

REGISTRATION REPORT

Part B

Section 8

Environmental Fate

Detailed summary of the risk assessment

Product code: CA3573

Product name(s): Carnadine / Kestrel

Chemical active substance:

Acetamiprid, 200 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(Re-authorisation acc. to Art. 43)

Applicant: Nufarm Europe GmbH

Submission date: July 2020

MS Finalisation date: May 2021 (initial Core Assessment)

November 2021, January 2022 (final Core Assessment)

Version history

When	What
July 2020	Version 1.0 (application)
December 2020	Update PEC groundwater calculations with different plant uptake factors
May 2021	Initial assessment by the zRMS The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information are struck through and shaded for transparency.
November 2021	Final report (Core Assessment updated following the commenting period) No additional information or assessments after the commenting period.
January 2022	Final report (Core Assessment after additional round of the commenting period) No additional information or assessments after the commenting period.

Usually, in dRRs for product renewal, all those paragraphs, endpoints etc. should be highlighted in yellow which were modified in comparison to the dossier submitted for the previous authorisation. This was not done in this B8 document since it would have meant highlighting more or less the entire document: The endpoints summarised in B8.1 to B8.6 and in B8.10 were completely reassessed during the last EU renewal and new studies were added. Additionally, the risk assessment in B8.7 to B8.9 was completely redone due to changes in endpoints, guidelines and modelling approaches.

Table of Contents

8	Fate and behaviour in the environment (KCP 9).....	4
8.1	Critical GAP and overall conclusions.....	5
8.2	Metabolites considered in the assessment.....	8
8.3	Rate of degradation in soil (KCP 9.1.1).....	9
8.3.1	Aerobic degradation in soil (KCP 9.1.1.1)	11
8.3.1.1	Acetamiprid and its metabolites.....	11
8.3.2	Anaerobic degradation in soil (KCP 9.1.1.1).....	16
8.4	Field studies (KCP 9.1.1.2).....	16
8.4.1	Soil dissipation testing on a range of representative soils (KCP 9.1.1.2.1). 16	
8.4.1.1	Acetamiprid and its metabolites.....	16
8.4.2	Soil accumulation testing (KCP 9.1.1.2.2)	18
8.5	Mobility in soil (KCP 9.1.2)	18
8.5.1	Acetamiprid and its metabolites.....	18
8.5.2	Column leaching (KCP 9.1.2.1).....	20
8.5.3	Lysimeter studies (KCP 9.1.2.2).....	20
8.5.4	Field leaching studies (KCP 9.1.2.3)	20
8.6	Degradation in the water/sediment systems (KCP 9.2, KCP 9.2.1, KCP 9.2.2, KCP 9.2.3)	21
8.6.1	Acetamiprid and its metabolites.....	21
8.7	Predicted Environmental Concentrations in soil (PEC _{soil}) (KCP 9.1.3)	23
8.7.1	Justification for new endpoints	23
8.7.2	Active substance and relevant metabolites	23
8.7.2.1	Acetamiprid and its metabolites.....	24
8.7.2.2	PEC _{soil} of CA3573	33
8.8	Predicted Environmental Concentrations in groundwater (PEC _{gw}) (KCP 9.2.4)	34
8.8.1	Justification for new endpoints	34
8.8.2	Active substance and relevant metabolites (KCP 9.2.4.1).....	35
8.8.2.1	Acetamiprid and its metabolites.....	37
8.9	Predicted Environmental Concentrations in surface water (PEC _{sw}) (KCP 9.2.5)	49
8.9.1	Justification for new endpoints	49
8.9.2	Active substance, relevant metabolites and the formulation (KCP 9.2.5) ...	49
8.9.2.1	Acetamiprid and its metabolites.....	51
8.9.2.2	PEC _{sw} of CA3573.....	76
8.10	Fate and behaviour in air (KCP 9.3, KCP 9.3.1)	78
Appendix 1	Lists of data considered in support of the evaluation.....	79
Appendix 2	Detailed evaluation of the new Annex II studies	85
A 2.1	KCP 9.2.4/01 Determination of Plant Uptake Factor (PUF)	85
Appendix 3	Additional information provided by the applicant (e.g. detailed modelling data).....	86

zRMS comments:

Formulation CA3573 was a subject of zonal evaluation in April 2018, but under different code name (MCW-2222). Evaluation presented in this report was performed in line with Article 43 of Regulation (EC) No 1107/2009 due to renewal of acetamiprid at the EU level in 2018 (Commission Implementing Regulation (EU) 2018/113) and the new List of Endpoints (LoEP) issued in EFSA Journal 2016;14(11):4610.

Although the code name has been changed from MCW-2222 to CA3573, composition of the product remains the same.

Nufarm GmbH & Co.KG was not the Applicant for the EU renewal of acetamiprid and the data matching process has been carried out by the RMS for acetamiprid (The Netherlands) with final conclusions issued in December 2020. According to the RMS conclusion, Nufarm dossier was acceptable for matching and data matching has been shown sufficiently with all argumentation and submitted alternative studies acceptable. Taking this into account, the list of endpoints reported in EFSA Journal 2016;14(11):4610 may be used for evaluation of formulation CA3573.

The report in the dRR format has been prepared by the Applicant, therefore all comments, additional evaluations and conclusions of the zRMS are presented in grey commenting boxes. Minor changes are introduced directly in the text and highlighted in grey. Not agreed or not relevant information is struck through and shaded for transparency.

8 Fate and behaviour in the environment (KCP 9)

8.1 Critical GAP and overall conclusions

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

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 Groundwater
					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 or kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max			
Zonal uses (field or outdoor uses, certain types of protected crops)														
1, 11	Central Zone	Apple (MABSD)	F	<i>Aphis</i> sp. (APHISP)	Foliar spraying overall	May-Oct/ BBCH 62- PHI	a) 1 b) 1	--	a) 0.125 b) 0.125	a) 25 b) 25	500-1000	14	Do not apply during flowering	A
2, 12	Central Zone	Apple (MABSD)	F	<i>Cydia pomonella</i> (CARPPO)	Foliar spraying overall	May-Oct/ BBCH 62- PHI	a) 1 b) 1	--	a) 0.25 b) 0.25	a) 50 b) 50	500-1000	14	Do not apply during flowering	A
3, 13	Central Zone	Potato (SOLTU)	F	<i>Leptinotarsa decemlineata</i> (LPTNDE)	foliar spraying, overall	Jun-Sep/ BBCH 12-79	a) 1 b) 1	--	a) 0.18 b) 0.18	a) 36 b) 36	200-400	7	0.12 – 0.18 L/ha	A
4, 5, 6, 7, 14, 15, 16	Central Zone	Winter oilseed rape (BRSNN)	F	<i>Various pests</i>	foliar spraying, overall	May-Jun/ BBCH 31-71	a) 1 b) 1	--	a) 0.3 b) 0.3	a) 60 b) 60	200-400	28	0.15 – 0.3 L/ha Do not apply during flowering	A
8, 9, 10, 17, 18	Central Zone	Spring oilseed rape (BRSNN)	F	<i>Various pests</i>	foliar spraying, overall	Mar-Jun/ BBCH 31-71	a) 1 b) 1	-	a) 0.3 b) 0.3	a) 60 b) 60	200-400	28	in label: 0.15-0.3 L/ha Do not apply during flowering	A
19, 20	Central Zone	Corn	F	<i>Various pests</i>	foliar spraying, overall	Apr-Aug/ BBCH 51-75	a) 1 b) 1	-	a) 0.3 b) 0.3	a) 60 b) 60	300-500	56	in label: 0.2-0.3 L/ha	A

* F: professional field use, G: 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:	<div> <div> (1) Numeration necessary to allow references</div> <div>(2) Use official codes/nomenclatures of EU</div> <div>(3) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)</div> <div>(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</div> <div>(5) Scientific names <u>and</u> 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</div> <div>(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</div> </div> <div> <div>(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</div> <div>(8) The maximum number of application possible under practical conditions of use must be provided</div> <div>(9) Minimum interval (in days) between applications of the same product.</div> <div>(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</div> <div>(11) The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</div> <div>(12) If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.</div> <div>(13) PHI - minimum pre-harvest interval</div> <div>(14) Remarks may include: Extent of use/economic importance/restrictions</div> </div>
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zRMS comments:

Originally the GAP table presented by the Applicant listed all intended uses of CA3573 in particular countries. However, zonal evaluation in area of environmental fate and behaviour has to cover all countries in the zone and is performed with consideration of the crop, its BBCH stage, number of applications, interval and application rate, while the pests against which the product is applied are not important. Taking this into account the original GAP table has been modified by the zRMS in order to construct the risk envelope GAP, which covers particular uses in each cMS. The detailed GAP for particular countries may be found in the Core Assessment, Part B, Section 0.

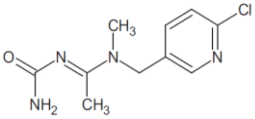
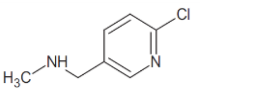
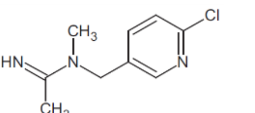
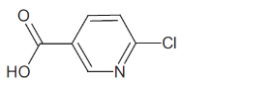
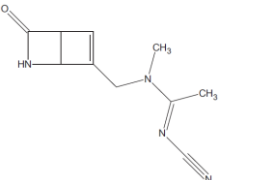
Table 8.1-2: Assessed (critical) uses during approval of acetamiprid concerning the Section Environmental Fate

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, G, 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 product/ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min/max		
1	EU	Tomato	G	Aphids	Foliar	BBCH 61 – 89 (January - December)	a) 2 b) 2	a) 7 b) 7	a) 0.5 b) 1.0	a) 0.100 b) 0.200	300 - 1500	3	Use in greenhouse is in permanent structure
2	EU	Pome fruit	F	Aphids	Foliar	BBCH 77 – 87 (June – September)	a) 2 b) 2	a) 14 b) 14	a) 0.375 b) 0.750	a) 0.075 b) 0.150	300 - 1000	14	
3	EU	Potato	F	Colorado potato beetle / aphids	Foliar	BBCH 45 – 93 (May – October)	a) 3 b) 3	a) 7 b) 7	a) 0.250 b) 0.750	a) 0.05 b) 0.150	400 - 600	7	

* F: professional field use, G: professional greenhouse use, I: indoor application

8.2 Metabolites considered in the assessment

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

Metabolite	Molar mass (g/mol)	Chemical structure	Maximum observed occurrence in compartments	Exposure assessment required due to
IM-1-2	240.69		Maximum in soil: 55% Maximum in water/sediment: 13.4%	PEC _{gw} : not covered by EU assessment PEC _{soil} : not covered by EU assessment PEC _{sw/sed} : not covered by EU assessment
IM-1-4	156.61		Maximum in soil: 72% Maximum in water/sediment: 81.5% *	PEC _{gw} : not covered by EU assessment PEC _{soil} : not covered by EU assessment PEC _{sw/sed} : not covered by EU assessment
IM-1-5	197.66		Maximum in soil: 20% (calcareous soils only)	PEC _{gw} : not covered by EU assessment PEC _{soil} : not covered by EU assessment PEC _{sw/sed} : not covered by EU assessment (formation in soil)
IC-0 6-Chloronicotinic Acid (IV-0)	157.55		Maximum in soil: 11.3% Maximum in water/sediment: 29.5%	PEC _{gw} : not covered by EU assessment PEC _{soil} : not covered by EU assessment PEC _{sw/sed} : not covered by EU assessment
IB-1-1	204.23		Maximum in water/sediment: 35% **	PEC _{sw/sed} : not covered by EU assessment (formation in water)

* Observed in aerobic mineralisation study

** Formed only via aqueous photochemical degradation

zRMS comments:

Information regarding acetamiprid metabolites is in line with EU agreed endpoints reported in EFSA Journal 2016;14(11):4610.

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.

The rate of degradation of acetamiprid in soil was evaluated during the EU review (**EFSA Journal 2016;14(11):4610**). Four major metabolites (> 10% applied radioactivity (AR)) - IM-1-2, IM-1-4, IC-0, and IM-1-5 (calcareous soils only) - were identified. The metabolites IM-1-2, IC-0 and IM-1-5 were only formed in relevant amounts through the aerobic degradation pathway. They were found at levels of 55% AR (IM-1-2), 11.3% AR (IC-0) and 20% AR (IM-1-5). The metabolite IM-1-4 formed in soil via aerobic degradation (72% AR), anaerobic degradation (46.7% AR) and through photolysis. In the photolysis study, formation on irradiated samples was 46.5% AR and on dark control samples 65.3% AR, hence photolysis is not the major route of degradation.

Aerobic and anaerobic degradation pathways are illustrated in Figure 8.3-1 and Figure 8.3-2.

Figure 8.3-1: Proposed pathway of acetamiprid degradation in soil under aerobic conditions

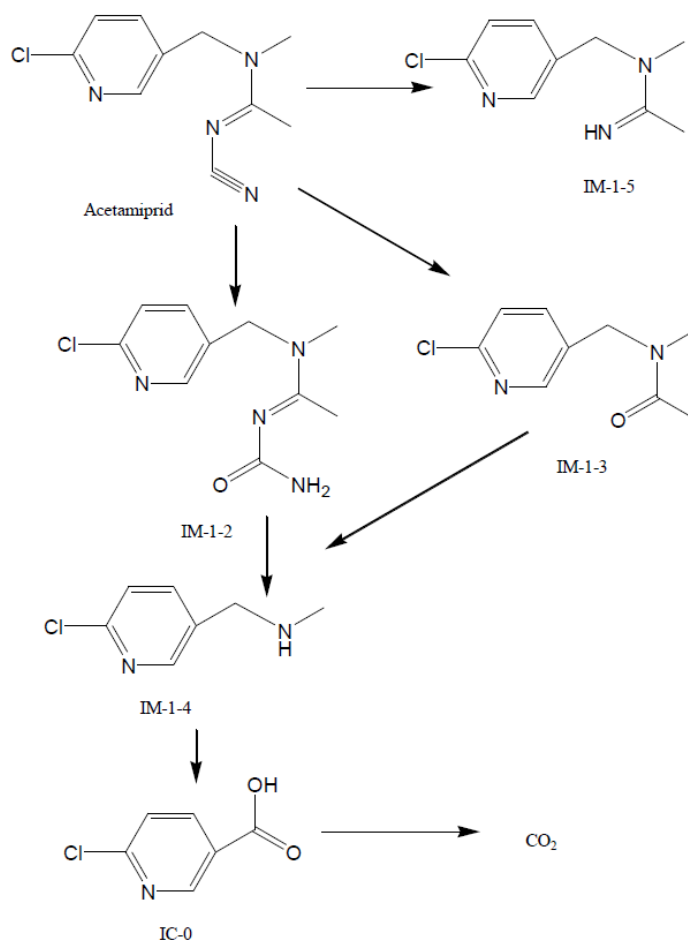
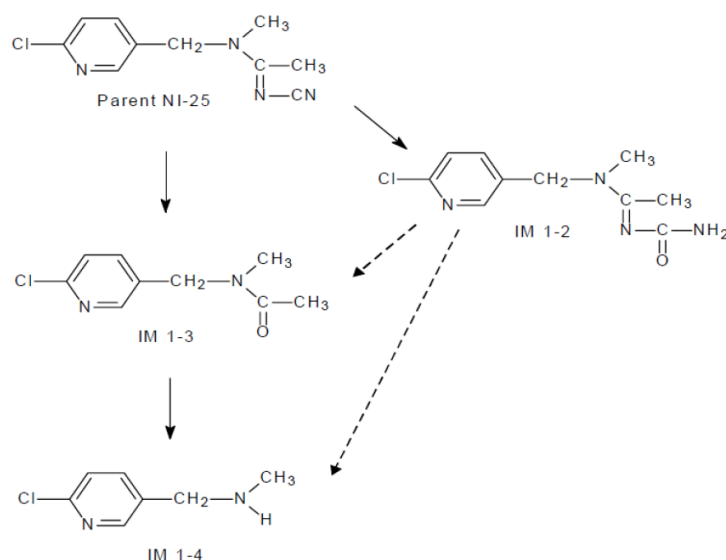


Figure 8.3-2: Proposed pathway of acetamiprid degradation in soil under anaerobic conditions



zRMS comments:

The metabolic pathway of acetamiprid in soil is in line with information available from the EU renewal process.

The zRMS would like to pay attention of the cMS to the metabolite IM-1-5, which according to the EFSA Journal 2016;14(11):4610, is formed only in calcareous soils. This conclusion is slightly confusing, although most probably “calcareous soils” refer here to the soil pH greater than 7. It should be, however, pointed out that calcareous and alkaline soils are not the same, as high pH of these soils may result from different properties. Overall, all calcareous soils will have a high pH, however not all soils with high pH will be calcareous.

The available EU agreed degradation data available in the LoEP and RAR, Vol. 3CA, B.8 (June 2016) were analysed by the zRMS and it was noted that soil metabolism of acetamiprid was investigated mainly in soils with pH >7 and only single acidic soil (pH 5.6) was included in the dataset. This was considered sufficient to fulfil requirements of Regulation 283/2013, but in opinion of the zRMS due to only single soil with pH <7 tested, the dataset was not sufficient to derive firm conclusion regarding lack of formation of metabolite IM-1-5 in acidic soils. For this reason it seems that information presented in the EFSA Journal 2016;14(11):4610 on formation of metabolite IM-1-5 in calcareous soils only should be rather considered as relevant for soils tested in studies submitted for the renewal process and should not be used to conclude on the actual dependence between soil pH and formation of IM-1-5.

It should be noted that metabolite IM-1-5 was also not detected in one soil with pH 7.6 (study by Morgenroth, 1997), however as more soils with high pH were tested, lack of formation of IM-1-5 in this study could be considered accidental. Taking into account that only one acidic soil was tested, it cannot be excluded that lack of formation of metabolite IM-1-5 in this soil was also pH, as it was in case of alkaline soil in the study by Morgenroth (1997).

No confirmation of this trend may be found in field studies, where metabolite IM-1-5 was not even analysed in single acidic soil tested (study by Wicks, 1999), and new studies provided for purposes of renewal (Kellner, 2012abc and Finger, 2013) were performed in soils with pH ranging from 7.0 to 8.9.

It should be also pointed out that no soil metabolism studies were performed on soils with pH between 5.7 and 6.9 and for this reason formation of metabolite IM-1-5 in soils with such pH is unknown.

As metabolite IM-1-5 is considered to be toxicologically relevant and due to its properties is also prone to leaching to groundwater, for reasons mentioned above potential leaching of this compound has been considered in relation to all soils, regardless of pH (see point 8.8 for more details).

8.3.1 Aerobic degradation in soil (KCP 9.1.1.1)

8.3.1.1 Acetamiprid and its metabolites

Aerobic degradation of acetamiprid and its metabolites in soil was evaluated during the EU review (EFSA Journal 2016;14(11):4610). Additional data was not required.

Triggering endpoints

A summary of the triggering endpoints of laboratory aerobic degradation studies for acetamiprid and its metabolites is given in the tables below.

Table 8.3-1: Summary of aerobic degradation rates for acetamiprid - laboratory studies: Triggering endpoints

Acetamiprid, Laboratory studies, dark aerobic conditions – Triggering endpoints									
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	Parameters bi-phasic model	Chi ² (%)	Kinetic model	Evaluated on EU level
Loamy sand	7.6	20	50% of pF2.5	1.4	4.7		7.7	SFO	Yes / EFSA, 2016
Clay loam	7.4	20	45	5.4	54.5	k1: 0.00806 k2: 0.1628 g: 0.155	6.9	DFOP	Yes / EFSA, 2016
Clay loam	7.4	10	45	7.9	49.3	k1: 0.1057 k2: 0.0065 g: 0.8686	3.7	DFOP	Yes / EFSA, 2016
Sandy loam	5.6	20	45	2.5	14.3	α : 1.744 β : 5.212	4.6	FOMC	Yes / EFSA, 2016
Silty clay loam	7.9-8.5	20	45	0.8	2.8		9.5	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	1.1	5.2	α : 2.278 β : 3.000	8.4	FOMC	Yes / EFSA, 2016
Clay	7.7	20	45	1.1	3.8		9.3	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	1	3.3		8.4	SFO	Yes / EFSA, 2016

^{a)} Measured in water

Table 8.3-2: Summary of aerobic degradation rates for IM-1-2 - laboratory studies: Triggering endpoints

IM-1-2, Laboratory studies, dark aerobic conditions – Triggering endpoints									
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	Parameters bi-phasic model	Chi ² (%)	Kinetic model	Evaluated on EU level
Sandy loam	8.0	20	45	1.9	6.3	-	9.6	SFO ^{b)}	Yes / EFSA, 2016
Clay	7.7	20	45	1.9	6.3	-	13.0	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	1.6	5.3	-	12.3	SFO	Yes / EFSA, 2016
Max (n=3)				1.9	6.3				

^{a)} Measured in water

^{b)} Parent fitted with FOMC model

Table 8.3-3: Summary of aerobic degradation rates for IM-1-4 - laboratory studies: Triggering endpoints

IM-1-4, Laboratory studies, dark aerobic conditions – Triggering endpoints									
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT₅₀ (d)	DT₉₀ (d)	Parameters bi-phasic model	Chi² (%)	Kinetic model	Evaluated on EU level
Loamy sand	7.6	20	45	46.2	154	-	22.8	SFO	Yes / EFSA, 2016
Clay loam	7.4	20	45	142	473	-	8.7	SFO ^{b)}	Yes / EFSA, 2016
Clay loam	7.4	10	45	171	569	-	5.3	SFO ^{b)}	Yes / EFSA, 2016
Sandy loam	5.6	20	45	146	483	-	6.2	SFO ^{c)}	Yes / EFSA, 2016
Silty clay loam	7.9-8.5	20	45	3.7	12.3	-	9.1	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	4.2	14	-	22	SFO ^{c)}	Yes / EFSA, 2016
Clay	7.7	20	45	2.3	7.8	-	18.1	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	3	10	-	14.9	SFO	Yes / EFSA, 2016
Max (n=8)				146	483				

^{a)} Measured in water

^{b)} Parent kinetics DFOP

^{c)} Parent kinetics FOMC

Table 8.3-4: Summary of aerobic degradation rates for IC-0 - laboratory studies: Triggering endpoints

IC-0, Laboratory studies, dark aerobic conditions – Triggering endpoints									
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT₅₀ (d)	DT₉₀ (d)	Parameters bi-phasic model	Chi² (%)	Kinetic model	Evaluated on EU level
Silty clay loam	7.9-8.5	20	45	3.6	11.8	-	32.6	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	1.2	4.1	-	4.3	SFO ^{b)}	Yes / EFSA, 2016
Clay	7.7	20	45	2.7	8.9	-	11.6	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	1.8	6.0	-	10.0	SFO	Yes / EFSA, 2016
Sandy loam	6.7	20	45	3.1	10.1	-	10	SFO	Yes / EFSA, 2016
Silty clay loam	7.8	20	45	2.4	8.0	-	9.1	SFO	Yes / EFSA, 2016
Clay loam	7.2	20	45	5.6	18.5	-	9.8	SFO	Yes / EFSA, 2016
Max (n=7)				5.6	18.5				

^{a)} Measured in water

^{b)} Parent kinetics FOMC

Table 8.3-5: Summary of aerobic degradation rates for IM-1-5 - laboratory studies: Triggering endpoints

IM-1-5, Laboratory studies, dark aerobic conditions – Triggering endpoints									
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	Parameters bi-phasic model	Chi ² (%)	Kinetic model	Evaluated on EU level
Silty clay loam	7.9-8.5	20	45	319	1059		5.1	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	-	-		-	SFO	Yes / EFSA, 2016
Clay	7.7	10	45	-	-		-	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	486	1614		10.3	SFO	Yes / EFSA, 2016
Loam (France)	7.5		78.4% pF2 moisture	663	2203		4.7	SFO	Yes / EFSA, 2016
Loam (Hungary)	7.8		60.7% pF2 moisture	420	1395		3.5	SFO	Yes / EFSA, 2016
Sandy clay loam	7.6		66.4% pF2 moisture	378	1254		2.8	SFO	Yes / EFSA, 2016

^{a)} Measured in water

Modelling endpoints

A summary of the modelling endpoints of laboratory aerobic degradation studies for acetamiprid and its metabolites is given in the tables below.

Table 8.3-6: Summary of aerobic degradation rates for acetamiprid - laboratory studies: Modelling endpoints

Acetamiprid, Laboratory studies, dark aerobic conditions – Modelling endpoints									
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	Chi ² (%)	Kinetic model	Evaluated on EU level
Loamy sand	7.6	20	50 (pF2.5)	1.4	4.7	1.2	7.7	SFO	Yes / EFSA, 2016
Clay loam	7.4	20	45	4.7	15.8	4.7	11.8	SFO	Yes / EFSA, 2016
Sandy loam	5.6	20	45	2.5	8.3	2.5	8.8	SFO	Yes / EFSA, 2016
Silty clay loam	7.9-8.5	20	45	0.8	2.8	0.8	9.5	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	1.1	3.7	1.1	9.9	SFO	Yes / EFSA, 2016
Clay	7.7	20	45	1.1	3.8	1.1	9.7	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	1	3.2	1	8.6	SFO	Yes / EFSA, 2016
Geometric mean (n=7)						1.45			
pH-dependency:						No			

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Table 8.3-7: Summary of aerobic degradation rates for IM-1-2 - laboratory studies: Modelling endpoints

IM-1-2, Laboratory studies, dark aerobic conditions – Modelling endpoints										
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	Formation fraction k _t /k _{dp} ^{c)}	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	Chi ² (%)	Kinetic model	Evaluated on EU level
Sandy loam	8.0	20	45	1.6	5.3	0.97	1.6	12.3	SFO	Yes / EFSA, 2016
Clay	7.7	20	45	1.9	6.3	0.68	1.9	13.0	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	1.6	5.3	0.66	1.6	12.3	SFO	Yes / EFSA, 2016
Geometric mean (n=3)							1.7			
Arithmetic mean (n=3)							0.77			
pH-dependency:							No			

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Formation from acetamiprid

Table 8.3-8: Summary of aerobic degradation rates for IM-1-4 - laboratory studies: Modelling endpoints

IM-1-4, Laboratory studies, dark aerobic conditions – Modelling endpoints										
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	Formation fraction k _t /k _{dp} ^{c)}	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	Chi ² (%)	Kinetic model	Evaluated on EU level
Loamy sand	7.6	20	50% of pF2.5	46.2	154	0.56	40.0	22.8	SFO	Yes / EFSA, 2016
Clay loam	7.4	20	45	169	560	0.61	169	10.5	SFO	Yes / EFSA, 2016
Sandy loam	5.6	20	45	166	552.8	0.75	166	6.7	SFO	Yes / EFSA, 2016
Silty clay loam	7.9-8.5	20	45	3.7	12.3	1	3.7	9.1	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	4.8	16.1	0.44	4.8	22.3	SFO	Yes / EFSA, 2016
Clay	7.7	20	45	2.3	7.8	0.97	2.3	18.1	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	3	10	0.71	3.0	14.9	SFO	Yes / EFSA, 2016
Geometric mean (n=7)							14.6			
Arithmetic mean (n=7)							0.72			
pH-dependency:							No			

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Formation from IM-1-2

Table 8.3-9: Summary of aerobic degradation rates for IC-0 - laboratory studies: Modelling endpoints

IC-0, Laboratory studies, dark aerobic conditions – Modelling endpoints										
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	Formation fraction k _f /k _{dp} ^{c)}	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	Chi ² (%)	Kinetic model	Evaluated on EU level
Silty clay loam	7.9-8.5	20	45	3.6	11.8	0.3	3.6	32.6	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	1.4	4.6	1	1.4	5.1	SFO	Yes / EFSA, 2016
Clay	7.7	20	45	2.7	8.9	0.39	2.7	11.6	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	1.8	6.0	1	1.8	11.9	SFO	Yes / EFSA, 2016
Sandy loam	6.7	20	45	3.1	10.1	-	3.1	10	SFO	Yes / EFSA, 2016
Silty clay loam	7.8	20	45	2.4	8.0	-	2.4	9.1	SFO	Yes / EFSA, 2016
Clay loam	7.2	20	45	5.6	18.5	-	5.6	9.8	SFO	Yes / EFSA, 2016
Geometric mean (n=7)							2.7			
Arithmetic mean (n=7)							0.67			
pH-dependency:							No			

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Formation from IM-1-4

Table 8.3-10: Summary of aerobic degradation rates for IM-1-5 - laboratory studies: Modelling endpoints

IM-1-5, Laboratory studies, dark aerobic conditions – Modelling endpoints										
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	Formation fraction k _f /k _{dp} ^{c)}	DT ₅₀ (d) 20°C pF2/10kPa ^{b)}	Chi ² (%)	Kinetic model	Evaluated on EU level
Silty clay loam	7.9-8.5	20	45	319	1059	0.21	319	5.1	SFO	Yes / EFSA, 2016
Sandy loam	8.0	20	45	-	-	0.16 ^{c)}	1000 ^{d)}	-	SFO	Yes / EFSA, 2016
Clay	7.7	20	45	-	-	0.12 ^{c)}	1000 ^{d)}	-	SFO	Yes / EFSA, 2016
Clay loam	7.9	20	45	486	1614	0.12	486	10.3	SFO	Yes / EFSA, 2016
Loam (France)	7.5	20	78.4% of pF2 moisture	663	2203	-	559	4.7	SFO	Yes / EFSA, 2016
Loam (Hungary)	7.8	20	60.7% of pF2 moisture	420	1395	-	296	3.5	SFO	Yes / EFSA, 2016
Sandy clay loam	7.6	20	66.4% of pF2 moisture	378	1254	-	284	2.8	SFO	Yes / EFSA, 2016
Max (n=7)							1000 ^{d)}			
Geometric mean (n=7)							495			
Arithmetic mean (n=4)							0.15			
pH-dependency:							No			

^{a)} Measured in water

^{b)} Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

^{c)} Formation fraction based on maximum fraction of occurrence (persistent metabolite)

^{d)} Default DT₅₀ value used as no decline of IM-1-5 was observed for this soil

^{e)} Formation from acetamiprid

zRMS comments:

Soil laboratory degradation data for acetamiprid and its metabolites are in line with EU agreed endpoints reported in EFSA Journal 2016;14(11):4610.

In line with the LoEP it is indicated that metabolite IM-1-5 is formed only in alkaline and calcareous soils. However, in opinion of the zRMS, this statement that is not accurate, as the soil metabolism studies included only single acidic soil (pH 5.6) and no soil with pH in range 5.7-7.3 was tested. Therefore in opinion of the zRMS the available dataset was too limited to derive such a conclusion and disregard formation of this compound in soils with pH in range 5.7-7.3 and <5.6. For more details regarding this issue, please refer to the zRMS comment in point 8.3 above.

8.3.2 Anaerobic degradation in soil (KCP 9.1.1.1)

Anaerobic degradation of acetamiprid was evaluated during the EU review (EFSA, 2016). In anaerobic degradation studies, only the metabolite IM-1-4 was identified with a maximum occurrence of 46.7% AR. Additional data was not required.

A summary of the degradation rates of acetamiprid under anaerobic conditions is given in the table below.

Table 8.3-11: Summary of anaerobic degradation rates for acetamiprid - laboratory studies

Acetamiprid, Laboratory studies, dark anaerobic conditions									
Soil type	pH ^{a)}	t (°C)	MWHC (%)	DT ₅₀ (d)	DT ₉₀ (d)	DT ₅₀ (d) 20°C	Chi ² (%)	Kinetic model	Evaluated on EU level
Loam	7.4	20	100	69.0	410.6	n.a.	4.7	FOMC α: 1.591 β: 126.319	Yes / EFSA, 2016

^{a)} Measured in water

zRMS comments:

Information on anaerobic soil degradation of for acetamiprid is in line with EU agreed data reported in EFSA Journal 2016;14(11):4610.

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 are commonly performed with a formulation, are considered to be data provided in support of the active substance.

8.4.1.1 Acetamiprid and its metabolites

Soil dissipation studies of acetamiprid and its metabolites were evaluated during the EU review (EFSA Journal 2016;14(11):4610). No additional studies have been performed.

The degradation rates of acetamiprid and the maximum occurrence of its metabolites in field dissipation studies are summarised in the tables below.

Table 8.4-1: Summary of aerobic degradation rates for acetamiprid - field studies

Acetamiprid, Field studies, aerobic conditions									
Soil type	Location	pH	Depth (cm)	DT ₅₀ (d) actual	DT ₉₀ (d) actual	Kinetic parameters	Chi ² (x ²)	Method of calculation	Evaluated on EU level
Clay loam	Italy	8.9 ^{a)}	0-30	0.4	19.8	k1: 4.122808 k2: 0.071185 g: 0.589717	14.1	DFOP	Yes / EFSA, 2016
Sandy loam	United Kingdom	5.9 ^{a)}	0-30	3.7	22.7	α : 1.544681 β : 6.600352	19.5	FOMC	Yes / EFSA, 2016
Silty clay loam	France	8.7 ^{a)}	0-30	9.6	31.3		16.4	SFO	Yes / EFSA, 2016
Sandy loam	Spain	7 ^{a)}	0-30	0.7	11.2	α : 0.67159 β : 0.374289	11.4	FOMC	Yes / EFSA, 2016
Loam	Spain	7.45 ^{b)}	0-50	12.96	43.06		28.1	SFO	Yes / EFSA, 2016
Loam	Southern France	7.36 ^{b)}	0-50	2.26	7.52		13.0	SFO	Yes / EFSA, 2016
Loam	Northern France	7.49 ^{b)}	0-50	2.24	7.43		12.1	SFO	Yes / EFSA, 2016
Loam	Hungary	8.06 ^{b)}	0-50	2.14	15.32	α and β : values not reported	25.9	FOMC	Yes / EFSA, 2016
Max (n=8)				12.96	43.06				
pH-dependency: No									

^{a)} Measured in 1 M KCl

^{b)} Measured in 0.01 M CaCl₂

Table 8.4-2: Summary of the maximum occurrence for relevant metabolites - field studies

Metabolite max. formation proportion of max. measured parent, Field studies, aerobic conditions							
Soil type	Location	pH	Depth (cm)	IM-1-4	IM-1-2	IM-1-5	Evaluated on EU level
Clay loam	Italy	8.9 ^{a)}	0-10 0-30	50% after 28 days	39% after 4 days	Not analysed	Yes / EFSA, 2016
Sandy loam	United Kingdom	5.9 ^{a)}	0-10 0-30	50% after 30 days	< 3.9% after 2-7 days	Not analysed	Yes / EFSA, 2016
Silty clay loam	France	8.7 ^{a)}	0-10 0-30	73% after 28 days	18% after 2 days	Not analysed	Yes / EFSA, 2016
Sandy loam	Spain	7 ^{a)}	0-10 0-30	55% after 31 days	9% after 2 days	Not analysed	Yes / EFSA, 2016
Loam	Spain	7.45 ^{b)}	0-10 0-50	Not analysed	Not analysed	60% after 28 days	Yes / EFSA, 2016
Loam	Southern France	7.36 ^{b)}	0-10 0-50	Not analysed	Not analysed	25% after 29 days	Yes / EFSA, 2016
Loam	Northern France	7.49 ^{b)}	0-10 0-50	Not analysed	Not analysed	45% after 7 days	Yes / EFSA, 2016
Loam	Hungary	8.06 ^{b)}	0-10 0-50	Not analysed	Not analysed	24% after 169 days	Yes / EFSA, 2016

^{a)} Measured in 1 M KCl

^{b)} Measured in 0.01 M CaCl₂

zRMS comments:

Soil field degradation data for acetamiprid and its metabolites are in general in line with EU agreed values reported in EFSA Journal 2016;14(11):4610 with some minor corrections regarding the soil depth given in Table 8.4-2, which in line with the LoEP should be 0-10 cm.

8.4.2 Soil accumulation testing (KCP 9.1.1.2.2)

No soil accumulation studies were performed. Plateau concentrations of persistent metabolites are obtained by modelling (see B.8.7.2).

zRMS comments:

Soil accumulation testing is not triggered for acetamiprid, in line with conclusions derived at the EU level and presented in EFSA Journal 2016;14(11):4610.

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 Acetamiprid and its metabolites

The mobility of acetamiprid and its metabolites in soil was evaluated during the EU review (EFSA Journal 2016;14(11):4610). Additional data was not required.

Summaries of all adsorption/desorption data for acetamiprid and its metabolites are given in the tables below.

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

Acetamiprid						
Soil type	OC (%)	pH ^{a)}	K _F (mL/g)	K _{Foc} (mL/g)	1/n (-)	Evaluated on EU level
I Sand	0.43	5.7	0.60	138.39	0.842	Yes / EFSA, 2016
II Loamy sand	1.04	7.6	1.35	129.98	0.825	Yes / EFSA, 2016
III Sandy loam	1.57	7.1	1.12	71.09	0.893	Yes / EFSA, 2016
IV Silt loam	1.39	7.7	1.69	121.81	0.835	Yes / EFSA, 2016
V Silt loam	4.39	7.1	3.13	71.38	0.907	Yes / EFSA, 2016
Arithmetic mean (n=5)				106.5	0.860	
Geometric mean (n=5)				102.1	-	
pH-dependency:				No		

^{a)} Measured in unknown medium

Table 8.5-2: Summary of soil adsorption/desorption for IM-1-2

IM-1-2						
Soil type	OC (%)	pH ^{a)}	K _F (mL/g)	K _{Foc} (mL/g)	1/n (-)	Evaluated on EU level
Clay loam 02/06	2.3	7.6	0.45	19	0.886	Yes / EFSA, 2016
Sandy loam 02/16	1.3	7.5	0.27	21	0.856	Yes / EFSA, 2016
Clay loam 01/24	3.8	6.1	3.60	95	0.927	Yes / EFSA, 2016
Sandy loam 02/18	0.2	7.4	0.16	80	0.944	Yes / EFSA, 2016
Arithmetic mean (n=4)				54	0.903	
Geometric mean (n=4)				42	-	
pH-dependency:				No		

^{a)} Measured in CaCl₂ medium

Table 8.5-3: Summary of soil adsorption/desorption for IM-1-4

IM-1-4						
Soil type	OC (%)	pH ^{a)}	K _F (mL/g)	K _{Foc} (mL/g)	1/n (-)	Evaluated on EU level
I Sand *	0.43	5.7	2.1	488	0.597	Yes / EFSA, 2016
II Laomy sand	1	7.6	2.24	223	0.714	Yes / EFSA, 2016
III Sandy loam	1.57	7.1	2.16	138	0.712	Yes / EFSA, 2016
IV Silt loam	1.39	7.7	2.67	192	0.816	Yes / EFSA, 2016
V Silt loam	4.39	7.1	5.79	132	0.813	Yes / EFSA, 2016
Arithmetic mean (n=5)				171	0.746	
Geometric mean (n=5)				167	-	
pH-dependency:				No		

^{a)} Measured in unknown medium

* Sand soil was already excluded during the previous evaluation due to low 1/n value

Table 8.5-4: Summary of soil adsorption/desorption for IC-0

IC-0						
Soil type	OC (%)	pH ^{a)}	K _F (mL/g)	K _{Foc} (mL/g)	1/n (-)	Evaluated on EU level
I Sand	0.43	5.7	0.643	258	0.967	Yes / EFSA, 2016
II Laomy sand	2.54	7.6	1.027	70	1.007	Yes / EFSA, 2016
III Sandy loam	0.76	7.1	0.569	129	0.971	Yes / EFSA, 2016
IV Silt loam	2.05	7.7	0.833	70	0.894	Yes / EFSA, 2016
V Silt loam	1.41	7.1	0.69	84	0.926	Yes / EFSA, 2016
Pond sediment *	4.32		2.121	85	0.867	Yes / EFSA, 2016
Arithmetic mean (n=5)				122	0.953	
Geometric mean (n=5)				106	-	
pH-dependency:				No		

^{a)} Measured in unknown medium

* Sediment already excluded during the previous evaluation

Table 8.5-5: Summary of soil adsorption/desorption for IM-1-5

IM-1-5						
Soil type	OC (%)	pH ^{a)}	K _F (mL/g)	K _{Foc} (mL/g)	1/n (-)	Evaluated on EU level
Spain (Canals)	3.3	7.6	5.70	173	0.8788	Yes / EFSA, 2016
S France (Meauzac)	1.14	7.6	4.89	429	0.9030	Yes / EFSA, 2016
Hungary	2.03	7.8	7.58	374	0.8454	Yes / EFSA, 2016
N France (Meistratzheim)	2.04	8.3	6.60	324	0.9176	Yes / EFSA, 2016
Arithmetic mean (n=4)				325	0.886	
Geometric mean (n=4)				308	-	
pH-dependency:				No		

^{a)} Measured in unknown medium

* Sediment already excluded during the previous evaluation

zRMS comments:

Soil mobility data for acetamiprid and its metabolites are in line with EU agreed endpoints reported in EFSA Journal 2016;14(11):4610.

8.5.2 Column leaching (KCP 9.1.2.1)

Column leaching studies are not required as reliable adsorption coefficients are available for the active substance acetamiprid and its metabolites. However, two studies were submitted for the last EU renewal; the outcome of these studies as given by EFSA Journal 2016;14(11):4610 is provided in the following table.

Table 8.5-6: Results of column leaching studies

Study 1	Leachate: 0.3-1.3 % total residues/radioactivity in leachate 0.06 % active substance, 0.84 % IM-1-4 88.9- 93.7 % total residues/radioactivity retained in the four upper soil layers
Study 2	Elution (mm): 1038 mm Time period (d): 20 d Leachate: 4.14 – 22.22 % total residues/radioactivity in leachate, all associated with metabolite IC-0 4.5 - 5.3 % total residues/radioactivity retained in top 6 cm

zRMS comments:

Information regarding column leaching studies with acetamiprid has been taken from EFSA Journal 2016;14(11):4610 and is confirmed to be correct.

8.5.3 Lysimeter studies (KCP 9.1.2.2)

No lysimeter studies with acetamiprid and its metabolites were performed as they are not required.

zRMS comments:

No lysimeter studies with acetamiprid and its metabolites were evaluated at the EU level.

8.5.4 Field leaching studies (KCP 9.1.2.3)

No field leaching studies with acetamiprid and its metabolites were performed as they are not required.

zRMS comments:

No field leaching studies with acetamiprid and its metabolites were evaluated at the EU level.

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.

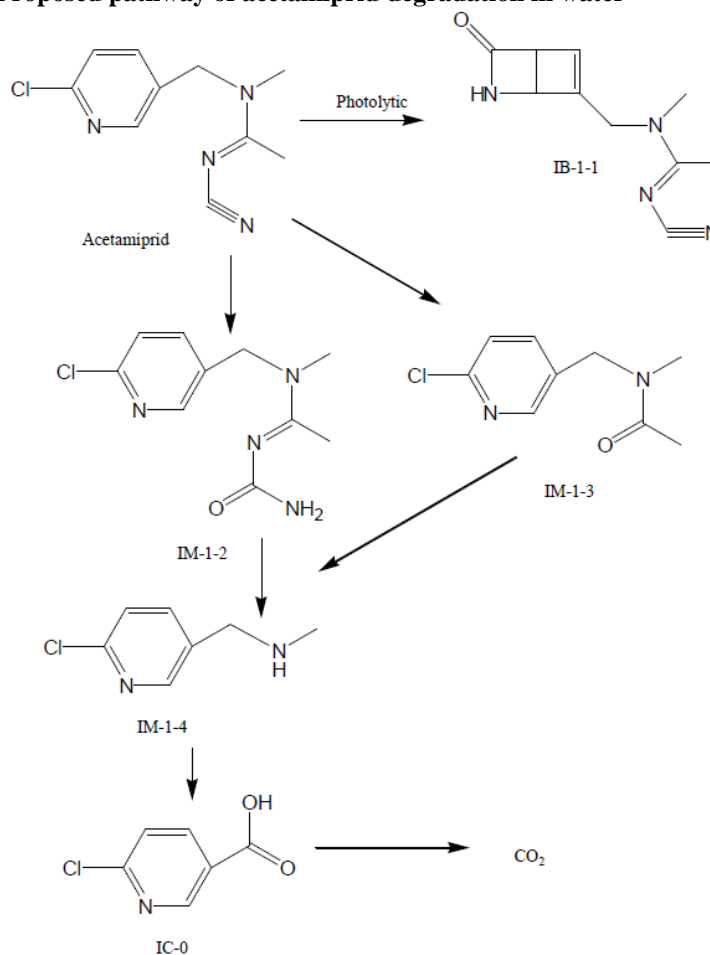
8.6.1 Acetamiprid and its metabolites

Studies on the degradation of acetamiprid in water/sediment systems have been evaluated during the EU review (EFSA Journal 2016;14(11):4610). Fate and behaviour of acetamiprid in the aquatic environment was investigated in two aerobic water/sediment systems. Thereby, three major metabolites (> 10% applied radioactivity (AR)) were identified in the water phase: IM-1-2 (max. 11% AR), IM-1-4 (max. 12% AR) and IC-0 (max. 26% AR). Metabolite IM-1-4 was also a major metabolite in the sediment phase (max. 31% AR).

One study investigating aerobic mineralisation in surface water was conducted and also evaluated during the EU review (EFSA Journal 2016;14(11):4610). Thereby, the major metabolite IM-1-4 was identified with a maximum occurrence of 81.5% AR. Further, the metabolite IB-1-1 was identified in aqueous photochemical degradation studies also evaluated during the EU review (EFSA Journal 2016;14(11):4610). Its maximum occurrence was 35% AR after 30 days and a DT₅₀ of 24 days was determined.

The proposed degradation pathway of acetamiprid in water is illustrated in Figure 8.6-1.

Figure 8.6-1: Proposed pathway of acetamiprid degradation in water



A summary of all data degradation rates of acetamiprid in water/sediment and aerobic mineralisation

studies, as well as a summary of the maximum occurrence of relevant metabolites is given in the following tables.

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

Acetamiprid distribution (max. water 101.42% after 0 days, max. sediment 39.05% after 14 days)											
Water/sediment system	pH water phase	pH sediment	t (°C)	DT ₅₀ whole syst. (d)	Chi ² (x ²)	DT ₅₀ water (d)	Chi ² (x ²)	DT ₅₀ sed. (d)	Chi ² (x ²)	Method of calculation	Evaluated on EU level
Manningtree	6.37/5.9	n.r.	20	23.1	7.6	4.9	8.3	n.c.		SFO/DFOP	Yes / EFSA, 2016
Ongar	7.58/7.3	n.r.	20	31.6	6.7	6.1	5.9	n.c.		SFO/DFOP	Yes / EFSA, 2016
Geometric mean at 20 °C ^{a)} (n=2)				27							

^{a)} Normalised using a Q10 of 2.58

Table 8.6-2: Summary of aerobic mineralisation of acetamiprid in surface water

Acetamiprid, aerobic mineralisation in surface water									
System identifier	pH water phase	pH sediment	t (°C)	Chi ² (x ²)	DT ₅₀ /DT ₉₀ water (d) (pelagic test)		Chi ² (x ²)	Method of calculation	Evaluated on EU level
					At study temp.	DT ₅₀ at 12°C ^{a)}			
Kolben-woog low dose system (2 µg/L)	5.41		20		2.4/36.9	5.1	4.2	DFOP	Yes / EFSA, 2016
Kolben-woog high dose system (10 µg/L)	5.41		20		6.8/87.8	14.5	7.1	FOMC	Yes / EFSA, 2016

^{a)} Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling

Table 8.6-3: Summary of observed metabolites

IM-1-2 Water/sediment system	Max. in total system 13.4% after 7 days (max. in water 10.96% after 7 days; max. in sediment 3.93% after 14 days). No acceptable fit possible	Yes / EFSA, 2016
IM-1-4 Water/sediment system	Max. in total system 43% after 30 days (max in water 12.33% after 30 days; max. in sediment 30.71% after 30 days); Max. 81.5% in aerobic mineralisation study. No acceptable fit possible	Yes / EFSA, 2016
IC-0 Water/sediment system	Max. in total system 29.5% after 62 days (max. in water 26.15% after 62 days; max. in sediment 5.61% after 100 days). No acceptable fit possible	Yes / EFSA, 2016

zRMS comments:

Information on degradation of acetamiprid and its metabolites in water/sediment systems presented above is in line with data reported in EFSA Journal 2016;14(11):4610.

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

8.7.1 Justification for new endpoints

For assessment of the PEC in soil (PEC_{soil}) of acetamiprid and its relevant metabolites, no new endpoints were defined. PEC_{soil} have been calculated using the maximum field dissipation DT₅₀ value of 12.96 days for acetamiprid and maximum laboratory DT₅₀ values for the metabolites, as suggested in the EFSA conclusion on acetamiprid (EFSA Journal 2016;14(11):4610).

8.7.2 Active substance and relevant metabolites

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

Use No.	1, 11^{a)}	1, 11, 2, 12	4, 5, 6, 7, 8, 9, 10, 14, 15, 16, 17, 18	3, 13	19, 20
Crop	Apple	Apple	Spring / Winter oilseed rape	Potato	Corn
Application rate (g a.s./ha)	25	50	60	36	60
Number of applications/interval	2/8	1/-	1/-	1/-	1/-
Application timing	BBCH 62^{b)}	BBCH 62 ^{b)}	BBCH 31	BBCH 12	BBCH 51
Crop interception (%)	60	60	80 ^{c)}	15	75
Application method	Foliar spraying, overall	Foliar spraying, overall	Foliar spraying, overall	Foliar spraying, overall	Foliar spraying, overall
Depth of soil layer (cm)	Initial concentration: 5 cm Plateau concentration: 5 cm (without tillage)	Initial concentration: 5 cm Plateau concentration: 5 cm (without tillage)	Initial concentration: 5 cm Plateau concentration: 20 cm (with tillage)	Initial concentration: 5 cm Plateau concentration: 20 cm (with tillage)	Initial concentration: 5 cm Plateau concentration: 20 cm (with tillage)

^{a)} In the context of a risk envelope, calculations were performed for twofold applications instead of only a single application per year as given in the GAP.

^{b)} Also covering uses with later BBCH 69.

^{c)} Calculated with the minimum interception at BBCH 31, but also covering all uses with later application timings.

Table 8.7-2: Input parameter for active substance and relevant metabolites for PEC_{soil} calculation

Compound	Molar mass (g/mol)	Max. occurrence (%)	DT ₅₀ (days)	Value in accordance to EU endpoint / Reference
Acetamiprid	223	-	12.96 (SFO, non-normalised worst case field DT ₅₀)	Yes / EFSA, 2016
IM-1-2	240.69	55	1.9 (SFO, non-normalised/normalised worst case lab DT ₅₀)	Yes / EFSA, 2016
IM-1-4	156.61	72	146 (SFO, non-normalised worst case lab DT ₅₀)	Yes / EFSA, 2016
IC-0	157.55	11.3	5.6 (SFO, non-normalised/normalised worst case lab DT ₅₀)	Yes / EFSA, 2016
IM-1-5	197.66	20	1000 (SFO, default DT ₅₀)	Yes / EFSA, 2016

zRMS comments:

For evaluation of the input parameters and application data please refer to zRMS comments in point 8.7.2.1 below.

8.7.2.1 Acetamiprid and its metabolites

Table 8.7-3: PEC_{soil} for acetamiprid on apple (1 x 50 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Single application	
		Actual	TWA
Initial		0.027	-
Short term	24h	0.025	0.026
	2d	0.024	0.025
	4d	0.022	0.024
Long term	7d	0.018	0.022
	14d	0.013	0.019
	21d	0.009	0.016
	28d	0.006	0.014
	50d	0.002	0.009
	100d	<0.001	0.005
Plateau concentration (5 cm) after year 26		- ^{a)}	-
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (5 cm))		- ^{a)}	-

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-4: PEC_{soil} for acetamiprid on apple (2 x 25 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Multiple applications	
		Actual	TWA
Initial		0.022	-
Short term	24h	0.021	0.021
	2d	0.020	0.021
	4d	0.018	0.020
Long term	7d	0.015	0.018
	14d	0.010	0.016
	21d	0.007	0.014
	28d	0.005	0.013
	50d	0.002	0.009
	100d	<0.001	0.005
Plateau concentration (5 cm) after year 26		- ^{a)}	-
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (5 cm))		- ^{a)}	-

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-5: PEC_{soil} for acetamiprid on spring and winter oilseed rape (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Spring and winter oilseed rape	
		Single application	
		Actual	TWA
Initial		0.016	-
Short term	24h	0.015	0.016
	2d	0.014	0.015
	4d	0.013	0.014
Long term	7d	0.011	0.013
	14d	0.008	0.011
	21d	0.005	0.010
	28d	0.004	0.008
	50d	0.001	0.006
	100d	<0.001	0.003
Plateau concentration (20 cm) after year 26		- ^{a)}	-
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (20 cm))		- ^{a)}	-

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-6: PEC_{soil} for acetamiprid on potato (1 x 36 g a.s./ha)

PEC _{soil} (mg/kg)		Potato	
		Single application	
		Actual	TWA
Initial		0.041	-
Short term	24h	0.039	0.040
	2d	0.037	0.039
	4d	0.033	0.037
Long term	7d	0.028	0.034
	14d	0.019	0.029
	21d	0.013	0.025
	28d	0.009	0.021
	50d	0.003	0.014
	100d	<0.001	0.008
Plateau concentration (20 cm) after year 26		- ^{a)}	-
PEC _{accumulation} (PEC _{act} (5 cm) +PEC _{soil plateau} (20 cm))		- ^{a)}	-

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-7: PEC_{soil} for acetamiprid on corn (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Corn	
		Single application	
		Actual	TWA
Initial		0.020	-
Short term	24h	0.019	0.019
	2d	0.018	0.019
	4d	0.016	0.018
Long term	7d	0.014	0.017
	14d	0.009	0.014
	21d	0.007	0.012
	28d	0.004	0.010
	50d	0.001	0.007
	100d	0.000	0.004
Plateau concentration (20 cm) after year 26		- ^{a)}	-
PEC _{accumulation} (PEC _{act} (5 cm) +PEC _{soil plateau} (20 cm))		- ^{a)}	-

^{a)} Not calculated due to DT₅₀ < 90 days

PEC_{soil} of metabolites

Table 8.7-8: PEC_{soil} for IM-1-2 on apple (1 x 50 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Single application	
		Actual	TWA
Initial		0.016	–
Short-term	24h	0.011	0.013
	2d	0.008	0.011
	4d	0.004	0.008
Long-term	7d	0.001	0.006
	14d	<0.001	0.003
	21d	<0.001	0.002
	28d	<0.001	0.002
	50d	<0.001	0.001
	100d	<0.001	<0.001
Plateau concentration (5 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (5 cm))		– ^{a)}	–

^{a)} – Not calculated due to DT₅₀ < 90 days

Table 8.7-9: PEC_{soil} for IM-1-2 on apple (2 x 25 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Multiple applications	
		Actual	TWA
Initial		0.008	–
Short-term	24h	0.006	0.007
	2d	0.004	0.006
	4d	0.002	0.005
Long-term	7d	0.001	0.003
	14d	<0.001	0.003
	21d	<0.001	0.002
	28d	<0.001	0.002
	50d	<0.001	0.001
	100d	<0.001	0.001
Plateau concentration (5 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (5 cm))		– ^{a)}	–

^{a)} – Not calculated due to DT₅₀ < 90 days

Table 8.7-10: PEC_{soil} for IM-1-2 on spring and winter oilseed rape (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Spring and winter oilseed rape	
		Single application	
		Actual	TWA
Initial		0.009	–
Short-term	24h	0.007	0.008
	2d	0.005	0.007
	4d	0.002	0.005
Long-term	7d	0.001	0.003
	14d	<0.001	0.002
	21d	<0.001	0.001
	28d	<0.001	0.001
	50d	<0.001	0.001
	100d	<0.001	<0.001
Plateau concentration (20 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (20 cm))		– ^{a)}	–

^{a)} – Not calculated due to DT₅₀ < 90 days

Table 8.7-11: PEC_{soil} for IM-1-2 on potato (1 x 36 g a.s./ha)

PEC _{soil} (mg/kg)		Potato	
		Single application	
		Actual	TWA
Initial		0.024	–
Short term	24h	0.017	0.020
	2d	0.012	0.017
	4d	0.006	0.013
Long term	7d	0.002	0.009
	14d	<0.001	0.005
	21d	<0.001	0.003
	28d	<0.001	0.002
	50d	<0.001	0.001
	100d	<0.001	0.001
Plateau concentration (20 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{soil} (5 cm) + PEC _{soil plateau} (20 cm))		– ^{a)}	–

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-12: PEC_{soil} for IM-1-2 on corn (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Corn	
		Single application	
		Actual	TWA
Initial		0.012	–
Short term	24h	0.008	0.010
	2d	0.006	0.008
	4d	0.003	0.006
Long term	7d	0.001	0.004
	14d	<0.001	0.002
	21d	<0.001	0.002
	28d	<0.001	0.001
	50d	<0.001	0.001
	100d	<0.001	<0.001
Plateau concentration (20 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{soil} (5 cm) + PEC _{soil plateau} (20 cm))		– ^{a)}	–

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-13: PEC_{soil} for IM-1-4 on apple (1 x 50 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Single application	
		Actual	TWA
Initial		0.013	–
Short term	24h	0.013	0.013
	2d	0.013	0.013
	4d	0.013	0.013
Long term	7d	0.013	0.013
	14d	0.013	0.013
	21d	0.012	0.013
	28d	0.012	0.013
	50d	0.011	0.012
	100d	0.008	0.011
Plateau concentration (5 cm) after year 21		0.003	–
PEC _{accumulation} (PEC _{soil} (5 cm) + PEC _{soil plateau} (5 cm))		0.016	–

Table 8.7-14: PEC_{soil} for IM-1-4 on apple (2 x 25 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Multiple applications	
		Actual	TWA
Initial		0.013	-
Short term	24h	0.013	0.013
	2d	0.013	0.013
	4d	0.013	0.013
Long term	7d	0.013	0.013
	14d	0.012	0.013
	21d	0.012	0.013
	28d	0.012	0.012
	50d	0.010	0.012
	100d	0.008	0.011
Plateau concentration (5 cm) after year 21		0.003	-
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (5 cm))		0.016	-

Table 8.7-15: PEC_{soil} for IM-1-4 on spring and winter oilseed rape (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Spring and winter oilseed rape	
		Single application	
		Actual	TWA
Initial		0.008	-
Short term	24h	0.008	0.008
	2d	0.008	0.008
	4d	0.008	0.008
Long term	7d	0.008	0.008
	14d	0.008	0.008
	21d	0.007	0.008
	28d	0.007	0.008
	50d	0.006	0.007
	100d	0.005	0.006
Plateau concentration (20 cm) after year 21		<0.001	-
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (20 cm))		0.009	-

Table 8.7-16: PEC_{soil} for IM-1-4 on potato (1 x 36 g a.s./ha)

PEC _{soil} (mg/kg)		Potato	
		Single application	
		Actual	TWA
Initial		0.021	-
Short term	24h	0.021	0.021
	2d	0.020	0.021
	4d	0.020	0.020
Long term	7d	0.020	0.020
	14d	0.019	0.020
	21d	0.019	0.020
	28d	0.018	0.019
	50d	0.016	0.018
	100d	0.013	0.016
Plateau concentration (20 cm) after year 20		0.001	-
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (20 cm))		0.022	-

Table 8.7-17: PEC_{soil} for IM-1-4 on corn (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Corn	
		Single application	
		Actual	TWA
Initial		0.010	–
Short term	24h	0.010	0.010
	2d	0.010	0.010
	4d	0.010	0.010
Long term	7d	0.010	0.010
	14d	0.009	0.010
	21d	0.009	0.010
	28d	0.009	0.009
	50d	0.008	0.009
	100d	0.006	0.008
Plateau concentration (20 cm) after year 20		0.001	–
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (20 cm))		0.011	–

Table 8.7-18: PEC_{soil} for IC-0 on apple (1 x 50 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Single application	
		Actual	TWA
Initial		0.002	–
Short term	24h	0.002	0.002
	2d	0.002	0.002
	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 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (5 cm))		– ^{a)}	–

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-19: PEC_{soil} for IC-0 on apple (2 x 25 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Multiple applications	
		Actual	TWA
Initial		0.001	–
Short term	24h	0.001	0.001
	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 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{act} (5 cm) + PEC _{soil plateau} (5 cm))		– ^{a)}	–

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-20: PEC_{soil} for IC-0 on spring and winter oilseed rape (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Spring and winter oilseed rape	
		Single application	
		Actual	TWA
Initial		0.001	–
Short term	24h	0.001	0.001
	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 (20 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{soil} (5 cm) + PEC _{soil plateau} (20 cm))		– ^{a)}	–

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-21: PEC_{soil} for IC-0 on potato (1 x 36 g a.s./ha)

PEC _{soil} (mg/kg)		Potato	
		Single application	
		Actual	TWA
Initial		0.003	–
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.002	0.003
Long term	7d	0.001	0.002
	14d	0.001	0.002
	21d	<0.001	0.001
	28d	<0.001	0.001
	50d	<0.001	0.001
	100d	<0.001	<0.001
Plateau concentration (20 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{soil} (5 cm) + PEC _{soil plateau} (20 cm))		– ^{a)}	–

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-22: PEC_{soil} for IC-0 on corn (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Corn	
		Single application	
		Actual	TWA
Initial		0.002	–
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 (20 cm) after year 26		– ^{a)}	–
PEC _{accumulation} (PEC _{soil} (5 cm) + PEC _{soil plateau} (20 cm))		– ^{a)}	–

^{a)} Not calculated due to DT₅₀ < 90 days

Table 8.7-23: PEC_{soil} for IM-1-5 on apple (1 x 50 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Single application	
		Actual	TWA
Initial		0.005	-
Short term	24h	0.005	0.005
	2d	0.005	0.005
	4d	0.005	0.005
Long term	7d	0.005	0.005
	14d	0.005	0.005
	21d	0.005	0.005
	28d	0.005	0.005
	50d	0.005	0.005
	100d	0.004	0.005
Plateau concentration (5 cm) after year 26		0.016	-
PEC _{accumulation} (PEC _{act} (5 cm) +PEC _{soil plateau} (5 cm))		0.021	-

Table 8.7-24: PEC_{soil} for IM-1-5 on apple (2 x 25 g a.s./ha)

PEC _{soil} (mg/kg)		Apple	
		Multiple applications	
		Actual	TWA
Initial		0.005	-
Short term	24h	0.005	0.005
	2d	0.005	0.005
	4d	0.005	0.005
Long term	7d	0.005	0.005
	14d	0.005	0.005
	21d	0.005	0.005
	28d	0.005	0.005
	50d	0.005	0.005
	100d	0.004	0.005
Plateau concentration (5 cm) after year 26		0.016	-
PEC _{accumulation} (PEC _{act} (5 cm) +PEC _{soil plateau} (5 cm))		0.021	-

Table 8.7-25: PEC_{soil} for IM-1-5 on spring and winter oilseed rape (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Spring and winter oilseed rape	
		Single application	
		Actual	TWA
Initial		0.003	-
Short term	24h	0.003	0.003
	2d	0.003	0.003
	4d	0.003	0.003
Long term	7d	0.003	0.003
	14d	0.003	0.003
	21d	0.003	0.003
	28d	0.003	0.003
	50d	0.003	0.003
	100d	0.003	0.003
Plateau concentration (20 cm) after year 26		0.005	-
PEC _{accumulation} (PEC _{act} (5 cm) +PEC _{soil plateau} (20 cm))		0.008	-

Table 8.7-26: PEC_{soil} for IM-1-5 on potato (1 x 36 g a.s./ha)

PEC _{soil} (mg/kg)		Potato	
		Single application	
		Actual	TWA
Initial		0.007	-
Short term	24h	0.007	0.007
	2d	0.007	0.007
	4d	0.007	0.007
Long term	7d	0.007	0.007
	14d	0.007	0.007
	21d	0.007	0.007
	28d	0.007	0.007
	50d	0.007	0.007
	100d	0.007	0.007
Plateau concentration (20 cm) after year 26		0.006	-
PEC _{accumulation} (PEC _{act} (5 cm) +PEC _{soil plateau} (20 cm))		0.014	-

Table 8.7-27: PEC_{soil} for IM-1-5 on corn (1 x 60 g a.s./ha)

PEC _{soil} (mg/kg)		Corn	
		Single application	
		Actual	TWA
Initial		0.004	-
Short term	24h	0.004	0.004
	2d	0.004	0.004
	4d	0.004	0.004
Long term	7d	0.004	0.004
	14d	0.004	0.004
	21d	0.003	0.004
	28d	0.003	0.004
	50d	0.003	0.003
	100d	0.003	0.003
Plateau concentration (20 cm) after year 26		0.003	-
PEC _{accumulation} (PEC _{act} (5 cm) +PEC _{soil plateau} (20 cm))		0.007	-

zRMS comments:

Input parameters for acetamiprid and its metabolites presented in Table 8.7-2 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(11):4610.

The use pattern was in general in line with the GAP table presented in point 8.1 with exception of application of lower rate to apples, as currently only single application at 25 g a.s./ha is proposed. Since calculations performed for higher application rate (1 x 50 g a.s./ha) cover rate of 25 g a.s./ha, results obtained for double application at 25 g a.s./ha were not validated by the zRMS and are thus struck through.

According to information available from ecotox section, only metabolite IM-1-5 was deemed relevant for the soil risk assessment, so the soil exposure was validated for acetamiprid and IM-1-5 only. As soil exposure for remaining metabolites was not necessary for the risk assessment purposes, it was not validated by the zRMS and obtained results are thus struck through in tables above for clarity.

Soil exposure estimates for acetamiprid and metabolite IM-1-5 were independently validated by the zRMS using ESCAPE ver. 2. Metabolite was simulated as the parent using pseudo-application rate calculated with consideration of the molar ratio (0.886) and maximum occurrence in soil (20%).

For acetamiprid the same PEC_{soil} values were obtained by the zRMS. For metabolite actual and TWA PEC_{soil} values were the same, while plateau concentration and accumulated PEC_{soil} derived by the zRMS were lower. Taking this into account, results obtained by the Applicant for metabolite may be used in the soil risk assessment as representing worst case.

8.7.2.2 PEC_{soil} of CA3573

Table 8.7-28: PEC_{soil} for CA3573

Crop	Application rate	PEC _{act} (mg/kg)
Apple	0.125 L/ha = 0.1420 kg/ha ^{a)}	0.076
	0.25 L/ha = 0.2840 kg/ha ^{a)}	0.151
Winter and spring oilseed rape	0.3 L/ha = 0.3408 kg/ha ^{a)}	0.091
Potato	0.18 L/ha = 0.2045 kg/ha ^{a)}	0.232
Corn	0.3 L/ha = 0.3408 kg/ha ^{a)}	0.114

^{a)} The application rate of the formulation was calculated based on a density of 1.136 g/mL and the maximum application rate for each crop.

zRMS comments:

Soil exposure for CA3573 presented in Table 8.7-28 above is agreed by the zRMS. Please note, however, that PEC_{soil} values for the formulated product were not used in the risk assessment for soil organisms, which was based on soil exposure calculated for the active compound.

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

8.8.1 Justification for new endpoints

For estimation of the PEC in groundwater (PEC_{gw}) of acetamiprid and its metabolites, no new end-points were defined. PEC_{gw} have been assessed with FOCUS groundwater models and the endpoints as proposed in the EFSA conclusion of acetamiprid (EFSA Journal 2016;14(11):4610).

The on-going study on determination of TSCF value for metabolite IM-1-5 could not be finalised due to many technical flaws in the study. Hence, for the plant uptake factor of the metabolite IM-1-5, a tiered approach is followed in PEC_{gw} calculations:

- Tier 1: A conservative default value of PUF = 0 was assumed for metabolite IM-1-5. As per the Scientific Panel on Plant Protection Products and their Residues (PPR Panel) on higher tier leaching assessments (EFSA Journal 2013;11(6):3291), a default plant uptake factor of 0 as a tier-1 approach is advocated.
- Tier 2: A plant uptake factor of PUF = 0.45 was assumed for IM-1-5 according to the equation proposed by Briggs et al. (1982)¹. The PPR Panel on higher tier leaching assessments (EFSA Journal 2013;11(6):3291) recommends considering plant uptake factor via roots in the leaching assessment for systemic compounds. The PPR Panel proposes the Briggs formula as tier-2 for estimating the plant uptake factor using the logKow, as proposed by FOCUS (2000, 2009). Also, as per the RAR (Volume 3 – Annex B (PPP) - B.8 Environmental fate and behaviour) for Acetamiprid, the systemic uptake of IM-1-5 was confirmed. Therefore, as IM-1-5 is positively evaluated as a systemic compound in active substance renewal and as PPR Panel recommends using the Briggs equation to estimate the PUF of systemic compounds, as Tier 2, we have presented the Tier 2 calculations with a PUF = 0.45 based on the log Kow value of 0.62. The logKow value was determined experimentally in the Nufarm study (Fent et al. 2020), which was submitted to Ctgb during data matching after the active substance renewal. The study has been evaluated positively by Ctgb.
- Tier 3: A plant uptake factor of PUF = 0.23 was assumed for IM-1-5. The value 0.23 is a generic default value suggested by the German UBA (2019)² for substances:
 - with molecular weights ≤ 394 g/mol that are evidentially taken up in above-ground parts of the plants. This condition is fulfilled as the molecular weight of IM-1-5 is 197.66 g/mol.
 - The compound is evidently taken up by the roots into the above ground parts of the plant: This pre-condition is fulfilled as RMS clearly concluded that IM-1-5 is a systemic compound during the evaluation of the active substance Acetamiprid in 2016 (Please refer to RAR (Volume 3 – Annex B (PPP) - B.8 Environmental fate and behavior).
- Tier 4: A plant uptake factor of 0.5 was used as proposed in the EFSA conclusion of acetamiprid.

Calculations with MACRO were only performed for the active substance acetamiprid and the metabolite IM-1-5, as calculations with FOCUS PEARL and PELMO already showed results of PEC_{gw} < 0.01 µg/L for the metabolites IM-1-2, IM-1-4 and IC-0.

¹ Briggs, G.G., Bromilow, R.H., and Evans, A.A. (1982): Relationships Between Lipophilicity and Root Uptake and Translocation of Non-Ionized Chemicals by Barley, Pesticide Science 13: 495-504.

² German federal environmental agency 'Umweltbundesamt' / 'UBA' (2019): The plant uptake factor – Tiered approach for the regulatory use. v0 (draft version for discussion), dated July 2019.

zRMS comments:

The additional groundwater modelling based on various refined PUF values has been submitted by the Applicant due to PEC_{gw} values of toxicologically relevant metabolite IM-1-5 exceeding the threshold concentration of 0.1 µg/L in scenario Thiva following single application of CA3573 to apples at 50 g a.s./ha and twofold application to apples at 25 g a.s./ha.

It is, however, noted that according to the Central Zone guidance document in area of Section 8³, scenario Thiva is not relevant for the Central Zone. Furthermore, only single applications to apples at either 50 or 25 g a.s./ha are currently included in the Central Zone GAP for CA3573, so results obtained for twofold application at 25 g a.s./ha are currently not relevant. Additional calculations performed by the zRMS for single application at 25 g a.s./ha resulted with PEC_{gw} <0.1 µg/L in all scenarios modelled using PEARL and PELMO (for details, see Tables 8.8-4 and 8.8-5 in point 8.8.2.1 below).

As concentration of IM-1-5 in all scenarios relevant for the Central Zone (i.e. Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto) were <0.1 µg/L for all intended uses, proposed PUF refinement and results of modelling carried out at Tier 2-4 were not evaluated by the zRMS as not necessary. The information on the proposed refinement has been retained above for information of cMS, but the text was shaded to clearly separate the not necessary from relevant information.

8.8.2 Active substance and relevant metabolites (KCP 9.2.4.1)

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

Use No.	1, 11 ^{a)}	2, 12	8, 9, 10, 17, 18 ^{b)}	4, 5, 6, 7, 14, 15, 16 ^{b)}	3, 13	19, 20
Crop	Apple	Apple	Spring oilseed rape	Winter oilseed rape	Potato	Corn
Application rate (g a.s./ha)	25	Tier 1, 2 & 3: 50 Tier 4: 70 ^{d)}	60	60	36	60
Number of applications / interval (d)	1 2/8	1 1/-	1 2/7	1 2/7	1 1/-	1 1/-
Application timing (as given in the GAP)	BBCH 62 - PHI ^{c)}	BBCH 62 - PHI ^{c)}	BBCH 31 - 71	BBCH 31 - 71	BBCH 12 - 79	BBCH 51 - 75
Crop interception (%)	60	60	80	80	15	75
Soil load (g a.s./ha)	10	20 28	12	12	30.6	15
Frequency of application	annual	annual (all tiers) & biennial (tier 1 only)	annual	annual	annual	annual
Models used for calculation	FOCUS PEARL v4.4.4, FOCUS PELMO v5.5.3, FOCUS MACRO v5.5.4					

^{a)} In the context of a risk envelope, calculations were performed for twofold applications instead of only a single application per year as given in the GAP.

^{b)} In the context of a risk envelope, calculations were performed for twofold applications instead of only a single application per year as given in the GAP.

^{c)} Also covering uses with BBCH 69 as earliest application timing.

^{d)} In the context of a risk envelope, calculations were performed with an application rate of 70 g a.s./ha instead of 50 g a.s./ha as given in the GAP.

Application dates for modelling were selected with AppDate v3.06 (see table below).

³ Working document of the Central Zone in the authorisation of plant protection products, Section 8, Environmental Fate and behaviour. Version 1, rev. 1, June 2018

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

Crop	Scenario	Application dates (Julian Day absolute)	
		1 st application	2 nd application
Apple	Châteaudun	19-May (139)	27-May (147)
	Hamburg	16-Jun	24-Jun
	Jokioinen	22-May	30-May
	Kremsmünster	16-Jun	24-Jun
	Okehampton	30-May	07-Jun
	Piacenza	19-May	27-May
	Porto	09-Jun	17-Jun
	Sevilla	16-May	24-May
	Thiva	09-Jun	17-Jun
Winter oilseed rape	Châteaudun	13-Mar (72)	20-Mar (79)
	Hamburg	19-Apr	26-Apr
	Kremsmünster	16-Apr	23-Apr
	Okehampton	10-Apr	17-Apr
	Piacenza	09-Mar	16-Mar
	Porto	04-Jan	11-Jan
Spring oilseed rape	Jokioinen	14-Jun	21-Jun
	Okehampton	24-Apr	01-May
	Porto	28-Apr	05-May
Potato	Châteaudun	02-May (122 123)	-
	Hamburg	15-May	-
	Jokioinen	10-Jun.	-
	Kremsmünster	15-May	-
	Okehampton	05-May	-
	Piacenza	23-Apr.	-
	Porto	20-Mar.	-
	Sevilla	04-Feb.	-
	Thiva	05-Mar.	-
Corn	Châteaudun	15-Jul (196)	-
	Hamburg	05-Jul	-
	Kremsmünster	05-Jul	-
	Okehampton	30-Jun	-
	Piacenza	08-Jul	-
	Porto	15-Jul	-
	Sevilla	16-May	-
	Thiva	30-May	-

zRMS comments:

The application pattern assumed in groundwater exposure calculations is in general in line with Central Zone GAP as presented in Table 8.1-1. Assumption of twofold application of CA3573 in apples and oilseed rape would form a risk envelope approach, however due to potential exceedance of the threshold concentration of metabolite IM-1-5 in some scenarios, additional modelling has been performed by the zRMS for the relevant GAP indicated for the Central Zone (i.e. single application in these crops). Information in Table 8.8-1 was thus amended accordingly, while in Table 8.8-2 application dates for the second application were struck through as being not relevant.

It is also noted that after application of 50 g a.s./ha in orchards the rate reaching soil should be 20 g a.s./ha (60% CI). The Applicant indicated 28 g a.s./ha, which is relevant for application of 70 g a.s./ha assumed at Tier 4 simulations, which were, however, not validated by the zRMS as not necessary (please, refer to zRMS comment in point 8.8.1 for more information on higher tier modelling). For the same reason all information related to higher tier modelling has been struck through in tables above.

8.8.2.1 Acetamiprid and its metabolites

Table 8.8-3: Input parameters related to active substance acetamiprid and relevant metabolites for PEC_{gw} calculations

Compound	Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5	Value in accordance with EU endpoint / Reference
Molecular weight (g/mol)	223	240.69	156.61	157.55	197.66	Yes / EFSA, 2016
Water solubility (g/mol)	2950 (pH 7 and 25°C)	1 x 10 ⁶ (pH 7 and 25°C)	1 x 10 ⁶ (pH 7 and 25°C)	1 x 10 ⁶ (pH 7 and 25°C)	1 x 10 ⁶ (pH 7 and 25°C)	Yes / EFSA, 2016
Saturated vapour pressure (Pa)	1 x 10 ⁻⁶ (20°C)	1 x 10 ⁻⁸ (20°C)	1 x 10 ⁻⁸ (20°C)	1 x 10 ⁻⁸ (20°C)	1 x 10 ⁻⁸ (20°C)	Yes / EFSA, 2016
DT ₅₀ in soil (d)	1.45 (geometric mean, lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	1.7 (geometric mean, lab, n = 3, normalised to pF2, 20°C, Q ₁₀ of 2.58)	14.6 (geometric mean, lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	2.7 (geometric mean, lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	495 (geometric mean, lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	Yes / EFSA, 2016
K _{foc} / K _{fom} (mL/g)	106.5 / 61.8 (arithmetic mean, n = 5)	54 / 31.3 (arithmetic mean, n = 4)	171 / 99.2 (arithmetic mean, n = 4)	122 / 70.8 (arithmetic mean, n = 5)	325 / 188.5 (arithmetic mean, n = 4)	Yes / EFSA, 2016
1/n	0.86 (arithmetic mean, n = 5)	0.90 (arithmetic mean, n = 4)	0.764 (arithmetic mean, n = 4)	0.953 (arithmetic mean, n = 5)	0.886 (arithmetic mean, n = 4)	Yes / EFSA, 2016
Plant uptake factor	0	0	0	0	Tier 1: 0 Tier 2: 0.45 * Tier 3: 0.23 ** Tier 4: 0.5 ***	FOCUS recommendation * According to Briggs et al. (1982) ⁴ ** UBA (2019) ⁵ *** Yes / EFSA, 2016
Formation fraction	-	0.77 (from parent)	0.72 (from IM-1-2)	0.67 (from IM-1-4)	0.15 (from parent)	Yes / EFSA, 2016
Conversion factor for MACRO	-	0.832	0.390	0.263	0.133	Calculated ^{a)}

^{a)} Calculated as: Formation fraction x MolarMassMetabolite / MolarMassParent

Since MACRO can only handle a one metabolite, it was assumed that all metabolites are directly formed from the parent.

For the relevant member states Poland and Slovakia, only the groundwater scenarios Hamburg, Kremsmünster and Châteaudun are required. However, for the sake of completeness also all other available scenarios are listed in the following tables.

⁴ Briggs, G.G., Bromilow, R.H., and Evans, A.A. (1982): Relationships Between Lipophilicity and Root Uptake and Translocation of Non-Ionized Chemicals by Barley, Pesticide Science 13: 495-504.

⁵ German federal environmental agency 'Umweltbundesamt' / 'UBA' (2019): The plant uptake factor – Tiered approach for the regulatory use. v0 (draft version for discussion), dated July 2019.

Tier 1: PUF = 0 - Annual application

Table 8.8-4: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PEARL 4.4.4.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.089
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.090
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.059
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.065
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.080
	Porto	<0.001	<0.001	<0.001	<0.001	0.037
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.073
	Thiva	<0.001	<0.001	<0.001	<0.001	0.112
Apple 1 x 25 g a.s./ha 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.034 0.089
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.036 0.090
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001 0.000
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.022 0.058
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.027 0.065
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.032 0.080
	Porto	<0.001	<0.001	<0.001	<0.001	0.015 0.037
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.029 0.073
	Thiva	<0.001	<0.001	<0.001	<0.001	0.045 0.110
Winter oilseed rape 1 x 60 g a.s./ha 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.002 0.021
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.029 0.076
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.021 0.055
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.029 0.071
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.014 0.037
	Porto	<0.001	<0.001	<0.001	<0.001	0.016 0.043
Spring oilseed rape 1 x 60 g a.s./ha 2 x 60 g a.s./ha	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001 <0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.026 0.066
	Porto	<0.001	<0.001	<0.001	<0.001	0.014 0.036
Potato 1 x 36 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.040
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.070
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.056
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.084
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.066
	Porto	<0.001	<0.001	<0.001	<0.001	0.038
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.002
	Thiva	<0.001	<0.001	<0.001	<0.001	0.022
Corn 1 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.022
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.037
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.026
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.041
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.036
	Porto	<0.001	<0.001	<0.001	<0.001	0.019
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.016

Table 8.8-5: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.082
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.061
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.051
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.076
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.068
	Porto	<0.001	<0.001	<0.001	<0.001	0.041
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.026
	Thiva	<0.001	<0.001	<0.001	<0.001	0.070
Apple 1 x 25 g a.s./ha 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.030 0.081
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.021 0.061
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001 <0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.017 0.051
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.031 0.076
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.029 0.068
	Porto	<0.001	<0.001	<0.001	<0.001	0.017 0.041
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.008 0.026
	Thiva	<0.001	<0.001	<0.001	<0.001	0.025 0.070
Winter oilseed rape 1 x 60 g a.s./ha 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.001 0.005
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.020 0.066
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.018 0.056
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.034 0.083
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.014 0.041
	Porto	<0.001	<0.001	<0.001	<0.001	0.020 0.055
Spring oilseed rape 1 x 60 g a.s./ha 2 x 60 g a.s./ha	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001 <0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.027 0.069
	Porto	<0.001	<0.001	<0.001	<0.001	0.017 0.043
Potato 1 x 36 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.026
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.054
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.000
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.048
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.085
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.063
	Porto	<0.001	<0.001	<0.001	<0.001	0.050
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.019
Corn 1 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.010
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.025
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.021
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.038
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.034
	Porto	<0.001	<0.001	<0.001	<0.001	0.019
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.010

Table 8.8-6: PEC_{gw} for acetamiprid and metabolite IM-1-5 (with FOCUS MACRO 5.5.4.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Acetamiprid	IM-1-5
Apple, 1 x 50 g a.s./ha	Châteaudun	<0.001	0.011
Apple, 1 x 25 g a.s./ha	Châteaudun	<0.001	0.002
Winter oilseed rape, 1 x 60 g a.s./ha	Châteaudun	<0.001	0.002
Spring oilseed rape, 2 x 60 g a.s./ha	Châteaudun	-a)	-a)
Potato, 1 x 36 g a.s./ha	Châteaudun	<0.001	0.031
Corn, 1 x 60 g a.s./ha	Châteaudun	<0.001	0.010

a) Spring oilseed rape not defined in FOCUS scenario Châteaudun

Tier 1: PUF = 0 – Application every 2nd year

Table 8.8-7: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PEARL 4.4.4.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.037
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.050
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.006
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.028
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.028
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.039
	Porto	<0.001	<0.001	<0.001	<0.001	0.016
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.032
Apple 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.038
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.050
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.006
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.028
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.028
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.039
	Porto	<0.001	<0.001	<0.001	<0.001	0.016
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.032
Winter oilseed rape 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.013
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.037
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.026
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.031
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.016
Spring oilseed rape 2 x 60 g a.s./ha	Porto	<0.001	<0.001	<0.001	<0.001	0.018
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.004
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.029
Potato 1 x 36 g a.s./ha	Porto	<0.001	<0.001	<0.001	<0.001	0.015
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.023
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.037
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.005
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.027
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.037
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.029
	Porto	<0.001	<0.001	<0.001	<0.001	0.016
Corn 1 x 60 g a.s./ha	Sevilla	<0.001	<0.001	<0.001	<0.001	0.002
	Thiva	<0.001	<0.001	<0.001	<0.001	0.012
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.012
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.019
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.013
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.018
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.015
	Porto	<0.001	<0.001	<0.001	<0.001	0.008
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.009

Table 8.8-8: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.037
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.034
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.004
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.026
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.033
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.029
	Porto	<0.001	<0.001	<0.001	<0.001	0.018
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.014
Apple 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.037
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.034
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.004
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.026
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.033
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.029
	Porto	<0.001	<0.001	<0.001	<0.001	0.018
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.014
Winter oilseed rape 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.010
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.037
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.027
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.036
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.019
	Porto	<0.001	<0.001	<0.001	<0.001	0.024
Spring oilseed rape 2 x 60 g a.s./ha	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.004
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.030
	Porto	<0.001	<0.001	<0.001	<0.001	0.018
Potato 1 x 36 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.017
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.034
	Jokioinen	<0.001	<0.001	<0.001	<0.001	0.004
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.026
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.037
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.028
	Porto	<0.001	<0.001	<0.001	<0.001	0.022
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.001
Corn 1 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.008
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.016
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.012
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.017
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.015
	Porto	<0.001	<0.001	<0.001	<0.001	0.008
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.005

Calculations with FOCUS MACRO for the application every 2nd-year were not considered necessary, as annual application already showed results of PEC_{gw} < 0.1 µg/L for IM 1-5 in all uses.

Tier 2: PUF = 0.45 – Annual application

Table 8.8-9: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PEARL 4.4.4.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.055
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.060
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.042
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.052
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.046
	Porto	<0.001	<0.001	<0.001	<0.001	0.029
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.036
Apple 2 x 25 g a.s./ha	Thiva	<0.001	<0.001	<0.001	<0.001	0.054
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.055
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.060
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.042
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.052
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.046
	Porto	<0.001	<0.001	<0.001	<0.001	0.029
Winter oilseed rape 2 x 60 g a.s./ha	Sevilla	<0.001	<0.001	<0.001	<0.001	0.036
	Thiva	<0.001	<0.001	<0.001	<0.001	0.053
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.015
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.058
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.043
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.060
Spring oilseed rape 2 x 60 g a.s./ha	Piacenza	<0.001	<0.001	<0.001	<0.001	0.033
	Porto	<0.001	<0.001	<0.001	<0.001	0.035
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
Potato 1 x 36 g a.s./ha	Okehampton	<0.001	<0.001	<0.001	<0.001	0.055
	Porto	<0.001	<0.001	<0.001	<0.001	0.030
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.030
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.059
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.046
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.071
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.051
Corn 1 x 60 g a.s./ha	Porto	<0.001	<0.001	<0.001	<0.001	0.035
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.013
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.017
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.029
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.021
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.034
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.027
	Porto	<0.001	<0.001	<0.001	<0.001	0.016
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.009

Table 8.8-10: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth ($\mu\text{g/L}$)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.047
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.039
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.032
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.052
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.046
	Porto	<0.001	<0.001	<0.001	<0.001	0.029
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.009
Apple 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.046
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.039
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.032
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.052
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.046
	Porto	<0.001	<0.001	<0.001	<0.001	0.029
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.009
Winter oilseed rape 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.003
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.044
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.037
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.060
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.030
	Porto	<0.001	<0.001	<0.001	<0.001	0.041
Spring oilseed rape 2 x 60 g a.s./ha	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.051
	Porto	<0.001	<0.001	<0.001	<0.001	0.031
Potato 1 x 36 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.016
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.038
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.034
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.063
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.044
	Porto	<0.001	<0.001	<0.001	<0.001	0.038
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
Corn 1 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.006
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.017
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.015
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.028
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.025
	Porto	<0.001	<0.001	<0.001	<0.001	0.014
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.005

Table 8.8-11: PEC_{gw} for acetamiprid and metabolite IM-1-5 (with FOCUS MACRO 5.5.4.)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth ($\mu\text{g/L}$)	
		Acetamiprid	IM-1-5
Apple, 1 x 50 g a.s./ha	Châteaudun	<0.001	0.007
Apple, 2 x 25 g a.s./ha	Châteaudun	<0.001	0.008
Winter oilseed rape, 2 x 60 g a.s./ha	Châteaudun	<0.001	0.009
Spring oilseed rape, 2 x 60 g a.s./ha	Châteaudun	^{a)}	^{a)}
Potato, 1 x 36 g a.s./ha	Châteaudun	<0.001	0.025
Corn, 1 x 60 g a.s./ha	Châteaudun	<0.001	0.008

^{a)} Spring oilseed rape not defined in FOCUS scenario Châteaudun

Tier 3: PUF = 0.23 – Annual application

Table 8.8-12: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PEARL 4.4.4.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.070
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.072
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.049
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.058
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.060
	Porto	<0.001	<0.001	<0.001	<0.001	0.033
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.050
Apple 2 x 25 g a.s./ha	Thiva	<0.001	<0.001	<0.001	<0.001	0.072
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.070
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.072
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.050
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.058
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.060
	Porto	<0.001	<0.001	<0.001	<0.001	0.033
Winter oilseed rape 2 x 60 g a.s./ha	Sevilla	<0.001	<0.001	<0.001	<0.001	0.051
	Thiva	<0.001	<0.001	<0.001	<0.001	0.074
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.018
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.066
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.049
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.065
Spring oilseed rape 2 x 60 g a.s./ha	Piacenza	<0.001	<0.001	<0.001	<0.001	0.035
	Porto	<0.001	<0.001	<0.001	<0.001	0.038
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
Potato 1 x 36 g a.s./ha	Okehampton	<0.001	<0.001	<0.001	<0.001	0.060
	Porto	<0.001	<0.001	<0.001	<0.001	0.033
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.034
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.064
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.050
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.077
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.058
Corn 1 x 60 g a.s./ha	Porto	<0.001	<0.001	<0.001	<0.001	0.036
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.017
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.019
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.032
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.023
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.037
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.030
	Porto	<0.001	<0.001	<0.001	<0.001	0.017
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.012

Table 8.8-13: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth ($\mu\text{g/L}$)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 50 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.061
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.048
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.040
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.063
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.055
	Porto	<0.001	<0.001	<0.001	<0.001	0.034
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.015
Apple 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.062
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.048
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.040
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.063
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.055
	Porto	<0.001	<0.001	<0.001	<0.001	0.034
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.015
Winter oilseed rape 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.004
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.053
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.045
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.070
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.035
	Porto	<0.001	<0.001	<0.001	<0.001	0.047
Spring oilseed rape 2 x 60 g a.s./ha	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.059
	Porto	<0.001	<0.001	<0.001	<0.001	0.036
Potato 1 x 36 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.020
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.045
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.040
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.073
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.052
	Porto	<0.001	<0.001	<0.001	<0.001	0.043
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.001
Corn 1 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.008
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.020
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.018
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.033
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.029
	Porto	<0.001	<0.001	<0.001	<0.001	0.016
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.007

Table 8.8-14: PEC_{gw} for acetamiprid and metabolite IM-1-5 (with FOCUS MACRO 5.5.4)

Crop	Scenario	80 th Percentile PEC_{gw} at 1 m Soil Depth ($\mu\text{g/L}$)	
		Acetamiprid	IM-1-5
Apple, 1 x 50 g a.s./ha	Châteaudun	<0.001	0.009
Apple, 2 x 25 g a.s./ha	Châteaudun	<0.001	0.010
Winter oilseed rape, 2 x 60 g a.s./ha	Châteaudun	<0.001	0.010
Spring oilseed rape, 2 x 60 g a.s./ha	Châteaudun	- ^{a)}	- ^{a)}
Potato, 1 x 36 g a.s./ha	Châteaudun	<0.001	0.028
Corn, 1 x 60 g a.s./ha	Châteaudun	<0.001	0.009

^{a)} Spring oilseed rape not defined in FOCUS scenario Châteaudun

Tier 4: PUF = 0.5 — Annual application

Table 8.8-15: ——— PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PEARL 4.4.4.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 70 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.081
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.089
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.062
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.077
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.067
	Porto	<0.001	<0.001	<0.001	<0.001	0.044
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.052
	Thiva	<0.001	<0.001	<0.001	<0.001	0.077
Apple 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.053
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.058
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.040
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.050
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.044
	Porto	<0.001	<0.001	<0.001	<0.001	0.028
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.034
	Thiva	<0.001	<0.001	<0.001	<0.001	0.049
Winter oilseed rape 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.015
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.057
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.042
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.058
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.032
	Porto	<0.001	<0.001	<0.001	<0.001	0.034
Spring oilseed rape 2 x 60 g a.s./ha	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.054
	Porto	<0.001	<0.001	<0.001	<0.001	0.029
Potato 1 x 36 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.029
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.058
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.045
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.070
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.049
	Porto	<0.001	<0.001	<0.001	<0.001	0.034
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.001
Corn 1 x 60 g a.s./ha	Thiva	<0.001	<0.001	<0.001	<0.001	0.013
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.017
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.028
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.021
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.033
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.026
	Porto	<0.001	<0.001	<0.001	<0.001	0.016
	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.009

Table 8.8-16: PEC_{gw} for acetamiprid and metabolites IM-1-2, IM-1-4, IC-0 and IM-1-5 (with FOCUS PELMO 5.5.3)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)				
		Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5
Apple 1 x 70 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.069
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.061
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.049
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.076
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.067
	Porto	<0.001	<0.001	<0.001	<0.001	0.042
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.014
Apple 2 x 25 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.044
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.037
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.030
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.050
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.044
	Porto	<0.001	<0.001	<0.001	<0.001	0.027
	Sevilla	<0.001	<0.001	<0.001	<0.001	0.008
Winter oilseed rape 2 x 60 g a.s./ha	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.003
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.042
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.036
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.058
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.029
Spring oilseed rape 2 x 60 g a.s./ha	Porto	<0.001	<0.001	<0.001	<0.001	0.039
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.049
Potato 1 x 36 g a.s./ha	Porto	<0.001	<0.001	<0.001	<0.001	0.030
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.015
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.037
	Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.033
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.061
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.043
	Porto	<0.001	<0.001	<0.001	<0.001	0.037
Corn 1 x 60 g a.s./ha	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.008
	Châteaudun	<0.001	<0.001	<0.001	<0.001	0.006
	Hamburg	<0.001	<0.001	<0.001	<0.001	0.016
	Kremsmünster	<0.001	<0.001	<0.001	<0.001	0.014
	Okehampton	<0.001	<0.001	<0.001	<0.001	0.027
	Piacenza	<0.001	<0.001	<0.001	<0.001	0.024
	Porto	<0.001	<0.001	<0.001	<0.001	0.013
Corn, 1 x 60 g a.s./ha	Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001
	Thiva	<0.001	<0.001	<0.001	<0.001	0.004

Table 8.8-17: PEC_{gw} for acetamiprid and metabolite IM-1-5 (with FOCUS MACRO 5.5.4.)

Crop	Scenario	80 th Percentile PEC _{gw} at 1 m Soil Depth (µg/L)	
		Acetamiprid	IM-1-5
Apple, 1 x 70 g a.s./ha	Châteaudun	<0.001	0.012
Apple, 2 x 25 g a.s./ha	Châteaudun	<0.001	0.007
Winter oilseed rape, 2 x 60 g a.s./ha	Châteaudun	<0.001	0.009
Spring oilseed rape, 2 x 60 g a.s./ha	Châteaudun	— ^{a)}	— ^{a)}
Potato, 1 x 36 g a.s./ha	Châteaudun	<0.001	0.024
Corn, 1 x 60 g a.s./ha	Châteaudun	<0.001	0.008

^{a)} Spring oilseed rape not defined in FOCUS scenario Châteaudun

zRMS comments:

Input parameters considered in the Tier 1 groundwater modelling are in line with EU agreed endpoints reported in EFSA Journal 2016;14(11):4610. The only exception is PUF value for metabolite IM-1-5, for which at the EU level PUF of 0.5 relevant for systemic substances was assumed, in line with indications of FOCUS groundwater guidance valid at the time of evaluation. However, since acetamiprid renewal process new version of the FOCUS groundwater guidance has been issued (version of 2014) which states that at Tier 1 PUF of 0 must be assumed for all compounds regardless if systemic or not. For this reason it was relevant to assume PUF of 0 at Tier 1 simulations for CA3573.

The Tier 1 groundwater modelling has been independently validated by the zRMS in additional modelling performed with FOCUS PEARL 4.4.4, PELMO 5.5.3 and FOCUS MACRO 5.5.4 using the same EU agreed input parameters and PUF of 0. For orchards (at 50 g a.s./ha), potatoes and maize the same application pattern as indicated in Table 8.8-1 has been assumed and results the same as in Applicants' calculations were obtained. For orchards (at 25 g a.s./ha) and oilseed rape single application has been considered, in line with the Central Zone GAP, resulting with lower PEC_{gw} values comparing to Applicants' results.

For all intended uses, PEC_{gw} far below the threshold concentration of 0.1 µg/L were obtained at Tier 1 for acetamiprid and metabolites IM-1-2, IM-1-4 and IC-0. Metabolite IM-1-5 showed some leaching potential, but in neither crop its PEC_{gw} exceeded 0.1 µg/L in scenarios relevant for the Central Zone (i.e. Châteaudun, Hamburg, Kremsmünster, Okehampton, Piacenza and Porto). The only exception was scenario Thiva following single application at 50 g a.s./ha in orchards (modelled with PEARL) and for this reason additional Tier 1 calculations for biennial application and higher tier modelling based on refined PUF values were provided by the Applicant. However, as Thiva scenario is not relevant for the Central Zone and acceptable risk to groundwater in CZ scenarios could be concluded already based on Tier 1 calculations performed for annual application, the higher tier modelling was not validated by the zRMS and its results were thus struck through in Tables 8.8-7 to 8.8-17.

Tables 8.8-4 to 8.8-6 were amended by the zRMS in order to present Tier 1 results relevant for GAP intended in the Central Zone (i.e. single application in all crops).

Overall, based on Applicants' and zRMS modelling it may be concluded that no unacceptable contamination of groundwater is expected following intended uses of CA3573 in the Central Zone.

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

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

8.9.1 Justification for new endpoints

For estimation of the PEC values in surface water and sediment (PEC_{sw/sed}) of acetamiprid and its metabolites, no new endpoints were defined. PEC_{sw/sed} have been assessed with FOCUS surface water models and the endpoints as proposed in the EFSA conclusion for acetamiprid (EFSA Journal 2016;14(11):4610).

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

Table 8.9-1: Input parameters related to application for PEC_{sw/sed} calculations

Plant protection product	CA3573						
Use No.	1, 11	2	12	4, 5, 6, 7, 14, 15, 16 ^{a)}	8, 9, 10 17, 18	3, 13	19, 20
Crop	Apple ^{b)}	Apple ^{b)}	Apple ^{b)}	Winter oilseed rape	Spring oilseed rape	Potato	Corn
Application rate (g a.s./ha)	25	50	50	60	60	36	60
Number of applications/interval (d)	1/-	1/-	1/-	1/-	1/-	1/-	1/-
Application timing (as given in the GAP)	BBCH 69 - PHI	BBCH 62 - PHI	BBCH 69 - PHI	BBCH 31 - 71	BBCH 31 - 71	BBCH 12 - 79	BBCH 51 - 75
Application timing (STEP 1-2)	N-EU: Oct-Feb Mar-May Jun-Sep S-EU: Oct-Feb Mar-May Jun-Sep						
Crop interception (STEP 1-2)	Full canopy	Full canopy	Full canopy	Intermediate crop cover	Intermediate crop cover	Minimal crop cover	Full canopy
Application method (STEP 3-4)	Foliar ground spray (field crops) / air blast (orchards)						
CAM (Chemical application method) (STEP 3-4)	2 (appln. foliar linear)						
Soil depth (cm) (STEP 3-4)	4						
Models used for calculation	FOCUS STEPS 1-2 v3.2, FOCUS SWASH v5.3, FOCUS PRZM v4.3.1, FOCUS MACRO v5.5.4, FOCUS TOXWA v5.5.3, SWAN v5.0						

^{a)} Calculated with an application timing based on the earliest and lasted BBCH stage (as given in the GAP), but also covering all uses with other application timings in between.

^{b)} Calculated as 'pome fruit, early' for early application at BBCH 62 and BBCH 69 and as 'pome fruit, late' for late application before harvest.

The application windows used in SWASH v5.3 for all crops were chosen based on the model AppDate v.3.06 (28 June 2019) and the corresponding earliest and latest BBCH values (used as start / end date for early / late application) as given in the GAP. For late application to apples, the end date of the application window was set to the date given for BBCH 89 by AppDate. For spring oilseed rape and corn, calculations for the earliest possible application timing were considered sufficient since the intended BBCH range is narrow and the application windows for early and late timing in SWASH would overlap.

Table 8.9-2: FOCUS Step 3 and 4: Scenario related input parameters for PEC_{sw/sed} calculations for the application of CA3573

Crop	Scenario	Application window used in modelling	
		Early application	Late application
Use ID: 1, 2 Apple 1 x 25 or 50 g a.s./ha, BBCH 62-PHI	D3	16-Jun 2001 – 16-Jul 2001	24-Sept 2001 – 24-Oct 2001
	D4	20-Jun 2001 – 20-Jul 2001	24-Sept 2001 – 24-Oct 2001
	D5	19-May 2001 – 18-Jun 2001	03-Sept 2001 – 03-Oct 2001
	R1	16-Jun 2001 – 16-Jul 2001	24-Sept 2001 – 24-Oct 2001
	R2	04-Jul 2001 – 03-Aug 2001	28-Aug 2001 – 27-Sept 2001
	R3	19-May 2001 – 18-Jun 2001	08-Sept 2001 – 08-Oct 2001
	R4	16-May 2001 – 15-Jun 2001	08-Sept 2001 – 08-Oct 2001
Use ID: 11, 12 Apple 1 x 25 or 50 g a.s./ha, BBCH 69-PHI	D3	29-Jun 2001 – 29-Jul 2001	24-Sept 2001 – 24-Oct 2001
	D4	03-Jul 2001 – 02-Aug 2001	24-Sept 2001 – 24-Oct 2001
	D5	30-May 2001 – 29-Jun 2001	03-Sept 2001 – 3-Oct 2001
	R1	29-Jun 2001 – 29-July 2001	24-Sept 2001 – 24-Oct 2001
	R2	28-July 2001 – 27-Aug 2001	28-Aug 2001 – 27-Sept 2001
	R3	30-May 2001 – 29-Jun 2001	08-Sept 2001 – 8-Oct 2001
	R4	29-May 2001 – 28-Jun 2001	08-Sept 2001 – 8-Oct 2001
Use ID: 4, 5, 6, 7, 14, 15, 16 Winter oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	D2	15-Mar 2001 – 14-Apr 2001	27-May 2001 – 26-Jun 2001
	D3	26-Feb 2001 – 28-Mar 2001	16-May 2001 – 15-Jun 2001
	D4	06-Mar 2001 – 05-Apr 2001	30-May 2001 – 29-Jun 2001
	D5	05-Mar 2001 – 04-Apr 2001	01-May 2001 – 31-May 2001
	R1	17-Apr 2001 – 17-May 2001	12-May 2001 – 11-Jun 2001
	R3	09-Mar 2001 – 08-Apr 2001	07-Apr 2001 – 07-May 2001
Use ID: 8, 9, 10 17, 18 Spring oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	D1	13-Jun 2001 – 13-July 2001	Separate calculations for late timing not considered necessary
	D3	15-May 2001 – 14-Jun 2001	
	D4	26-May 2001 – 25-Jun 2001	
	D5	22-Apr 2001 – 22-May 2001	
	R1	11-May 2001 – 10-Jun 2001	
Use ID: 3, 13 Potato 1 x 36 g a.s./ha, BBCH 12-79	D3	15-May 2001 – 14-Jun 2001	26-July 2001 – 25-Aug 2001
	D4	28-May 2001 – 27-Jun 2001	12-Aug 2001 – 11-Sep 2001
	D6 – 1 st season	13-Apr 2001 – 13-May 2001	29-May 2001 – 28-Jun 2001
	D6 – 2 nd season	09-Aug 2001 – 08-Sep 2001	05-Oct 2001 – 04-Nov 2001
	R1	09-May 2001 – 08-Jun 2001	13-July 2001 – 12-Aug 2001
	R2	20-Mar 2001 – 19-Apr 2001	10-May 2001 – 09-Jun 2001
	R3	13-Apr 2001 – 13-May 2001	29-Jun 2001 – 29-July 2001
Use ID: 19, 20 Corn 1 x 60 g a.s./ha, BBCH 51-75	D3	12-Jul 2001 – 11-Aug 2001	Separate calculations for late timing not considered necessary
	D4	19-Jul 2001 – 18-Aug 2001	
	D5	26-Jun 2001 – 26-Jul 2001	
	D6	30-May 2001 – 29-Jun 2001	
	R1	10-Jul 2001 – 09-Aug 2001	
	R2	15-Jul 2001 – 14-Aug 2001	
	R3	30-Jun 2001 – 30-Jul 2001	
	R4	27-May 2001 – 26-Jun 2001	

zRMS comments:

The application pattern assumed by the Applicant in performed simulations is in line with the Central Zone GAP presented in Table 8.1-1.

Application windows provided in Table 8.9-2 were checked by the zRMS using AppDate ver. 3.06 and are considered acceptable.

It is noted that two application windows were considered by the Applicant in modelling performed for orchards, oilseed rape and potato, which correspond to early and late applications. This is considered acceptable, since CA3573 in these crops will be at broad BBCH window, and the Applicants' approach cover application at early and

late stages of each crop. For the late application the end dates of the application window were set to the latest possible application date from BBCH for each crop and the start day was assumed to be 30 days earlier. The maximum $PEC_{sw/sed}$ obtained for either early or late application is recommended for the risk assessment purposes.

8.9.2.1 Acetamiprid and its metabolites

Table 8.9-3: Input parameters related to active substance acetamiprid and metabolites IM-1-2, IM-1-4, IC-0, IM-1-5 and IB-1-1 for $PEC_{sw/sed}$ calculations at STEP 1-2 and STEP 3-4

Compound	Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5	IB-1-1	Value in accordance to EU endpoint /Reference
Molecular weight (g/mol)	223	240.69	156.61	157.55	197.66	204.23	Yes / EFSA, 2016
Saturated vapour pressure (Pa)	1×10^{-6} (20°C)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	Yes / EFSA, 2016
Water solubility (mg/L)	2950 (pH 7 and 25°C)	1×10^6 (pH 7 and 25°C)	1×10^6 (pH 7 and 25°C)	1×10^6 (pH 7 and 25°C)	1×10^6 (pH 7 and 25°C)	1×10^6 (pH 7 and 25°C)	Yes / EFSA, 2016
Diffusion coefficient in water (m ² /d)	4.3×10^{-5}	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
Diffusion coefficient in air (m ² /d)	0.43	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	default
K_{foc} / K_{fom} (mL/g)	106.5 / 61.8 (arithmetic mean, n = 5)	54 / 31.3 (arithmetic mean, n = 4)	171 / 99.2 (arithmetic mean, n = 4)	122 / 70.8 (arithmetic mean, n = 5)	325 / 188.5 (arithmetic mean, n = 4)	0 (default value)	Yes / EFSA, 2016
Freundlich Exponent 1/n	0.86 (arithmetic mean, n = 5)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	Yes / EFSA, 2016
Plant Uptake	0	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
Wash-Off factor from Crop (1/mm)	0.05 (MACRO) 0.50 (PRZM)	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	not required for Step 1+2	
DT _{50,soil} (d)	1.45 (geometric mean lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	1.7 (geometric mean lab, n = 3, normalised to pF2, 20°C, Q ₁₀ of 2.58)	14.6 (geometric mean lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	2.7 (geometric mean lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	495 (geometric mean lab, n = 7, normalised to pF2, 20°C, Q ₁₀ of 2.58)	***	Yes / EFSA, 2016
DT _{50,water} (d)	27 (whole system value)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes / EFSA, 2016
DT _{50,sed} (d)	Step1-2: 27 (whole system value) Step 3-4: 1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default value)	1000 (default)	Yes / EFSA, 2016

Compound	Acetamiprid	IM-1-2	IM-1-4	IC-0	IM-1-5	IB-1-1	Value in accordance to EU endpoint /Reference
DT _{50,whole system} (d)	27 (geometric mean water / sediment studies, n = 2)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	1000 (default)	Yes / EFSA, 2016
Maximum occurrence (% molar basis with respect to the parent)	-	Soil: 55 Total w/s system: 13.4	Soil: 72 Total w/s system: 81.5 (max. in aerobic mineralisation study)	Soil: 11.3 Total w/s system: 29.5	Soil: 20 Total w/s system: 0*	Soil: 0** Total w/s system: 35	Yes / EFSA, 2016

* Soil metabolite; not formed in water or sediment

** Only formed in water through photochemical degradation

PEC_{sw/sed}

For the relevant member states Poland and Slovakia, only the surface water scenarios D3, D4, D5 and R1 are of relevance. However, for the sake of completeness, also all other available scenarios are listed in the following tables.

Table 8.9-4: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 62, early application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	9.73	-	7.29	9.79
Step 2					
Northern Europe	Oct - Feb	2.43	-	1.80	2.19
	Mar - May	2.43	-	1.72	2.07
	Jun - Sep	2.43	-	1.72	2.07
Southern Europe	Oct - Feb	2.43	-	1.77	2.15
	Mar - May	2.43	-	1.77	2.15
	Jun - Sep	2.43	-	1.75	2.11
Step 3					
D3	ditch	1.95	Drift	0.162	0.675
D4	pond	0.118	Drift	0.090	0.190
D4	stream	2.07	Drift	0.027	0.273
D5	pond	0.118	Drift	0.093	0.204
D5	stream	2.23	Drift	0.040	0.358
R1	pond	0.118	Drift	0.089	0.184
R1	stream	1.58	Drift	0.019	0.180
R2	stream	2.12	Drift	0.011	0.139
R3	stream	2.23	Drift	0.040	0.358
R4	stream	1.55	Drift	0.009	0.115

Table 8.9-5: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 62, late application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	9.73	-	7.29	9.79
Step 2					
Northern Europe	Oct - Feb	2.43	-	1.80	2.19
	Mar - May	2.43	-	1.72	2.07
	Jun - Sep	2.43	-	1.72	2.07
Southern Europe	Oct - Feb	2.43	-	1.77	2.15
	Mar - May	2.43	-	1.77	2.15
	Jun - Sep	2.43	-	1.75	2.11
Step 3					
D3	ditch	0.919	Drift	0.087	0.355
D4	pond	0.041	Drift	0.034	0.091
D4	stream	0.901	Drift	0.007	0.082
D5	pond	0.041	Drift	0.032	0.077
D5	stream	0.995	Drift	0.018	0.169
R1	pond	0.041	Drift	0.033	0.087
R1	stream	0.706	Drift	0.007	0.083
R2	stream	0.946	Drift	0.005	0.063
R3	stream	0.994	Drift	0.020	0.165
R4	stream	0.705	Drift	0.011	0.082

Table 8.9-6: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 69, early application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	9.73	-	7.29	9.79
Step 2					
Northern Europe	Oct - Feb	2.43	-	1.80	2.19
	Mar - May	2.43	-	1.72	2.07
	Jun - Sep	2.43	-	1.72	2.07
Southern Europe	Oct - Feb	2.43	-	1.77	2.15
	Mar - May	2.43	-	1.77	2.15
	Jun - Sep	2.43	-	1.75	2.11
Step 3					
D3	ditch	1.95	Drift	0.171	0.691
D4	pond	0.118	Drift	0.090	0.190
D4	stream	2.07	Drift	0.027	0.273
D5	pond	0.118	Drift	0.093	0.202
D5	stream	2.23	Drift	0.041	0.364
R1	pond	0.118	Drift	0.089	0.184
R1	stream	1.58	Drift	0.019	0.180
R2	stream	2.12	Drift	0.011	0.139
R3	stream	2.23	Drift	0.040	0.358
R4	stream	1.55	Drift	0.009	0.115

Table 8.9-7: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 69, late application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	9.73	-	7.29	9.79
Step 2					
Northern Europe	Oct - Feb	2.43	-	1.80	2.19
	Mar - May	2.43	-	1.72	2.07
	Jun - Sep	2.43	-	1.72	2.07
Southern Europe	Oct - Feb	2.43	-	1.77	2.15
	Mar - May	2.43	-	1.77	2.15
	Jun - Sep	2.43	-	1.75	2.11
Step 3					
D3	ditch	0.919	Drift	0.087	0.355
D4	pond	0.041	Drift	0.034	0.091
D4	stream	0.901	Drift	0.007	0.082
D5	pond	0.041	Drift	0.032	0.077
D5	stream	0.995	Drift	0.018	0.169
R1	pond	0.041	Drift	0.033	0.087
R1	stream	0.706	Drift	0.007	0.083
R2	stream	0.946	Drift	0.005	0.063
R3	stream	0.994	Drift	0.020	0.165
R4	stream	0.705	Drift	0.011	0.082

Table 8.9-8: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 62, early application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	19.5	-	14.6	19.6
Step 2					
Northern Europe	Oct - Feb	4.87	-	3.60	4.38
	Mar - May	4.87	-	3.44	4.15
	Jun - Sep	4.87	-	3.44	4.15
Southern Europe	Oct - Feb	4.87	-	3.55	4.30
	Mar - May	4.87	-	3.55	4.30
	Jun - Sep	4.87	-	3.50	4.23
Step 3					
D3	ditch	3.90	Drift	0.325	1.29
D4	pond	0.236	Drift	0.180	0.364
D4	stream	4.13	Drift	0.054	0.531
D5	pond	0.236	Drift	0.187	0.391
D5	stream	4.46	Drift	0.080	0.693
R1	pond	0.236	Drift	0.178	0.352
R1	stream	3.16	Drift	0.038	0.351
R2	stream	4.24	Drift	0.022	0.273
R3	stream	4.46	Drift	0.080	0.692
R4	stream	3.09	Drift	0.018	0.225

Table 8.9-9: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 62, late application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	19.5	-	14.6	19.6
Step 2					
Northern Europe	Oct - Feb	4.87	-	3.60	4.38
	Mar - May	4.87	-	3.44	4.15
	Jun - Sep	4.87	-	3.44	4.15
Southern Europe	Oct - Feb	4.87	-	3.55	4.30
	Mar - May	4.87	-	3.55	4.30
	Jun - Sep	4.87	-	3.50	4.23
Step 3					
D3	ditch	1.84	Drift	0.174	0.680
D4	pond	0.082	Drift	0.067	0.174
D4	stream	1.80	Drift	0.013	0.161
D5	pond	0.082	Drift	0.064	0.147
D5	stream	1.99	Drift	0.037	0.326
R1	pond	0.082	Drift	0.067	0.168
R1	stream	1.41	Drift	0.014	0.162
R2	stream	1.89	Drift	0.010	0.124
R3	stream	1.99	Drift	0.039	0.320
R4	stream	1.41	Drift	0.022	0.161

Table 8.9-10: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 69, early application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	19.5	-	14.6	19.6
Step 2					
Northern Europe	Oct - Feb	4.87	-	3.60	4.38
	Mar - May	4.87	-	3.44	4.15
	Jun - Sep	4.87	-	3.44	4.15
Southern Europe	Oct - Feb	4.87	-	3.55	4.30
	Mar - May	4.87	-	3.55	4.30
	Jun - Sep	4.87	-	3.50	4.23
Step 3					
D3	ditch	3.90	Drift	0.342	1.32
D4	pond	0.236	Drift	0.180	0.364
D4	stream	4.13	Drift	0.054	0.531
D5	pond	0.236	Drift	0.186	0.387
D5	stream	4.46	Drift	0.082	0.704
R1	pond	0.236	Drift	0.178	0.352
R1	stream	3.16	Drift	0.038	0.351
R2	stream	4.24	Drift	0.022	0.273
R3	stream	4.46	Drift	0.080	0.692
R4	stream	3.09	Drift	0.018	0.225

Table 8.9-11: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 69, late application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	19.5	-	14.6	19.6
Step 2					
Northern Europe	Oct - Feb	4.87	-	3.60	4.38
	Mar - May	4.87	-	3.44	4.15
	Jun - Sep	4.87	-	3.44	4.15
Southern Europe	Oct - Feb	4.87	-	3.55	4.30
	Mar - May	4.87	-	3.55	4.30
	Jun - Sep	4.87	-	3.50	4.23
Step 3					
D3	ditch	1.84	Drift	0.174	0.680
D4	pond	0.082	Drift	0.067	0.174
D4	stream	1.80	Drift	0.013	0.161
D5	pond	0.082	Drift	0.064	0.147
D5	stream	1.99	Drift	0.037	0.326
R1	pond	0.082	Drift	0.067	0.168
R1	stream	1.41	Drift	0.014	0.162
R2	stream	1.89	Drift	0.010	0.124
R3	stream	1.99	Drift	0.039	0.320
R4	stream	1.41	Drift	0.022	0.161

Table 8.9-12: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to winter oilseed rape (1 x 60 g a.s./ha, early application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	18.1	-	13.9	18.7
Step 2					
Northern Europe	Oct - Feb	0.843	-	0.638	0.856
	Mar - May	0.610	-	0.458	0.614
	Jun - Sep	0.610	-	0.458	0.614
Southern Europe	Oct - Feb	0.765	-	0.578	0.775
	Mar - May	0.765	-	0.578	0.775
	Jun - Sep	0.688	-	0.518	0.694
Step 3					
D2	ditch	0.385	Drift	0.072	0.257
D2	stream	0.343	Drift	0.043	0.222
D3	ditch	0.379	Drift	0.015	0.101
D4	pond	0.013	Drift	0.011	0.031
D4	stream	0.284	Drift	0.001	0.008
D5	pond	0.013	Drift	0.011	0.030
D5	stream	0.303	Drift	0.001	0.008
R1	pond	0.013	Drift	0.011	0.034
R1	stream	0.250	Drift	0.009	0.057
R3	stream	0.404	Runoff	0.015	0.107

Table 8.9-13: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following multiple application of CA3573 to winter oilseed rape (1 x 60 g a.s./ha, late application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	18.1	-	13.9	18.7
Step 2					
Northern Europe	Oct - Feb	0.843	-	0.638	0.856
	Mar - May	0.610	-	0.458	0.614
	Jun - Sep	0.610	-	0.458	0.614
Southern Europe	Oct - Feb	0.765	-	0.578	0.775
	Mar - May	0.765	-	0.578	0.775
	Jun - Sep	0.688	-	0.518	0.694
Step 3					
D2	ditch	0.385	Drift	0.280	0.553
D2	stream	0.343	Drift	0.245	0.450
D3	ditch	0.381	Drift	0.026	0.134
D4	pond	0.013	Drift	0.010	0.026
D4	stream	0.320	Drift	0.002	0.029
D5	pond	0.013	Drift	0.010	0.027
D5	stream	0.355	Drift	0.007	0.063
R1	pond	0.058	Runoff	0.049	0.116
R1	stream	0.930	Runoff	0.031	0.266
R3	stream	0.715	Runoff	0.038	0.292

Table 8.9-14: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to spring oilseed rape (1 x 60 g a.s./ha)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	18.1	-	13.9	18.7
Step 2					
Northern Europe	Oct - Feb	0.843	-	0.638	0.856
	Mar - May	0.610	-	0.458	0.614
	Jun - Sep	0.610	-	0.458	0.614
Southern Europe	Oct - Feb	0.765	-	0.578	0.775
	Mar - May	0.765	-	0.578	0.775
	Jun - Sep	0.688	-	0.518	0.694
Step 3					
D1	ditch	0.388	Drift	0.283	0.526
D1	stream	0.337	Drift	0.016	0.115
D3	ditch	0.381	Drift	0.023	0.125
D4	pond	0.013	Drift	0.010	0.026
D4	stream	0.312	Drift	0.001	0.019
D5	pond	0.013	Drift	0.011	0.028
D5	stream	0.331	Drift	0.001	0.018
R1	pond	0.043	Runoff	0.037	0.087
R1	stream	0.765	Runoff	0.026	0.216

Table 8.9-15: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to potato (1 x 36 g a.s./ha, early application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	10.8	-	8.35	11.2
Step 2					
Northern Europe	Oct - Feb	0.933	-	0.713	0.957
	Mar – May	0.537	-	0.407	0.546
	Jun - Sep	0.537	-	0.407	0.546
Southern Europe	Oct - Feb	0.801	-	0.611	0.820
	Mar – May	0.801	-	0.611	0.820
	Jun - Sep	0.669	-	0.509	0.683
Step 3					
D3	ditch	0.189	Drift	0.010	0.062
D4	pond	0.008	Drift	0.006	0.015
D4	stream	0.161	Drift	0.001	0.009
D6 – 1 st	ditch	0.186	Drift	0.003	0.032
D6 – 2 nd	ditch	0.185	Drift	0.003	0.028
R1	pond	0.010	Runoff	0.008	0.024
R1	stream	0.165	Runoff	0.006	0.032
R2	stream	0.173	Drift	0.004	0.019
R3	stream	0.209	Runoff	0.013	0.089

Table 8.9-16: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following multiple application of CA3573 to potato (1 x 36 g a.s./ha, late application)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	10.8	-	8.35	11.2
Step 2					
Northern Europe	Oct - Feb	0.933	-	0.713	0.957
	Mar – May	0.537	-	0.407	0.546
	Jun - Sep	0.537	-	0.407	0.546
Southern Europe	Oct - Feb	0.801	-	0.611	0.820
	Mar – May	0.801	-	0.611	0.820
	Jun - Sep	0.669	-	0.509	0.683
Step 3					
D3	ditch	0.189	Drift	0.010	0.060
D4	pond	0.008	Drift	0.006	0.016
D4	stream	0.142	Drift	0.000	0.003
D6 – 1 st	ditch	0.188	Drift	0.005	0.044
D6 – 2 nd		0.189	Drift	0.010	0.062
R1	pond	0.024	Runoff	0.018	0.042
R1	stream	0.408	Runoff	0.012	0.122
R2	stream	0.176	Drift	0.002	0.028
R3	stream	0.185	Drift	0.010	0.096

Table 8.9-17: FOCUS Step 1, 2 and 3 PEC_{sw} and PEC_{sed} for acetamiprid following single application of CA3573 to corn (1 x 60 g a.s./ha)

Scenario FOCUS	Waterbody	Maximum PEC _{sw} (µg/L)	Dominant entry route	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Step 1	---	18.1	-	13.9	18.7
Step 2					
Northern Europe	Oct - Feb	0.778	-	0.588	0.788
	Mar – May	0.584	-	0.438	0.587
	Jun - Sep	0.584	-	0.438	0.587
Southern Europe	Oct - Feb	0.714	-	0.538	0.721
	Mar – May	0.714	-	0.538	0.721
	Jun - Sep	0.649	-	0.488	0.654
Step 3					
D3	ditch	0.315	Drift	0.016	0.095
D4	pond	0.013	Drift	0.010	0.024
D4	stream	0.282	Drift	0.003	0.032
D5	pond	0.013	Drift	0.010	0.024
D5	stream	0.308	Drift	0.006	0.055
D6	ditch	0.310	Drift	0.006	0.054
R1	pond	0.033	Runoff	0.025	0.060
R1	stream	0.535	Runoff	0.015	0.156
R2	stream	0.293	Drift	0.001	0.020
R3	stream	0.308	Drift	0.020	0.164
R4	stream	0.213	Drift	0.004	0.034

FOCUS Step 4

Table 8.9-18: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 62, early application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None				None				None			
No spray buffer (m)		None (FOCUS default) ³				5				10			
Nozzle reduction (%)		50	75	90		0	50	75	90	0	50	75	90
Scenario	Waterbody												
D3	ditch	0.974	0.487	0.195		1.53	0.765	0.383	0.153	0.940	0.470	0.235	0.094
D4	pond	0.059	0.030	0.012		0.133	0.066	0.033	0.013	0.073	0.036	0.018	0.007
D4	stream	1.03	0.516	0.206		1.77	0.887	0.444	0.177	1.09	0.545	0.272	0.109
D5	pond	0.059	0.030	0.012		0.133	0.066	0.033	0.013	0.073	0.036	0.018	0.007
D5	stream	1.12	0.558	0.223		1.92	0.958	0.479	0.192	1.18	0.588	0.294	0.118
R1	pond	0.059	0.030	0.014		0.133	0.066	0.033	0.015	0.073	0.036	0.019	0.011
R1	stream	0.791	0.396	0.158		1.36	0.680	0.340	0.136	0.835	0.417	0.209	0.083
R2	stream	1.06	0.530	0.212		1.82	0.911	0.456	0.182	1.12	0.559	0.280	0.112
R3	stream	1.12	0.558	0.223		1.92	0.958	0.479	0.192	1.18	0.588	0.294	0.118
R4	stream	0.773	0.387	0.155		1.33	0.664	0.332	0.133	0.816	0.408	0.204	0.082
Vegetative strip (m)		10				None				15			
No spray buffer (m)		10				15				20			
Nozzle reduction (%)		0	50	75	90	0	50	0	50	0	50	0	0
Scenario	Waterbody												
D3	ditch	0.940	0.470	0.235	0.094	0.423	0.211	0.423	0.211	0.215		0.215	
D4	pond	0.073	0.036	0.018	0.007	0.038	0.019	0.038	0.019	0.024		0.024	
D4	stream	1.09	0.545	0.272	0.109	0.490	0.245	0.490	0.245	0.249		0.249	
D5	pond	0.073	0.036	0.018	0.007	0.038	0.019	0.038	0.019	0.024		0.024	
D5	stream	1.18	0.588	0.294	0.118	0.529	0.265	0.529	0.265	0.269		0.269	
R1	pond	0.073	0.036	0.018	0.007	0.038	0.019	0.038	0.019	0.024		0.024	
R1	stream	0.835	0.417	0.209	0.083	0.376	0.188	0.376	0.188	0.191		0.191	
R2	stream	1.12	0.559	0.280	0.112	0.503	0.252	0.503	0.252	0.256		0.256	
R3	stream	1.18	0.588	0.294	0.118	0.529	0.265	0.529	0.265	0.269		0.269	
R4	stream	0.816	0.408	0.204	0.082	0.367	0.184	0.367	0.184	0.187		0.187	

Table 8.9-19: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 62, late application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None				None				None			
No spray buffer (m)		None (FOCUS default) ³				5				10			
Nozzle reduction (%)		50	75	90	0	50	75	90	0	50	75	90	0
Scenario	Waterbody												
D3	ditch	0.460	0.230	0.092	0.620	0.310	0.155	0.062	0.277	0.139	0.069	0.028	
D4	pond	0.021	0.010	0.004	0.047	0.024	0.012	0.005	0.026	0.013	0.007	0.003	
D4	stream	0.451	0.225	0.090	0.704	0.352	0.176	0.070	0.314	0.157	0.079	0.031	
D5	pond	0.021	0.010	0.004	0.047	0.024	0.012	0.005	0.026	0.013	0.007	0.003	
D5	stream	0.498	0.249	0.100	0.777	0.388	0.194	0.078	0.347	0.174	0.087	0.035	
R1	pond	0.021	0.010	0.004	0.047	0.024	0.012	0.005	0.026	0.013	0.007	0.003	
R1	stream	0.353	0.176	0.071	0.551	0.275	0.138	0.055	0.246	0.123	0.062	0.025	
R2	stream	0.473	0.236	0.095	0.738	0.369	0.185	0.074	0.330	0.165	0.082	0.033	
R3	stream	0.497	0.249	0.099	0.776	0.388	0.194	0.078	0.347	0.173	0.087	0.035	
R4	stream	0.353	0.176	0.071	0.551	0.275	0.138	0.059	0.246	0.123	0.062	0.059	
Vegetative strip (m)		10				None				20			
No spray buffer (m)		10				20				20			
Nozzle reduction (%)		0	50	75	90	0	50	75	90	0	50	75	90
Scenario	Waterbody												
D3	ditch	0.277	0.139	0.069	0.028	0.086				0.086			
D4	pond	0.026	0.013	0.007	0.003	0.012				0.012			
D4	stream	0.314	0.157	0.079	0.031	0.097				0.097			
D5	pond	0.026	0.013	0.007	0.003	0.012				0.012			
D5	stream	0.347	0.174	0.087	0.035	0.107				0.107			
R1	pond	0.026	0.013	0.007	0.003	0.012				0.012			
R1	stream	0.246	0.123	0.062	0.025	0.076				0.076			
R2	stream	0.330	0.165	0.082	0.033	0.102				0.102			
R3	stream	0.347	0.173	0.087	0.035	0.107				0.107			
R4	stream	0.246	0.123	0.062	0.025	0.076				0.076			

Table 8.9-20: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 69, early application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None				None				None			
No spray buffer (m)		None (FOCUS default) 3				5				10			
Nozzle reduction (%)		50	75	90	0	50	75	90	0	50	75	90	
Scenario	Waterbody												
D3	ditch	0.974	0.487	0.195	1.53	0.765	0.383	0.153	0.940	0.470	0.235	0.094	
D4	pond	0.059	0.030	0.012	0.133	0.066	0.033	0.013	0.073	0.036	0.018	0.007	
D4	stream	1.03	0.516	0.206	1.77	0.887	0.444	0.177	1.09	0.545	0.272	0.109	
D5	pond	0.059	0.030	0.012	0.133	0.066	0.033	0.013	0.073	0.036	0.018	0.007	
D5	stream	1.12	0.558	0.223	1.92	0.958	0.479	0.192	1.18	0.589	0.294	0.118	
R1	pond	0.059	0.030	0.014	0.133	0.066	0.033	0.015	0.073	0.036	0.019	0.011	
R1	stream	0.791	0.396	0.158	1.36	0.680	0.340	0.136	0.835	0.417	0.209	0.083	
R2	stream	1.06	0.530	0.212	1.82	0.911	0.456	0.182	1.12	0.559	0.280	0.112	
R3	stream	1.12	0.558	0.223	1.92	0.958	0.479	0.192	1.18	0.588	0.294	0.118	
R4	stream	0.773	0.387	0.155	1.33	0.664	0.332	0.133	0.816	0.408	0.204	0.082	
Vegetative strip (m)		10				None				15			
No spray buffer (m)		10				15				20			
Nozzle reduction (%)		0	50	75	90	0	50	0	50	0	50	0	
Scenario	Waterbody												
D3	ditch	0.940	0.470	0.235	0.094	0.423	0.211	0.423	0.211	0.215		0.215	
D4	pond	0.073	0.036	0.018	0.007	0.038	0.019	0.038	0.019	0.024		0.024	
D4	stream	1.09	0.545	0.272	0.109	0.490	0.245	0.490	0.245	0.249		0.249	
D5	pond	0.073	0.036	0.018	0.007	0.038	0.019	0.038	0.019	0.024		0.024	
D5	stream	1.18	0.589	0.294	0.118	0.530	0.265	0.530	0.265	0.269		0.269	
R1	pond	0.073	0.036	0.018	0.007	0.038	0.019	0.038	0.019	0.024		0.024	
R1	stream	0.835	0.417	0.209	0.083	0.376	0.188	0.376	0.188	0.191		0.191	
R2	stream	1.12	0.559	0.280	0.112	0.503	0.252	0.503	0.252	0.256		0.256	
R3	stream	1.18	0.588	0.294	0.118	0.529	0.265	0.529	0.265	0.269		0.269	
R4	stream	0.816	0.408	0.204	0.082	0.367	0.184	0.367	0.184	0.187		0.187	

Table 8.9-21: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 25 g a.s./ha, BBCH 69, late application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None				None				None			
No spray buffer (m)		None (FOCUS default) ³				5				10			
Nozzle reduction (%)		50	75	90	0	50	75	90	0	50	75	90	0
Scenario	Waterbody												
D3	ditch	0.460	0.230	0.092	0.620	0.310	0.155	0.062	0.277	0.139	0.069	0.028	
D4	pond	0.021	0.010	0.004	0.047	0.024	0.012	0.005	0.026	0.013	0.007	0.003	
D4	stream	0.451	0.225	0.090	0.704	0.352	0.176	0.070	0.314	0.157	0.079	0.031	
D5	pond	0.021	0.010	0.004	0.047	0.024	0.012	0.005	0.026	0.013	0.007	0.003	
D5	stream	0.498	0.249	0.100	0.777	0.388	0.194	0.078	0.347	0.174	0.087	0.035	
R1	pond	0.021	0.010	0.004	0.047	0.024	0.012	0.005	0.026	0.013	0.007	0.003	
R1	stream	0.353	0.176	0.071	0.551	0.275	0.138	0.055	0.246	0.123	0.062	0.025	
R2	stream	0.473	0.236	0.095	0.738	0.369	0.185	0.074	0.330	0.165	0.082	0.033	
R3	stream	0.497	0.249	0.099	0.776	0.388	0.194	0.078	0.347	0.173	0.087	0.035	
R4	stream	0.353	0.176	0.071	0.551	0.275	0.138	0.059	0.246	0.123	0.062	0.059	
Vegetative strip (m)		10				None				20			
No spray buffer (m)		10				20				20			
Nozzle reduction (%)		0	50	75	90	0	50	75	90	0	50	75	90
Scenario	Waterbody												
D3	ditch	0.277	0.139	0.069	0.028	0.086				0.086			
D4	pond	0.026	0.013	0.007	0.003	0.012				0.012			
D4	stream	0.314	0.157	0.079	0.031	0.097				0.097			
D5	pond	0.026	0.013	0.007	0.003	0.012				0.012			
D5	stream	0.347	0.174	0.087	0.035	0.107				0.107			
R1	pond	0.026	0.013	0.007	0.003	0.012				0.012			
R1	stream	0.246	0.123	0.062	0.025	0.076				0.076			
R2	stream	0.330	0.165	0.082	0.033	0.102				0.102			
R3	stream	0.347	0.173	0.087	0.035	0.107				0.107			
R4	stream	0.246	0.123	0.062	0.025	0.076				0.076			

Table 8.9-22: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 62, early application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None				None				None			
No spray buffer (m)		None (FOCUS default) 3				5				10			
Nozzle reduction (%)		50	75	90	0	50	75	90	0	50	75	90	
Scenario	Waterbody												
D3	ditch	1.95	0.974	0.390	3.06	1.53	0.765	0.306	1.88	0.940	0.470	0.188	
D4	pond	0.118	0.059	0.024	0.266	0.133	0.066	0.027	0.146	0.073	0.036	0.015	
D4	stream	2.07	1.03	0.413	3.55	1.77	0.887	0.355	2.18	1.09	0.545	0.218	
D5	pond	0.118	0.059	0.024	0.266	0.133	0.066	0.027	0.146	0.073	0.036	0.015	
D5	stream	2.23	1.12	0.446	3.83	1.92	0.958	0.383	2.35	1.18	0.588	0.235	
R1	pond	0.118	0.059	0.028	0.266	0.133	0.066	0.030	0.146	0.073	0.038	0.022	
R1	stream	1.58	0.791	0.316	2.72	1.36	0.680	0.272	1.67	0.835	0.417	0.169	
R2	stream	2.12	1.06	0.424	3.65	1.82	0.911	0.365	2.24	1.12	0.559	0.224	
R3	stream	2.23	1.12	0.446	3.83	1.92	0.958	0.383	2.35	1.18	0.588	0.235	
R4	stream	1.55	0.773	0.309	2.66	1.33	0.664	0.266	1.63	0.816	0.408	0.163	
Vegetative strip (m)		10				None				15			
No spray buffer (m)		10				15				20			
Nozzle reduction (%)		0	50	75	90	0	50	0	50	0	50	0	
Scenario	Waterbody												
D3	ditch	1.88	0.940	0.470	0.188	0.845	0.423	0.845	0.423	0.430		0.430	
D4	pond	0.146	0.073	0.036	0.015	0.077	0.038	0.077	0.038	0.047		0.047	
D4	stream	2.18	1.09	0.545	0.218	0.980	0.490	0.980	0.490	0.498		0.498	
D5	pond	0.146	0.073	0.036	0.015	0.077	0.038	0.077	0.038	0.047		0.047	
D5	stream	2.35	1.18	0.588	0.235	1.06	0.529	1.06	0.529	0.538		0.538	
R1	pond	0.146	0.073	0.036	0.015	0.077	0.039	0.077	0.038	0.047		0.047	
R1	stream	1.67	0.835	0.417	0.167	0.751	0.376	0.751	0.376	0.382		0.382	
R2	stream	2.24	1.12	0.559	0.224	1.01	0.503	1.01	0.503	0.512		0.512	
R3	stream	2.35	1.18	0.588	0.235	1.06	0.529	1.06	0.529	0.538		0.538	
R4	stream	1.63	0.816	0.408	0.163	0.734	0.367	0.734	0.367	0.373		0.373	

Table 8.9-23: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 62, late application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None				None				None			
No spray buffer (m)		None (FOCUS default) ³				5				10			
Nozzle reduction (%)		50	75	90		0	50	75	90	0	50	75	90
Scenario	Waterbody												
D3	ditch	0.919	0.460	0.184		1.24	0.620	0.310	0.124	0.554	0.277	0.139	0.055
D4	pond	0.041	0.021	0.008		0.094	0.047	0.024	0.009	0.052	0.026	0.013	0.005
D4	stream	0.902	0.451	0.180		1.41	0.704	0.352	0.141	0.629	0.314	0.157	0.063
D5	pond	0.041	0.021	0.008		0.094	0.047	0.024	0.009	0.052	0.026	0.013	0.005
D5	stream	0.995	0.498	0.199		1.55	0.777	0.388	0.155	0.694	0.347	0.174	0.069
R1	pond	0.041	0.021	0.008		0.094	0.047	0.024	0.009	0.052	0.026	0.013	0.005
R1	stream	0.706	0.353	0.141		1.10	0.551	0.275	0.110	0.492	0.246	0.123	0.049
R2	stream	0.946	0.473	0.189		1.48	0.738	0.369	0.148	0.660	0.330	0.165	0.066
R3	stream	0.995	0.497	0.199		1.55	0.776	0.388	0.155	0.694	0.347	0.173	0.069
R4	stream	0.706	0.353	0.141		1.10	0.551	0.275	0.125	0.492	0.246	0.123	0.052
Vegetative strip (m)		10				None				20			
No spray buffer (m)		10				20				20			
Nozzle reduction (%)		0	50	75	90	0	50	75	90	0	50	75	90
Scenario	Waterbody												
D3	ditch	0.554	0.277	0.139	0.055	0.171				0.171			
D4	pond	0.052	0.026	0.013	0.005	0.024				0.024			
D4	stream	0.629	0.314	0.157	0.063	0.194				0.194			
D5	pond	0.052	0.026	0.013	0.005	0.024				0.024			
D5	stream	0.694	0.347	0.174	0.069	0.214				0.214			
R1	pond	0.052	0.026	0.013	0.005	0.024				0.024			
R1	stream	0.492	0.246	0.123	0.049	0.152				0.152			
R2	stream	0.660	0.330	0.165	0.066	0.204				0.204			
R3	stream	0.694	0.347	0.173	0.069	0.214				0.214			
R4	stream	0.492	0.246	0.125	0.125	0.152				0.152			

Table 8.9-24: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 69, early application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None				None				None			
No spray buffer (m)		None (FOCUS default) ³				5				10			
Nozzle reduction (%)		50	75	90		0	50	75	90	0	50	75	90
Scenario	Waterbody												
D3	ditch	1.95	0.974	0.390		3.06	1.53	0.765	0.306	1.88	0.940	0.470	0.188
D4	pond	0.118	0.059	0.024		0.266	0.133	0.066	0.027	0.146	0.073	0.036	0.015
D4	stream	2.07	1.03	0.413		3.55	1.77	0.887	0.355	2.18	1.09	0.545	0.218
D5	pond	0.118	0.059	0.024		0.266	0.133	0.066	0.027	0.146	0.073	0.036	0.015
D5	stream	2.23	1.12	0.446		3.84	1.92	0.958	0.384	2.35	1.18	0.589	0.235
R1	pond	0.118	0.059	0.028		0.266	0.133	0.066	0.030	0.146	0.073	0.038	0.022
R1	stream	1.58	0.791	0.316		2.72	1.36	0.680	0.272	1.67	0.835	0.417	0.169
R2	stream	2.12	1.06	0.424		3.65	1.82	0.911	0.365	2.24	1.12	0.559	0.224
R3	stream	2.23	1.12	0.446		3.83	1.92	0.958	0.383	2.35	1.18	0.588	0.235
R4	stream	1.55	0.773	0.309		2.66	1.33	0.664	0.266	1.63	0.816	0.408	0.163
Vegetative strip (m)		10				None				15			
No spray buffer (m)		10				15				20			
Nozzle reduction (%)		0	50	75	90	0	50	0	50	0		0	
Scenario	Waterbody												
D3	ditch	1.88	0.940	0.470	0.188	0.845	0.423	0.845	0.423	0.430		0.430	
D4	pond	0.146	0.073	0.036	0.015	0.077	0.038	0.077	0.038	0.047		0.047	
D4	stream	2.18	1.09	0.545	0.218	0.980	0.490	0.980	0.490	0.498		0.498	
D5	pond	0.146	0.073	0.036	0.015	0.077	0.038	0.077	0.038	0.047		0.047	
D5	stream	2.35	1.18	0.589	0.235	1.06	0.529	1.06	0.529	0.538		0.538	
R1	pond	0.146	0.073	0.036	0.015	0.077	0.039	0.077	0.038	0.047		0.047	
R1	stream	1.67	0.835	0.417	0.167	0.751	0.376	0.751	0.376	0.382		0.382	
R2	stream	2.24	1.12	0.559	0.224	1.01	0.503	1.01	0.503	0.512		0.512	
R3	stream	2.35	1.18	0.588	0.235	1.06	0.529	1.06	0.529	0.538		0.538	
R4	stream	1.63	0.816	0.408	0.163	0.734	0.367	0.734	0.367	0.373		0.373	

Table 8.9-25: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to apples (1 x 50 g a.s./ha, BBCH 69, late application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid											
Vegetative strip (m)		None			None				None				
No spray buffer (m)		None (FOCUS default) ³			5				10				
Nozzle reduction (%)		50	75	90	0	50	75	90	0	50	75	90	
Scenario	Waterbody												
D3	ditch	0.919	0.460	0.184	1.24	0.620	0.310	0.124	0.554	0.277	0.139	0.055	
D4	pond	0.041	0.021	0.008	0.094	0.047	0.024	0.009	0.052	0.026	0.013	0.005	
D4	stream	0.902	0.451	0.180	1.41	0.704	0.352	0.141	0.629	0.314	0.157	0.063	
D5	pond	0.041	0.021	0.008	0.094	0.047	0.024	0.009	0.052	0.026	0.013	0.005	
D5	stream	0.995	0.498	0.199	1.55	0.777	0.388	0.155	0.694	0.347	0.174	0.069	
R1	pond	0.041	0.021	0.008	0.094	0.047	0.024	0.009	0.052	0.026	0.013	0.005	
R1	stream	0.706	0.353	0.141	1.10	0.551	0.275	0.110	0.492	0.246	0.123	0.049	
R2	stream	0.946	0.473	0.189	1.48	0.738	0.369	0.148	0.660	0.330	0.165	0.066	
R3	stream	0.995	0.497	0.199	1.55	0.776	0.388	0.155	0.694	0.347	0.173	0.069	
R4	stream	0.706	0.353	0.141	1.10	0.551	0.275	0.125	0.492	0.246	0.125	0.125	
Vegetative strip (m)		10				None				20			
No spray buffer (m)		10				20				20			
Nozzle reduction (%)		0	50	75	90	0				0			
Scenario	Waterbody												
D3	ditch	0.554	0.277	0.139	0.055	0.171			0.171				
D4	pond	0.052	0.026	0.013	0.005	0.024			0.024				
D4	stream	0.629	0.314	0.157	0.063	0.194			0.194				
D5	pond	0.052	0.026	0.013	0.005	0.024			0.024				
D5	stream	0.694	0.347	0.174	0.069	0.214			0.214				
R1	pond	0.052	0.026	0.013	0.005	0.024			0.024				
R1	stream	0.492	0.246	0.123	0.049	0.152			0.152				
R2	stream	0.660	0.330	0.165	0.066	0.204			0.204				
R3	stream	0.694	0.347	0.173	0.069	0.214			0.214				
R4	stream	0.492	0.246	0.123	0.052	0.152			0.152				

Table 8.9-26: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to winter oilseed rape (1 x 60 g a.s./ha, early application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid										
Vegetative strip (m)		None			None				None	10	None	20
No spray buffer (m)		None (FOCUS default) ³			5				10	10	20	20
Nozzle reduction (%)		50	75	90	0	50	75	90	0	0	0	0
Scenario	Waterbody											
D2	ditch	0.193	0.118	0.118	0.118	0.118	0.118	0.118	0.118	0.118	0.118	0.118
D2	stream	0.171	0.086	0.077	0.125	0.077	0.077	0.077	0.077	0.077	0.077	0.077
D3	ditch	0.190	0.095	0.038	0.103	0.051	0.026	0.010	0.055	0.055	0.028	0.028
D4	pond	0.007	0.003	0.001	0.011	0.006	0.003	0.001	0.008	0.008	0.005	0.005
D4	stream	0.142	0.071	0.028	0.104	0.052	0.026	0.010	0.055	0.055	0.029	0.029
D5	pond	0.007	0.003	0.001	0.011	0.006	0.003	0.001	0.008	0.008	0.005	0.005
D5	stream	0.151	0.076	0.030	0.111	0.055	0.028	0.011	0.059	0.059	0.031	0.031
R1	pond	0.007	0.005	0.004	0.011	0.007	0.005	0.004	0.008	0.008	0.007	0.005
R1	stream	0.231	0.231	0.231	0.231	0.231	0.231	0.231	0.231	0.097	0.231	0.050
R3	stream	0.404	0.404	0.404	0.404	0.404	0.404	0.404	0.404	0.182	0.404	0.095

Table 8.9-27: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to winter oilseed rape (1 x 60 g a.s./ha, late application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid										
Vegetative strip (m)		None			None				None	10	None	20
No spray buffer (m)		None (FOCUS default) ³			5				10	10	20	20
Nozzle reduction (%)		50	75	90	0	50	75	90	0	0	0	0
Scenario	Waterbody											
D2	ditch	0.193	0.096	0.039	0.104	0.052	0.026	0.010	0.055	0.055	0.029	0.029
D2	stream	0.171	0.086	0.034	0.125	0.063	0.031	0.013	0.066	0.066	0.035	0.035
D3	ditch	0.191	0.095	0.038	0.103	0.052	0.026	0.010	0.055	0.055	0.028	0.028
D4	pond	0.007	0.003	0.001	0.011	0.006	0.003	0.001	0.008	0.008	0.005	0.005
D4	stream	0.160	0.080	0.032	0.117	0.059	0.029	0.012	0.062	0.062	0.032	0.032
D5	pond	0.007	0.003	0.001	0.011	0.006	0.003	0.001	0.008	0.008	0.005	0.005
D5	stream	0.177	0.089	0.035	0.130	0.065	0.032	0.013	0.069	0.069	0.036	0.036
R1	pond	0.053	0.050	0.048	0.057	0.052	0.049	0.048	0.054	0.026	0.052	0.014
R1	stream	0.930	0.930	0.930	0.930	0.930	0.930	0.930	0.930	0.422	0.930	0.221
R3	stream	0.715	0.715	0.715	0.715	0.715	0.715	0.715	0.715	0.326	0.715	0.171

Table 8.9-28: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to spring oilseed rape (1 x 60 g a.s./ha)

PEC _{sw} (µg/L)		STEP 4 acetamiprid				
Vegetative strip (m)		None	None	10	None	20
No spray buffer (m)		5	10	10	20	20
Scenario	Waterbody					
D1	ditch	0.107	0.058	0.058	0.032	0.032
D1	stream	0.123	0.065	0.065	0.034	0.034
D3	ditch	0.103	0.055	0.055	0.028	0.028
D4	pond	0.011	0.008	0.008	0.005	0.005
D4	stream	0.114	0.060	0.060	0.031	0.031
D5	pond	0.011	0.008	0.008	0.005	0.005
D5	stream	0.121	0.064	0.064	0.033	0.033
R1	pond	0.042	0.039	0.020	0.037	0.011
R1	stream	0.765	0.765	0.347	0.765	0.182

Table 8.9-29: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to potato (1 x 36 g a.s./ha, early application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid				
Vegetative strip (m)		None	None	10	None	20
No spray buffer (m)		5	10	10	20	20
Scenario	Waterbody					
D3	ditch	0.062	0.033	0.033	0.017	0.017
D4	pond	0.007	0.005	0.005	0.003	0.003
D4	stream	0.068	0.036	0.036	0.019	0.019
D6	ditch	0.061	0.032	0.032	0.017	0.017
D6	ditch	0.061	0.032	0.032	0.017	0.017
R1	pond	0.009	0.008	0.005	0.007	0.003
R1	stream	0.165	0.165	0.068	0.165	0.034
R2	stream	0.073	0.071	0.039	0.071	0.020
R3	stream	0.209	0.209	0.095	0.209	0.050

Table 8.9-30: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to potato (1 x 36 g a.s./ha, late application)

PEC _{sw} (µg/L)		STEP 4 acetamiprid				
Vegetative strip (m)		None	None	10	None	20
No spray buffer (m)		5	10	10	20	20
Scenario	Waterbody					
D3	ditch	0.062	0.033	0.033	0.017	0.017
D4	pond	0.007	0.005	0.005	0.003	0.003
D4	stream	0.060	0.032	0.032	0.016	0.016
D6	ditch	0.061	0.033	0.033	0.017	0.017
D6	ditch	0.062	0.033	0.033	0.017	0.017
R1	pond	0.023	0.021	0.011	0.020	0.006
R1	stream	0.408	0.408	0.185	0.408	0.097
R2	stream	0.074	0.039	0.039	0.020	0.020
R3	stream	0.144	0.144	0.066	0.144	0.034

Table 8.9-31: FOCUS Step 4 PEC_{sw} values for acetamiprid, following single application of CA3573 to corn (1 x 60 g a.s./ha)

PEC _{sw} (µg/L)		STEP 4 acetamiprid				
Vegetative strip (m)		None	None	10	None	20
No spray buffer (m)		5	10	10	20	20
Scenario	Waterbody					
D3	ditch	0.103	0.055	0.055	0.028	0.028
D4	pond	0.011	0.008	0.008	0.005	0.005
D4	stream	0.119	0.063	0.063	0.033	0.033
D5	pond	0.011	0.008	0.008	0.005	0.005
D5	stream	0.130	0.069	0.069	0.036	0.036
D6	ditch	0.102	0.054	0.054	0.028	0.028
R1	pond	0.032	0.030	0.016	0.028	0.009
R1	stream	0.535	0.535	0.243	0.535	0.127
R2	stream	0.123	0.065	0.065	0.034	0.034
R3	stream	0.292	0.292	0.133	0.292	0.070
R4	stream	0.090	0.087	0.048	0.087	0.025

zRMS comments:

Input parameters considered by the Applicant in surface water modelling for acetamiprid presented in Table 8.9-3 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(11):4610.

Step 4 simulations were performed in line with indications of *Landscape and mitigation factors in aquatic ecological risk assessment* (SANCO/10422/2005).

Applicants' calculations performed for acetamiprid at Steps 1-4 were independently validated by the zRMS in additional modelling based on the same input parameters. Obtained results were in agreement with Applicants' values.

It is noted that additional calculations performed by the Applicant for application to apples at BBCH 69 were not necessary as they are covered by calculations performed for BBCH 62 (early and late) which is confirmed by the same PEC_{sw} values obtained for BBCH 62 and 69.

With regard to Step 4 it was noted that in case of calculations performed with spray drift reduction as the only mitigation measure for applications to apples and winter oilseed rape, the Applicant indicated the buffer zone of 3 m. However, in the course of the validation performed by the zRMS it turned out that actually no buffer zone was assumed in these calculations and default FOCUS buffer has been used. Tables 8.9-18 to 8.9-27 were thus amended accordingly in order to provide relevant information regarding considered risk mitigation measures.

Overall, the surface water modelling performed by the Applicant is considered acceptable and exposure reported in Tables 8.9-4 to 8.9-31 may be used in the aquatic risk assessment.

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

Metabolites of acetamiprid

Table 8.9-32: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IM-1-2

Crop, rate	Number of applications	Scenario FOCUS	Season	Maximum PEC _{sw} (µg/L)	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Use ID: 1, 11 Apple 1 x 25 g a.s./ha, BBCH 62-PHI or BBCH 69-PHI	1	Step 1	-	6.09	6.02	3.27
		Step 2				
		Northern Europe	Oct - Feb	0.522	0.511	0.278
			Mar – May	0.410	0.400	0.217
			Jun - Sep	0.410	0.400	0.217
		Southern Europe	Oct - Feb	0.485	0.474	0.257
			Mar – May	0.485	0.474	0.257
			Jun - Sep	0.447	0.437	0.237
Use ID: 2, 12 Apple 1 x 50 g a.s./ha, BBCH 62-PHI	1	Step 1	-	12.2	12.0	6.55
		Step 2				
		Northern Europe	Oct - Feb	1.04	1.02	0.555
			Mar – May	0.819	0.799	0.434
			Jun - Sep	0.819	0.799	0.434
		Southern Europe	Oct - Feb	0.969	0.948	0.515
			Mar – May	0.969	0.948	0.515
			Jun - Sep	0.894	0.873	0.475
Use ID: 4, 5, 6, 7, 14, 15, 16 Winter oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	13.9	13.7	7.47
		Step 2				
		Northern Europe	Oct - Feb	0.461	0.456	0.248
			Mar – May	0.230	0.227	0.123
			Jun - Sep	0.230	0.227	0.123
		Southern Europe	Oct - Feb	0.384	0.380	0.206
			Mar – May	0.384	0.380	0.206
			Jun - Sep	0.307	0.303	0.165
Use ID: 8, 9, 10 17, 18 Spring oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	13.9	13.7	7.47
		Step 2				
		Northern Europe	Oct - Feb	0.461	0.456	0.248
			Mar – May	0.230	0.227	0.123
			Jun - Sep	0.230	0.227	0.123
		Southern Europe	Oct - Feb	0.384	0.380	0.206
			Mar – May	0.384	0.380	0.206
			Jun - Sep	0.307	0.303	0.165
Use ID: 3, 13 Potato 1 x 36 g a.s./ha, BBCH 12-79	1	Step 1	-	8.31	8.25	4.48
		Step 2				
		Northern Europe	Oct - Feb	0.700	0.694	0.377
			Mar – May	0.307	0.304	0.165
			Jun - Sep	0.307	0.304	0.165
		Southern Europe	Oct - Feb	0.569	0.564	0.307
			Mar – May	0.569	0.564	0.307
			Jun - Sep	0.438	0.434	0.236
Use ID: 19, 20 Corn 1 x 60 g a.s./ha, BBCH 51-75	1	Step 1	-	13.9	13.7	7.47
		Step 2				
		Northern Europe	Oct - Feb	0.397	0.392	0.213
			Mar – May	0.204	0.201	0.109
			Jun - Sep	0.204	0.201	0.109
		Southern Europe	Oct - Feb	0.333	0.329	0.179
			Mar – May	0.333	0.329	0.179
			Jun - Sep	0.268	0.265	0.144

Table 8.9-33: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IM-1-4

Crop, rate	Number of applications	Scenario FOCUS	Season	Maximum PEC _{sw} (µg/L)	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Use ID: 1, 11 Apple 1 x 25 g a.s./ha, BBCH 62-PHI or BBCH 69-PHI	1	Step 1	-	8.71	8.39	14.4
		Step 2				
		Northern Europe	Oct - Feb	1.80	1.72	2.95
			Mar – May	1.44	1.36	2.34
			Jun - Sep	1.44	1.36	2.34
		Southern Europe	Oct - Feb	1.68	1.60	2.75
			Mar – May	1.68	1.60	2.75
			Jun - Sep	1.56	1.48	2.54
Use ID: 2, 12 Apple 1 x 50 g a.s./ha, BBCH 62-PHI	1	Step 1	-	17.4	16.8	28.9
		Step 2				
		Northern Europe	Oct - Feb	3.61	3.43	5.91
			Mar – May	2.89	2.72	4.68
			Jun - Sep	2.89	2.72	4.68
		Southern Europe	Oct - Feb	3.37	3.20	5.50
			Mar – May	3.37	3.20	5.50
			Jun - Sep	3.13	2.96	5.09
Use ID: 4, 5, 6, 7, 14, 15, 16 Winter oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	17.9	17.7	30.4
		Step 2				
		Northern Europe	Oct - Feb	1.50	1.47	2.54
			Mar – May	0.765	0.743	1.28
			Jun - Sep	0.765	0.743	1.28
		Southern Europe	Oct - Feb	1.26	1.23	2.12
			Mar – May	1.26	1.23	2.12
			Jun - Sep	1.01	0.987	1.70
Use ID: 8, 9, 10 17, 18 Spring oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	17.9	17.7	30.4
		Step 2				
		Northern Europe	Oct - Feb	1.50	1.47	2.54
			Mar – May	0.765	0.743	1.28
			Jun - Sep	0.765	0.743	1.28
		Southern Europe	Oct - Feb	1.26	1.23	2.12
			Mar – May	1.26	1.23	2.12
			Jun - Sep	1.01	0.987	1.70
Use ID: 3, 13 Potato 1 x 36 g a.s./ha, BBCH 12-79	1	Step 1	-	10.7	10.6	18.3
		Step 2				
		Northern Europe	Oct - Feb	2.25	2.23	3.83
			Mar – May	1.00	0.982	1.69
			Jun - Sep	1.00	0.982	1.69
		Southern Europe	Oct - Feb	1.83	1.81	3.12
			Mar – May	1.83	1.81	3.12
			Jun - Sep	1.42	1.40	2.40
Use ID: 19, 20 Corn 1 x 60 g a.s./ha, BBCH 51-75	1	Step 1	-	17.9	17.7	30.4
		Step 2				
		Northern Europe	Oct - Feb	1.30	1.27	2.19
			Mar – May	0.683	0.662	1.14
			Jun - Sep	0.683	0.662	1.14
		Southern Europe	Oct - Feb	1.09	1.07	1.84
			Mar – May	1.09	1.07	1.84
			Jun - Sep	0.888	0.865	1.49

Table 8.9-34: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IC-0

Crop, rate	Number of applications	Scenario FOCUS	Season	Maximum PEC _{sw} (µg/L)	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Use ID: 1, 11 Apple 1 x 25 g a.s./ha, BBCH 62-PHI or BBCH 69-PHI	1	Step 1	-	2.57	2.49	3.05
		Step 2				
		Northern Europe	Oct - Feb	0.531	0.506	0.621
			Mar – May	0.507	0.464	0.567
			Jun - Sep	0.507	0.464	0.567
		Southern Europe	Oct - Feb	0.516	0.492	0.603
			Mar – May	0.516	0.492	0.603
			Jun - Sep	0.507	0.476	0.585
Use ID: 2, 12 Apple 1 x 50 g a.s./ha, BBCH 62-PHI	1	Step 1	-	5.15	4.97	6.10
		Step 2				
		Northern Europe	Oct - Feb	1.06	1.01	1.24
			Mar – May	1.01	0.927	1.13
			Jun - Sep	1.01	0.927	1.13
		Southern Europe	Oct - Feb	1.03	0.983	1.21
			Mar – May	1.03	0.983	1.21
			Jun - Sep	1.01	0.952	1.17
Use ID: 4, 5, 6, 7, 14, 15, 16 Winter oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	5.07	5.02	6.17
		Step 2				
		Northern Europe	Oct - Feb	0.257	0.250	0.307
			Mar – May	0.165	0.159	0.195
			Jun - Sep	0.165	0.159	0.195
		Southern Europe	Oct - Feb	0.226	0.220	0.270
			Mar – May	0.226	0.220	0.270
			Jun - Sep	0.195	0.189	0.232
Use ID: 8, 9, 10 17, 18 Spring oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	5.07	5.02	6.17
		Step 2				
		Northern Europe	Oct - Feb	0.257	0.250	0.307
			Mar – May	0.165	0.159	0.195
			Jun - Sep	0.165	0.159	0.195
		Southern Europe	Oct - Feb	0.226	0.220	0.270
			Mar – May	0.226	0.220	0.270
			Jun - Sep	0.195	0.189	0.232
Use ID: 3, 13 Potato 1 x 36 g a.s./ha, BBCH 12-79	1	Step 1	-	3.04	3.01	3.70
		Step 2				
		Northern Europe	Oct - Feb	0.323	0.317	0.390
			Mar – May	0.166	0.162	0.199
			Jun - Sep	0.166	0.162	0.199
		Southern Europe	Oct - Feb	0.271	0.266	0.326
			Mar – May	0.271	0.266	0.326
			Jun - Sep	0.218	0.214	0.263
Use ID: 19, 20 Corn 1 x 60 g a.s./ha, BBCH 51-75	1	Step 1	-	5.07	5.02	6.17
		Step 2				
		Northern Europe	Oct - Feb	0.231	0.225	0.276
			Mar – May	0.155	0.149	0.183
			Jun - Sep	0.155	0.149	0.183
		Southern Europe	Oct - Feb	0.206	0.200	0.245
			Mar – May	0.206	0.200	0.245
			Jun - Sep	0.180	0.174	0.214

Table 8.9-35: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IM-1-5

Crop, rate	Number of applications	Scenario FOCUS	Season	Maximum PEC _{sw} (µg/L)	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Use ID: 1, 11 Apple 1 x 25 g a.s./ha, BBCH 62-PHI or BBCH 69-PHI	1	Step 1	-	1.03	1.02	3.35
		Step 2				
		Northern Europe	Oct - Feb	0.179	0.178	0.583
			Mar – May	0.072	0.071	0.233
			Jun - Sep	0.072	0.071	0.233
		Southern Europe	Oct - Feb	0.144	0.142	0.466
			Mar – May	0.144	0.142	0.466
			Jun - Sep	0.108	0.107	0.350
Use ID: 2, 12 Apple 1 x 50 g a.s./ha, BBCH 62-PHI	1	Step 1	-	2.06	2.05	6.70
		Step 2				
		Northern Europe	Oct - Feb	0.359	0.356	1.17
			Mar – May	0.144	0.142	0.466
			Jun - Sep	0.144	0.142	0.466
		Southern Europe	Oct - Feb	0.287	0.285	0.933
			Mar – May	0.287	0.285	0.933
			Jun - Sep	0.215	0.214	0.700
Use ID: 4, 5, 6, 7, 14, 15, 16 Winter oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	2.47	2.46	8.04
		Step 2				
		Northern Europe	Oct - Feb	0.369	0.366	1.20
			Mar – May	0.148	0.147	0.480
			Jun - Sep	0.148	0.147	0.480
		Southern Europe	Oct - Feb	0.295	0.293	0.959
			Mar – May	0.295	0.293	0.959
			Jun - Sep	0.221	0.220	0.720
Use ID: 8, 9, 10 17, 18 Spring oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	2.47	2.46	8.04
		Step 2				
		Northern Europe	Oct - Feb	0.369	0.366	1.20
			Mar – May	0.148	0.147	0.480
			Jun - Sep	0.148	0.147	0.480
		Southern Europe	Oct - Feb	0.295	0.293	0.959
			Mar – May	0.295	0.293	0.959
			Jun - Sep	0.221	0.220	0.720
Use ID: 3, 13 Potato 1 x 36 g a.s./ha, BBCH 12-79	1	Step 1	-	1.48	1.47	4.82
		Step 2				
		Northern Europe	Oct - Feb	0.627	0.623	2.04
			Mar – May	0.251	0.249	0.815
			Jun - Sep	0.251	0.249	0.815
		Southern Europe	Oct - Feb	0.502	0.498	1.63
			Mar – May	0.502	0.498	1.63
			Jun - Sep	0.376	0.374	1.22
Use ID: 19, 20 Corn 1 x 60 g a.s./ha, BBCH 51-75	1	Step 1	-	2.47	2.46	8.04
		Step 2				
		Northern Europe	Oct - Feb	0.308	0.305	0.999
			Mar – May	0.123	0.122	0.400
			Jun - Sep	0.123	0.122	0.400
		Southern Europe	Oct - Feb	0.246	0.244	0.799
			Mar – May	0.246	0.244	0.799
			Jun - Sep	0.185	0.183	0.600

Table 8.9-36: FOCUS Step 1 and 2 PEC_{sw} and PEC_{sed} for IB-1-1

Crop, rate	Number of applications	Scenario FOCUS	Season	Maximum PEC _{sw} (µg/L)	21 day TWA PEC _{sw} (µg/L)	Maximum PEC _{sed} (µg/kg)
Use ID: 1, 11 Apple 1 x 25 g a.s./ha, BBCH 62-PHI or BBCH 69-PHI	1	Step 1	-	3.45	3.43	0.000
		Step 2				
		Northern Europe	Oct - Feb	0.847	0.841	0.000
			Mar – May	0.805	0.800	0.000
			Jun - Sep	0.805	0.800	0.000
		Southern Europe	Oct - Feb	0.833	0.827	0.000
			Mar – May	0.833	0.827	0.000
			Jun - Sep	0.819	0.813	0.000
Use ID: 2, 12 Apple 1 x 50 g a.s./ha, BBCH 62-PHI	1	Step 1	-	6.90	6.85	0.000
		Step 2				
		Northern Europe	Oct - Feb	1.69	1.68	0.000
			Mar – May	1.61	1.60	0.000
			Jun - Sep	1.61	1.60	0.000
		Southern Europe	Oct - Feb	1.67	1.65	0.000
			Mar – May	1.67	1.65	0.000
			Jun - Sep	1.64	1.63	0.000
Use ID: 4, 5, 6, 7, 14, 15, 16 Winter oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	6.59	6.54	0.000
		Step 2				
		Northern Europe	Oct - Feb	0.319	0.316	0.000
			Mar – May	0.233	0.232	0.000
			Jun - Sep	0.233	0.232	0.000
		Southern Europe	Oct - Feb	0.290	0.288	0.000
			Mar – May	0.290	0.288	0.000
			Jun - Sep	0.262	0.260	0.000
Use ID: 8, 9, 10 17, 18 Spring oilseed rape 1 x 60 g a.s./ha, BBCH 31-71	1	Step 1	-	6.59	6.54	0.000
		Step 2				
		Northern Europe	Oct - Feb	0.319	0.316	0.000
			Mar – May	0.233	0.232	0.000
			Jun - Sep	0.233	0.232	0.000
		Southern Europe	Oct - Feb	0.290	0.288	0.000
			Mar – May	0.290	0.288	0.000
			Jun - Sep	0.262	0.260	0.000
Use ID: 3, 13 Potato 1 x 36 g a.s./ha, BBCH 12-79	1	Step 1	-	3.95	3.92	0.000
		Step 2				
		Northern Europe	Oct - Feb	0.347	0.345	0.000
			Mar – May	0.203	0.201	0.000
			Jun - Sep	0.203	0.201	0.000
		Southern Europe	Oct - Feb	0.299	0.297	0.000
			Mar – May	0.299	0.297	0.000
			Jun - Sep	0.251	0.249	0.000
Use ID: 19, 20 Corn 1 x 60 g a.s./ha, BBCH 51-75	1	Step 1	-	6.59	6.54	0.000
		Step 2				
		Northern Europe	Oct - Feb	0.295	0.293	0.000
			Mar – May	0.224	0.222	0.000
			Jun - Sep	0.224	0.222	0.000
		Southern Europe	Oct - Feb	0.271	0.269	0.000
			Mar – May	0.271	0.269	0.000
			Jun - Sep	0.247	0.246	0.000

zRMS comments:

Input parameters considered by the Applicant in surface water modelling for metabolites IM-1-2, IM-1-4, IC-0, IM-1-5, IB-1-1 presented in Table 8.9-3 are in line with EU agreed endpoints reported in EFSA Journal 2016;14(11):4610.

Applicants' calculations performed for all acetamiprid metabolites were independently validated by the zRMS in additional modelling based on the same input parameters. Obtained results were in agreement with Applicants' values.

It is noted that additional calculations performed by the Applicant for application to apples at BBCH 69 were not necessary as they are covered by calculations performed for BBCH 62 (early and late) which is confirmed by the same PEC_{sw} values obtained for BBCH 62 and 69.

Overall, the surface water modelling performed by the Applicant is considered acceptable and exposure reported in Tables 8.9-32 to 8.9-36 may be used in the aquatic risk assessment.

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

8.9.2.2 PEC_{sw} of CA3573

The PEC_{sw} of the formulation CA3573 were calculated based on the FOCUS spray drift values of the SWASH drift calculator for a water body of 30 cm depth and 1 m width (FOCUS 'ditch'), and the density of the formulation of 1.136 g/mL.

Table 8.9-37: PEC_{sw} for CA3573

Crop	Application rate	Non-sprayed buffer distance	Nozzle reduction	PEC _{sw} (µg/L)
Apple	0.125 L/ha = 0.142 kg/ha ^{a)}	3	-	12.4
			50%	6.18
			75%	3.09
			90%	1.24
		5	-	8.78
			50%	4.39
			75%	2.19
			90%	0.878
		10	-	5.39
			50%	2.69
			75%	1.35
			90%	0.539
		15	-	2.42
			50%	1.21
			75%	0.606
			90%	0.242
		20	-	1.23
	0.25 L/ha = 0.284 kg/ha ^{a)}	3	-	24.7
			50%	12.36
			75%	6.18
			90%	2.47
		5	-	17.6
			50%	8.78
			75%	4.39
			90%	1.76
		10	-	10.8
			50%	5.39

Crop	Application rate	Non-sprayed buffer distance	Nozzle reduction	PEC _{sw} (µg/L)
			75%	2.69
			90%	1.08
		15	-	4.85
			50%	2.42
			75%	1.21
			90%	0.485
		20		2.47
Winter and spring oilseed rape	0.3 L/ha = 0.341 kg/ha ^{a)}	1	-	2.19
			50%	1.09
			75%	0.547
			90%	0.219
		3	-	0.927
			50%	0.463
			75%	0.232
			90%	0.093
		5		0.593
		10		0.315
		20		0.164
Potato	0.18 L/ha = 0.204 kg/ha ^{a)}	1		1.31
		5		0.356
		10		0.189
		20		0.098
Corn	0.3 L/ha = 0.341 kg/ha ^{a)}	1		2.19
		5		0.593
		10		0.315
		20		0.164

^{a)} The application rate of the formulation was calculated based on a density of 1.136 g/mL and the maximum application rate for each crop.

zRMS comments:

The surface water exposure to the formulated product was validated by the zRMS using the Spray Drift Calculator. Obtained results were in agreement with Applicants' values presented in Table 8.9-37.

Please note, however, that the aquatic risk assessment has been based on exposure calculated for the active compound and for this reason PEC_{sw} values for CA3573 are deemed not necessary.

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

Table 8.10-1 Summary of atmospheric degradation and behaviour

Compound	Acetamiprid
Direct photolysis in air	No data required
Quantum yield of direct phototransformation	-
Photochemical oxidative degradation in air	Overall rate constant: $76.435 \text{ cm}^3 \times \text{molecule}^{-1} \times \text{sec}^{-1}$ DT ₅₀ : 0.140 days (derived by the Atkinson model assuming a OH (12 h) concentration of $1.5 \times 10^6 \text{ OH/cm}^3$)
Volatilisation	Vapour pressure (Pa): 1.73×10^{-7} Henry's Law Constant (Pa m ³ /mol): $< 5.3 \times 10^{-8}$ (25 °C)
Metabolites	No data

The vapour pressure at 20 °C of the active substance acetamiprid is $< 10^{-5}$ Pa. Hence, the active substance acetamiprid is regarded as non-volatile. Its volatilisation from plant and soil surfaces is regarded to be very low. Additionally, it is rapidly degraded in air (DT₅₀ = 0.14 days). Therefore, exposure of adjacent surface waters and terrestrial ecosystems by the active substance acetamiprid due to volatilization with subsequent deposition does not have to be considered.

zRMS comments:

Provided above information is in line with EU agreed data reported in EFSA Journal 2016;14(11):4610.

Taking into account the low vapour pressure ($<10^{-5}$ Pa) and DT₅₀ in air (<2 days), acetamiprid is not expected to be subject to volatilisation and the long- or short-range transport. Taking this into account, contamination of the atmosphere with acetamiprid from the intended uses of CA3573 is considered to be negligible.

Appendix 1 Lists of data considered in support of the evaluation

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
Additional studies submitted by the Applicant in support of evaluation of CA3573 in area of Section 8 were not relied upon (see justification in table below).					

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

zRMS comments:

Please note that all endpoints for acetamiprid and its metabolites were taken from the EU review. The full list of respective studies may be found in the RAR, Vol. 2 (June 2016).

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 #
CA 7.1.1.1/01, 7.1.2.1.1/02, 7.1.2.1.2/03	Morgenroth, U.	1997	¹⁴ C-NI-25: Metabolism in One Soil Incubated under Aerobic Conditions Report/file: RCC Project 373994 Amended final report Nippon Soda Doc No. RD-09624N GLP Not published	N	Nippon Soda
CA 7.1.1.1/02	Feung, C.S.	1998	Acetamiprid (NI-25): Metabolism in Collombey Soil Report/file: RPAC Report N° EC-97-406 Nippon Soda Doc No. RD-09961 Non-GLP Not published	N	Nippon Soda
CA 7.1.1.1/03, 7.1.2.1.1/03, 7.1.2.1.2/04	Burr, C.M.	1997	[¹⁴ C]-NI-25: Rate of Aerobic Degradation in Three Soil Types at 20°C and One Soil Type at 10°C Report/file: RPAL Study Report 11256 Nippon Soda Doc No. RD-09962 GLP Not published	N	Nippon Soda

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 #
CA 7.1.1.1/04, 7.1.2.1.1/04, 7.1.2.1.2/05	Simmonds, M.B.	2002	[¹⁴ C]-Acetamiprid: Rate of Degradation in Three Calcareous Soils at 20°C Aventis CropScience SA., report C019428 Nippon Soda Doc No. RD-00168 GLP Not published	N	Nippon Soda
CA 7.1.1.2/01, 7.1.2.1.3/02	Burr, C.M., Doble, M.L	1997	[¹⁴ C]-NI-25: Anaerobic Soil Degradation Report/file: RPAL Study Report 11444 Nippon Soda Doc No. RD-09860 GLP Not published	N	Nippon Soda
CA 7.1.1.3/01	Mislankar, S.G.	1998	Acetamiprid (NI-25) Soil Photolysis Report/file: RPAC Study N° EC-97-359 Nippon Soda Doc No. RD-09833 GLP Not published	N	Nippon Soda
CA 7.1.2.1.1/01, 7.1.2.1.2/02	Jarvis, T. & Hilton, M	2014	Re-calculation of laboratory aerobic degradation rates of acetamiprid and its metabolites, according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD-02913 Non-GLP Not published	N	Nippon Soda
CA 7.1.2.1.2/01	Jewkes, Y.	2014	Rate of Degradation of [¹⁴ C]-IM-1-5 in Three Soils at 20°C Nippon-Soda Report No.: RD-02811 GLP Not published	N	Nippon Soda
CA 7.1.2.1.2/06	Lowden, P., Oddy, A.M., Jones, M.K.	1997	NI-25: Rate of Degradation of the Acid Metabolite, [¹⁴ C]-IC-0 in Three Soils Report/file: RPAL Study Report 11257 Nippon Soda Doc No. RD-9963 GLP Not published	N	Nippon Soda
CA 7.1.2.1.3/01	Jarvis, T. & Montesano, V	2014a	Re-calculation of laboratory anaerobic degradation rate of acetamiprid according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD-02910 Non-GLP Not published	N	Nippon Soda

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 #
CA 7.1.3.1.1/01	Flückiger, J.	1997	Adsorption/Desorption of ¹⁴ C-NI-25 on Five Soils Report/file: RCC Project 374016 Nippon Soda Doc No. RD-09564N GLP Not published	N	Nippon Soda
CA 7.1.3.1.2/01	Sugiyama, H.	2010	Adsorption / desorption study of IM-1-5 on soils Nippon Soda Co. Ltd. (NSM), Japan Report No. NSM10-013 Document No. RD-02101 GLP Not published	N	Nippon Soda
CA 7.1.3.1.2/02	Mamouni, A.	1997	Adsorption/Desorption of IM-1-4 on Five Soils Report/file:RCC Project 383826 Nippon Soda Doc No. RD-09567N GLP Not published	N	Nippon Soda
CA 7.1.3.1.2/03	Liu, A.C.	1997	6-Chloronicotinic Acid (Acetamiprid Metabolite) Soil Adsorption/Desorption Study Report/file: RPAC Study N° EC-97-370 Nippon Soda Doc No. RD-9973 GLP Not published	N	Nippon Soda
CA 7.1.3.1.2/04	Mackenzie E. & Price O.	2003	[¹⁴ C]-IM-1-2 : Adsorption to and Desorption from Four Soils and One Sediment BayerCropScience SA, report C030079 Nippon Soda Doc No. RD-03056 GLP Not published	N	Nippon Soda
CA 7.2.1.2/01	Hausmann, S., & Class, T.	1998	Aqueous Photodegradation of [¹⁴ C]-Acetamiprid at pH 7 and Determination of Quantum Yield Report/file: PTRL Europe Study N° P 196 G, RPA Study N°96-82 Nippon Soda Doc No. RD-00403 GLP Not published	N	Nippon Soda

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 #
CA 7.2.2.2/01	Möndel, M.	2014	[Pyridine-2,6- ¹⁴ C]-Acetamiprid: Aerobic Degradation in Natural Water RLP Agroscience, Germany Nippon-Soda Report No.: RD- 02800 GLP Not published	N	Nippon Soda
CA 7.2.2.3/01	Jarvis, T. & Montesano, V.	2014c	Recalculation of acetamiprid sediment water kinetics according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD-02911 Non-GLP Not published	N	Nippon Soda
CA 7.2.2.3/02	McMillan-Staff, S.L., & Austin, D.J.	1997	[¹⁴ C]-NI-25: Degradation in Two Water/Sediment Systems. Report/file: RPAL Study 11263 Nippon Soda Doc No. RD-9968 GLP Not published	N	Nippon Soda
CP 9.1.1.2/01	Jarvis, T. & Hilton, M	2014	Re-calculation of acetamiprid field dissipation rates from Wicks (1999) according to FOCUS (2006, 2011) guidance Exponent International Ltd., UK Nippon-Soda Report No.: RD-02912 Non-GLP Not published	N	Nippon Soda
CP 9.1.1.2/02	Kellner, T.	2012a	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Spain in 2010-2011 Eurofins Agroscience Services Nippon Soda Co. Ltd Report No.: RD-02404 GLP Not published	N	Nippon Soda
CP 9.1.1.2/03	Kellner, T.	2012b	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Southern France in 2010-2011 Eurofins Agroscience Services Nippon Soda Co. Ltd Report No.: RD-02405 GLP Not published	N	Nippon Soda
CP 9.1.1.2/04	Kellner, T.	2012c	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Northern France in 2010-2011 Eurofins Agroscience Services Nippon Soda Co. Ltd Report No.: RD-02406 GLP Not published	N	Nippon Soda

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 #
CP 9.1.1.2/05	Finger, N.	2013	Soil Dissipation study with Acetamiprid and its Soil Metabolite IM-1-5, in or on Soil in Hungary in 2011-2012 Eurofins Agroscience Services Nippon Soda Co. Ltd Report No.: RD-02599 GLP Not published	N	Nippon Soda
CP 9.1.1.2/07	Jarvis, T. & Montesano, V.	2014b	Calculation of Acetamiprid soil DT ₅₀ values from new field dissipation studies in 2010 and 2011 using FOCUS kinetics Non-GLP Not published	N	-
CP 9.1.1.2/08	Wicks, R.J.	1999	Acetamiprid : Field Soil Dissipation Study in Europe RPA Study 11258, Doc 202052 Nippon Soda Doc No. RD-9997 GLP Not published	N	Nippon Soda

Matching data have been conducted and submitted to Ctgb to demonstrate access to a complete package according to Reg(EU)283/2013 and for data matching step. According to RMS evaluation finalised in December 2020, the data matching has been demonstrated sufficiently. ~~RMS Opinion on GLP compliance, guidance compliance and equivalent endpoint can be provided as soon as evaluation is finalised.~~

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	Reason for rejection
KCP 9.2.4/01	Weinfurtner, K.H.	2020	Determination of plant Uptake Factor (PUF)/Transpiration Stream Concentration factor (TSCF) in wheat and oilseed rape plants of Acetamiprid metabolite [¹⁴ C]-IM-1-5 Report/file: Fraunhofer IME Project NFM-003/5-52 GLP Not published	N	Nufarm	Study not finalised, but not necessary to finalise the exposure assessment.

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

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
There were no studies relied on and not submitted by the Applicant.					

Appendix 2 Detailed evaluation of the new Annex II studies

A 2.1 KCP 9.2.4/01 Determination of Plant Uptake Factor (PUF)

Comments of zRMS:	<p>Due technical reasons the study was not finalised and hence no study report has been submitted.</p> <p>Nevertheless, the study was not necessary to finalise the exposure assessment ,which was based on EU agreed endpoints and FOCUS default values.</p>
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Reference:	KCP 9.2.4/01
Report	<p>Weinfurther K.H. (2020): Determination of Plant Uptake Factor (PUF)/Transpiration Stream Concentration Factor (TSCF) in wheat and oil seed rape plants of Acetamiprid metabolite [¹⁴C]-IM-1-5</p> <p>Report/file: Fraunhofer IME Project NFM-003/5-52</p>
Guideline(s):	<p>No EU agreed guidelines.</p> <p>The study was conducted according to ECPA/IVA Working group "Plant Uptake Factor" (2017): Study design to determine uptake of chemicals by plant roots, Frankfurt/Main, Germany, May 26,2017</p>
Deviations:	Yes/No
GLP:	Yes
Acceptability:	Study not finalised, but not necessary to finalise the exposure assessment

~~Appendix A 2.1 will be completed as soon as the study is finalised (see comment in 8.8.1.).~~

~~Materials and methods~~
~~Results and discussions~~
~~Conclusion~~

~~No additional information is provided as the study was never finalised due to technical issues in the study.~~

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

No additional information is provided.