European Commission

Draft Renewal Assessment Report prepared according to the Commission Regulation (EU) N° 1107/2009

INDOXACARB

Volume 3 – B.8 (PPP) – INDOXACARB 150 g/L EC

Rapporteur Member State: France
Co-Rapporteur Member State: Spain

Version History

When	What
2016-12	Initial RAR

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B.8. ENVIRONMENTAL FATE AND BEHAVIOUR

Environmental fate studies using the formulation Indoxacarb 150 g/L EC were not conducted, since data from studies with the active substance indoxacarb (DPX-KN128) are available and adequate to enable extrapolation to the behaviour of the formulated product. A summary of the environmental fate parameters of indoxacarb can be found in Indoxacarb EU Renewal Dossier, Volume 3 – B.8 (AS).

Context surrounding representative use(s)

Indoxacarb is a broad-spectrum lepidopteran insecticide that is used in a variety of crops. The maximum label use rate in Europe for indoxacarb to the representative crops are 2 × 37.5 g a.s./ha in maize and sweet corn and 4 × 37.5 g a.s./ha in lettuce.

Endpoints considered relevant in assessing the fate of indoxacarb and its metabolites are shown under Points B.8.2, B.8.3 and B.8.5 in this document. The residue definitions for the exposure assessment are summarised in Table 1.

Table 1:Indoxacarb and metabolites considered in the assessment

Code number/name[a]	Compartment(s)
Indoxacarb (DPX-KN128)	Groundwater, soil, surface water
IN-JT333	Groundwater, soil, surface water
IN-JU873	Groundwater, soil, surface water
IN-ML438	Groundwater, soil, surface water
IN-KG433	Groundwater, soil, surface water
IN-MK643	Groundwater, soil, surface water
IN-MK638	Groundwater, soil, surface water
IN-KT413	Groundwater, soil, surface water
IN-MP819	Surface water
IN-MS775	Surface water
IN-KB687	Groundwater, soil, surface water
IN-U8E24	Groundwater, soil, surface water
IN-UYG23	Surface water

For the purpose of supporting protective exposure PEC_{soil}, PEC_{gw} and PEC_{sw} assessments summarised in this document, modelling has been carried out based upon the representative uses considering usage in maize and lettuce.

B.8.1. FATE AND BEHAVIOUR IN SOIL

B.8.1.1. Route and rate of degradation in soil

No laboratory route/rate studies were conducted with formulation. See Volume 3 – B.8 (AS) for studies with active substance.

B.8.1.2. Mobility in soil

No mobility studies were conducted with formulation. See Volume 3 – B.8 (AS) for studies with active substance.

B.8.2. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SOIL (PEC$_S$)

Data point:	
Author(s)	Russell, M.H. (2004)
Title:	**Predicted concentrations of DPX-MP062 30WG and major metabolites in soil; surface water; sediment and air: Focus simulation of applications to crops in the EU**
Document No:	DuPont-15748 EU
Guidelines:	
GLP:	Not applicable
Previous evaluation:	Yes
Acceptability:	No

The estimation of concentrations of indoxacarb in soil (DuPont-15748 EU) was originally submitted under EU rev 8 point number IIIA 9.2.3. A review of this position paper indicates that it does not meet the current guideline (FOCUS 1997 & 2012; EU 2000) and has been superseded with DuPont-36914 EU, Revision No. 1, and therefore it is not relied upon.

Data point:	**CP 9.1.3/01**
Author(s)	Juraske, R., Ball, M.A. (2015);
Title:	**Predicted environmental concentrations of indoxacarb and its major soil metabolites in soil after application to various crops in the European Union**
Document No:	DuPont-36914 EU, Revision No. 1
Guidelines:	FOCUS 1997[1] & 2012[2]
GLP:	Not applicable
Deviations:	None
Previous evaluation:	No
Acceptability:	No

RMS did not totally agree with the notifier proposed calculations, as the persistence DT_{50} values were not always adequately selected.

Calculations done by RMS are presented below.

RMS calculations

Predicted environmental concentrations in soil (PEC$_s$) were calculated based upon the maximum proposed use rate following EU and FOCUS recommendations (EU, 2000[3], FOCUS, 1997[4] & 2012[5]). PEC$_s$ values were generated to simulate applications of Indoxacarb 150 g/L EC to maize and lettuce in EU, using the FOCUS crop interception values (FOCUS 2009). It is noticeable that crop interception values from new EFSA guidance (2014) are unchanged for these crops.

Table 2: Critical use pattern used for PECsoil calculations

Crop group	Application rate (kg a.s./ha)	Number of applications	Minimum application interval (days)	Application timing	Crop interception (%)
Maize	0.0375	2	20	BBCH 34-77	50%/75%
Lettuce	0.0375	4	7	BBCH 13-49	25%

[1] FOCUS (1997): Soil Persistence Models and EU Registration. Final Report of the Soil Modeling Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their Use).
[2] FOCUS (2012): Generic guidance for Tier 1 FOCUS ground water assessments, version 2.1. FOCUS groundwater scenarios working group.
[3] EU (2000): Guidance Document on Persistence in Soil, EC Document Reference Sanco/9188/VI/97 rev. 8, 17pp.
[4] FOCUS (1997): Soil Persistence Models and EU Registration. Final Report of the Soil Modeling Work Group of FOCUS (Forum for the Co-ordination of pesticide fate models and their Use).
[5] FOCUS (2012): Generic guidance for Tier 1 FOCUS ground water assessments, version 2.1. FOCUS groundwater scenarios working group.

Actual and TWA concentration

The concentrations of indoxacarb (DPX-KN128) and its major soil metabolites (IN-JT333, IN-JU873, IN-KB687, IN-KG433, IN-KT413, IN-MK638, IN-MK643, IN-ML438, IN-U8E24) in the top 5 cm of soil were calculated as a function of time following applications to the crops maize and lettuce.

PEC_s calculations for indoxacarb and its metabolites were performed using the worst case, temperature-normalised laboratory $DegT_{50}$ value. No degradation was assumed to occur between applications. Input parameters for the simulation runs are summarized in Table 3. Using these assumptions, the concentration of test substance in soil immediately after the last application of the year were calculated using FOCUS guidance[6]

Maximum initial PECs for the soil metabolites were calculated considering a pseudo application of the metabolite, with application rates obtained with following equation:

$$A_{metabolite}\ (g/ha) = A_{parent} \times \frac{\text{maximum metabolite amount observed (\%)}}{100} \times \frac{MM_{metabolite}}{MM_{parent}}$$

As a worst-case the calculations were based on a single application of the total applied dose of parent active substance. This simplified approach ignores the timing of peak occurrence and application intervals for multiple application patterns and calculates the maximum theoretical peak occurrence for each metabolite.

Plateau concentration

$PEC_{s,plateau}$ values are determined for substances with half-lives longer than three months (EU, 2000). A soil bulk density of 1.5 g/cm^3 and a soil depth of 5 cm were assumed. A soil depth of 20 cm was assumed calculating $PEC_{s,max,plateau}$ for annual crops expecting ploughing between the treatments

$PEC_{s,plateau}$ expressed as background concentration resulting from long-term use was calculated using equations following the recommendations of FOCUS (1997) and by the Guidance Document on Persistence of Soil (EU, 2000).

Plateau concentrations are calculated for the metabolites in the same way as they are calculated for the parent.

[6] FOCUS (1997) Soil persistence models and EU Registration - The Final Report of the Soil Modelling Workgroup of FOCUS (Forum for the Co-ordination of Pesticide Fate Models and their Use) – 29 February 1997.

Table 3: Key input parameters used in simulation of PEC_s for indoxacarb and relevant metabolites, degradation, and reaction products

Parameter	Compound	Value	Units	Reference
Molecular weight	Indoxacarb	528	g/mol	
	IN-JT333	470		
	IN-JU873	458		
	IN-ML438	379		
	IN-KG433	516		
	IN-MK643	218		
	IN-MK638	220		
	IN-KT413	514		
	IN-KB687	235		
	IN-U8E24	478		
Laboratory Soil $DegT_{50}$ (temperature corrected)				See Volume 3 – B.8 (SA)
Worst case (laboratory n = 5)	Indoxacarb	231	Days	DFOP k2 from Speyer 2.2
Worst case (laboratory n = 10[b])	IN-JT333	147.5		DFOP k2 from Speyer 2.2
Worst case (laboratory n = 5)	IN-JU873	103.5		DFOP k2 from Mattapex
Worst case (laboratory n = 6[b])	IN-ML438	186.5		DFOP k2 from Sassafras
Worst case (laboratory n = 5)	IN-KG433	17.4		FOMC/3.32 from Speyer 2.2
Worst case (laboratory n = 5)	IN-MK643	314.2		SFO
Worst case (laboratory n = 5)	IN-MK638	17.3		SFO
Worst case (laboratory n = 3)	IN-KT413	10.34		DFOP k2 from Mattapex
Worst case (laboratory n = 2)	IN-KB687	0.67		SFO
Default	IN-U8E24	1000*		
Maximum occurrence in soil				
default	Indoxacarb	100	% AR	See Volume 3 – B.8 (SA)
laboratory degradation study	IN-JT333	18.6		
laboratory degradation study	IN-JU873	12.9		
laboratory degradation study	IN-ML438	9.7		
laboratory degradation study	IN-KG433	39.7		
laboratory degradation study	IN-MK643	12.0		
laboratory degradation study	IN-MK638	28.1		
laboratory degradation study	IN-KT413	18.4		
soil photolysis study	IN-KB687	22.0		
laboratory degradation study	IN-U8E24	13.8		

[a] Summarised in this document

* since no reliable DT_{50} for IN-U8E24 under aerobic condition is available, default DT_{50} is used for calculation.

Initial and long-term PEC_{soil} value

Active substance

Table 4: Actual and time-weighted average (TWA) concentrations of indoxacarb in soil (PEC_s and $PEC_{s,plateau}$) following application to maize (2 × 37.5 g a.s./ha, interval 20 d, 50% + 75% crop interception) in Europe

PEC_s (mg/kg)		Indoxacarb	
		Soil depth: 5 cm	
		Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	0.038	-
Short-term	24 h	0.037	0.037
	2 d	0.037	0.037
	4 d	0.037	0.037
Long-term	7 d	0.037	0.037
	14 d	0.036	0.037
	21 d	0.035	0.036
	28d	0.034	0.036
	50 d	0.032	0.035
	100 d	0.028	0.032
Plateau concentration	Soil depth: 20 cm	0.042 after 3 years	-

Table 5: Actual and time-weighted average (TWA) concentrations of indoxacarb in soil (PEC_s and $PEC_{s,plateau}$) following application to lettuce (4 × 37.5 g a.s./ha, interval 7 d, 25% crop interception) in Europe

PEC_s (mg/kg)		Indoxacarb	
		Soil depth: 5 cm	
		Actual PEC_{soil} (mg/kg)	TWA PEC_{soil} (mg/kg)
Initial	0 h	0.150	-
Short-term	24 h	0.149	0.150
	2 d	0.149	0.149
	4 d	0.147	0.149
Long-term	7 d	0.147	0.148
	14 d	0.144	0.147
	21 d	0.140	0.145
	28d	0.138	0.144
	50 d	0.129	0.139
	100 d	0.111	0.130
Plateau concentration	Soil depth: 20 cm	0.169 after 4 year	-

Metabolites

Maize

Table 6: Actual and time-weighted average (TWA) concentrations of IN-JT333, IN-JU873, and IN-ML438 in soil (PEC_s and $PEC_{s,plateau}$) following application of indoxacarb to maize (2 × 37.5 g a.s./ha, interval 20 d) in Europe

PEC_s		IN-JT333 Soil depth: 5 cm		IN-JU873 Soil depth: 5 cm		IN-ML438 Soil depth: 5 cm	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial	0 h	0.006	-	0.004	-	0.003	-
Short-term	24 h	0.006	0.006	0.004	0.004	0.003	0.003
	2 d	0.006	0.006	0.004	0.004	0.003	0.003
	4 d	0.006	0.006	0.004	0.004	0.003	0.003
Long-term	7 d	0.006	0.006	0.004	0.004	0.002	0.003
	14 d	0.006	0.006	0.004	0.004	0.002	0.002
	21 d	0.006	0.006	0.004	0.004	0.002	0.002
	28d	0.005	0.006	0.003	0.004	0.002	0.002
	50 d	0.005	0.006	0.003	0.004	0.002	0.002
	100 d	0.004	0.005	0.002	0.003	0.002	0.002
Plateau concentration	Soil depth: 20 cm	0.007 after 2 years	-	0.004 after 2 years	-	0.003 after 3 years	-

Table 7: Actual and time-weighted average (TWA) concentrations of IN-KG433, IN-MK643, and IN-MK638 in soil (PEC_s and $PEC_{s,plateau}$) following application of indoxacarb to maize (2 × 37.5 g a.s./ha, interval 20 d) in Europe

PEC_s		IN-KG433 Soil depth: 5 cm		IN-MK643 Soil depth: 5 cm		IN-MK638 Soil depth: 5 cm	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial	0 h	0.015	-	0.002	-	0.004	-
Short-term	24 h	0.014	0.015	0.002	0.002	0.004	0.004
	2 d	0.014	0.014	0.002	0.002	0.004	0.004
	4 d	0.013	0.014	0.002	0.002	0.004	0.004
Long-term	7 d	0.011	0.013	0.002	0.002	0.003	0.004
	14 d	0.008	0.011	0.002	0.002	0.003	0.003
	21 d	0.006	0.010	0.002	0.002	0.002	0.003
	28d	0.005	0.009	0.002	0.002	0.001	0.003
	50 d	0.002	0.006	0.002	0.002	<0.001	0.002
	100 d	<0.001	0.004	0.001	0.002	<0.001	0.001
Plateau concentration	Soil depth: 20 cm	-	-	0.002 after 3 years	-	-	-

Table 8: Actual and time-weighted average (TWA) concentrations of IN-KT413, IN-KB687, and IN-U8E24 in soil (PEC_s and $PEC_{s,plateau}$) following application of indoxacarb to maize (2 × 37.5 g a.s./ha, interval 20 d) in Europe

PEC_s		IN-KT413		IN-KB687		IN-U8E24	
		Soil depth: 5 cm		Soil depth: 5 cm		Soil depth: 5 cm	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial	0 h	0.007	-	0.004	-	0.005	-
Short-term	24 h	0.006	0.007	0.001	0.002	0.005	0.005
	2 d	0.006	0.006	<0.001	0.002	0.005	0.005
	4 d	0.005	0.006	<0.001	0.001	0.005	0.005
Long-term	7 d	0.004	0.006	<0.001	0.001	0.005	0.005
	14 d	0.003	0.004	<0.001	<0.001	0.005	0.005
	21 d	0.002	0.004	<0.001	<0.001	0.005	0.005
	28d	0.001	0.003	<0.001	<0.001	0.005	0.005
	50 d	<0.001	0.002	<0.001	<0.001	0.005	0.005
	100 d	<0.001	<0.001	<0.001	<0.001	0.005	0.005
Plateau concentration	Soil depth: 20 cm	-	-	-	-	0.022 after 12 years	-

Lettuce

Table 9: Actual and time-weighted average (TWA) concentrations of IN-JT333, IN-JU873, and IN-ML438 in soil (PEC_s and $PEC_{s,plateau}$) following application of indoxacarb to lettuce (4 × 37.5 g a.s./ha, interval 7 d) in Europe

PEC_s		IN-JT333		IN-JU873		IN-ML438	
		Soil depth: 5 cm		Soil depth: 5 cm		Soil depth: 5 cm	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial	0 h	0.025	-	0.017	-	0.010	-
Short-term	24 h	0.025	0.025	0.017	0.017	0.010	0.010
	2 d	0.025	0.025	0.017	0.017	0.010	0.010
	4 d	0.024	0.025	0.016	0.017	0.010	0.010
Long-term	7 d	0.024	0.024	0.016	0.016	0.010	0.010
	14 d	0.023	0.024	0.015	0.016	0.010	0.010
	21 d	0.023	0.024	0.015	0.016	0.010	0.010
	28d	0.022	0.023	0.014	0.015	0.009	0.010
	50 d	0.020	0.022	0.012	0.014	0.009	0.009
	100 d	0.016	0.020	0.009	0.012	0.007	0.009
Plateau concentration	Soil depth: 20 cm	0.026 after 2 years	-	0.017 after 2 years	-	0.011 after 3 years	-

Table 10: Actual and time-weighted average (TWA) concentrations of IN-KG433, IN-MK643, and IN-MK638 in soil (PEC_s and $PEC_{s,plateau}$) following application of indoxacarb to lettuce (4 × 37.5 g a.s./ha, interval 7 d) in Europe

PEC$_s$		IN-KG433		IN-MK643		IN-MK638	
		Soil depth: 5 cm		Soil depth: 5 cm		Soil depth: 5 cm	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial	0 h	0.059	-	0.007	-	0.018	-
Short-term	24 h	0.056	0.057	0.007	0.007	0.017	0.018
	2 d	0.054	0.056	0.007	0.007	0.016	0.017
	4 d	0.050	0.054	0.007	0.007	0.015	0.016
Long-term	7 d	0.044	0.051	0.007	0.007	0.013	0.015
	14 d	0.033	0.045	0.007	0.007	0.010	0.013
	21 d	0.025	0.039	0.007	0.007	0.008	0.011
	28d	0.019	0.035	0.007	0.007	0.006	0.010
	50 d	0.008	0.025	0.007	0.007	0.002	0.008
	100 d	0.001	0.014	0.006	0.007	<0.001	0.004
Plateau concentration	Soil depth: 20 cm	-	-	0.009 after 3 years	-	-	-

Table 11: Actual and time-weighted average (TWA) concentrations of IN-KT413 and IN-KB687 in soil (PEC$_s$ and PEC$_{s,plateau}$) following application of indoxacarb to lettuce (4 × 37.5 g a.s./ha, interval 7 d) in Europe

PEC$_s$		IN-KT413		IN-KB687		IN-U8E24	
		Soil depth: 5 cm		Soil depth: 5 cm		Soil depth: 5 cm	
		Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)	Actual (mg/kg)	TWA (mg/kg)
Initial	0 h	0.027	-	0.015		0.019	-
Short-term	24 h	0.025	0.026	0.06	0.009	0.019	0.019
	2 d	0.023	0.025	<0.001	0.006	0.019	0.019
	4 d	0.020	0.024	<0.001	0.003	0.019	0.019
Long-term	7 d	0.017	0.021	<0.001	0.002	0.019	0.019
	14 d	0.010	0.017	<0.001	0.001	0.019	0.019
	21 d	0.007	0.014	<0.001	<0.001	0.018	0.019
	28d	0.004	0.012	<0.001	<0.001	0.018	0.019
	50 d	<0.001	0.007	<0.001	<0.001	0.018	0.019
	100 d	<0.001	0.004	<0.001	<0.001	0.018	0.019
Plateau concentration	Soil depth: 20 cm	-	-	-	-	0.035 after 12 years	-

<u>**RMS (2016)**</u>

Actual and accumulation PECsoil were calculated by RMS and are used for risk assessment.

B.8.3. Predicted environmental concentrations in ground water (PEC_{GW})

The predicted groundwater concentrations (PEC_{gw}) of indoxacarb (DPX-KN128) and its soil degradates were determined using methods, scenarios, and models specified by the FOCUS Groundwater report (FOCUS, 2002[7]). The FOCUS models PELMO (ver. 5.5.3), and PEARL (ver. 4.4.4) were used to generate the PEC_{gw} values in order to assess the potentially safe use regions in the context of EU active substance renewal. Each scenario involves a fixed combination of crop, soil, and climatic parameters to represent the range of conditions across Europe. PEC_{gw} values were generated to simulate applications of Indoxacarb 150 g/L EC to maize and lettuce in EU.

Table 12: Application regimes simulated for indoxacarb and its metabolite for PECgw calculations

Crop group	FOCUS scenario	Application rate (kg a.s./ha)	Number of applications	Minimum application interval (days)	Application timing	Crop interception (%)
Maize	Maize	0.0375	2	20	BBCH 34-77	50%/75%
Lettuce	Cabbage	0.0375	4	7	BBCH 13-49	25%

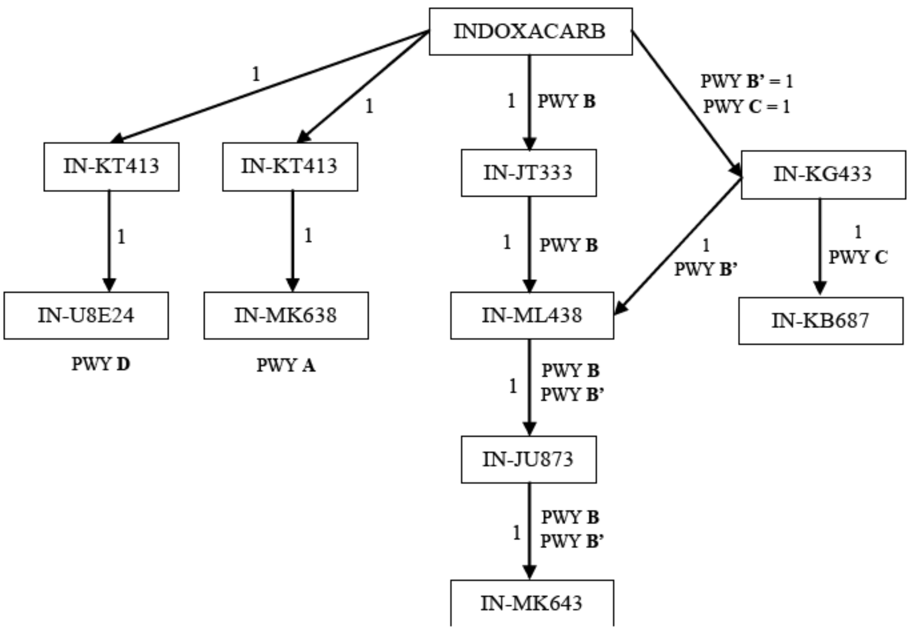
Simulated pathways

Applicant initially considered that a robust formation fraction of 0.24 was only available for the primary metabolite IN-JT333. For all other metabolites a conservative formation fraction of 1.00 was assumed in order to represent worst-case conditions.

The ffm of 0.24 was not accepted by RMS (see kinetics evaluation of degradation rate in Volume 3 – B.8 (AS) for details) and thus RMS proposes to retain default ffm of 1 for metabolite IN-JT333 as well. The simulated pathways were thus modified by RMS and calculation were done again for the concerned metabolites

These worst-case assumptions concerning the formation fractions led to a schematic degradation of compounds of more than 100%, as demonstrated in Figure 1. This issue was addressed by simulating five sets of pathways independently and choosing the worst-case PEC_{gw} value for the relevant compounds.

Figure 1: Schematic pathway describing the degradation of indoxacarb (RMS)



7 FOCUS (2002): Generic guidance for FOCUS groundwater scenarios. Version 1.1, April 2002.

Table 13: Key input parameters used in PEC_{gw} simulations for indoxacarb and its soil metabolites

Parameter	Compound	Value	Units	Reference
Molecular weight	Indoxacarb	528	g/mol	
	IN-JT333	470		
	IN-JU873	458		
	IN-ML438	379		
	IN-KG433	516		
	IN-MK643	218		
	IN-MK638	220		
	IN-KT413	514		
	IN-KB687	235		
	IN-U8E24	478		
Water Solubility (25°C)	Indoxacarb and all metabolites	0.2	mg/L	
Vapour Pressure (20°C)	Indoxacarb and all metabolites	9.8×10^{-9}	Pa	
Freundlich Organic Matter Sorption Coefficients (K_{fom})				
arithmetic mean (n = 4)	Indoxacarb	2973	mL/g	See Volume 3 – B8 (SA)
arithmetic mean (n = 4)	IN-JT333	10035		
arithmetic mean (n = 4)	IN-JU873	7637		
arithmetic mean (n = 4)	IN-ML438	11369		
arithmetic mean (n = 5)	IN-KG433	182		
arithmetic mean (n = 5)	IN-MK643	156		
arithmetic mean (n = 5)	IN-MK638	88		
arithmetic mean (n = 4)	IN-KT413	200		
arithmetic mean (n = 5)	IN-KB687	138		
-	IN-U8E24	-		See RMS comments
Freundlich sorption exponent (1/n)				
worst-case default	Indoxacarb	1.00	-	See Volume 3 – B8 (SA)
worst-case default	IN-JT333	1.00		
arithmetic mean (n = 5)	IN-JU873	0.99		
worst case default	IN-ML438	1.00		
arithmetic mean (n = 5)	IN-KG433	0.92		
arithmetic mean (n = 5)	IN-MK643	0.81		
arithmetic mean (n = 5)	IN-MK638	0.84		
arithmetic mean (n = 4)	IN-KT413	0.95		
arithmetic mean (n = 5)	IN-KB687	0.85		
-	IN-U8E24	-		See RMS comments
Freundlich organic carbon sorption coefficients (K_{foc})				
arithmetic mean (n = 4)	Indoxacarb	5125	mL/g	See Volume 3 – B8 (SA)
arithmetic mean (n = 4)	IN-JT333	17300		
arithmetic mean (n = 4)	IN-JU873	13167		
arithmetic mean (n = 4)	IN-ML438	19601		
arithmetic mean (n = 5)	IN-KG433	314		
arithmetic mean (n = 5)	IN-MK643	269		
arithmetic mean (n = 5)	IN-MK638	151		
arithmetic mean (n = 4)	IN-KT413	344		
arithmetic mean (n = 5)	IN-KB687	237		
-	IN-U8E24	-		See RMS comments

Formation fractions				
worst-case assumption	Ind → IN-JT333	1.00	-	See Volume 3 – B8 (SA)
worst-case-default	Ind → IN-KG433	1.00		
worst-case-default	Ind → IN-KT413	1.00		
worst-case default	IN-JT333 → IN-JU873	1.00		
worst-case default	IN-JU873 → IN-ML438	1.00		
worst-case default	IN-ML438 → IN-MK643	1.00		
worst-case default	IN-KG433 → IN-JU873	1.00		
worst-case default	IN-KG433 → IN-KB687	1.00		
worst-case default	IN-KT413 → IN-MK638	1.00		
worst-case default	IN-KT413 → IN-U8E24	1.00		
Laboratory soil $DegT_{50}$				
geometric mean lab (n = 3)	Indoxacarb	32.1*	days	See Volume 3 – B8 (SA)
geometric mean lab (n = 7)	IN-JT333	16.4		
geometric mean lab (n = 5)	IN-JU873	32.1		
geometric mean lab (n = 6)	IN-ML438	73.7		
geometric mean lab (n = 5)	IN-KG433	4.2		
geometric mean lab (n = 5)	IN-MK643	169.5		
geometric mean lab (n = 5)	IN-MK638	8.7		
geometric mean lab (n=3)	IN-KT413	1.7		
maximum value lab (n = 2)	IN-KB687	0.67		
-	IN-U8E24	-		See RMS comments
Plant uptake worst-case default	Indoxacarb and all metabolites	0.0		FOCUS recommendation
Q_{10}	Indoxacarb and all metabolites	2.58		EFSA recommentation

* The geomean for indoxacarb was recalculated to be 32.1 days by RMS. In PECgw calculated by applicant, and kept by RMS (pathway A) the initial value of 39.9 days proposed by applicant was used, but it is not considered to impact significantly the results. In uptdated PECgw recalculated by RMS (pathways B, B' and C), the value of 32.1 days was used.

Application dates

Table 14: Application dates assumed for the simulation of PECgw

Focus Crop	First possible BBCH stage	Reference event	Application date relative to reference event (days)
Maize	34	Emergence	+ 25
Cabbage (lettuce)	13	Emergence	+ 7

Results obtained by FOCUS PEARL and FOCUS PELMO are summarised below (80^{th} percentile average annual PEC_{gw} at 1-m depth) for indoxacarb and its soil metabolites associated with early season and late season uses on cabbage (4 × 37.5 g a.s./ha, interval 7 d) and on maize (2 × 37.5 g a.s./ha, interval 20 d) in Europe.

FINDINGS

In tables of results presented below, PECgw for metabolites IN-KT413 and IN-MK638 are PECgw initially proposed by applicant and validated by RMS. PECgw for metabolites IN-JT333, IN-JU873, IN-ML438, IN-MK643, IN-KG433, IN-KB687 (changes in the simulated pathway) were recalculated by RMS.

PECgw proposed by applicant for metabolite IN-U8E24 were not validated by RMS since the DT_{50} and Koc value used for calculation were not considered reliable. No recalculation was made by RMS, and a data gap is proposed (see RMS comments).

Results from PEARL

Table 15: FOCUS PEARL predicted 80th percentile PEC_{gw} at 1-m depth for indoxacarb and its metabolites after applications to cabbage (4 × 37.5 g a.s./ha, interval 7 d, early season) in Europe

80th Percentile PEC_{gw} (µg/L)[a]										
Scenario	**Indoxacarb**	**IN-JT333**	**IN-JU873**	**IN-ML438**	**IN-KG433**	**IN-MK643**	**IN-MK638**	**IN-KT413**	**IN-KB687**	**IN-U8E24**
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	See RMS comments
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	

[a] Results from all degradation pathways (A, B, C, and D) were combined.

Table 16: FOCUS PEARL predicted 80th percentile PEC_{gw} at 1-m depth for indoxacarb and its metabolites after applications to cabbage (4 × 37.5 g a.s./ha, interval 7 d, late season) in Europe

80th Percentile PEC_{gw} (µg/L)[a]										
Scenario	**Indoxacarb**	**IN-JT333**	**IN-JU873**	**IN-ML438**	**IN-KG433**	**IN-MK643**	**IN-MK638**	**IN-KT413**	**IN-KB687**	**IN-U8E24**
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	See RMS comments
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	

[a] Results from all degradation pathways (A, B, C, and D) were combined.

Table 17: FOCUS PEARL predicted 80th percentile PEC_{gw} at 1-m depth for indoxacarb and its metabolites after applications to maize (2 × 37.5 g a.s./ha, interval 20 d) in Europe

80th Percentile PEC_{gw} (µg/L)[a]										
Scenario	**Indoxacarb**	**IN-JT333**	**IN-JU873**	**IN-ML438**	**IN-KG433**	**IN-MK643**	**IN-MK638**	**IN-KT413**	**IN-KB687**	**IN-U8E24**
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	See RMS comments
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	

[a] Results from all degradation pathways (A, B, C, and D) were combined.

<u>Results from PELMO</u>

Table 18: FOCUS PELMO predicted 80th percentile PEC$_{gw}$ at 1-m depth for indoxacarb and its metabolites after applications to cabbage. (4 × 37.5 g a.s./ha, interval 7 d, early season) in Europe

80th Percentile PEC$_{gw}$ (µg/L)[a]										
Scenario	**Indoxacarb**	**IN-JT333**	**IN-JU873**	**IN-ML438**	**IN-KG433**	**IN-MK643**	**IN-MK638**	**IN-KT413**	**IN-KB687**	**IN-U8E24**
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	See RMS comments
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Jokioinen	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	

[a] Results from all degradation pathways (A, B, C, and D) were combined.

Table 19: FOCUS PELMO predicted 80th percentile PEC$_{gw}$ at 1-m depth for indoxacarb and its metabolites after applications to cabbage. (4 × 37.5 g a.s./ha, interval 7 d, late season) in Europe

80th Percentile PEC$_{gw}$ (µg/L)[a]										
Scenario	**Indoxacarb**	**IN-JT333**	**IN-JU873**	**IN-ML438**	**IN-KG433**	**IN-MK643**	**IN-MK638**	**IN-KT413**	**IN-KB687**	**IN-U8E24**
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	See RMS comments
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	0.001	<0.001	<0.001	<0.001	
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	0.002	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	

[a] Results from all degradation pathways (A, B, C, and D) were combined.

Table 20: FOCUS PELMO predicted 80th percentile PEC$_{gw}$ at 1-m depth for indoxacarb and its metabolites after applications to maize. (2 × 37.5 g a.s./ha, interval 20 d) in Europe

80th Percentile PEC$_{gw}$ (µg/L)[a]										
Scenario	**Indoxacarb**	**IN-JT333**	**IN-JU873**	**IN-ML438**	**IN-KG433**	**IN-MK643**	**IN-MK638**	**IN-KT413**	**IN-KB687**	**IN-U8E24**
Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	See RMS comments
Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Kremsmünster	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Okehampton	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Piacenza	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Porto	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Sevilla	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	
Thiva	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	

[a] Results from all degradation pathways (A, B, C, and D) were combined.

In all use/ scenario combinations, maximum PEC$_{gw}$ values did not exceed the regulatory threshold concentration of 0.1 µg/L for the parent compound and any of its metabolites.

RMS (2016)

RMS did not agree with the ffm of 0.24 initially proposed by applicant for IN-JT333 as the kinetic evaluation showed that the fit for the associated DT_{50} for IN-JT333 was not acceptable (see point B8.1.1.2.1.3. of Voume_3CA_B8 for details). RMS thus modified the initial schematic degradation pathway proposed by applicant and recalculate the PECgw for the metabolites IN-JT333, IN-JU873, IN-ML438, IN-MK643, IN-KG433, IN-KB687.It is however noticeable that no significant changes were observed in the results, all PECgw were <0.1 µg/l for all metabolites (max 0.002 µg/L), for all representative scenarios.

Metabolite IN-U8E24: for this metabolite which was seen as major during the first aerobic phase of the anaerobic study, applicant proposed PECgw calculation considering a Koc value of 1910 mL/g calculated with EPIsuite and DT_{50} calculated from the anaerobic degradation data. All PECgw results were <0.001 µg/L. However,

- RMS considered that the K_{OC} determination with EPIsuite could not be considered reliable. Indeed, comparison was made with metabolite IN-KT413 which has a very similar structure: the Koc values predicted by the model EPISuite for these two metabolites were indeed similar (1910 and 1991 mL/g), but were much higher than the Kfoc value determined for IN-KT413 from batch equilibrium study (mean of 344 mL/g).
- RMS considered that the DT_{50} calculated from the anaerobic data could obviously not be representative of aerobic conditions.

As indicated in Volume 3 – B8 (SA), RMS proposes a data gap for the determination of Kfoc value and aerobic DT_{50} for metabolite IN-U8E24. Updated risk assessment for ground water contamination should be provided when these data are available.

For information, PECgw for metabolite IN-U8E24 calculated with Koc of 344 mL/g (1/n = 0.95) and DT_{50} of 141 days (re-evaluation of anaerobic data) would give the following results:

Table 21: PECgw for IN-U8E24 for maize calculated with PELMO 5.5.3

Scenario	**IN-U8E24**
Châteaudun	0.017
Hamburg	0.037
Kremsmünster	0.041
Okehampton	0.057
Piacenza	0.068
Porto	0.032
Sevilla	0.000
Thiva	0.005

Table 22: PECgw for IN-U8E24 for cabbage (early and late) calculated with PELMO 5.5.3

Scenario	IN-U8E24
Early	
Châteaudun	0.084
Hamburg	0.164
Jokionen	0.038
Kremsmünster	0.164
Porto	0.185
Sevilla	0.001
Late	
Châteaudun	0.072
Hamburg	0.190
Kremsmünster	0.178
Porto	0.173
Sevilla	0.001
Thiva	0.017

B.8.4. FATE AND BEHAVIOUR IN WATER AND SEDIMENT

B.8.4.1. Aerobic mineralisation in surface water

No aerobic mineralisation studies were conducted with formulation. See Volume 3 – B.8 (AS) for studies with active substance.

B.8.4.2. Water/sediment study

No water/sediment studies were conducted with formulation. See Volume 3 – B.8 (AS) for studies with active substance.

B.8.4.3. Irradiated water/sediment study

No irradiated water/sediment studies were conducted with formulation. See Volume 3 – B.8 (AS) for studies with active substance.

B.8.5. PREDICTED ENVIRONMENTAL CONCENTRATIONS IN SURFACE WATER AND SEDIMENT (PEC_{SW}, PEC_{SD})

Predicted environmental concentrations of indoxacarb and its major soil and water metabolites (IN-JT333, IN-JU873, IN-KB687, IN-KG433, IN-KT413, IN-ML438, IN-MK638, IN-MK643, IN-MP819, IN-MS775, IN-U8E24, and IN-UYG24) were calculated in surface water (PEC_{sw}) and sediment (PEC_{sed}) after application to the following representative uses:

- maize (2 × 37.5 g a.s./ha, 20 days application interval),
- leafy vegetables (lettuce) (4 × 37.5 g a.s./ha, 7 days application interval).

The predicted surface water (PEC_{sw}) and sediment (PEC_{sed}) concentrations of indoxacarb and relevant soil and aquatic metabolites were determined using a tiered approach based on the FOCUS standard (FOCUS, 2012).

Step 1-2 simulations

PEC_{sw} and PEC_{sed} values for the parent and IN-JT333, IN-JU873, IN-KB687, IN-KG433, IN-KT413, IN-ML438, IN-MK638, IN-MK643, IN-MP819, IN-MS775, IN-U8E24, and IN-UYG24 were determined using the FOCUS Step 1-2 calculator ver. 2.1. All applications summarized in Table 23 were simulated at Step 1-2.

Table 23: Application regimes simulated for indoxacarb in surface water in Europe

Focus Crop	Appl. Rate (g a.s./ha)	Interval (days)	BBCH Growth Stage[a]	Focus Interception[b] (%)	Appl. Method	Step 1-2 Southern And Northern Europe season
Maize	2 × 37.5	20	34	50 (intermediate)	Spray	March – May, June-Sept
Vegetables leafy (lettuce)	4 × 37.5	7	13-89	25 (minimal)	Spray	March – May June-Sept, Oct-Feb

[a] Growth stage at first application
[b] Based on FOCUS surface water report (2012)

Step 1-2 key input parameters for indoxacarb and its degradation products are summarized in Table 24. Details of endpoints determination can be found in the Volume 3 – B8 (AS).

For some of the water metabolites (IN-MP819, IN-MS775, IN-U8E24 and IN-UYE24) no Kfoc values were available. Thus the following default values were retained:

- For IN-U8E24 and IN-UYE24, Kfoc value was set to default value 0, since the Koc value modelled with EPIsuite are not considered reliable by RMS. This default value provides a worst-case assessment for water compartment (only PECsw are used for assessment for these 2 metabolites, see Volume 3 – B9 (PPP) for details).

- For IN-MS775 and IN-MP819, applicant proposed to use the Kfoc = 19601 mL/g of metabolite IN-ML438 based on similarity of structure. This was accepted by RMS since this very high Koc reflects the behaviour of these 2 metabolites in water-sediment compartment (metabolite only detected in sediment and never detected in the water column).

Finally for IN-U8E24, which is also considered as soil metabolite, default worst-case DT_{50} of 1000 days was used, since no aerobic reliable DT_{50} is available.

Table 24 : Key input parameters used in PEC_{sw} Step 1-2 simulations for indoxacarb and its soil and water/ sediment metabolites

Parameter	Compound	Value	Units	Reference
Molecular weight	Indoxacarb IN-JT333 IN-JU873 IN-ML438 IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819 IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	528 470 458 379 516 218 220 514 470 412 235 478 318	g/mol	
Water Solubility (25°C)	Indoxacarb & all metabolites	0.2	mg/L	
Organic Carbon Sorption Coefficients (K_{FOC}) arithmetic mean (n = 4) arithmetic mean (n = 4) arithmetic mean (n = 4) arithmetic mean (n = 4) arithmetic mean (n = 5) arithmetic mean (n = 5) arithmetic mean (n = 5) arithmetic mean (n = 4) estimated based on structural similarity to IN-ML438 estimated based on structural similarity to IN-ML438 arithmetic mean (n = 5) single value single value	 Indoxacarb IN-JT333 IN-JU873 IN-ML438 IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819 IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	 5125 17300 13167 19601 314 269 151 344 19601 19601 237 0 0	 mL/g	 See Volume 3 – B8 (SA) Default worst-case Kfoc
Freundlich sorption exponent (1/n) worst-case default worst-case default	 Indoxacarb IN-JT333	 1.00 1.00	 - -	
Laboratory Soil $DegT_{50}$ geometric mean lab (n = 3) geometric mean lab (n = 6) geometric mean lab (n = 5) geometric mean lab (n = 6) geometric mean lab (n = 5) geometric mean lab (n = 5) geometric mean lab (n = 5) geometric mean lab (n = 3) default, not detected in soil default, not detected in soil geometric mean lab (n = 2) default worst-case default, not detected in soil	 Indoxacarb IN-JT333 IN-JU873 IN-ML438 IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819 IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	 39.9* 16.4 32.1 73.7 4.2 169.5 8.7 1.7 1×10^{-10} 1×10^{-10} 0.67 1000 1×10^{-10}	 days	 See Volume 3 – B8 (SA) Default worst-case
	* RMS recalculated the geomean value of indoxacarb being 32.1 days.			
DT_{50} in total system geometric mean (n = 4) geometric mean (n = 6) default geometric mean (n = 2)	 Indoxacarb IN-JT333 IN-JU873 IN-ML438	 5.8 60.4 1000 213.1	 days	 See Volume 3 – B8 (SA)

default default default geometric mean (n = 7) default default default geometric mean (n = 4) geometric mean (n = 2)	IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819 IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	1000 1000 1000 28 1000 1000 1000 393.2 118.7		
DT_{50} in Water geometric mean (n = 4) geometric mean (n = 6) default geometric mean (n = 2) default default default geometric mean (n = 7) default default default geometric mean (n = 4) geometric mean (n = 2)	 Indoxacarb IN-JT333 IN-JU873 IN-ML438 IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819 IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	 5.8 60.4 1000 213.1 1000 1000 1000 28 1000 1000 1000 393.2 118.7	 days	 See Volume 3 – B8 (SA)
DT_{50} in Sediment geometric mean (n = 4) geometric mean (n = 6) default geometric mean (n = 2) default default default geometric mean (n = 7) default default default geometric mean (n = 4) geometric mean (n = 2)	 Indoxacarb IN-JT333 IN-JU873 IN-ML438 IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819 IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	 5.8 60.4 1000 213.1 1000 1000 1000 28 1000 1000 1000 393.2 118.7	 days	 See Volume 3 – B8 (SA)
Maximum occurrence in soil aerobic soil degradation study aerobic soil degradation study aerobic soil degradation study aerobic soil degradation study aerobic soil degradation study aerobic soil degradation study aerobic soil degradation study default, not detected in soil-default, not detected in soil soil photolysis study aerobic phase of anaerobic degradation study default, not detected in soil	 IN-JT333 IN-JU873 IN-ML438 IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819 IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	 18.6 12.9 9.7 39.7 12.0 28.1 18.4 1.6 1×10^{-10} 22.0 13.8 1×10^{-10}	 % AR	 See Volume 3 – B8 (SA)
Maximum occurrence in water/ sediment water/ sediment study default, not detected in water/ sediment water/ sediment study water/ sediment study default, not detected in water/ sediment water/ sediment study hydrolysis study (pH 9) water/ sediment study	 IN-JT333 IN-JU873 IN-ML438 IN-KG433 IN-MK643 IN-MK638 IN-KT413 IN-MP819	 25.7 1×10^{-10} 3.6 7.7 1×10^{-10} 26.9* 90.8 21.3	 % AR	 See Volume 3 – B8 (SA)

water/ sediment study aquatic photolysis study (pH 5) water/ sediment study water/ sediment study	IN-MS775 IN-KB687 IN-U8E24 IN-UYG24	14.7 28.7 24.3 31.6		

[a] Summarised in this document

* Metabolite IN-MK638 level in sediment reaches 9% and is still increasing at the end of the study in the Chula system. As it is formed in sediment from metabolite IN-MP819, it is considered by default that all the remaining residue of IN-MP819 at the end of the study is transformed into IN-MK638. Maximum occurrence of 26.9% is used in PEC calculations.

Step 3 simulations

Step 3 simulations were carried out only for those compounds that did not pass the environmental risk assessment at Step 2, using a variety of tools (SWASH ver 3.1; MACRO ver. 4.4.2; PRZM ver. 3.1.1 and TOXSWA ver. 3.3.1). Step 3 key input parameters for indoxacarb and its metabolite in sediment IN-JT333 are summarized in Table 25. As the formation of metabolites in water bodies and sediment cannot be simulated straightforward using the SWASH tool (FOCUS, 2012), an initial concentration of the metabolite in sediment has to be calculated manually and added to the sediment at the beginning of the TOXSWA simulation.

Table 25: Key input parameters used in PEC_{sw} STEP 3-4 simulations for indoxacarb and IN-JT333

Parameter	Compound	Value	Units	Reference
Wash-off: MACRO PRZM	Indoxacarb and IN-JT333	0.05 0.50	1/mm 1/cm	FOCUS recommendation
Water solubility (25°):	Indoxacarb and IN-JT333	0.2	mg/L	Indoxacarb EU Renewal Dossier, Document M-CA, Section 2, DuPont-41106 EU
Crop uptake factor:	Indoxacarb and IN-JT333	0	Unitless	FOCUS recommendation
Vapour pressure (20°C):	Indoxacarb and IN-JT333	9.8×10^{-9}	Pa	Indoxacarb EU Renewal Dossier, Document M-CA, Section 2, DuPont-41106 EU
Molecular weight:	Indoxacarb IN-JT333	528 470	g/mol	Indoxacarb EU Renewal Dossier, Document N, Part 3, DuPont-41117 EU
Freundlich K_{FOC}: arithmetic mean (n = 4) arithmetic mean (n = 4)	Indoxacarb IN-JT333	5125 17300	mL/g	DuPont-36913 EU[a]
Freundlich 1/n: linear sorption linear sorption	Indoxacarb IN-JT333	1 1	Unitless	DuPont-36913 EU[a]
Half-life in soil: geometric mean lab (n = 3) geometric mean lab (n = 7)	Indoxacarb IN-JT333	39.9* 16.4	Days	DuPont-36913 EU[a]
Water phase DT_{50}:default default	Indoxacarb IN-JT333	1000 1000	Days	DuPont-36913 EU[a]
Sediment phase DT_{50}: geometric mean (n = 5) geometric mean (n =5)	Indoxacarb IN-JT333	5.8 66.2	Days	DuPont-36913 EU[a]
Maximum occurrence in water/ sediment	IN-JT333	25.7	% AR	DuPont-36913 EU[a]

[a] Summarised in this document

* Geomean finally recalculated and retained by RMS is 32.1 days for indoxacarb. However, calculation were not done again, and considered worst-case.

The following application windows were selected for simulation. Application in maize took place at emergence +25 days and in lettuce at emergence +7 days.

Table 26: Application dates for indoxacarb in the FOCUS Step 3 and Step 4 scenarios following application to various crops in Europe

Crop	Location[a]	Date of emergence	Application window	Julian days	Application dates found by PAT[b]
Maize (1 × 37.5 g a.s./ha)	D3	05-May	30-May - 29-Jun	150-180	21-Jun
	D4	10-May	4-Jun - 4-Jul	155-185	4-Jun
	D5	10-May	4-Jun - 4-Jul	155-185	9-Jun
	D6	20-Apr	15-May - 14-Jun	135-165	20-May
	R1	03-May	28-May - 27-Jun	148-178	13-Jun
	R2	01-May	26-May - 25-Jun	146-176	26-May
	R3	01-May	26-May - 25-Jun	146-176	1-Jun
	R4	10-Apr	5-May - 4-Jun	125-155	5-May
Maize (2 × 37.5 g a.s./ha)	D3	05-May	30-May - 19-Jul	150-200	21-Jun, 11-Jul
	D4	10-May	4-Jun - 24-Jul	155-205	4-Jun, 4-Jul
	D5	10-May	4-Jun - 24-Jul	155-205	9-Jun, 19-Jul
	D6	20-Apr	15-May - 4-Jul	135-185	20-May, 20-Jun
	R1	03-May	28-May - 17-Jul	148-198	13-Jun, 5-Jul
	R2	01-May	26-May - 15-Jul	146-196	26-May, 25-Jun
	R3	01-May	26-May - 15-Jul	146-196	1-Jun, 29-Jun
	R4	10-Apr	5-May - 24-Jun	125-175	5-May, 27-May
Leafy Vegetables (lettuce) (1 × 37.5 g a.s./ha)	D3 (1st)	25-Apr	2-May - 1-Jun	122-152	4-May
	D3 (2nd)	05-Aug	12-Aug - 11-Sep	224-254	18-Aug
	D4	10-May	17-May - 16-Jun	137-167	17-May
	D6	15-Aug	22-Aug - 21-Sep	234-264	25-Aug
	R1 (1st)	20-Apr	27-Apr - 27-May	117-147	27-Apr
	R1 (2nd)	31-Jul	7-Aug - 6-Sep	219-249	20-Aug
	R2 (1st)	28-Feb	7-Mar - 6-Apr	66-96	22-Mar
	R2 (2nd)	31-Jul	7-Aug - 6-Sep	219-249	7-Aug
	R3 (1st)	01-Mar	8-Mar - 7-Apr	67-97	10-Mar
	R3 (2nd)	15-Jun	22-Jun - 22-Jul	173-203	25-Jun
	R4 (1st)	01-Mar	8-Mar - 7-Apr	67-97	8-Mar
	R4 (2nd)	15-Jun	22-Jun - 22-Jul	173-203	23-Jun
Leafy Vegetables (lettuce) (4 × 37.5 g a.s./ha)	D3 (1st)	25-Apr	2-May - 22-Jun	122-173	4-May, 14-May, 22-May, 29-May
	D3 (2nd)	05-Aug	12-Aug - 2-Oct	224-275	18-Aug, 17-Sep, 24-Sep, 1-Oct
	D4	10-May	17-May - 7-Jul	137-188	17-May, 29-May, 19-Jun, 2-Jul
	D6	15-Aug	22-Aug - 12-Oct	234-285	25-Aug, 1-Sep, 15-Sep, 23-Sep
	R1 (1st)	20-Apr	27-Apr - 17-Jun	117-168	27-Apr, 8-May, 15-May, 31-May
	R1 (2nd)	31-Jul	7-Aug - 27-Sep	219-270	20-Aug, 2-Sep, 13-Sep, 20-Sep
	R2 (1st)	28-Feb	7-Mar - 27-Apr	66-117	7-Mar, 14-Mar, 21-Mar, 29-Mar
	R2 (2nd)	31-Jul	7-Aug - 27-Sep	219-270	7-Aug, 14-Aug, 19-Sep, 26-Sep
	R3 (1st)	01-Mar	7-Mar - 28-Apr	66-118	10-Mar, 28-Mar, 4-Apr, 11-Apr
	R3 (2nd)	15-Jun	22-Jun - 12-Aug	173-224	25-Jun, 6-Jul, 18-Jul, 25-Jul
	R4 (1st)	01-Mar	8-Mar - 28-Apr	67-118	8-Mar, 3-Apr, 14-Apr, 23-Apr
	R4 (2nd)	15-Jun	22-Jun - 12-Aug	173-224	23-Jun, 30-Jun, 12-Jul, 24-Jul

[a] Scenarios are intended to represent agricultural regions of Europe, not specific locations.

[b] PAT is pesticide application timing calculator in MACRO and PRZM model. Selects application date as a function of proximity to rainfall events as defined in the FOCUS surface water report (FOCUS, 2001[8], 2012).

[8] FOCUS (2001): FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001 rev. 2, 245 pp.

Metabolite PEC_{sed} simulations in Step 3

The metabolite IN-JT333 did not pass the environmental risk assessment at Step 2, and therefore an assessment at Step 3 was necessary. However the FOCUS SWASH model package has some inherent restrictions concerning the simulation of metabolites. Metabolites can only enter the water body *via* the soil passage. Within the water body TOXSWA simulates the fate of the metabolite but is not able to simulate the formation of metabolites. Two general situations (and their combination) are possible:

1) The metabolite is detected in the soil.

2) The metabolite is detected in the water/ sediment system
   a. The metabolite is detected in the water column.
   b. The metabolite is detected in the sediment.

FOCUS (2012) recommends the following approaches for the three situations:

1) Metabolites occurring in soil solely can be simulated using PRZM (simulation of two primary metabolites is possible) and MACRO (simulation of one primary metabolite is possible). The metabolites consequently enter the water body via runoff and/ or drainage, an input *via* drift is not considered. TOXSWA subsequently simulates the behavior of the metabolite within the water body. This situation can be simulated with the standard SWASH package without any modifications.

2) Metabolites occurring in water/ sediment systems cannot readily be simulated with the SWASH package, because the TOXSWA model is not able to simulate the formation of metabolites in the water body. That means that TOXSWA simulates the fate of metabolites in water and sediment, but their entry into the water body has to be defined by the user. FOCUS (2012) recommends first comparing the time of formation of the metabolite (i.e. the days until their maximum occurrence) to the mean residence time in the water bodies. If the residence time is shorter than the time of formation, then the parent substance has probably flowed out before formation of the metabolite. Consequently the formation of the metabolite is negligible. If the time of formation is shorter than the residence time, than the metabolite has to be considered in the risk assessment.

   a. Metabolites occurring in the water column solely cannot readily be simulated with the SWASH package, because the TOXSWA model is not able to simulate the formation of metabolites in the water body. FOCUS (2012, p. 127) recommends inserting the metabolite as an artificial spray drift entry on the day and in the amount of its maximum occurrence.

   b. According to point 2 above, metabolites occurring in sediment solely cannot readily be simulated with the SWASH package, because the TOXSWA model is not able to simulate the formation of metabolites in the water body. FOCUS (2012, p. 127) recommends inserting the maximum percentage formed as an initial sediment concentration in the upper 5 cm of the sediment.

In case the metabolite occurs in more than one compartment the approaches should be combined.

In the case of indoxacarb, its metabolite IN-JT333 did not pass the environmental risk assessment at Step 2 after application to leafy vegetables (lettuce). IN-JT333 is a primary metabolite of indoxacarb which was detected in soil as well as in sediment. In order to represent formation in soil and the entry into the water body via runoff and drainage, the SWASH database was set up in the standard manner for parent and metabolite. Subsequently the simulations with PRZM, MACRO and TOXSWA were carried out. The comparison of the time of formation to the residence time in FOCUS water bodies (Table 27) yields that IN-JT333 formation is only relevant in ponds and ditches. Thus for the FOCUS pond scenarios the initial sediment concentration of IN-JT333 was calculated according to equations 9 to 11 (based on FOCUS, 2007) below.

This concentration was inserted into the txw-files for the metabolite. TOXSWA was subsequently run again to generate the PEC_{sed} values including the initial sediment concentration.

Table 27: Comparison of mean residence time in FOCUS water bodies to time of formation for IN-JT333

FOCUS water body	Mean residence time (days)[a]	Time of formation (days) of IN-JT333	Metabolite relevant in water body?
Stream	0.1		No
Ditch	5	14	Yes
Pond	150		Yes

[a] According to FOCUS (2012), p. 127

The following sediment concentrations were entered in the Txw files. RMS checked the results with SWASH drift calculator (Sediment concentration calculated based on the SWASH mass loading per drift event (mg/m²) over the volume of sediment (0.05 m^3/m^2 of water body), and converted into $\mu g/m^3$)

Water body	Sediment concentration 1 application	Sediment concentration 4 applications
Ditch	0.00033 $\mu g/m^3$	0.00089 $\mu g/m^3$
Pond	0.00000095 $\mu g/m^3$	0.000000065 $\mu g/m^3$

Step 4 simulations

At Step 4, the minimum drift buffer necessary to pass environmental risk assessment was introduced for each Step 3 scenario. Simulations were carried out with the SWAN ver. 3.0.0 tool and only for those scenarios that did not pass the environmental risk assessment at Step 3. As runoff was the main entry route for indoxacarb to surface waters at Step 3, a vegetated filter strip (VFS) was introduced at Step 4. The coefficient for run-off reduction used for 10m and 20 m of VFS were in accordance with Lanscape and mitigation guidance[9].

Buffer width (m)	10-12	18-20
Reduction in volume of runoff water (%)	60	80
Reduction in mass of pesticide transported in aqueous phase (%)	60	80
n (for aqueous phase)	*36*	*30*
Reduction in mass of eroded sediment (%)	85	95
Reduction in mass of pesticide transported in sediment phase (%)	85	95
n (for sediment phase)	*19*	*11*

Input parameters used in Step 4 simulations were similar to those in Step 3. See Table 25 for details.

[9] FOCUS (2007). "Landscape And Mitigation Factors In Aquatic Risk Assessment. Volume 1. Extended Summary and Recommendations". Report of the FOCUS Working Group on Landscape and Mitigation Factors in Ecological Risk Assessment, EC Document Reference SANCO/10422/2005 v2.0. 169 pp.

Results of the Step 1-2 simulations

MAIZE

Only results of STEP 2 PECsw and PECsed calculations for the worst-case application period were reported for each application zone, i.e. March-May for both Northern and Southern Europe.

Table 28: Summary of Step 1-2 maximum PEC_{sw} values of indoxacarb and its metabolites resulting from application of 37.5 g a.s./ha to maize (Mar-May)

Substance	Step 1 (All application periods)		Step 2 Northern Europe (March-May worst-case)		Step 2 Southern Europe (March-May worst-case)	
	Maximum Single PEC_{sw} (µg/L)	Maximum Multiple PEC_{sw} (µg/L)	Maximum Single PEC_{sw} (µg/L)	Maximum Multiple PEC_{sw} (µg/L)	Maximum Single PEC_{sw} (µg/L)	Maximum Multiple PEC_{sw} (µg/L)
Indoxacarb	1.941	1.941	0.345	0.310	0.345	0.546
IN-JT333	0.165	0.330	0.079	0.073	0.079	0.073
IN-JU873	0.075	0.151	0.007	0.011	0.014	0.023
IN-ML438	0.041	0.082	0.009	0.008	0.009	0.012
IN-KG433	3.444	6.889	0.197	0.219	0.374	0.402
IN-MK643	0.456	0.912	0.045	0.086	0.090	0.173
IN-MK638	1.232	2.463	0.120	0.166	0.209	0.272
IN-KT413	1.840	3.680	0.305	0.396	0.305	0.396
IN-MP819	0.089	0.178	0.083	0.077	0.083	0.077
IN-MS775	0.040	0.079	0.040	0.037	0.040	0.037
IN-KB687	0.975	1.950	0.044	0.071	0.044	0.071
IN-U8E24	0.516	3.546	0.329	0.637	0.593	1.141
IN-UYG24	0.066	0.131	0.066	0.107	0.066	0.107

Table 29: Summary of Step 1-2 maximum PECsed values of indoxacarb and its metabolites resulting from application of 37.5 g a.s./ha to maize (Mar-May)

Substance	Step 1		Step 2 Northern Europe		Step 2 Southern Europe	
	Maximum Single PEC_{sed} (µg/kg)	Maximum Multiple PEC_{sed} (µg/kg)	Maximum Single PEC_{sed} (µg/kg)	Maximum Multiple PEC_{sed} (µg/kg)	Maximum Single PEC_{sed} (µg/kg)	Maximum Multiple PEC_{sed} (µg/kg)
Indoxacarb	81.782	81.782	8.935	14.279	16.564	27.299
IN-JT333	15.267	30.535	1.781	2.633	3.038	4.428
IN-JU873	-	-	-	-	-	-
IN-ML438	6.333	12.666	0.668	1.214	1.273	2.321
IN-KG433	10.784	21.568	0.612	0.675	1.166	1.250
IN-MK643	-	-	-	-	-	-
IN-MK638	-	-	-	-	-	-
IN-KT413	5.854	11.707	0.737	1.006	0.838	1.107
IN-MP819	1.882	3.764	0.583	1.024	0.583	1.024
IN-MS775	0.286	0.571	0.279	0.490	0.279	0.490
IN-KB687	-	-	-	-	-	-
IN-U8E24	-	-	-	-	-	-
IN-UYG24	-	-	-	-	-	-

- PECsed not required for ecotox assessment, see section 6 for details.

LETTUCE

Only results of STEP 2 PECsw and PECsed calculations for the worst-case application period were reported for each application zone, i.e. Oct-Feb for both Northern and Southern Europe.

Table 30: Summary of Step 1-2 maximum PECsw values of indoxacarb and its metabolites resulting from application of 37.5 g a.s./ha to leafy vegetables

Substance	Step 1 (All application periods)		Step 2 Northern Europe (Oct-Feb worst-case)		Step 2 Southern Europe (March-May worst-case)	
	Maximum Single PEC_{sw} (µg/L)	Maximum Multiple PEC_{sw} (µg/L)	Maximum Single PEC_{sw} (µg/L)	Maximum Multiple PEC_{sw} (µg/L)	Maximum Single PEC_{sw} (µg/L)	Maximum Multiple PEC_{sw} (µg/L)
Indoxacarb	1.941	7.763	0.511	1.818	0.486	1.547
IN-JT333	0.165	0.660	0.079	0.071	0.079	0.071
IN-JU873	0.075	0.302	0.021	0.067	0.021	0.067
IN-ML438	0.041	0.164	0.010	0.035	0.010	0.035
IN-KG433	3.444	13.778	0.550	0.820	0.550	0.820
IN-MK643	0.456	1.825	0.135	0.516	0.135	0.516
IN-MK638	1.232	4.927	0.364	0.784	0.277	0.586
IN-KT413	1.840	7.359	0.320	0.720	0.28	0.700
IN-MP819	0.089	0.357	0.083	0.065	0.083	0.065
IN-MS775	0.040	0.158	0.040	0.031	0.040	0.031
IN-KB687	0.975	3.901	0.044	0.103	0.044	0.103
IN-U8E24	0.516	7.090	0.709	2.723	0.583	2.219
IN-UYG24	0.066	0.262	0.066	0.160	0.066	0.160

Table 31: Summary of Step 1-2 maximum PEC_{sed} values of indoxacarb and its metabolites resulting from application of 37.5 g a.s./ha to leafy vegetables (Oct-Feb)

Substance	Step 1 (All application periods)		Step 2 Northern Europe (Oct-Feb worst-case)		Step 2 Southern Europe (March-May worst-case)	
	Maximum Single PEC_{sed} (µg/kg)	Maximum Multiple PEC_{sed} (µg/kg)	Maximum Single PEC_{sed} (µg/kg)	Maximum Multiple PEC_{sed} (µg/kg)	Maximum Single PEC_{sed} (µg/kg)	Maximum Multiple PEC_{sed} (µg/kg)
Indoxacarb	81.782	327.128	26.196	92.404	23.802	74.220
IN-JT333	15.267	61.069	4.294	11.481	3.540	9.439
IN-JU873	-	-	-	-	-	-
IN-ML438	6.333	25.332	1.879	6.765	1.516	5.445
IN-KG433	10.784	43.136	1.720	2.557	1.388	2.076
IN-MK643	-	-	-	-	-	-
IN-MK638	-	-	-	-	-	-
IN-KT413	5.854	23.414	0.938	1.672	0.938	1.672
IN-MP819	1.882	7.528	0.583	1.564	0.583	1.564
IN-MS775	0.286	1.142	0.279	0.749	0.279	0.749
IN-KB687	-	-	-	-	-	-
IN-U8E24	-	-	-	-	-	-
IN-UYG24	-	-	-	-	-	-

- PECsed not required for ecotox assessment, see section 6 for details.

Results of the Step 3 simulations

Maize

Table 32: Summary of maximum Step 3 PEC_{sw} and PEC_{sed} values for indoxacarb following single and multiple applications to maize

Scenarios	Single application 1 × 37.5 g a.s./ha			Multiple application 2 × 37.5 g a.s./ha		
	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} caused by	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} caused by
D3, ditch	**0.195**	0.104	Drift	**0.170**	0.100	Drift
D4, pond	0.008	0.025	Drift	0.010	0.033	Drift
D4,stream	**0.170**	0.014	Drift	0.148	0.015	Drift
D5, pond	0.008	0.024	Drift	0.010	0.029	Drift
D5,stream	0.180	0.012	Drift	0.165	0.043	Drift
D6, ditch	0.193	0.055	Drift	**0.171**	0.141	Drift
R1, pond	0.011	0.042	Runoff	0.014	0.083	Drift
R1,stream	0.136	**0.315**	Drift	0.117	**0.316**	Drift
R2,stream	**0.182**	**0.651**	Drift	0.157	**0.651**	Drift
R3,stream	**0.192**	0.253	Drift	0.165	**0.715**	Drift
R4,stream	0.134	**0.667**	Runoff	0.159	**0.667**	Runoff

Lettuce

Table 33: Summary of maximum Step 3 PEC_{sw} and PEC_{sed} values for indoxacarb following single and multiple applications to leafy vegetables

Scenarios	Single application 1 × 37.5 g a.s./ha			Multiple application 4 × 37.5 g a.s./ha		
	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} caused by	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} caused by
D3, ditch (1st)	**0.237**	0.137	Drift	0.160	0.139	Drift
D3, ditch (2nd)	**0.237**	0.135	Drift	0.160	0.130	Drift
D4, pond (1st)	0.008	0.029	Drift	0.014	0.050	Drift
D4, stream (1st)	**0.189**	0.010	Drift	0.127	0.007	Drift
D6, ditch (1st)	**0.232**	0.047	Drift	0.159	0.069	Drift
R1, pond (1st)	0.013	0.050	Runoff	0.057	0.218	Runoff
R1, pond (2nd)	0.017	0.113	Runoff	0.084	0.551	Runoff
R1, stream (1st)	0.156	**0.426**	Drift	**0.215**	**3.168**	Runoff
R1, stream (2nd)	0.157	**0.373**	Drift	**0.177**	**2.164**	Runoff
R2, stream (1st)	**0.206**	**0.721**	Drift	0.139	**2.640**	Drift
R2, stream (2nd)	**0.210**	**0.722**	Drift	0.141	**2.572**	Drift
R3, stream (1st)	**0.219**	0.178	Drift	**0.277**	**1.217**	Runoff
R3, stream (2nd)	**0.220**	**0.443**	Drift	0.169	**0.984**	Runoff
R4, stream (1st)	0.156	0.124	Drift	**0.385**	**0.975**	Runoff
R4, stream (2nd)	0.155	0.206	Drift	**0.280**	**0.453**	Runoff

Table 34: Summary of maximum Step 3 PEC_{sw} and PEC_{sed} values for IN-JT333 following single and multiple applications to vegetables leafy

Scenarios	Single application 1 × 37.5 g a.s./ha			Multiple application 4 × 37.5 g a.s./ha		
	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} caused by	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} caused by
D3, ditch (1st)	<0.001	0.412	Drainage	<0.001	1.112	Drainage
D3, ditch (2nd)	<0.001	0.412	Drainage	<0.001	1.112	Drainage
D4, pond (1st)	<0.001	0.050	Drainage	<0.001	0.125	Drainage
D4, stream (1st)	<0.001	0.000	Drainage	<0.001	0.000	Drainage
D6, ditch (1st)	<0.001	0.412	Drainage	0.001	1.112	Drainage
R1, pond (1st)	<0.001	0.050	Runoff	0.002	0.125	Runoff
R1, pond (2nd)	0.001	0.050	Runoff	0.002	0.125	Runoff
R1, stream (1st)	0.001	0.124	Runoff	0.004	0.695	Runoff
R1, stream (2nd)	0.001	0.143	Runoff	0.004	0.511	Runoff
R2, stream (1st)	0.000	0.050	Runoff	0.002	0.182	Runoff
R2, stream (2nd)	0.000	0.540	Runoff	0.001	1.523	Runoff
R3, stream (1st)	0.001	0.075	Runoff	0.005	0.448	Runoff
R3, stream (2nd)	0.001	0.054	Runoff	0.004	0.216	Runoff
R4, stream (1st)	0.002	0.030	Runoff	0.006	0.158	Runoff
R4, stream (2nd)	0.002	0.022	Runoff	0.006	0.080	Runoff

Results of the Step 4 Simulations

<u>Maize</u>

Table 35: Summary of maximum Step 4 PEC_{sw} and PEC_{sed} values for indoxacarb following single and multiple application to maize at 37.5 g a.s./ha, 10 m VFS

Scenarios	Single application 1 × 37.5 g a.s./ha			Multiple application 2 × 37.5 g a.s./ha		
	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} Caused by	Maximum PEC_{sw} (µg/L)	Maximum PEC_{sed} (µg/kg)	Maximum PEC_{sw} Caused by
D3, ditch	0.034	0.018	Drift	0.028	0.016	Drift
D4, pond	0.005	0.016	Drift	0.006	0.021	Drift
D4,stream	0.038	0.003	Drift	0.031	0.003	Drift
D5, pond	0.005	0.015	Drift	0.006	0.018	Drift
D5,stream	0.040	0.003	Drift	0.035	0.009	Drift
D6, ditch	0.034	0.010	Drift	0.028	0.023	Drift
R1, pond	0.006	0.021	Runoff	0.008	0.035	Drift
R1,stream	0.033	0.060	Runoff	0.040	0.060	Runoff
R2,stream	0.041	0.103	Drift	0.033	0.103	Drift
R3,stream	0.043	0.047	Drift	0.056	0.127	Runoff
R4,stream	0.061	0.147	Runoff	0.072	0.147	Runoff

<u>Lettuce</u>

Table 36: Summary of maximum Step 4 PEC_{sw} and PEC_{sed} values for indoxacarb following single application to leafy vegetables at 37.5 g a.s./ha, 10 m VFS

	Single application 1 × 37.5 g a.s./ha			Multiple application 4 × 37.5 g a.s./ha		
Scenarios	**Maximum PEC_{sw} (µg/L)**	**Maximum PEC_{sed} (µg/kg)**	**Maximum PEC_{sw} Caused by**	**Maximum PEC_{sw} (µg/L)**	**Maximum PEC_{sed} (µg/kg)**	**Maximum PEC_{sw} Caused by**
D3, ditch (1st)	Not available					
D3, ditch (2nd)						
D4, pond (1st)						
D4, stream (1st)						
D6, ditch (1st)						
R1, pond (1st)	0.006	0.024	Runoff	0.025	0.088	Runoff
R1, pond (2nd)	0.007	0.048	Runoff	0.036	0.229	Runoff
R1, stream (1st)	0.031	0.070	Runoff	0.098	**0.501**	Runoff
R1, stream (2nd)	0.030	0.065	Drift	0.080	**0.369**	Runoff
R2, stream (1st)	0.040	0.116	Drift	0.048	**0.428**	Runoff
R2, stream (2nd)	0.041	0.112	Drift	0.027	**0.399**	Drift
R3, stream (1st)	0.088	0.178	Runoff	0.126	0.202	Runoff
R3, stream (2nd)	0.071	**0.432**	Runoff	0.077	0.177	Runoff
R4, stream (1st)	0.107	0.124	Runoff	**0.175**	0.263	Runoff
R4, stream (2nd)	0.133	0.201	Runoff	0.127	0.117	Runoff

Table 37:Summary of maximum Step 4 PEC_{sw} and PEC_{sed} values for indoxacarb following single application to leafy vegetables at 37.5 g a.s./ha, 20 m VFS

	Single application 1 × 37.5 g a.s./ha			Multiple application 4 × 37.5 g a.s./ha		
Scenarios	**Maximum PEC_{sw} (µg/L)**	**Maximum PEC_{sed} (µg/kg)**	**Maximum PEC_{sw} Caused by**	**Maximum PEC_{sw} (µg/L)**	**Maximum PEC_{sed} (µg/kg)**	**Maximum PEC_{sw} Caused by**
D3, ditch (1st)	0.018	0.010	Drift	0.012	0.010	Drift
D3, ditch (2nd)	0.018	0.010	Drift	0.012	0.010	Drift
D4, pond (1st)	0.003	0.012	Drift	0.006	0.020	Drift
D4, stream (1st)	0.019	0.002	Drift	0.013	0.006	Drift
D6, ditch (1st)	0.017	0.005	Drift	0.041	0.011	Drainage
R1, pond (1st)	0.003	0.014	Drift	0.013	0.046	Runoff
R1, pond (2nd)	0.004	0.025	Drift	0.018	0.117	Runoff
R1, stream (1st)	0.016	0.025	Runoff	0.051	0.175	Runoff
R1, stream (2nd)	0.016	0.024	Drift	0.042	0.136	Runoff
R2, stream (1st)	0.021	0.041	Drift	0.025	0.152	Runoff
R2, stream (2nd)	0.021	0.038	Drift	0.014	0.137	Drift
R3, stream (1st)	0.022	0.016	Drift	0.066	0.083	Runoff
R3, stream (2nd)	0.022	0.029	Drift	0.041	0.068	Runoff
R4, stream (1st)	0.026	0.021	Runoff	0.092	0.121	Runoff
R4, stream (2nd)	0.032	0.023	Runoff	0.067	0.053	Runoff

Conclusions

At Step 2, indoxacarb did not pass the environmental risk assessment for all uses. Metabolite IN-JT333 passed the environmental risk assessment at Step 2 for all applications except leafy vegetables (lettuce). For all other indoxacarb metabolites (IN-JU873, IN-KB687, IN-KG433, IN-KT413, IN-ML438, IN-MK638, IN-MK643, IN-MP819, IN-MS775, IN-U8E24, and IN-UYG24) no risk to aquatic organisms was identified for all application regimes.

At Step 3, indoxacarb PEC_{sw} and PEC_{sed} values were higher than the regulatory acceptable concentration (RAC) in at least one scenario of leafy vegetables (lettuce) and maize (maize and sweet corn). PEC_{sw} and PEC_{sed} values for IN-JT333 were below the RAC.

At the final Step 4, a maximum runoff buffer of 10 m was introduced into the simulations for indoxacarb after single and multiple applications to maize (sweet corn and maize) and a maximum runoff buffer of 20 m was introduced into the simulations for indoxacarb after single and multiple applications to leafy vegetables (lettuce). Assuming these buffer distances, no unacceptable risk to aquatic organisms is expected if indoxacarb is used in compliance with label recommendations.

RMS (2016)

Calculations presented above can be used for ecotox assessment.
For metabolites, some of the input values were changed by RMS and thus some PEC calculation were done again.

B.8.6. FATE AND BEHAVIOUR IN AIR

B.8.6.1. Route and rate of degradation in air and transport via air

No studies were conducted with formulation. See Volume 3 (AS), B.8 for studies with active substance.

B.8.6.2. Predicted environmental concentrations from airborne transport

The low vapour pressure (9.8×10^{-9} Pa at 20°C) of indoxacarb indicate a negligible potential for volatilisation of the active substance from soil under practical conditions of use.

B.8.7. PREDICTED ENVIRONMENTAL CONCENTRATIONS FROM OTHER ROUTES OF EXPOSURE

No information submitted. Not required.

B.8.8. References relied on

Data Point	Author(s)	Year	Title Compagny Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner	Previous evaluation
CP, 9.1.3/01	Juraske, R., Ball, M.A.	2015	Predicted environmental concentrations of indoxacarb and its major soil metabolites in soil after application to various crops in the European Union Dr. Knoell Consult GmbH DuPont-36914 EU, Revision No. 1 GLP: No Published: No	N	N		DuPont	N, submitted for the purpose of renewal
CP, 9.2.4/01	Juraske, R., Ball, M.A.	2015	Predicted environmental concentrations of indoxacarb and its metabolites in groundwater following the application to various crops - a modelling assessment for Europe using the focus groundwater scenarios Dr. Knoell Consult GmbH DuPont-36912 EU GLP: No Published: No	N	N		DuPont	N, submitted for the purpose of renewal
CP, 9.2.5/01	Juraske, R., Ball, M.A.	2015	Predicted environmental concentrations of indoxacarb and its metabolites in surface water and sediment following application to various crops in Europe: A modeling study conducted with focus surface water scenarios Dr. Knoell Consult GmbH DuPont-36913 EU GLP: No Published: No	N	N		DuPont	N, submitted for the purpose of renewal