FOCUS values

Info: Dimensions of receiving water body and field site (m)

Width: 1 Depth: 0.30 Length: 100

Distance: Crop <-- 0.50 --> Top of bank <-- 1.00 --> Water

Info: Drift regression terms to provide overall 90th percentile drift data

Regression parameters A: 2.7593 B: -0.9778 C: 2.7593 D: -0.9778

Distance for change in regression (m) 1.0

Output: Drift deposition in water body per drift event

Drift percentile per event 90 based on a total of 1 applications.

	at edge nearest field	farthest from field	areic mean
Distance from crop: (m)	1.50	2.50	
% of application rate:	1.8562	1.1264	1.4304

Output: Drift loading onto water body

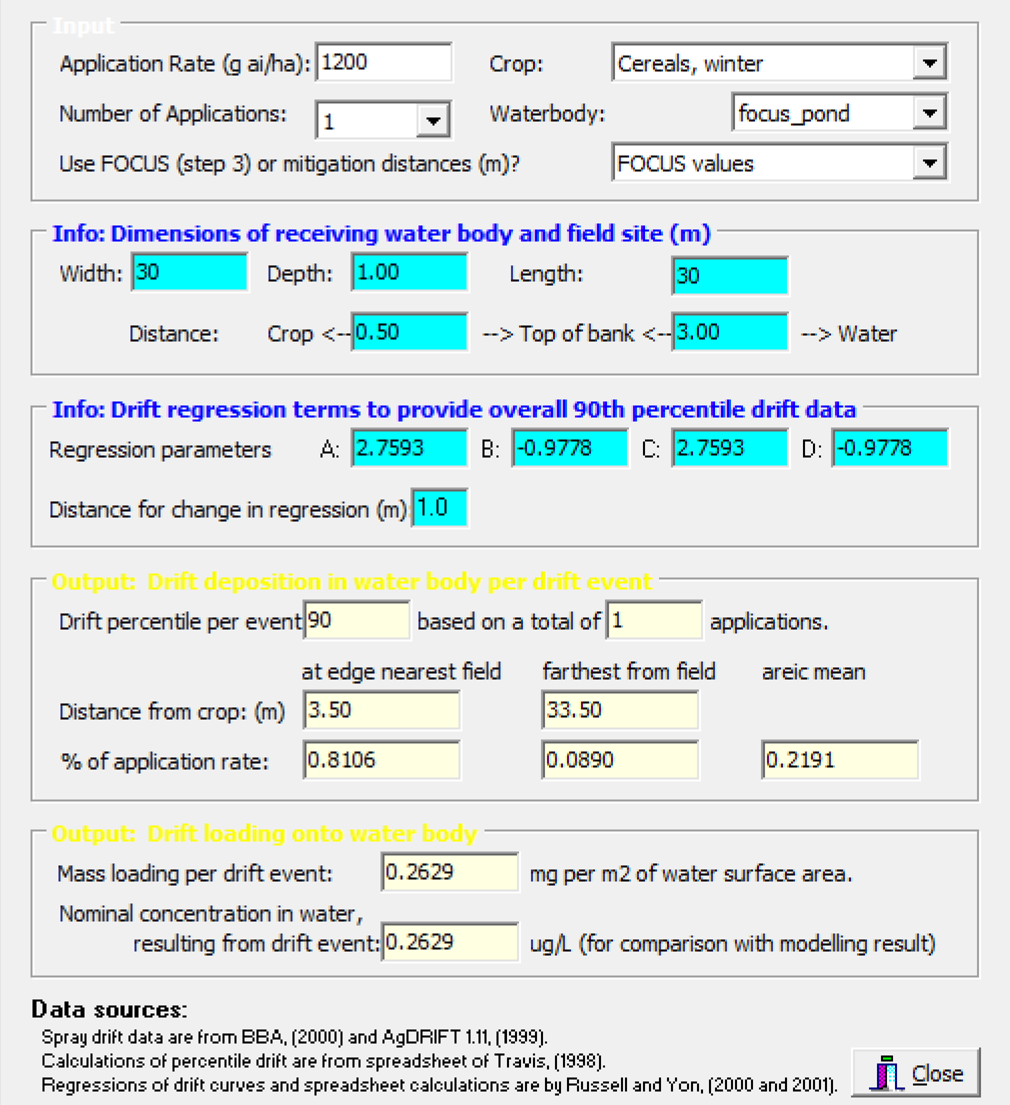
Mass loading per drift event: 1.7164 mg per m2 of water surface area.

Nominal concentration in water, resulting from drift event: 5.7214 ug/L (for comparison with modelling result)

Data sources:

Spray drift data are from BBA, (2000) and AgDRIFT 1.11, (1999).
Calculations of percentile drift are from spreadsheet of Travis, (1998).
Regressions of drift curves and spreadsheet calculations are by Russell and Yon, (2000 and 2001).

Close



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

In accordance with the active substance renewal assessment, EFSA Journal 2018;16(3):5229, PEC_{sw} values are required for water metabolites M2 and WaterM3Photolysis (hereafter referred to as M3). However, the required endpoints are not available. The PEC_{sw} values for these two metabolites are derived from the PEC_{sw} values of trinexapac-ethyl as follows:

$$\frac{\text{MW metabolite}}{\text{MW parent}} \times \frac{\text{Max. observed}}{100} \times \text{parent } PEC_{sw} = \text{Metabolite } PEC_{sw}$$

Details of PEC_{sw} calculations can be found in report Hicks J., 2020b, TXP/EFA/02 submitted as KCP 9.2.5-01.

8.9.1 Justification for new endpoints

Reference is made to EFSA Journal 2018;16(3):5229.

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

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

Plant protection product	ADM.09050.H.1.A		
Use No.	7	14	25
Crop	Spring cereals	Winter cereals	Grass
Application rate (kg as/ha)	105	210	140
Number of applications/interval (d)	1/not applicable	1/not applicable	1/not applicable
Application window	NEU + SEU, Mar-May, Jun-Sep, Oct-Feb	NEU + SEU, Mar-May, Jun-Sep, Oct-Feb	NEU + SEU, Mar-May, Jun-Sep, Oct-Feb
Application method	Ground spray	Ground spray	Ground spray
CAM (Chemical application method)	Not applicable	Not applicable	Not applicable
Soil depth (cm)	Not applicable	Not applicable	Not applicable
Models used for calculation	FOCUS Steps 1 and 2 v. 3.2	FOCUS Steps 1 and 2 v. 3.2	FOCUS Steps 1 and 2 v. 3.2

Table 8.9-2: Input parameters related to active substance trinexapac-ethyl and metabolite(s) for $PEC_{sw/sed}$ calculations STEP 1/2

Compound	Trinexapac-ethyl	CGA179500	CGA300405	CGA275537	Value in accordance to EU endpoint y/n / Reference
Molecular weight (g/mol)	252.3	224.2	204.1	176.1	Y EFSA 2018; 16(3):5229
Saturated vapour pressure (Pa)	not required for Step 1+2/				
Water solubility (mg/L)	21100	200000	21100	200000	Y EFSA 2018; 16(3):5229
Diffusion coefficient in water (m²/d)	not required for Step 1+2				default
Diffusion coefficient in air (m²/d)	not required for Step 1+2/0.43				default
K_{foc} (mL/g)	60/34.9 (worst-case)	145/84.3 (worst-case)	1/0.58 (calculated using KOCWIN™)	4.35/2.53 (worst-case)	Y EFSA 2018; 16(3):5229

Compound	Trinexapac-ethyl	CGA179500	CGA300405	CGA275537	Value in accordance to EU endpoint y/n / Reference
Freundlich Exponent 1/n	0.92 (associated with worst-case Kf_{oc})	0.9 (associated with worst-case Kf_{oc})	1 (calculated using KOCWIN™)	0.71 (associated with worst-case Kf_{oc})	Y EFSA 2018; 16(3):5229
Plant Uptake	not required for Step 1+2				
Wash-Off factor from Crop (1/mm)	not required for Step 1+2				
$DT_{50,soil}$ (d)	0.13 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =4)	5.4 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =4)	0.23 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =3)	0.21 (geomean, normalisation to 10 kPa or pF2, 20 °C with Q_{10} of 2.58 and Walker coefficient of 0.7, n =3)	Y EFSA 2018; 16(3):5229
$DT_{50,water}$ (d)	4.4 (geomean, normalisation Q_{10} of 2.58, n =2)	16/1000	1000	1000	Y EFSA 2018; 16(3):5229
$DT_{50,sed}$ (d)	1000	1000/16	1000	1000	default
$DT_{50,whole\ system}$ (d)	4.4	16	1000	1000	Y EFSA 2018; 16(3):5229
Maximum occurrence observed (% molar basis with respect to the parent)	-	Soil: 93.1 Total water/sediment system: 70.9	Soil: 12.5 Total water/sediment system: 41.0	Soil: 10.8 Total water/sediment system: 0	Y EFSA 2018; 16(3):5229

$PEC_{sw/sed}$

Table 8.9-3: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for trinexapac-ethyl following single application of ADM.09050.H.1.A to spring barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	26.698	Runoff/drainage	Not triggered	15.556
Step 2					
Northern Europe	March-May	0.7725	Drift	Not triggered	0.2859
Northern Europe	June-Sept	0.7725	Drift	Not triggered	0.2859
Northern Europe	Oct-Feb	0.7725	Drift	Not triggered	0.2859
Southern Europe	March-May	0.7725	Drift	Not triggered	0.2859
Southern Europe	June-Sept	0.7725	Drift	Not triggered	0.2859
Southern Europe	Oct-Feb	0.7725	Drift	Not triggered	0.2859
Step 3	Not triggered				

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

Table 8.9-4: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for trinexapac-ethyl following single application of ADM.09050.H.1.A to winter barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	13.349	Runoff/drainage	Not triggered	7.7778
Step 2					
Northern Europe	March-May	0.3863	Drift	Not triggered	0.1430
Northern Europe	June-Sept	0.3863	Drift	Not triggered	0.1430
Northern Europe	Oct-Feb	0.3863	Drift	Not triggered	0.1430
Southern Europe	March-May	0.3863	Drift	Not triggered	0.1430
Southern Europe	June-Sept	0.3863	Drift	Not triggered	0.1430
Southern Europe	Oct-Feb	0.3863	Drift	Not triggered	0.1430

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 3	Not triggered				

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

Table 8.9-5: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for trinexapac-ethyl following single application of ADM.09050.H.1.A to grass

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominant entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	17.799	Runoff/drainage	Not triggered	10.370
Step 2					
Northern Europe	March-May	0.5150	Drift	Not triggered	0.1906
Northern Europe	June-Sept	0.5150	Drift	Not triggered	0.1906
Northern Europe	Oct-Feb	0.5150	Drift	Not triggered	0.1906
Southern Europe	March-May	0.5150	Drift	Not triggered	0.1906
Southern Europe	June-Sept	0.5150	Drift	Not triggered	0.1906
Southern Europe	Oct-Feb	0.5150	Drift	Not triggered	0.1906
Step 3	Not triggered				

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

Metabolites of trinexapac-ethyl

Table 8.9-6: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA179500 following single application to spring barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	28.093	Runoff/drainage	Not triggered	40.029
Step 2					
Northern Europe	March-May	1.903	Runoff/drainage	Not triggered	2.731
Northern Europe	June-Sept	1.903	Runoff/drainage	Not triggered	2.731
Northern	Oct-Feb	4.205	Runoff/drainage	Not triggered	6.066

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Europe					
Southern Europe	March-May	3.437	Runoff/drainage	Not triggered	4.955
Southern Europe	June-Sept	2.670	Runoff/drainage	Not triggered	3.843
Southern Europe	Oct-Feb	3.437	Runoff/drainage	Not triggered	4.955
Step 3	Not triggered				

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

Table 8.9-7: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA179500 following single application to winter barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	14.046	Runoff/drainage	Not triggered	20.014
Step 2					
Northern Europe	March-May	0.951	Runoff/drainage	Not triggered	1.365
Northern Europe	June-Sept	0.951	Runoff/drainage	Not triggered	1.365
Northern Europe	Oct-Feb	2.102	Runoff/drainage	Not triggered	3.033
Southern Europe	March-May	1.719	Runoff/drainage	Not triggered	2.477
Southern Europe	June-Sept	1.335	Runoff/drainage	Not triggered	1.921
Southern Europe	Oct-Feb	1.719	Runoff/drainage	Not triggered	2.477
Step 3	Not triggered				

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

Table 8.9-8: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA179500 following single application to grass

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	18.728	Runoff/drainage	Not triggered	26.686
Step 2					
Northern Europe	March-May	1.268	Runoff/drainage	Not triggered	1.820
Northern Europe	June-Sept	1.268	Runoff/drainage	Not triggered	1.820
Northern Europe	Oct-Feb	2.803	Runoff/drainage	Not triggered	4.044
Southern Europe	March-May	2.292	Runoff/drainage	Not triggered	3.303
Southern Europe	June-Sept	1.780	Runoff/drainage	Not triggered	2.562
Southern Europe	Oct-Feb	2.292	Runoff/drainage	Not triggered	3.303
Step 3	Not triggered				

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

Table 8.9-9: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA300405 following single application to spring barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	12.3583	Runoff/drainage	Not triggered	0.1235
Step 2					
Northern Europe	March-May	0.2562	Drift	Not triggered	0.0026
Northern Europe	June-Sept	0.2562	Drift	Not triggered	0.0026
Northern Europe	Oct-Feb	0.2562	Drift	Not triggered	0.0026
Southern Europe	March-May	0.2562	Drift	Not triggered	0.0026
Southern Europe	June-Sept	0.2562	Drift	Not triggered	0.0026
Southern Europe	Oct-Feb	0.2562	Drift	Not triggered	0.0026
Step 3	Not triggered				

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

Table 8.9-10: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA300405 following single application to winter barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	6.179	Runoff/drainage	Not triggered	0.0617
Step 2					
Northern Europe	March-May	0.1281	Drift	Not triggered	0.0013
Northern Europe	June-Sept	0.1281	Drift	Not triggered	0.0013
Northern Europe	Oct-Feb	0.1281	Drift	Not triggered	0.0013
Southern Europe	March-May	0.1281	Drift	Not triggered	0.0013
Southern Europe	June-Sept	0.1281	Drift	Not triggered	0.0013
Southern Europe	Oct-Feb	0.1281	Drift	Not triggered	0.0013
Step 3	Not triggered				

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

Table 8.9-11: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA300405 following single application to grass

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	8.239	Runoff/drainage	Not triggered	0.081
Step 2					
Northern Europe	March-May	0.1708	Drift	Not triggered	0.0017
Northern Europe	June-Sept	0.1708	Drift	Not triggered	0.0017
Northern Europe	Oct-Feb	0.1708	Drift	Not triggered	0.0017
Southern Europe	March-May	0.1708	Drift	Not triggered	0.0017
Southern Europe	June-Sept	0.1708	Drift	Not triggered	0.0017
Southern Europe	Oct-Feb	0.1708	Drift	Not triggered	0.0017
Step 3	Not triggered				

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

Table 8.9-12: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA275537 following single application to spring barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	2.0971	Runoff/drainage	Not triggered	0.0912
Step 2					
Northern Europe	March-May	<0.001	Not applicable	Not triggered	<0.001
Northern Europe	June-Sept	<0.001	Not applicable	Not triggered	<0.001
Northern Europe	Oct-Feb	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	March-May	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	June-Sept	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	Oct-Feb	<0.001	Not applicable	Not triggered	<0.001
Step 3	Not triggered				

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

Table 8.9-13: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA275537 following single application to winter barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.0493	Runoff/drainage	Not triggered	0.0456
Step 2					
Northern Europe	March-May	<0.001	Not applicable	Not triggered	<0.001
Northern Europe	June-Sept	<0.001	Not applicable	Not triggered	<0.001
Northern Europe	Oct-Feb	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	March-May	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	June-Sept	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	Oct-Feb	<0.001	Not applicable	Not triggered	<0.001
Step 3	Not triggered				

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

Table 8.9-14: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for CGA275537 following single application to grass

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	1.3990	Runoff/drainage	Not triggered	0.0609
Step 2					
Northern Europe	March-May	<0.001	Not applicable	Not triggered	<0.001
Northern Europe	June-Sept	<0.001	Not applicable	Not triggered	<0.001
Northern Europe	Oct-Feb	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	March-May	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	June-Sept	<0.001	Not applicable	Not triggered	<0.001
Southern Europe	Oct-Feb	<0.001	Not applicable	Not triggered	<0.001
Step 3	Not triggered				

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

Table 8.9-15: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for M2 following single application to spring barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	5.4987	Runoff/drainage	Not triggered	3.2039
Step 2					
Northern Europe	March-May	0.1591	Not applicable	Not triggered	0.0589
Northern Europe	June-Sept	0.1591	Not applicable	Not triggered	0.0589
Northern Europe	Oct-Feb	0.1591	Not applicable	Not triggered	0.0589
Southern Europe	March-May	0.1591	Not applicable	Not triggered	0.0589
Southern Europe	June-Sept	0.1591	Not applicable	Not triggered	0.0589
Southern Europe	Oct-Feb	0.1591	Not applicable	Not triggered	0.0589
Step 3	Not triggered				

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

Table 8.9-16: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for M2 following single application to winter barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	2.7494	Runoff/drainage	Not triggered	1.6019
Step 2					
Northern Europe	March-May	0.0796	Not applicable	Not triggered	0.0295
Northern Europe	June-Sept	0.0796	Not applicable	Not triggered	0.0295
Northern Europe	Oct-Feb	0.0796	Not applicable	Not triggered	0.0295
Southern Europe	March-May	0.0796	Not applicable	Not triggered	0.0295
Southern Europe	June-Sept	0.0796	Not applicable	Not triggered	0.0295
Southern Europe	Oct-Feb	0.0796	Not applicable	Not triggered	0.0295
Step 3	Not triggered				

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

Table 8.9-17: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for M2 following single application to grass

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.6659	Runoff/drainage	Not triggered	2.1358
Step 2					
Northern Europe	March-May	0.1061	Not applicable	Not triggered	0.0393
Northern Europe	June-Sept	0.1061	Not applicable	Not triggered	0.0393
Northern Europe	Oct-Feb	0.1061	Not applicable	Not triggered	0.0393
Southern Europe	March-May	0.1061	Not applicable	Not triggered	0.0393
Southern Europe	June-Sept	0.1061	Not applicable	Not triggered	0.0393
Southern Europe	Oct-Feb	0.1061	Not applicable	Not triggered	0.0393
Step 3	Not triggered				

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

Table 8.9-18: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for M3 following single application to spring barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	4.5120	Runoff/drainage	Not triggered	2.6290
Step 2					
Northern Europe	March-May	0.1306	Not applicable	Not triggered	0.0483
Northern Europe	June-Sept	0.1306	Not applicable	Not triggered	0.0483
Northern Europe	Oct-Feb	0.1306	Not applicable	Not triggered	0.0483
Southern Europe	March-May	0.1306	Not applicable	Not triggered	0.0483
Southern Europe	June-Sept	0.1306	Not applicable	Not triggered	0.0483
Southern Europe	Oct-Feb	0.1306	Not applicable	Not triggered	0.0483
Step 3	Not triggered				

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

Table 8.9-19: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for M3 following single application to winter barley

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	2.2560	Runoff/drainage	Not triggered	1.3144
Step 2					
Northern Europe	March-May	0.0653	Not applicable	Not triggered	0.0242
Northern Europe	June-Sept	0.0653	Not applicable	Not triggered	0.0242
Northern Europe	Oct-Feb	0.0653	Not applicable	Not triggered	0.0242
Southern Europe	March-May	0.0653	Not applicable	Not triggered	0.0242
Southern Europe	June-Sept	0.0653	Not applicable	Not triggered	0.0242
Southern Europe	Oct-Feb	0.0653	Not applicable	Not triggered	0.0242
Step 3	Not triggered				

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

Table 8.9-20: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for M3 following single application to grass

Scenario FOCUS	Waterbody	Max PEC_{sw} (µg/L)*	Dominat entry route	xx d- $PEC_{sw,twa}$ (µg/L)**	Max PEC_{sed} (µg/kg)*
Step 1	---	3.0080	Runoff/drainage	Not triggered	1.7525
Step 2					
Northern Europe	March-May	0.0870	Not applicable	Not triggered	0.0322
Northern Europe	June-Sept	0.0870	Not applicable	Not triggered	0.0322
Northern Europe	Oct-Feb	0.0870	Not applicable	Not triggered	0.0322
Southern Europe	March-May	0.0870	Not applicable	Not triggered	0.0322
Southern Europe	June-Sept	0.0870	Not applicable	Not triggered	0.0322
Southern Europe	Oct-Feb	0.0870	Not applicable	Not triggered	0.0322
Step 3	Not triggered				

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

8.9.2.1 $PEC_{sw/sed}$ of ADM.09050.H.1.A

Calculation of PECsw/sed for the formulation is not required as this can be extrapolated from the active substance. Reference is made to the section B9 Ecotoxicology.

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 Trinexapac-ethyl 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 Trinexapac-ethyl due to volatilization with subsequent deposition is not expected (the compound degrade quickly).

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Trinexapac-ethyl
Direct photolysis in air	No study available
Quantum yield of direct phototransformation	Not provided

Photochemical oxidative degradation in air	Trinexapac-ethyl: DT_{50} (h): 4.08 derived by the Atkinson model, kOH = 94.3 x 10^{-12} cm^3/molecule/sec DT_{50} (h): 1.29-10.8 derived by the Atmospheric Oxidation program (ver. 1.85), OH (12h) concentration assumed 99.2 x 10^{-12} – 11.9 x 10^{-12} cm^3/molecule/sec CGA179500: DT_{50} (h): 3.2 – 3.9 derived by the Atkinson model, kOH = 99.0 x 10^{-12} – 119.8 x 10^{-12} cm^3/molecule/sec
Volatilisation	From plant surfaces (BBA guideline): <15% after 24 hours From soil surfaces (BBA guideline): negligible after 20 days
Metabolites	None

The vapour pressure at 20 °C of the active substance trinexapac-ethyl is not available. The vapour pressure at 25 °C of the active substance trinexapac-ethyl is > 10^{-4} Pa. Hence the active substance trinexapac-ethyl is regarded as volatile (volatilisation from soil and plant surfaces). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance trinexapac-ethyl due to volatilization with subsequent deposition should be considered. However, studies of volatilisation from plant surfaces and soil indicate that exposure to adjacent surface water and terrestrial ecosystems will be low to negligible, therefore, additional risk calculations were not carried out.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCP 9.2.4/01	Hicks J.	2020a	PECgroundwater Calculations for Trinexapac-ethyl and Metabolites For Submission to Central EU Regulatory Zone TXP/EFA/01 Agrexis AG., Switzerland Sponsor reference number: 000106647 non GLP Unpublished	N	Adama
KCP 9.2.5/01	Hicks J.	2020b	PECsurfacewater and PECsediment calculations for Trinexapac-ethyl and Metabolites – FOCUS Steps 1 and 2 For Submission to Central Regulatory Zone TXP/EFA/02 Agrexis AG., Switzerland Sponsor reference number: 000106646 non GLP Unpublished	N	Adama

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

None

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

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

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

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

Appendix 2 Detailed evaluation of the new Annex II studies

New reports are summaries of environmental fate modelling, please see Appendix 3.

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

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

Reference:	KCP 9.2.4/01
Report	PECgroundwater Calculations for Trinexapac-ethyl and Metabolites For Submission to Central EU Regulatory Zone, Hicks J., 2020a, TXP/EFA/01
Guideline(s):	Yes: SANCO/13144/2010 v. 3, 10 October 2014
Deviations:	No
GLP:	No: not applicable
Acceptability:	Yes

Materials and methods

Predicted environmental concentrations of trinexapac-ethyl and its metabolites were calculated in accordance with SANCO/13144/2010 v. 3 using the following modelling software:

- FOCUS PEARL version 4.4.4
- FOCUS PELMO version 5.5.3
- FOCUS MACRO version 5.5.4

There are two different degradation pathways of trinexapac-ethyl in soil which result in different metabolites. CGA179500 is formed by aerobic degradation. Photolytic degradation of trinexapac-ethyl results in formation of metabolites CGA17950, CGA300405 and CGA275537.

Due to the restrictions of the models, aerobic degradation PEC_{gw} values were calculated with CGA179500 designated as a metabolite of trinexapac-ethyl, whereas PEC_{gw} concentrations for trinexapac-ethyl and all metabolites were calculated separately as if each substance was a parent substance. Pseudo-application rates were calculated for each metabolite as follows:

$$\frac{\text{MW metabolite}}{\text{MW parent}} \times \frac{\text{Max. observed}}{100} \times \text{parent app. rate} = \text{pseudo app. Rate}$$

Input parameters were taken from EFSA Journal 2018;16(3):5229 and are presented in section 8.8.2 of this document.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

Absolute application dates for spring barley and winter barley were used in all calculations, taken from EFSA Journal 2018;16(3):5229.

Results and discussions

All PEG_{gw} values are presented in 8.8.2 of this document. There were no PEC_{gw} values above <0.001

μg/L for any substance.

Conclusion

All PEC_{gw} values for trinexapac-ethyl and its metabolites were <0.001 μg/L.

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

Reference:	KCP 9.2.5/01
Report	PECsurfacewater and PECsediment calculations for Trinexapac-ethyl and Metabolites – FOCUS Steps 1 and 2 For Submission to Central Regulatory Zone, Hicks J., 2020b, TXP/EFA/02
Guideline(s):	Yes: Generic guidance for FOCUS surface water Scenarios v. 1.4, May 2015
Deviations:	No
GLP:	No: not applicable
Acceptability:	Yes

Materials and methods

Predicted environmental concentrations of trinexapac-ethyl and its metabolites were calculated in accordance with Generic guidance for FOCUS surface water Scenarios v. 1.4 using FOCUS steps 1 and 2.

There are 5 metabolites of trinexapac-ethyl; CGA179500, CGA300405, CGA275537, M2 and M3. PEC_{sw} and PEC_{sed} values for CGA179500, CGA300405 and CGA275537 were calculated using Focus steps 1 and 2. Input parameters were not available for metabolites M2 and M3, so PEC_{sw} and PEC_{sed} values were calculated based on the PECsw values for trinexapac-ethyl, in compliance with EFSA Journal 2018;16(3):5229, using the following formula:

$$\frac{\text{MW metabolite}}{\text{MW parent}} \times \frac{\text{Max. observed}}{100} \times \text{parent } PEC_{sw/sed} = \text{Metabolite } PEC_{sw/sed}$$

Input parameters were taken from EFSA Journal 2018;16(3):5229 and are presented in section 8.9.2 of this document.

The critical GAPs presented in section 8.1 of this document were assessed, with crop interception values in accordance with EFSA Journal 2014;12(5):3662.

PEC_{sw} values were calculated for both north and south scenarios and for all three application timings; March – May, June – September, October- February.

Results and discussions

All PEC_{sw} and PEC_{sed} values are presented in 8.8.2 of this document.

Further calculations at step 3 were not triggered by the aquatic organism risk assessments.

Conclusion

The risks to aquatic organisms from exposure to trinexapac-ethyl and its metabolites in surface water were acceptable based on step 2 PEC_{sw} values.