European Commission

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

INDOXACARB

LOEP

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

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Identity, Physical and Chemical Properties, Details of Uses, Further Information (Regulation (EU) N° 283/2013, Annex Part A, points 1.3 and 3.2)

Active substance (ISO Common Name)	Indoxacarb
Function (*e.g.* fungicide)	Insecticide

Rapporteur Member State	France
Co-rapporteur Member State	Spain

Identity (Regulation (EU) N° 283/2013, Annex Part A, point 1)

Chemical name (IUPAC)	methyl (S)-N-[7-chloro-2,3,4a,5-tetrahydro-4a-(methoxycarbonyl)indeno[1,2-e][1,3,4]oxadiazin-2-ylcarbonyl]-4'-(trifluoromethoxy)carbanilate
Chemical name (CA)	methyl (4aS)-7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]amino]carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate
CIPAC No	612
CAS No	173584-44-6
EC No (EINECS or ELINCS)	Not available
FAO Specification (including year of publication)	Not available
Minimum purity of the active substance as manufactured	930 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	Impurity IN-06439 corresponds to “tetraethyl base”: <0.0025g/kg (<2.5ppm) Impurity IN-R1T94 corresponds to “tetraethyl hydrol”; <0.0025g/kg (<2.5 ppm) Impurity IN-J1063 corresponds to “tetraethyl ketone”; <0.0018g/kg (<1.8ppm) Impurity IN-C0800 corresponds to “Ethyl violet”; <0.0025g/kg (<2.5ppm) Toluene: 14 g/kg
Molecular formula	$C_{22}H_{17}ClF_3N_3O_7$
Molar mass	527.84 g/mol

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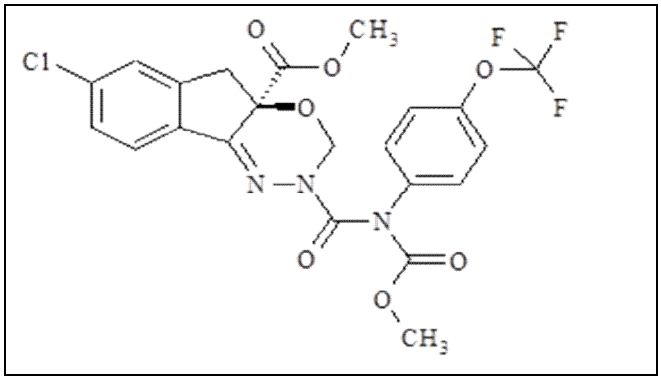
Structural formula



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Physical and chemical properties (Regulation (EU) N° 283/2013, Annex Part A, point 2)

Melting point (state purity)	88.1°C (99.7% w/w)
Boiling point (state purity)	No boiling point, decomposition start at around 235 - 255°C
Temperature of decomposition (state purity)	295°C (99.06% w/w)
Appearance (state purity)	Physical state: Pale green solid (95% w/w) Odour: Toluene (95% w/w)
Vapour pressure (state temperature, state purity)	9.8 x 10 -9 Pa at 20°C (99.7 % w/w) 1.9 x 10 -10 Pa at 25°C (99.7 % w/w)
Henry's law constant (state temperature)	< 6 x 10^{-5} $Pa.m^3$ mol^{-1} at 25 ^{0}C (99.7% w/w)
Solubility in water (state temperature, state purity and pH)	0.2 mg/l at 25 °C (99.7% w/w)
Solubility in organic solvents (state temperature, state purity)	In n-octanol: 11.31 mg/mL at 20°C (99.9%w/w) In methanol: 109.9 mg/ml at 20°C(99.9% w/w) In hexane: 1.307 mg/ml (99.9% w/w) The test solubility of indoxacarb at 20°C in acetone, acetonitrile, ethyl acetate, dichloromethane, dimethylformamide, and o xylene was determined to be > 250 mg/mL (g/L), respectively.
Surface tension (state concentration and temperature, state purity)	76.8 dyne/cm at 20°C (90 % saturated solution) (98.4% w/w)
Partition coefficient (state temperature, pH and purity)	log K_{OW} = 4.65 at 25°C (99.7% w/w)
Dissociation constant (state purity)	a.s. does not dissociate

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UV/VIS absorption (max.) incl. ε (state purity, pH)	In methanol solution: pH :0.91 (99.9 % w/w) Wavelength — ε (L mol^{-1} cm^{-1}) 203 nm 18075 230 nm 14342 285 nm 17871 290 nm 16507 311 nm 21106 pH: 7.05 (99.9 % w/w) Wavelength — ε (L mol^{-1} cm^{-1}) 235 nm 9272 285 nm 16345 290 nm 15290 311 nm 20502 pH:12.67 (99.9 % w/w) Wavelength — ε (L mol^{-1} cm^{-1}) 235 nm 17682 285 nm 16437 290 nm 15653 311 nm 20098
Flammability (state purity)	Active substance is not flammable. However, test should be performed according to CLP criteria (manual UN RTDG).
Explosive properties (state purity)	Active substance is not explosive according to DSD system. However, test should be performed according to CLP criteria (Part I Test series Section 11 of manual UN RTDG).
Oxidising properties (state purity)	Active substance has no oxidizing properties according to the criteria of EC Test A17. However test should be performed according to CLP criteria (method O.2 of manual UN RTDG)

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Summary of representative uses evaluated, for which all risk assessments needed to be completed (*name of active substance or the respective variant*) (Regulation (EU) N° 284/2013, Annex Part A, points 3, 4)

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k) a) per use b) per crop/ season	Interval between applications (min)	mL product/ ha a) max. rate per appl. b) max. total rate per crop/season	Water l/ha min max	g a.i./ha a) max. rate per appl. b) max. total rate per crop/season		
Maize, Sweet Corn	EU	Indoxacarb 150 g/L EC (DPX-KN128 150 g/L EC)	F	*Ostrinia nubilalis Diabrotica virgifera*	EC	150	hydraulic ground directed boom Note: application must be made from above the crop	BBCH 34-77	a) 2 b) 2	20 days	a) 250 b) 500	100-1000	a) 37.5 b) 75	BBCH 77	EU CRITICAL GAP
Maize (grain and silage)	South Zone	Indoxacarb 150 g/L EC (DPX-KN128 150 g/L EC)	F	*Ostrinia nubilalis Diabrotica virgifera*	EC	150	hydraulic ground directed boom Note: application must be made from above the crop	BBCH 34-77	a) 2 b) 2	20 days	a) 250 b) 500	100-1000	a) 37.5 b) 75	BBCH 77	
Maize (grain and silage)	Central Zone Northern Zone	Indoxacarb 150 g/L EC (DPX-KN128 150 g/L EC)	F	*Ostrinia nubilalis Diabrotica virgifera*	EC	150	hydraulic ground directed boom Note: application	BBCH 34-77	a) 2 b) 2	20 days	a) 250 b) 500	200-700	a) 37.5 b) 75	BBCH 77	

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							must be made from above the crop								
Sweet corn	South Zone	Indoxacarb 150 g/L EC (DPX-KN128 150 g/L EC)	F	*Ostrinia nubilalis*	EC	150	hydraulic ground directed boom Note: application must be made from above the crop	BBCH 34-77	a) 2 b) 2	20 days	a) 250 b) 500	100-1000	a) 37.5 b) 75	3	
Sweet corn	Central Zone Northern Zone	Indoxacarb 150 g/L EC (DPX-KN128 150 g/L EC)	F	*Ostrinia nubilalis*	EC	150	hydraulic ground directed boom Note: application must be made from above the crop	BBCH 34-77	a) 2 b) 2	20 days	a) 250 b) 500	200-700	a) 37.5 b) 75	3	
Lettuce	EU	Indoxacarb 150 g/L EC (DPX-KN128 150 g/L EC)	F	*Autographa gamma* *Chrysodeixis chalcites* *Helicoverpa armigera* *Mythimna unipuncta* *Spodoptera exigua* *Spodoptera littoralis*	EC	150	hydraulic ground directed boom	BBCH 13-49 Seed crops BBCH 13-59	a) 4 b) 4	7 days	a) 250 b) 1000	200-1000	a) 37.5 b) 150	1	EU CRITICAL GAP
Lettuce	South Zone except for France	Indoxacarb 150 g/L EC (DPX-KN128 150 g/L EC)	F	*Autographa gamma* *Chrysodeixis chalcites* *Helicoverpa armigera*	EC	150	hydraulic ground directed boom	BBCH 13-49 Seed crops BBCH	a) 4 b) 4	7 days	a) 250 b) 1000	200-1000	a) 37.5 b) 150	1	

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				Mythimna unipuncta *Spodoptera exigua* *Spodoptera littoralis*				13-59							

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds (d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR) (e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).** (j) Growth stage range from first to 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 (k) Indicate the minimum and maximum number of applications possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha (m) PHI - minimum pre-harvest interval

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Section 1 Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of additional intended uses for which MRL applications have been made, that in addition to the uses above, have also been considered in the consumer risk assessment (*name of active substance or the respective variant*)
Regulation (EC) N° 1107/2009 Article 8.1(g))

Important note: efficacy, environmental risk and risk to humans by exposure other than via their diet have not been assessed for these uses

Crop and/or situation (a)	**Member State or Country**	**Product name**	**F G or I** (b)	**Pests or Group of pests controlled** (c)	**Preparation**		**Application**				**Application rate per treatment**			**PHI (days)** (m)	**Remarks**
					Type (d-f)	Conc. a.s. (i)	method kind (f-h)	range of growth stages & season (j)	number min-max (k)	Interval between application (min)	kg a.s /hL min-max (l)	Water L/ha min-max	kg a.s./ha min-max (l)		
MRL Application (according to Article 8.1(g) of Regulation (EC) No 1107/2009)															

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide
(f) All abbreviations used must be explained
(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to 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
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval

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Further information, Efficacy

Effectiveness (Regulation (EU) N° 284/2013, Annex Part A, point 6.2)

	Indoxacarb based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

Adverse effects on field crops (Regulation (EU) N° 284/2013, Annex Part A, point 6.4)

	Indoxacarb based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

Observations on other undesirable or unintended side-effects (Regulation (EU) N° 284/2013, Annex Part A, point 6.5)

	Indoxacarb based products have been registered in many EU countries based on detailed national assessments of the efficacy package. More detailed consideration will be fully assessed in the context of subsequent applications for products authorization.

Groundwater metabolites: Screening for biological activity (SANCO/221/2000-rev.10-final Step 3 a Stage 1)

Activity against target organism	Not required

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Methods of Analysis

Analytical methods for the active substance (Regulation (EU) N° 283/2013, Annex Part A, point 4.1 and Regulation (EU) N° 284/2013, Annex Part A, point 5.2)

Technical a.s. (analytical technique)	Indoxacarb : HPLC/UV at 280 nm
Impurities in technical a.s. (analytical technique)	HPLC/UV (310 - 230 - 210 - 254 - 290 and 590 nm) Karl-Fischer titration
Plant protection product (analytical technique)	HPLC/UV at 280 nm

Analytical methods for residues (Regulation (EU) N° 283/2013, Annex Part A, point 4.2 & point 7.4.2)

Residue definitions for monitoring purposes

Food of plant origin		Parent compound (sum of isomers)
Food of animal origin		Parent (sum of isomers) and metabolite IN JT333
Soil		Parent (sum of isomers)
Sediment		Parent (sum of isomers)
Water	surface	Parent (sum of isomers)
	drinking/ground	Parent (sum of isomers)
Air		Parent (sum of isomers)
Body fluids and tissues		Parent (sum of isomers) and metabolite IN JT333

Monitoring/Enforcement methods

Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)	DFG S 19 (LC-MS/MS) Extraction efficiency for each matrix is required LOQ: 0.01 mg/kg in high water content, acidic, fatty and dry commodities
Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes)	DFG S19 (LC-MS/MS) Main method: Extraction efficiency for each matrix and validation data for milk matrix were required ILV is not validated and is required DFG S19 (LC-MS/MS) Main method: Extraction efficiency for each matrix and validation data for fat matrix were required ILV: is missing and is required
Soil (analytical technique and LOQ)	LC-MS/MS LOQ: 0.0010 mg/kg

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Water (analytical technique and LOQ)	LC-MS/MS LOQ: 0.05µg/kg in ground water, surface water and drinking water
Air (analytical technique and LOQ)	LC-MS/MS LOQ: 0.10 µg/m^3 the Breakthrough of the method is required
Body fluids and tissues (analytical technique and LOQ)	LC-MS/MS LOQ: 0,002 mg/L in plasma

Classification and labelling with regard to physical and chemical data (Regulation (EU) N° 283/2013, Annex Part A, point 10)

Substance	Indoxacarb
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][1]:	/
Peer review proposal [2] for harmonised classification according to Regulation (EC) No 1272/2008:	/

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[2] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

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Section 2 Mammalian Toxicology

Impact on Human and Animal Health

Absorption, distribution, metabolism and excretion (toxicokinetics) (Regulation (EU) N° 283/2013, Annex Part A, point 5.1)

Rate and extent of oral absorption/systemic bioavailability	Slow absorption, 60 % (overall, based on urinary excretion and tissue levels within 168 h, supported by urinary and biliary excretion within 48-hour – studies conducted on DPX-JW062 (50:50) and DPX-MP062 (75:25) in rats after a single dose of 5 mg/kg bw)
Toxicokinetics	DPX-JW062 (50:50) and DPX-MP062 (75:25) in rats after a single dose of 5 mg/kg bw: Plasma: Cmax = 2.3-2.4 µg/g in males, 2.9-3.0 µg/g in females; Tmax = 6.8-8.0 h in males, 5.3-7.3 h in females; $t_{1/2}$ = 35-39 h in males, 49-52 h in females Red blood cells: Cmax = 1.1 µg/g in males, 1.4-1.5 µg/g in females; Tmax = 6.8-8.7 h in males, 3.3-6.0 h in females; $t_{1/2}$ = 91-97 h in males, 68-74 h in females
Distribution	Highest levels in fat and blood (red blood cells); sex-specific (higher tissue levels in females)
Potential for bioaccumulation	Potential for accumulation in fat and red blood cells
Rate and extent of excretion	Slow excretion (37-55% via urine; 27-47% via faeces within 7 days - DPX-JW062 (50:50) and DPX-MP062 (75:25))
Metabolism in animals	Extensively metabolised, sex- and stereospecific. Biotransformation started with enzymatic removal of the methoxycarbonyl group leading to IN-JT333 (mostly in females) or hydroxylation at the benzylic position in the indanone moiety leading to 5-OH-JW062 (mostly in males).
In vitro metabolism	No comparative *in vitro* metabolism study available.
Toxicologically relevant compounds (animals and plants)	Parent compound, IN-JT333
Toxicologically relevant compounds (environment)	Parent compound

Acute toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.2)

Rat LD_{50} oral	DPX-KN128 (99:1): 179 mg/kg bw (f) DPX-MP062 (75:25): 268 mg/kg bw (f)	H301
Rat LD_{50} dermal	DPX-KN128 (99:1): > 5000 mg/kg bw DPX-MP062 (75:25): > 5000 mg/kg bw	
Rat LC_{50} inhalation	DPX-JW062 (50:50): 4.2 mg/L air /4h (nose-	H332

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	only) (f)	
Skin irritation	DPX-KN128 (99:1): Non-irritant DPX-MP062 (75:25): Non-irritant	
Eye irritation	DPX-KN128 (99:1): Non-irritant DPX-MP062 (75:25): Non-irritant	
Skin sensitisation	DPX-KN128 (99:1): Sensitising (M&K), non sensitising (Buehler 3-induction) DPX-MP062 (75:25): Sensitising (M&K)	H317 (1B)
Phototoxicity	DPX-KN128 (99:1): Not phototoxic	

Short-term toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.3)

Target organ / critical effect	Rat, mouse, dog: anaemia Mouse: clinical signs indicative of neurotoxicity	STOT-RE1 H372 (blood, nervous system)
Relevant oral NOAEL	90-day, rat: DPX-KN128 (99:1): 0.68 mg/kg bw per day DPX-MP062 (75:25): 0.62 mg/kg bw per day DPX-JW062 (50:50): 0.99 mg/kg bw per day 90-day, mouse: DPX-JW062 (50:50): 5.5 mg/kg bw per day 90-day, dog: DPX-JW062 (50:50): <1 mg/kg bw per day 1-year, dog: DPX-JW062 (50:50): <1.1 mg/kg bw per day	
Relevant dermal NOAEL	28-day, rat: <50 mg/kg bw per day	
Relevant inhalation NOAEL	No data - not required	

Genotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.4)

In vitro studies	DPX-KN128 (99:1) and DPX-MP062 (75:25): Ames test, *in vitro* mammalian cell gene mutation (CHO/HGPRT), *in vitro* chromosome aberration: negative DPX-MP062 (75:25): *in vitro* unscheduled DNA synthesis: negative	
In vivo studies	DPX-KN128 (99:1) and DPX-MP062 (75:25): mouse *in vivo* micronucleus: negative	

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Photomutagenicity	Not required	
Potential for genotoxicity	DPX-KN128 (99:1) is unlikely to be genotoxic	

Long-term toxicity and carcinogenicity (Regulation (EU) N°283/2013, Annex Part A, point 5.5)

Long-term effects (target organ/critical effect)	Rat: anaemia Mouse: clinical signs indicative of neurotoxicity; at higher doses: mortality, histopathological findings in heart (myocardial necrosis, haemorrhage) and brain (neuronal degeneration/necrosis)	STOT-RE1 H372 (blood, heart)
Relevant long-term NOAEL	2-year, rat: DPX- JW062 (50:50): 1.04 mg/kg bw per day 18-month, mouse: DPX- JW062 (50:50): 2.63 mg/kg bw per day	
Carcinogenicity (target organ, tumour type)	Rat & mouse: no tumours No carcinogenic potential	
Relevant NOAEL for carcinogenicity	2-year, rat: DPX- JW062 (50:50) > 7.83 mg/kg bw per day 18-month, mouse: DPX- JW062 (50:50) > 17.0 mg/kg bw per day	

Reproductive toxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parental toxicity: decreased body weight gains and food consumption, increased spleen weight Reproductive toxicity: no adverse effect observed in rat 2-generation study Offspring's toxicity: decreased F1 pup body weight during lactation	
Relevant parental NOAEL	1.2 mg/kg bw per day	
Relevant reproductive NOAEL	> 6.1 mg/kg bw per day	
Relevant offspring NOAEL	1.2 mg/kg bw per day	

Developmental toxicity

Developmental target / critical effect	Rat:	

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	DPX-KN128 (99:1), DPX-MP062 (75:25), DPX-JW062 (50:50) Maternal toxicity: decreased body weight gains Developmental toxicity: decreased fetal weights Rabbit: DPX-JW062 (50:50) Maternal toxicity: decreased body weights, body weight gains, food consumption Developmental toxicity: decreased fetal weights, retarded sternebral ossification	
Relevant maternal NOAEL	Rat: 0.5 mg/kg bw per day Rabbit: 500 mg/kg bw per day	
Relevant developmental NOAEL	Rat: 2 mg/kg bw per day Rabbit: 500 mg/kg bw per day	

Neurotoxicity (Regulation (EU) N° 283/2013, Annex Part A, point 5.7)

Acute neurotoxicity	DPX-MP062 (75:25): Neurotoxicity NOAEL: 50 mg/kg bw; decreased forelimb grip strength and foot splay in males, decreased motor activity in females Systemic NOAEL: 12.5 mg/kg bw; decreased body weights, body weight gains, food consumption	
Repeated neurotoxicity	DPX-MP062 (75:25): Neurotoxicity NOAEL >6.09 mg/kg bw per day; no effects Systemic NOAEL: 0.57 mg/kg bw per day; decreased body weights, body weight gains, food consumption	
Additional studies (e.g. delayed neurotoxicity, developmental neurotoxicity)	Developmental rat neurotoxicity DPX-KN128 (99:1) Maternal NOAEL: 1 mg/kg bw per day; decreased body weight gains. Mortality and clinical signs of neurotoxicity at 3 mg/kg bw per day Developmental NOAEL: 1.5 mg/kg bw per day; increased number of stillborn pups, increased pup mortality on PND1-4, decreased pup weight per litter PND0	STOT RE1 H372 (nervous system)

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Other toxicological studies (Regulation (EU) N° 283/2013, Annex Part A, point 5.8)

Supplementary studies on the active substance	Distribution of erythrocytes, rat single dose (111 mg/kg bw) gavage study with DPX-JW062 (50:50): IN-P0036 was the single radioactive species associated with erythrocytes 72h after administration Immunotoxicity mouse study with DPX-KN128 (99:1): Immunotoxicity NOAEL > 23 mg/kg bw per day; no effect on the humoral immune response Systemic NOAEL > 23 mg/kg bw per day; no effect
Endocrine disrupting properties	No evidence of endocrine disrupting properties
Studies performed on metabolites or impurities	<u>IN-KG433:</u> Rat: oral LD50 = >5000/174 mg/kg bw (m/f) Ames: negative *In vitro* gene mutation assay in mammalian cells: negative *In vitro* UDS assay in mammalian cells: negative <u>IN-JT333:</u> Rat: oral LD50 = 52/39 mg/kg bw (m/f) Ames: negative *In vitro* gene mutation assay in mammalian cells: negative *In vitro* chromosome aberrations assay: negative Proposed ADI = 0.0015 mg/kg bw per day (TTC approach), pending submission of a subchronic repeated dose toxicity study with IN-JT333 <u>IN-MT713:</u> *In vitro* haemolytic potential in erythrocytes of rats, dogs and humans (oxidative effect on glutathione) G6PDH-deficient individuals may be slightly more sensitive to the oxidative effects of IN-MT713 than G6PDH-normal individuals

Medical data (Regulation (EU) N° 283/2013, Annex Part A, point 5.9)

No detrimental effects on health attributed to exposure associated with the handling, testing of manufacturing of DPX-KN128 (99:1). Five published reports of clinical cases and poisoning incidents linked to indoxacarb use.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 2 Mammalian Toxicology

Summary[3] (Regulation (EU) N°1107/2009, Annex II, point 3.1 and 3.6)	Value (mg/kg bw (per day))	Study	Uncertainty factor
Acceptable Daily Intake (ADI)	0.005	Rat, developmental study with DPX-KN128 (99:1), supported by short- and long-term toxicity studies in rats and dogs	100
Acute Reference Dose (ARfD)	0.005	Rat, developmental study with DPX-KN128 (99:1)	100
Acceptable Operator Exposure Level (AOEL)	0.003*	Rat, developmental study with DPX-KN128 (99:1), supported by short-term toxicity studies in rats and dogs	100
Acute Acceptable Operator Exposure Level (AAOEL)	0.003*	Rat, developmental study with DPX-KN128 (99:1)	100

* Including correction for limited oral absorption/bioavailability (60 %).

Dermal absorption (Regulation (EU) N° 284/2013, Annex Part A, point 7.3)

Representative formulation (Indoxacarb 150 g/L EC; EC, 150 g/L DPX-KN128)	Concentrate: 2 % Spray dilution (0.4 g/L): 18 % *In vivo* rat study and *in vitro* rat/human skin study on the representative formulation – triple pack approach

Exposure scenarios (Regulation (EU) N° 284/2013, Annex Part A, point 7.2)

Operators	Use: maize and lettuce, tractor boom sprayer, application rate 0.0375 kg a.s./ha Exposure estimates (model): % of AOEL UK POEM Without PPE: 1737 PPE (gloves M/L and A): 271 German model Without PPE: 149 PPE (gloves and coverall): 10 EFSA calculator *Longer term:*

[3] If available include also reference values for metabolites

List of end points

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Section 2 Mammalian Toxicology

	Without PPE: 198 PPE (gloves and coverall): 13 *Acute:* Without PPE: 1753 PPE (gloves and coverall): 394
Workers	Use: maize Exposure estimates (model): % of AOEL EUROPOEM II: *2h/d* *1 application* Without PPE: 225 PPE: 23 *2 applications, 20 days between application (according to GAPs)* Without PPE: 360 PPE: 36 EFSA calculator: *inspection, irrigation – 2h/d – 2 applications, 20 days between application* Without PPE: 458 PPE (work wear): 51
	Use: lettuce Exposure estimates (model): % of AOEL EUROPOEM II: *8h/d* *1 application* Without PPE: 450 PPE: 45 *4 applications, 7 days between application (according to GAPs)* Without PPE: 1440 PPE: 144 EFSA calculator: *reaching, picking – 8h/d – 4 applications, 7 days between application* Without PPE: 1665 PPE (work wear and gloves): 167

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 2 Mammalian Toxicology

Bystanders and residents	Bystander Exposure estimates (model): % of AOEL EUROPOEM II 8.5 Martin *et al.* (2008) Adult 1.1 Child 0.9 EFSA calculator (95th percentile) Adult (maize: worst-case spray drift) 37 Adult (lettuce: worst-case entry into treated crops) 67 Child (maize: worst-case spray drift) 138 Child (lettuce: worst-case entry into treated crops) 121
	Resident Exposure estimates (model): % of AOEL Martin *et al.* (2008) Adult 9.3 Child 17.3 EFSA calculator (all pathways, mean) Adult (maize) 44 Adult (lettuce) 68 Child (maize) 123 Child (lettuce) 158

Classification with regard to toxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance :	Indoxacarb DPX-KN128
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][4] :	Commission Regulation (EU) No 944/2013 (5th adaptation to technical and scientific progress of Regulation (EC) No 1272/2008): Acute Tox 3 H301 Acute Tox 4 H332 STOT RE 1 H372 (blood, nervous system, heart) Skin Sens 1B H317
Peer review proposal [5] for harmonised classification according to Regulation (EC) No 1272/2008:	No change of the current harmonised classification is proposed.

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[5] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 3 Residues

Residues in or on treated products food and feed

Metabolism in plants (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.1, 6.5.1, 6.6.1 and 6.7.1)

Primary crops (Plant groups covered) **OECD Guideline 501**	**Crop groups**	**Crop(s)**	**Application(s)**	**DAT** (days)
	Fruit crops	Grapes	Foliar application 1 x 0.250 kg DPX-KN128/ha	0, 14, 46, 66
		Tomatoes	Foliar application 4 x 0.075 kg DPX-KN128/ha	0, 3, 7, 14
	Root crops	-	-	-
	Leafy crops	Lettuce	Foliar application 1 x 0.250 kg DPX-KN128/ha	0, 7, 14, 21, 28, 35
		Lettuce	Foliar application 4 x 0.313 kg DPX-KN128/ha	0, 7, 14, 21, 28
	Cereals/grass crops	-	-	-
	Pulses/Oilseeds	Cotton	Foliar application 1 x 0.250 kg DPX-KN128/ha	0, 7, 14, 30, 59, 90
		Cotton	Foliar application 4 x 0.313 kg DPX-KN128/ha	0, 9, 20, 30 and at maturity
	Miscellaneous	-	-	-
	Metabolism studies conducted with ^{14}C-indoxacarb show a similar pathway, indicating the S and R isomers were found in similar amounts showing that the metabolism of indoxacarb is not stereo specific. Overdosed studies were conducted to facilitate identification of metabolites.			

Rotational crops (metabolic pattern) **OECD Guideline 502**	**Crop groups**	**Crop(s)**	**PBI** (days)	**Comments**
	Root/tuber crops	Carrot	0, 36, 90, 125	At 36, 90 and 125 days after soil treatment no single main metabolite was observed exceeding 0.05 mg/kg Significant residue of indoxacarb and metabolite IN-JT333 were not detected in the crop samples
		Soybean		
	Leafy crops	Lettuce		
	Cereal (small grain)	Spring wheat		
	Other	-	-	
Rotational crop and primary crop metabolism similar?	(up to 250 characters)			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 3 Residues

Processed commodities (standard hydrolysis study) **OECD Guideline 507**	**Conditions**	TMP-^{14}C-DPX-JW062 (DPX-KN128/IN-KN127 (50/50))		IND-^{14}C-DPX-JW062 (DPX-KN128/IN-KN127 (50/50))	
	20 min, 90°C, pH 4	86-90 %		85-94 %	
	60 min, 100°C, pH 5	87-89 %		67-71 %	
	20 min, 120°C, pH 6	-	-	-	-
Residue pattern in processed commodities similar to residue pattern in raw commodities?	Pasteurisation and baking/boiling conditions were not resulting in a formation of toxicologically significant degradation products. No residue was found in maize and sweet corn at the intended maximum application rate and lettuce is not a crop that undergoes processing.				

Plant residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Parent compound (sum of isomers)
Plant residue definition for risk assessment (RD-RA)	Parent compound (sum of isomers)
Conversion factor (monitoring to risk assessment)	CF:1

Metabolism in livestock (Regulation (EU) N° 283/2013, Annex Part A, points 6.2.2, 6.2.3, 6.2.4, 6.2.5 6.7.1)

OECD Guideline 503 and **SANCO/11187/2013 rev. 3** (fish) **Animals covered**	**Animal**	**Dose** (mg/kg bw/d)	**Duration** (days)	**N rate/comment**
	Laying hen	0.705 mg/kg bw/d	5	50N (overdosed)
	Goat/Cow	0.408 mg/kg bw/d	5	9N
	Pig	-	-	-
	Fish	mg/kg DM		
	The duration of the studies does not allow to reach a plateau concentration in milk or eggs.			

Time needed to reach a plateau concentration in milk and eggs (days)	
Animal residue definition for monitoring (RD-Mo) **OECD Guidance, series on pesticides No 31**	Parent compound (sum of isomers)
Animal residue definition for risk assessment (RD-RA)	Pigs and ruminants: Parent compound (sum of isomers)
	Poultry: Parent compound (sum of isomers) and separately N-decarboxylated metabolite (IN-JT333)

List of end points

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RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 3 Residues

Conversion factor (monitoring to risk assessment)	None
Metabolism in rat and ruminant similar (Yes/No)	Yes
Fat soluble residues (Yes/No) **(FAO, 2009)**	Yes (4.65 for DPX-KN128)

Residues in succeeding crops (Regulation (EU) N° 283/2013, Annex Part A, point 6.6.2)

Confined rotational crop study (Quantitative aspect) **OECD Guideline 502**	Not necessary
Field rotational crop study **OECD Guideline 504**	Not necessary

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 3 Residues

Stability of residues (Regulation (EU) N° 283/2013, Annex Part A, point 6.1)

OECD Guideline 506

Plant products (Category)	**Commodity**	**T** (°C)	**Stability** (Month)
			DPX-KN128/IN-KN127
High water content	Apples	- 20	18
	Apples juice		6
	Tomatoes		12
	Lettuces		10
High oil content	/	/	/
High protein content	/	/	/
High starch content	Maize grain	- 20	13
High acid content	Grapes	- 20	18
	Wine		3
/			
Animal	**Animal commodity**	**T** (°C)	**Stability** (Month)
			DPX-KN128/IN-KN127, IN-KB687, IN-KG433, IN-KT319, IN-JU873 and IN-JT333
Hen	Whole eggs	- 20	16
	Muscle		
	Fat		
	Liver		
/			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = France	**2016-12**	**Indoxacarb**

Section 3 Residues

Summary of residues data from the supervised residue trials (Regulation (EU) N° 283/2013, Annex Part A, point 6.3) OECD Guideline 509, OECD Guidance, series on pesticides No 66 and OECD MRL calculator

Crop	**Region/ Indoor** (a)	**Residue levels** (mg/kg) **observed in the supervised residue trials relevant to the supported GAPs** (b)	**Recommendations/comments** (OECD calculations)	**MRL** proposals (mg/kg)	**HR** (mg/kg) (c)	**STMR** (mg/kg) (d)
Representative uses (row to be deleted if not relevant)						
Maize grain	NEU outdoor	8 × <0.01	From trials performed at the intended GAP	0.01*	0.01	0.01
	SEU outdoor	9 × <0.01		0.01*	0.01	0.01
Maize forage	NEU outdoor	0.14, 0.18, 0.22, 0.26	From trials performed at the intended GAP	0.6	0.260	0.200
	SEU outdoor	0.048, 0.094, 0.11, 0.11, 0.14, 0.18, 0.26, 0.28, 0.32, 0.34, 0.44, 0.77	Sampling at forage stage or at an early PHI (14 days)	1.5	0.770	0.220
Sweet corn	NEU outdoor	<0.01	Extrapolated results from the immature maize (at the intended GAP)	0.01*	0.01*	0.01*
	SEU outdoor	4 x <0.01		0.01*	0.01*	0.01*
Lettuce	NEU outdoor	0.14, 0.18, 0.27, 0.28, 0.29, 0.45, 0.59, 0.85	From trials performed at the intended GAP	1.5	0.850	0.285
	SEU outdoor	0.06, 0.29, 0.35, 0.36, 0.53, 0.67, 0.80		1.5	0.8	0.360

Summary of the data on formulation equivalence OECD Guideline 509

No information provided and not requested

Summary of data on residues in pollen and bee products (Regulation (EU) No 283/2013, Annex Part A, point 6.10.1)

Product(s)	**Region**	**Residue data** (mg/kg)	**Recommendations/comments**			
No information provided and not requested						

(a): **NEU** or **SEU** for northern or southern **outdoor** trials in EU member states (**N+SEU** if both zones), **Indoor** for glasshouse/protected crops, **Country** if non-EU location.
(b): Residue levels in trials conducted according to GAP reported in ascending order (*e.g.* 3x <0.01, 0.01, 6x 0.02, 0.04, 0.08, 3x 0.10, 2x 0.15, 0.17). When residue definition for monitoring and risk assessment differs, use **Mo/RA** to differentiate data expressed according to the residue definition for **Mo**nitoring and **R**isk **A**ssessment.
(c): **HR**: Highest residue. When residue definition for monitoring and risk assessment differs, HR according to residue definition for monitoring reported in brackets (HR_{Mo}).
(d): **STMR:** Supervised Trials Median Residue. When residue definition for monitoring and risk assessment differs, STMR according to definition for monitoring reported in brackets ($STMR_{Mo}$).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 3 Residues

Inputs for animal burden calculations

Feed commodity	Median dietary burden		Maximum dietary burden	
	(mg/kg)	**Comment**	(mg/kg)	**Comment**
Representative uses				
Maize grain	0.01	Median residue	0.01	Median residue
Maize by-products: milled by-products, hominy meal, gluten feed, gluten (meal)	0.01	Median residue	0.01	Median residue
Maize silage/forage	0.22	Median residue	0.77	Highest residue

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	2016-12	**Indoxacarb**

Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**				**Pig/Swine**		**Poultry**		**Fish**	
Highest expected intake (mg/kg bw/d) (mg/kg DM for fish)	Beef cattle	0.037	Ram/Ewe	0.000	Breeding	0.009	Broiler	0.001	Carp	
	Dairy cattle	0.045	Lamb	0.000	Finishing	0.000	Layer	0.014	Trout	
							Turkey	0.001	Fish intake >0.1 mg/kg DM	
Intake >0.004 mg/kg bw	Yes		No		Yes (breeding)		Yes (layer)		Not expected	
Feeding study submitted	Yes (evaluated in the initial DAR)						Yes (evaluated by the JMPR (FAO) 2009) **Mo:** Parent compound (sum of isomers) **RA1:** Parent compound (sum of isomers) **RA2:** N-decarboxylated metabolite (IN-JT333)		No study provided	
Representative feeding level (mg/kg bw/d, mg/kg DM for fish) and **N rates**	Level 0.3 mg/kg bw	Beef: 8.1 N Dairy: 6.7 N	Level 0.3 mg/kg bw	Lamb: 647 N Ewe: 825 N	Level 0.3 mg/kg bw	33 N Breed 857 N Finish	Level 0.111 mg/kg bw	Turkey: 134 N Layer: 8 N	Level	N rate Carp/Trout
	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals	Estimated HR[(a)] at 1N	**MRL** proposals
Muscle	0,032	0,04	-	-	0,01*	0,01*	0,01*	0,01*		
Fat	0,048	0,04	-	-	0.01*	0.01*	0,01*	0,01*		
Meat[(b)]	0,033		-	-	0.01*	-	0,01*			
Liver	0,010	0,01*	-	-	0,01*	0.01*	0,01*	0,01*		
Kidney	0,01*	0,01*	-	-	0.01*	0.01*				
Milk[(a)]	0,01*	0,01*	-	-		-				
Eggs							0,01*	0,01*		

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 3 Residues

Residues from livestock feeding studies (Regulation (EU) N° 283/2013, Annex Part A, points 6.4.1, 6.4.2, 6.4.3 and 6.4.4)

OECD Guideline 505 and OECD Guidance, series on pesticides No 73

MRL calculations	**Ruminant**	**Pig/Swine**	**Poultry**	**Fish**
Method of calculation[(c)]	Calculated MRL for bovine, sheep and swine and poultry are lower than the in force MRLs. Therefore, no new MRLs are proposed in the framework of the renewal.			

[(a)]: Estimated HR calculated at 1N level (**estimated mean level for milk**).
[(b)]: HR in meat calculated for mammalian on the basis of 20% fat + 80% muscle and 10% fat + 90% muscle for poultry
[(c)]: The OECD guidance document on residues in livestock (series on pesticides 73) recommends three different approaches to derive MRLs for animal products; by applying a transfer factor (Tf), by intrapolation (It) or by linear regression (Ln). Fill in method(s) considered to derive the MRL proposals.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 3 Residues

Conversion Factors (CF) for monitoring to risk assessment

Processing factors (Regulation (EU) N° 283/2013, Annex Part A, points 6.5.2 and 6.5.3)

OECD Guideline 508 and OECD Guidance, series on testing and assessment No 96

Crop (RAC)/Edible part or Crop (RAC)/Processed product	Number of studies[(a)]	Processing Factor (PF)		Conversion Factor (CF_P) for RA[(b)]
		Individual values	Median PF	
Representative uses				
As no residues were found in maize and sweet corn grain/kernel at the intended maximum application rate, no studies on the effects of processing on the nature of the residue were considered necessary. Also lettuce is not a crop that undergoes processing.				

[(a)]: Studies with residues in the RAC at or close to the LOQ should be disregarded (unless concentration)
[(b)]: When the residue definition for risk assessment differs from the residue definition for monitoring

Consumer risk assessment (Regulation (EU) N° 283/2013, Annex Part A, point 6.9)

Including all uses (representative uses and uses related to an MRL application).

ADI	0.005 mg/kg bw per day
TMDI according to EFSA PRIMo	Highest TMDI: 473.9 % ADI (NL, child)
NTMDI, according to (to be specified)	Not provided, not required
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: 106.2 % ADI (NL, child)
NEDI (% ADI), according to (to be specified)	Not provided, not required
Factors included in the calculations	/
ARfD	0.005 mg/kg bw
IESTI (% ARfD), according to EFSA PRIMo	Highest IESTI: 1964.4 % ARfD (grape)
NESTI (% ARfD), according to (to be specified)	Not provided, not required
Factors included in IESTI and NESTI	

Consumer risk assessment limited to the representative uses (Residue definition : Parent compounds (sum of isomers))

TMDI (% ADI), according to EFSA PRIMo	Highest TMDI: 17.6 % ADI (ES, adult)
NTMDI (% ADI), according to (to be specified)	Not provided, not required
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: NA
NEDI (% ADI), according to (to be specified)	Not provided, not required
Factors included in the calculations	
IESTI (% ARfD, according to EFSA PRIMo)	Highest IESTI: 457.4 % ARfD (Lettuce)
NESTI (% ARfD, according to (to be specified)	Not provided, not required
Factors included in IESTI and NESTI	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 3 Residues

Consumer risk assessment limited to the representative uses (Residue definition tentative: N-decarboxylated metabolite IN-JT333 only for poultry)

TMDI (% ADI), according to EFSA PRIMo	Highest TMDI: 1.3 % ADI (ES, child)
NTMDI (% ADI), according to (to be specified)	Not provided, not required
IEDI (% ADI), according to EFSA PRIMo	Highest IEDI: NA
NEDI (% ADI), according to (to be specified)	Not provided, not required
Factors included in the calculations	
IESTI (% ARfD, according to EFSA PRIMo)	Highest IESTI: 7.5 % ARfD (Poultry: meat)
NESTI (% ARfD, according to (to be specified)	Not provided, not required
Factors included in IESTI and NESTI	

Additional contribution to the consumer intakes through drinking water resulting from groundwater metabolite(s) expected to be present above 0.75 µg/L

Metabolite(s)	
ADI (mg/kg bw per day)	
Intake of groundwater metabolites (% ADI)	Adult (60 kg bw, 2 L): XX % ADI Child (10 kg bw, 1 L): XX % ADI Infant (5 kg bw, 0.75 L): XX % ADI
WHO Guideline (WHO, 2009)	

Proposed MRLs (Regulation (EU) No 283/2013, Annex Part A, points 6.7.2 and 6.7.3)

Code[a]	Commodity/Group	MRL/Import tolerance[b] (mg/kg) and Comments	
Plant commodities			
Representative uses			
500030	Maize	0.01*	
234000	Sweet corn	0.01*	
Animal commodities			

(a): Commodity code number, as listed in Annex I of Regulation (EC) No 396/2005
(b): MRLs proposed at the LOQ, should be annotated by an asterisk (*) after the figure.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Environmental fate and behaviour

Route of degradation (aerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.1)

Mineralisation after 100 days	29 % after 120 d, [^{14}C-Ind]-label (n[6]= 7) 8.4 % after 120 d, [^{14}C-TFMP]-label (n= 7)
Non-extractable residues after 100 days	45 % after 120 d, [^{14}C-Ind]-label (n= 7) 56 % after 240 d, [^{14}C-TFMP]-label (n= 7)
Metabolites requiring further consideration - name and/or code, % of applied (range and maximum)	IN-JT333 – 18.6 % at 7 d, [^{14}C-TFMP]-label IN-KG433 - 40% at 62 d, [^{14}C-TFMP]-label IN-KB687 - 6.9% at 3 7 d, [^{14}C-TFMP]-label IN-JU873 - 12.9% at 30 d, [^{14}C-TFMP]-label IN-KT413 - 18.4% at 3 d, [^{14}C-Ind]-label IN-ML438 - 9.7% at 24 d, [^{14}C-TFMP]-label IN-MK638 - 28% at 90 d, [^{14}C-TFMP]-label IN-MK643 max. 12% at 10 d, [^{14}C-TFMP]-label Sterile conditions: no data

Route of degradation (anaerobic) in soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.2)

Mineralisation after 100 days	1.2 % after 122 d, [^{14}C-Ind]-label (n=1) 0.1 % after 122 d, [^{14}C-TFMP]-label (n=1)
Non-extractable residues after 100 days	37.3 % after 122 d, [^{14}C-Ind]-label (n=1) 33.4 % after 122 d, [^{14}C-TFMP]-label (n=1)
Metabolites that may require further consideration for risk assessment - name and/or code, % of applied (range and maximum)	IN-KT413 – 25.2-23.2 % at 4 d (n= 1), [^{14}C-Ind] & [^{14}C-TFMP] labels IN-IN-U8E24 –39.4-40.0 % at 23 d (n= 1), [^{14}C-Ind] & [^{14}C-TFMP] labels IN-MP819–5.9-5.3 % at 52 & 23 d (n= 1), [^{14}C-Ind] & [^{14}C-TFMP] labels IN-KN125 (S-enantiomer of IN-JT333) – 10.1-10.6 % at 4 d (n= 1), [^{14}C-Ind] & [^{14}C-TFMP] labels IN-MS775 – 28.2-34.4 % at 122 d (n= 1), [^{14}C-Ind] & [^{14}C-TFMP] labels IN-U8F52 – 14.7 % at 31 d (n= 1), [^{14}C-Ind] label IN-MK638 – 9.4 % at 16 d (n= 1), [^{14}C-TFMP] label

Route of degradation (photolysis) on soil (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3)

Metabolites that may require further consideration for risk assessment - name and/or code, % of	IN-KB687 – 22.0 % at 13 d, [^{14}C-TFMP]-label

[6] n corresponds to the number of soils.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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applied (range and maximum)	Sterile conditions: no data
Mineralisation at study end	4.5 % after 15 d (study end), [^{14}C-Ind]-label (n=1) 2.9 % after 15 d (study end), [^{14}C-TFMP]-label (n=1)
Non-extractable residues at study end	5.8 % after 15 d (study end), [^{14}C-Ind]-label (n=1) 9.8 % after 15 d (study end), [^{14}C-TFMP]-label (n=1)

Rate of degradation in soil (aerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Indoxacarb **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions					
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Speyer 2.2 (both labels) – Loamy sand	6.2 [a)]	20°C / 50% MWHC	2.4/216.9	-	5	FOMC
Tama (both labels) - Silt Loam	6.2	20°C / 75% MWHC	5.4/23.2	-	2	DFOP
Speyer 2.2 (TFMP) - Sandy loam	5.9	20°C / 50-60 % MWHC	10.3/404.7	-	6	DFOP
Nambsheim (TFMP) – Silt loam	7.7	20°C / 50-60 % MWHC	7.0/134.1	-	11	DFOP
Tama (Original) (both labels) – Silt loam	6.3	25°C / 75% pF2.5	3.4[c]/15.7[c]	-	12	DFOP
Geometric mean (if not pH dependent)				-		

a) Measured in Water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Corrected to 20°C

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Indoxacarb **Modelling endpoints**	Dark aerobic conditions						
Soil type	pH	t. °C / % MWHC	DT_{50} /DT_{90} (d)	Modelling DT_{50} (d) 20°C	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Speyer 2.2 (both labels) – Loamy sand	6.2 [a)]	20°C / 50% MWHC	2.4/216.9	65.3	65.3	5	FOMC (DT_{90}/3.32)
Tama (both labels) - Silt Loam	6.2	20°C / 75% MWHC	5.2/24.7	7.44	6.1	4	FOMC (DT_{90}/3.32)
Speyer 2.2 (TFMP) - Sandy loam	5.9	20°C / 50-60 % MWHC	10.5/322.9	164.5	164.5	6	HS (Slow phase DT_{50})
Nambsheim (TFMP) – Silt loam	7.7	20°C / 50-60 % MWHC	7.0/134.1	120.1	113.2	11	DFOP (Slow phase DT_{50})
Tama (Original) (both labels) – Silt loam	6.3	25°C / 75% pF2.5	2.0/11.8[f]	5.6[g]	4.6	14	FOMC (DT_{90}/3.32)
Geometric mean (if not pH dependent)					32.1		
pH dependence					No		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Value at 25°C
d) Corrected to 20°C

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Rate of degradation in soil (aerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

IN-JT333 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was Indoxacarb							
Soil type	X^{7}	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Gross Umstadt - Sandy loam		7.1	20°C / 50% MWHC	4.3/37.8	-	72.5	6.9	DFOP (Slow phase k2)
Lleida - Light clay		8.0	20°C / 50% MWHC	9.6/79.2	-	55.9	2.8	DFOP (Slow phase k2)
Nambsheim - Sandy loam		7.7	20°C / 50% MWHC	6.0/43.2	-	99.9	8.2	DFOP (Slow phase k2)
Speyer 2.2 - Sandy loam		5.6	20°C / 50% MWHC	7.9/228.8	-	147.5	4.8	DFOP (Slow phase k2)
Tama - Light clay		6.0	20°C / 50% MWHC	7.0/47.0	-	14.2	5.1	FOMC (DT90/3.32)
Speyer 2.2 (TFMP) – Loamy sand		6.2	20°C / 50% MWHC	11.5/149.2	-	45	13	FOMC (DT_{90}/3.32, fit from peak)
Tama (both labels) - Silt Loam		6.2	20°C / 75% MWHC	34.6/168.9	-	50.9	7	FOMC (DT_{90}/3.32, fit from peak)
Speyer 2.2 (TFMP) - Sandy loam		5.9	20°C / 50-60 % MWHC	11.3/65.2	-	19.6	9	FOMC (DT_{90}/3.32, fit from peak)
Nambsheim (TFMP) – Silt loam		7.7	20°C / 50-60 % MWHC	26.5/88.1	-	26.5	11	SFO(fit from peak)
Persistence endpoint						147.5		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

IN-JT333 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was Indoxacarb							
Soil type	X^7	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Gross Umstadt - Sandy loam		7.1	20°C / 50% MWHC	5.0/16.7	-	5.0	17.4	SFO
Lleida - Light clay		8.0	20°C / 50% MWHC	12.3/40.7	-	10.8	11.4	SFO
Nambsheim - Sandy loam		7.7	20°C / 50% MWHC	6.9/22.9	-	6.9	14.6	SFO
Speyer 2.2 - Sandy loam		5.6	20°C / 50% MWHC	6.2/57.2	-	111.0	4.1	HS (Slow phase DT_{50})
Tama - Light clay		6.0	20°C / 50% MWHC	9.7/32.3	-	9.7	12.2	SFO
Speyer 2.2 (TFMP) – Loamy sand		6.2	20°C / 50% MWHC	19.8/65.6	-	19.8	25	SFO
Tama (both labels) - Silt Loam		6.2	20°C / 75% MWHC	40.6/134.7	-	33.2	9	SFO (fit from peak)
Speyer 2.2 (TFMP) - Sandy loam		5.9	20°C / 50-60 % MWHC	12.4/41.3	-	12.4	11.3	SFO (fit from peak)
Nambsheim (TFMP) – Silt loam		7.7	20°C / 50-60 % MWHC	26.5/88.1	-	25.0	11	SFO (fit from peak)
Geometric mean (if not pH dependent)						16.3		
Arithmetic mean					-			
pH dependence,						No		

a) Measured in water

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

IN-KT413

IN-KT413 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions - Metabolite dosed							
Soil type	X^7	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
Hidalgo – Sandy clay loam		8.1	20°C / 50% MWHC	4.0/20.5	-	10.4	1	DFOP (slow phase DT_{50})
Lleida – Clay loam		8.1	20°C / 50% MWHC	1.9/10.4	-	3.1	4	FOMC (DT_{90}/3.32)
Mattapex - Silt loam		6.7	20°C / 50% MWHC	0.6/2.6	-	0.8	3	FOMC (DT_{90}/3.32)
Persistence endpoint						10.4		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

IN-KT413 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed							
Soil type	X^7	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Hidalgo – Sandy clay loam		8.1	20°C / 50% MWHC	4.6/15.3	-	3.7	6	SFO
Lleida – Clay loam		8.1	20°C / 50% MWHC	2.3/7.6	-	2.2	9	SFO
Mattapex - Silt loam		6.7	20°C / 50% MWHC	0.7/2.3	-	0.6	8	SFO
Geometric mean (if not pH dependent)						1.7		
Arithmetic mean					-			
pH dependence,						No		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

IN-KG433

IN-KG433 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions - Metabolite dosed							
Soil type	X^7	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
Speyer 2.2 – Loamy sand		6.2	20°C / 50% MWHC	1.9/57.8	-	17.4	5	FOMC (DT_{90}/3.32)
Mattapex – Silt loam		6.2	20°C / 50% MWHC	1.6/14.0	-		6	DFOP
Pesaro – Silty clay loam		8.5	20°C / 50% MWHC	2.5/13.1	-	3.95	8	FOMC (DT_{90}/3.32)
Lleida – Clay loam		8.2	20°C / 50% MWHC	1.7/13.1	-	3.95	2	FOMC (DT_{90}/3.32)
Hidalgo – Sandy clay loam		8.4	20°C / 50% MWHC	1.9/13.8	-	4.15	14	FOMC (DT_{90}/3.32)
Persistence endpoint						17.4		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

IN-KG433 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed							
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	Moisture correction factor	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Speyer 2.2 – Loamy sand	6.2	20°C / 50% MWHC	1.9/57.8	-	1	17.4	5	FOMC (DT_{90}/3.32)
Mattapex – Silt loam	6.2	20°C / 50% MWHC	1.6/10.4	-	0.86	2.7	8	FOMC (DT_{90}/3.32)
Pesaro – Silty clay loam	8.5	20°C / 50% MWHC	2.5/13.1	-	0.99	2.9	9	SFO
Lleida – Clay loam	8.2	20°C / 50% MWHC	1.713.1	-	0.98	3.8	2	FOMC (DT_{90}/3.32)
Hidalgo – Sandy clay loam	8.4	20°C / 50% MWHC	1.9/13.8	-	1	2.6	17	SFO
Geometric mean (if not pH dependent)						4.2		
Arithmetic mean				-				
pH dependence,						No		

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

IN-JU873

IN-JU873 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions - Metabolite dosed							
Soil type	X^7	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
Speyer 2.2 – Loamy sand		6.2	20°C / 50% MWHC	32.8/186.1		66.1	4	DFOP (slow phase DT_{50})
Mattapex – Silt loam		6.2	20°C / 50% MWHC	19.0/242.5		103.5	5	DFOP (slow phase DT_{50})
Pesaro – Silty clay loam		8.5	20°C / 50% MWHC	10.0/66.4		24.8	4	DFOP (slow phase DT_{50})
Lleida – Clay loam		8.2	20°C / 50% MWHC	13.8/136.6		65.4	6	DFOP (slow phase DT_{50})
Hidalgo – Sandy clay loam		8.4	20°C / 50% MWHC	18.1/212.5		88.9	8	DFOP (slow phase DT_{50})
Persistence endpoint						103.5		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

IN-JU873 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed							
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	Moisture correction factor	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Speyer 2.2 – Loamy sand	6.2	20°C / 50% MWHC	47.2/156.8	-	1	47.2	10	SFO
Mattapex – Silt loam	6.2	20°C / 50% MWHC	42.4/140.9	-	0.86	36.7	14	SFO
Pesaro – Silty clay loam	8.5	20°C / 50% MWHC	15.7/52.2	-	0.99	15.6	13	SFO
Lleida – Clay loam	8.2	20°C / 50% MWHC	32.2/107.0	-	0.98	31.5	16	SFO
Hidalgo – Sandy clay loam	8.4	20°C / 50% MWHC	40.3/134.0	-	1	40.3	15	SFO
Geometric mean (if not pH dependent)						32.1		
Arithmetic mean				-				
pH dependence,						No		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

IN-KB687

IN-KB687 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions - Metabolite dosed							
Soil type	*X*[7]	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
Sassafras - Loam		5.5	20°C / 50% MWHC	0.67/2.21	-	0.67	2	SFO
Tama – Silty clay loam		6.3	20°C / 50% MWHC	0.56/1.85	-	0.56	9	SFO
Persistence endpoint						0.67		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

IN-KB687 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed							
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	Moisture correction factor	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Sassafras - Loam	5.5	20°C / 50% MWHC	0.67/2.21	-	1	0.67	2	SFO
Tama – Silty clay loam	6.3	20°C / 50% MWHC	0.56/1.85	-	0.91	0.51	9	SFO
Worst-case value						0.67		
Arithmetic mean				-				
pH dependence,						No		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

IN-ML438

IN-ML438 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions - Metabolite dosed or the precursor from which the f.f. was derived was Indoxacarb							
Soil type	*X*[7]	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
Gross Umstadt - Sandy loam		6.9	20°C / 50% MWHC	40.6/258.6		97.4		DFOP (slow phase DT_{50})
Lleida - Light clay		7.9	20°C / 50% MWHC	107.1/507.7		172.8		DFOP (slow phase DT_{50})
Nambsheim - Sandy loam		7.6	20°C / 50% MWHC	54.11/241.9		80.9		DFOP (slow phase DT_{50})
Sassafras – Sandy loam		6.0	20°C / 50% MWHC	59.73/586.2		186.5		DFOP (slow phase DT_{50})
Tama - Light clay		6.1	20°C / 50% MWHC	72.2/384.7		134.8		DFOP (slow phase DT_{50})
Tama (Original) (both labels) – Silt loam		6.3	25°C / 75% pF2.5	24.3[u)]/315.5[u)]		144.6[u)]		DFOP, fit from peak (slow phase DT_{50})
Persistence endpoint						186.5		

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Corrected to 20°C

IN-ML438 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed or the precursor from which the f.f. was derived was Indoxacarb							
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	Moisture correction factor	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Gross Umstadt - Sandy loam	6.9	20°C / 50% MWHC	53.5/177.8	-	1	53.5	7.0	SFO
Lleida - Light clay	7.9	20°C / 50% MWHC	109.5/363.7	-	0.78	65.8	6.1	SFO
Nambsheim - Sandy loam	7.6	20°C / 50% MWHC	62.8/208.2	-	1	62.7	5.4	SFO
Sassafras – Sandy loam	6.0	20°C / 50% MWHC	74.9/248.9	-	1	74.9	8.0	SFO
Tama - Light clay	6.1	20°C / 50% MWHC	81.0/269.3	-	1	81.1	5.8	SFO
Tama (Original) (Indanon) – Silt loam	6.3	25°C / 75% pF2.5	24.3[x)]/315.5 [x)]	-	0.8293	119.9	6	DFOP, fit from peak (slow phase DT_{50})
Geometric mean (if not pH dependent)						73.7		
Arithmetic mean				-				
pH dependence,						No		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7
c) Corrected to 20°C

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

IN-MK643

IN-MK643 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions - Metabolite dosed							
Soil type	X^7	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
Speyer 2.2 – Sand		6.3	20°C / 50% MWHC	314.2/1043.8	-	314.2	4	SFO
Mattapex –Loam		6.1	20°C / 50% MWHC	275.5/915.2	-	275.5	5	SFO
Pesaro – Clay loam		8.2	20°C / 50% MWHC	177.8/590.8	-	177.8	7	SFO
Lleida – Clay loam		8.0	20°C / 50% MWHC	199.4/662.3	-	199.4	8	SFO
Hidalgo – Sandy clay loam		8.1	20°C / 50% MWHC	123.3/490.6	-	123.3	7	SFO
Persistence endpoint						314.2		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

IN-MK643 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed							
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	Moisture correction factor	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Speyer 2.2 – Sand	6.3	20°C / 50% MWHC	314.2/1043.8	-	1	314.2	4	SFO
Mattapex –Loam	6.1	20°C / 50% MWHC	275.5/915.2	-	0.73	201.1	5	SFO
Pesaro – Clay loam	8.2	20°C / 50% MWHC	177.8/590.8	-	0.84	149.0	7	SFO
Lleida – Clay loam	8.0	20°C / 50% MWHC	199.4/662.3	-	0.84	167.7	8	SFO
Hidalgo – Sandy clay loam	8.1	20°C / 50% MWHC	123.3/490.6	-	0.72	88.7	7	SFO
Geometric mean (if not pH dependent)						169.5		
Arithmetic mean				-				
pH dependence,						No		

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

IN-MK638

IN- MK638 **Trigger and persistence endpoints** **Best fit kinetic**	Dark aerobic conditions - Metabolite dosed							
Soil type	X^7	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20 °C	St. (χ^2)	Method of calculation
Speyer 2.2 – Sand		6.3	20°C / 50% MWHC	15.4/51.0	-	15.4	4	SFO
Mattapex –Loam		6.1	20°C / 50% MWHC	17.3/57.5	-	17.3	5	SFO
Pesaro – Clay loam		8.2	20°C / 50% MWHC	4.8/16.1	-	4.8	7	SFO
Lleida – Clay loam		8.0	20°C / 50% MWHC	5.9/19.7	-	5.9	8	SFO
Hidalgo – Sandy clay loam		8.1	20°C / 50% MWHC	10.7/57.5	-	10.7	7	SFO
Persistence endpoint						17.3		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

IN-MK638 **Modelling endpoints**	Dark aerobic conditions Metabolite dosed							
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	Moisture correction factor	DT_{50} (d) 20 °C pF2/10kPa[b)]	St. (χ^2)	Method of calculation
Speyer 2.2 – Loamy sand	6.3	20°C / 50% MWHC	15.4/51.0	-	1	15.4	4	SFO
Mattapex –Loam	6.2	20°C / 50% MWHC	17.3/57.5	-	0.92	16.0	5	SFO
Pesaro – Silty clay loam	8.1	20°C / 50% MWHC	4.8/16.1	-	0.84	4.0	7	SFO
Lleida – Clay loam	8.0	20°C / 50% MWHC	5.6/21.9	-	0.94	5.6	8	SFO
Hidalgo – Sandy clay loam	8.4	20°C / 50% MWHC	10.7/57.5	-	0.82	8.8	7	SFO
Geometric mean (if not pH dependent)						8.7		
Arithmetic mean				-				
pH dependence,						No		

a) Measured in water
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7

Rate of degradation field soil dissipation studies (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.1)

Parent	Aerobic conditions							
Soil type (indicate if bare or cropped soil was used).	Location (country or USA state).	pH[a)]	Depth (cm)	DT_{50} (d) actual	DT_{90}(d) actual	St. (χ^2)	DT_{50} (d) Norm[b)].	Method of calculation
Silt loam (bare soil)	Douai, FR	5.8	0-5	9.4	31.2	12.1	-	SFO
Clay loam(bare soil)	Termens, north SP	8.0	0-5	7.16	23.8	19.4	-	SFO
Loam(bare soil)	Graffignana, IT	5.9	0-5	7.08	23.5	11.9	-	SFO
Loam(bare soil)	Bühren, north GR	6.3	0-5	7.32	24.3	29.9	-	SFO
Geometric mean (if not pH dependent)							-	
pH dependence,				No				

a) Measured in [medium to be stated, usually calcium chloride solution or water]
b) Normalised using a Q10 of 2.58 and Walker equation coefficient of 0.7, values are DegT50matrix
- no normalization of the data was performed.

List of end points

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Combined laboratory and field kinetic endpoints for modelling (when not from different populations)*

Rate of degradation in soil active substance, normalised geometric mean (if not pH dependent)	Not performed, no normalized field DT_{50} available
Rate of degradation in soil transformation products, normalised geometric mean (if not pH dependent)	
Kinetic formation fraction (f. f. k_f / k_{dp}) of transformation products, arithmetic mean	

* Only relevant after implementation of the published EFSA guidance describing how to amalgamate laboratory and field endpoints.

Soil accumulation (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.2.2)

Soil accumulation and plateau concentration	For the worst-case representative use on Lettuce, the following plateau concentration were calculated: Indoxacarb : Plateau concentration of 0.169 mg/kg reached after 4 years Metabolite IN-JT333: Plateau concentration of 0.026 mg/kg reached after 2 years Metabolite IN-JU873: Plateau concentration of 0.017mg/kg reached after 2 years Metabolite IN-ML438: Plateau concentration of 0.011 mg/kg reached after 2 years Metabolite IN-MK643: Plateau concentration of 0.009 mg/kg reached after 3 years Metabolite IN-U8E24: Plateau concentration of 0.035 mg/kg reached after 12 years

Rate of degradation in soil (anaerobic) laboratory studies active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

Parent	Dark anaerobic conditions					
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} / DT_{90} (d)	DT_{50} (d) 20 °C[b)]	St. (χ^2)	Method of calculation
Nambsheim - Sandy loam	7.6	20°C	2.08/33.2		3.86	FOMC α = 0.6843 β = 1.189
Geometric mean (if not pH dependent)						

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58

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Rate of degradation in soil (anaerobic) laboratory studies transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.2.1.4 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.1.1)

IN-U8E24	Dark anaerobic conditions Parent dosed study – fit from metabolite peak.						
Soil type	pH[a)]	t. °C / % MWHC	DT_{50}/ DT_{90} (d)	f. f. k_f / k_{dp}	DT_{50} (d) 20°C[b)]	St. (χ^2)	Method of calculation
Nambsheim - Sandy loam	7.6	20°C	-		-		-
Geometric mean (if not pH dependent)							
Arithmetic mean							

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58

Rate of degradation on soil (photolysis) laboratory active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.1.3

Parent	Soil photolysis				
Soil type	pH[a)]	t. °C / % MWHC	DT_{50} calculated at 39°40'N	St. (χ^2)	Method of calculation
Tama – Silt loam	6.2	25°C / dry soil	28.9		First order

[c)] Measured in water

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Soil adsorption active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Indoxacarb							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Myaka, Sand	0.58	6.2	29	5100	-	-	
Donna, Sandy clay loam	0.81	7.8	26	3300	-	-	
Chino, Loam	0.99	7.6	95	9600	-	-	
Tama, Silt Loam	1.5	6.2	35	2500	-	-	
Geometric mean (if not pH dependent)*						4483[b)]	
Arithmetic mean (if not pH dependent)						**5125**[b)]	**1 (default)**
pH dependence,			No				

[a)] No precision of the medium is given
[b)] Arithmetic and geometric mean of Kdoc value.
* Only relevant after implementation of the published EFSA guidance.

Soil adsorption transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.3.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

IN-JT333							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Myaka, Sand	0.58	6.2	147	25000			
Donna, Sandy clay loam	0.81	7.8	96	12000			
Chino, Loam	0.99	7.6	241	24000			
Tama, Silt Loam	1.5	6.2	114	8200			
Geometric mean (if not pH dependent)*						15587[b)]	
Arithmetic mean (if not pH dependent)						**17300**[b)]	**1 (default)**
pH dependence,			No				

[a)] No precision of the medium is given
[b)] Arithmetic and geometric mean of Kdoc value.

* Only relevant after implementation of the published EFSA guidance.

IN-JU873							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n

Speyer 2.2, Sandy loam	2.2	6.7	409			27500	1.061
Mattapex, Loam	*0.8*	*5.2*	*141*			*31750*	*1.123*
Pesaro, Clay loam	1.2	8	87			5750	0.954
Lleida, Clay loam	1.2	8.1	90			5417	0.939
Hidalgo, Sandy clay loam	0.4	8	53			14000	1.025
Geometric mean (if not pH dependent)*						10465	
Arithmetic mean (if not pH dependent), n=4						**13166**	**1.02**
pH dependence,			No				

[a)] Measured in water

* Only relevant after implementation of the published EFSA guidance.

IN-KG433							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Speyer 2.2, Sandy loam	2.2	6.7	11.4	518	8.7	395	0.9154
Mattapex, Loam	0.8	5.2	2.9	360	2.4	300	0.9278
Pesaro, Clay loam	1.2	8	5.2	433	3.7	308	0.8774
Lleida, Clay loam	1.2	8.1	4.2	348	3.2	267	0.8979
Hidalgo, Sandy clay loam	0.4	8	1.4	343	1.2	300	0.9475
Geometric mean (if not pH dependent)*						311	
Arithmetic mean (if not pH dependent), n=4						**314**	**0.913**
pH dependence,			No				

[b)] Measured in water

* Only relevant after implementation of the published EFSA guidance.

IN-KT413							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Speyer 2.2, Sandy loam	1.7	6.5	7.3	431	6.1	358	0.96
Mattapex, Loam	2.2	6.7	10.0	453	10.3	469	1.01
Lleida, Clay loam	1.2	8.1	4.4	364	4.1	346	0.99
Hidalgo, Sandy clay loam	0.5	8.6	2.2	441	1.0	204	0.83
Geometric mean (if not pH dependent)*						323	
Arithmetic mean (if not pH dependent), n=4						**344**	**0.95**
pH dependence,			No				

[c)] Measured in water

* Only relevant after implementation of the published EFSA guidance.

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Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Speyer 2.2, Sandy loam	2.0	6.3	5.6	278	2.6	130	0.85
Mattapex, Loam	1.5	6.2	2.2	145	1.0	67	0.84
Pesaro, Silty clay loam	1.4	8.1	4.6	325	1.3	93	0.76
Lleida, Clay loam	1.1	8	5.1	463	1.8	164	0.80
Hidalgo, Sandy clay loam	0.3	8.4	1.2	397	0.9	300	0.94
Geometric mean (if not pH dependent)*						**132**	
Arithmetic mean (if not pH dependent), n=4						**151**	**0.84**
pH dependence,			No				

[d)] Measured in water
* Only relevant after implementation of the published EFSA guidance.

IN-KB687							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Speyer 2.2, Sandy loam	2.0	6.4	7.56	383	4.83	244	0.8727
Nambsheim, Sandy loam	1.7	7.8	5.34	317	3.07	182	0.8389
Lleida, Clay loam	1.9	8.0	8.66	452	5.37	280	0.8740
Tama, Silty clay loam	3.3	6.8	13.5	408	5.45	164	0.7728
Sassafras, Sandy loam	0.93	5.7	4.02	432	2.94	316	0.9035
Geometric mean (if not pH dependent)*						230	
Arithmetic mean (if not pH dependent), n=4						**237**	**0.85**
pH dependence,			No				

[e)] Measured in water
* Only relevant after implementation of the published EFSA guidance.

IN-ML438							
Soil Type	OC %	Soil pH[a)]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n

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Gross-Umstadt	1.2	6.5	231	19908	-	-	-
Lleida	1.9	7.6	381	20498	-	-	-
Nambsheim	1.7	7.3	263	15082	-	-	-
Sassafras	0.76	5.4	156	20667	-	-	-
Tama	1.8	5.5	312	17332	-	-	-
Geometric mean (if not pH dependent)*					18564		
Arithmetic mean (if not pH dependent), n=4					**19601**		**1 (default)**
pH dependence,			No				

[f] Measured in water
* Only relevant after implementation of the published EFSA guidance.

IN-MK643							
Soil Type	OC %	Soil pH[a]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Speyer 2.2, Sandy loam	2.1	6.3	9.39	447	3.96	189	0.83
Mattapex, Loam	0.9	6.1	4.88	543	2.03	226	0.81
Pesaro, Clay loam	1.2	8.2	10.7	893	4.23	353	0.83
Lleida, Clay loam	1.1	8.0	8.91	810	2.67	243	0.77
Hidalgo, Sandy clay loam	0.4	8.1	3.06	765	1.34	335	0.81
Geometric mean (if not pH dependent)*						261	
Arithmetic mean (if not pH dependent), n=4						**269**	**0.81**
pH dependence,			No				

[g] Measured in water
* Only relevant after implementation of the published EFSA guidance.

IN-U8E24							
Soil Type	OC %	Soil pH[a]	K_d (mL/g)	K_{doc} (mL/g)	K_F (mL/g)	K_{Foc} (mL/g)	1/n
Data gap							

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Mobility in soil column leaching active substance (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.1 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	Aged leaching studies performed on 4 soils Elution (mm): 200 mm Time period (d): 48 to 65 hours
	Leachate: < LOD (0.18%) total residues/radioactivity in leachate > 82 to 97 % total residues/radioactivity retained in top 15 cm of column and in aged soil.

Mobility in soil column leaching transformation products (Regulation (EU) N° 283/2013, Annex Part A, point 7.1.4.1.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.1.2.1)

Column leaching	No data – not required

Lysimeter / field leaching studies (Regulation (EU) N° 283/2013, Annex Part A, points 7.1.4.2 / 7.1.4.3 and Regulation (EU) N° 284/2013, Annex Part A, points 9.1.2.2 / 9.1.2.3)

Lysimeter/ field leaching studies	Not performed – not required

Hydrolytic degradation (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.1.1

Hydrolytic degradation of the active substance and metabolites > 10 %	pH 4: Stable
	pH 7: 17.6 d h at 20 °C (1^{st} order, χ^2=x) IN-KT413: 66.9 % AR (30 d) IN-MP819: 16.2 % AR (15 d)
	pH 9: 0.37 d h at 20 °C (1^{st} order, χ^2=x) IN-KT413: 99.1 % AR (1.2 d)

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Aqueous photochemical degradation (Regulation (EU) N° 283/2013, Annex Part A, points 7.2.1.2 / 7.2.1.3)

Photolytic degradation of active substance and metabolites above 10 %	DT_{50} : 4.5 d Natural light, 39°40'N; DT_{50} 3 days IN-MF014: 37.6 % AR (15 d), [^{14}C-TFMP]-label IN-KB687: 28.7 % AR (10 d), [^{14}C-TFMP]-label IN-C0639: 10.2 % AR (15 d), [^{14}C-Ind]-label IN-MA573: 19.9 % AR (10 d), [^{14}C-Ind]-label IN-MH304: 32.3 % AR (15 d), [^{14}C-Ind]-label No estimated DT_{50} for metabolites
Quantum yield of direct phototransformation in water at Σ > 290 nm	0.00038

'Ready biodegradability' (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.1)

Readily biodegradable (yes/no)	No

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Aerobic mineralisation in surface water (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.2 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.1)

Parent										
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to *x* °C[c]		At study temp	Normalised to x °C[c]		
Chula, USA (Fresh water)	7.4	-	20° C	-	-		5.93	*	7.6	SFO

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
[c] Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).
* Temperature was not recorded at sampling time.

Metabolite IN-KT413	Max in total system 88.6 % after 28 days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C[c]		At study temp	Normalised to x °C[c]		
Chula, USA (Fresh water)	No DT_{50} calculated.									

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Temperature of incubation=temperature that the environmental media was collected or std temperature of 20°C
[c] Normalised using a Q10 of 2.58 to the temperature of the environmental media at the point of sampling. (note temp of x should be stated).

Metabolite IN-MK638	Max in total system 8.5 % after 60 days									
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed [a]	t. °C[b]	DT_{50} /DT_{90} whole sys. (suspended sediment test)		St. (χ^2)	DT_{50} /DT_{90} Water (pelagic test)		St. (χ^2)	Method of calculation
				At study temp	Normalised to x °C[c]		At study temp	Normalised to x °C[c]		
Chula, USA (Fresh water)	No DT_{50} calculated.									

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Mineralisation and non extractable residues (for parent dosed experiments)					
System identifier (indicate fresh, estuarine or marine)	pH water phase	pH sed	Mineralisation *x* % after *n* d. (end of the study).	Non-extractable residues. max *x* % after *n* d (suspended sediment test)	Non-extractable residues. max *x* % after *n* d (end of the study) (suspended sediment test)
Chula, USA (Fresh water)	7.4	-	5.8 to 43.4 % after 60 days	-	-

Water / sediment study (Regulation (EU) N° 283/2013, Annex Part A, point 7.2.2.3 and Regulation (EU) N° 284/2013, Annex Part A, point 9.2.2)

Parent – persistence endpoint	Distribution (max in water 0.2 after 120 d. Max. sed 60.5 % after 1 d)									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury pond	7.9	8.1	20°C	4.8/97.6						DFOP
Chatsworth	6.9	7.6	20°C	2.8/9.3						HS
Chula	8.6	7.6	20°C	5.2/17.3						SFO
Gosse river	7.4	6.7	20°C	2.2/11.2						HS

[a)] Measured in water
[b)] Normalised using a Q10 of 2.58

Parent – modelling endpoints	Distribution (max in water 0.2 after 120 d. Max. sed 60.5 % after 1 d)									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury pond	7.9	8.1	20°C	4.8/97.6 (29.4*)						DFOP (DT_{90}/3.32)
Chatsworth	6.9	7.6	20°C	2.8/9.3 (2.8*)						HS (DT_{90}/3.32)
Chula	8.6	7.6	20°C	5.2/17.3						SFO
Gosse river	7.4	6.7	20°C	2.6/8.5						SFO
Geometric mean at 20°C[b)]				5.8						

[c)] Measured in water
[d)] Normalised using a Q10 of 2.58
* The DT_{50} value into brackets corresponds to pseudo-SFO value calculated with method indicated in last column and included in the mean calculation

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Metabolite IN-JT333	Distribution (max in water 0 % after 100 d. Max. sed 25.7 % after 14 d). Max in total system 25.7 % after 14 days, kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury Pond (Indanone)	7.9	8.1	20° C	-		-		-		-
Bury Pond (TFMP)				73.1/519.1 (156*)		-				DFOP slow phase, from decline
Chatsworth (both labels)	6.9	7.6	20° C	38.3/127.4		-		-		From parent, HS-SFO **For step 3**
Chatsworth (Indanone)	*6.9*	*7.6*	*20° C*	*32.4/107.7*		-		-		*SFO, from decline* ***For step 2***
Chatsworth (TFMP)				*45.6/151.5*		-		-		*SFO, from decline* ***For step 2***
Chula (Indanone)	8.6	7.6	20° C	10.1/336 (101*)		-		-		DFOP, from decline
Chula (TFMP)				7.1/50.2 (15.1*)		-		-		HS (DT_{90}/3.32), from decline
Goose River (Indanone)	7.4	6.7	20° C	11.4/302.1 (137.5*)		-		-		HS (slow phase), from decline
Goose River (TFMP)				-		-		-		
Geometric mean at 20°C[b] (n=6) for step 1-2				60.3						
Geometric mean at 20°C[b] (n=5) for step 3				66.2 (step 3)						

[a] Measured in [medium to be stated, usually calcium chloride solution or water]
[b] Normalised using a Q10 of 2.58
* The DT_{50} value into brackets corresponds to pseudo-SFO value calculated with method indicated in last column and included in the mean calculation

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Metabolite IN-KT413	Distribution (max in water 69.1% after 14 d. Max. sed 10.7 % after 14 d). Max in total system 83.0% after 7 days, kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury Pond (Indanone)	7.9	8.1	20° C	12.4/100.2 (30.12*)		-		-		FOMC (DT_{90}/3.32), from decline
Bury Pond (TFMP)				53.0/176.2		-		-		SFO, from decline
Chatsworth (Indanone)	6.9	7.6	20° C	23.4/77.9		-		-		SFO, from decline
Chatsworth (TFMP)				5.3/113.8 (34.3*)		-		-		FOMC (DT_{90}/3.32), from decline
Chula (Indanone)	8.6	7.6	20° C	23.6/78.5		-		-		SFO, from decline
Chula (TFMP)				-		-		-		
Goose River (Indanone)	7.4	6.7	20° C	20.6/68.5		-		-		SFO, from decline
Goose River (TFMP)				22.7/75.5		-		-		SFO, from decline
Geometric mean at 20°C[b)]				28		-		-		

[c)] Measured in [medium to be stated, usually calcium chloride solution or water]
[d)] Normalised using a Q10 of 2.58
* The DT_{50} value into brackets corresponds to pseudo-SFO value calculated with method indicated in last column and included in the mean calculation

Metabolite IN-KG433	Distribution (max in water 0 % after 102 d. Max. sed 7.7% after 14 d). Max in total system 7.7 % after 14 days. kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury pond	7.9	8.1	20° C	No reliable DT_{50}		-		-		-
Chatsworth	6.9	7.6	20° C	No reliable DT_{50}		-		-		-
Geometric mean at 20°C[b)]				1000 (default)						

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Metabolite IN-ML438	Distribution (max in water 0 % after 102 d. Max. sed 3.6% after 28 d). Max in total system 3.6 % after 28 days. kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury pond	7.9	8.1	20° C	1000 (default)		-		-		-
Chatsworth	6.9	7.6	20° C	45.4/150.9		-		-		SFO, from decline
Geometric mean at 20°C[b)]				213.1						

Metabolite IN-MK638	Distribution (max in water 4.0 % after 100 d. Max. sed 5 % after 100 d). Max in total system 9 % after 100 days, and sill increasing at the end of the study. kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Chula	8.6	7.6	20° C	No reliable DT_{50}		-		-		-
Gosse river	7.4	6.7	20° C	No reliable DT_{50}		-		-		-
Geometric mean at 20°C[b)]				1000 (default)						

Metabolite IN-MP819	Distribution (max in water 0.4% after 52 d. Max. sed 21.3 % after 74 d). Max in total system 21.3% after 74 days, kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury pond	7.9	8.1	20° C	No reliable DT_{50}		-		-		-
Chatsworth	6.9	7.6	20° C	No reliable DT_{50}		-		-		-
Chula	8.6	7.6	20° C	No reliable DT_{50}		-		-		-
Gosse river	7.4	6.7	20° C	No reliable DT_{50}		-		-		-
Geometric mean at 20°C[b)]				1000 (default)						

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Metabolite IN-U8E24	Distribution (max in water 10.5 % after 52 d. Max. sed 16.0 % after 28 d). Max in total system 24.3 % after 28 days, kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Chula	8.6	7.6	20° C	23.9/79.5		-		-		SFO, from decline
Gosse river	7.4	6.7	20° C	1000 (default)		-		-		-
Geometric mean at 20°C[b)]				393.2						

Metabolite IN-UYG24	Distribution (max in water 31.6 % after 52 d. Max. sed 0 % after 100 d). Max in total system 31.6 % after 52 days, kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Chula	8.6	7.6	20° C	1000 (default)		-		-		-
Gosse river	7.4	6.7	20° C	14.1/46.7		-		-		SFO, from decline
Geometric mean at 20°C[b)]				118.7						

Metabolite IN-MS775	Distribution (max in water 0 % after 100 d. Max. sed 14.7 % after 70 d). Max in total system 14.7 % after 70 days, kinetic formation fraction (k_f/k_{dp}): no reliable data									
Water / sediment system	pH water phase	pH sed [a)]	t. °C	DT_{50} /DT_{90} whole sys.	St. (χ^2)	DT_{50} /DT_{90} water	St. (χ^2)	DT_{50} /DT_{90} sed	St. (χ^2)	Method of calculation
Bury pond	7.9	8.1	20° C	No reliable DT_{50}						
Chatsworth	6.9	7.6	20° C	No reliable DT_{50}						
Chula	8.6	7.6	20° C	No reliable DT_{50}		-		-		-
Gosse river	7.4	6.7	20° C	No reliable DT_{50}		-		-		-
Geometric mean at 20°C[b)]				1000 (default)						

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Mineralisation and non extractable residues (from parent dosed experiments)					
Water / sediment system	pH water phase	pH sed	Mineralisation x % after n d. (end of the study).	Non-extractable residues in sed. max x % after n d	Non-extractable residues in sed. max x % after 100 d (end of the study)
Bury pond (^{14}C-Ind– ^{14}C-TFMP)	7.9	8.1	9.6-1.5%	23.9 – 22.7 % after 56-70 d	28.6-16.7%
Chatsworth (^{14}C-Ind– ^{14}C-TFMP)	6.9	7.6	25.8-6.8%	50.4 – 65.4 % after 56 d	43.7-62.3%
Chula (^{14}C-Ind– ^{14}C-TFMP)	8.6	7.6	6.2-0.9 %	35.3-32.3 % after 100 d	35.3-32.3 %
Gosse river(^{14}C-Ind– ^{14}C-TFMP)	7.4	6.7	7.0-1.8%	60.5-66.1 % after 100 d	60.5-66.1 %

Fate and behaviour in air (Regulation (EU) N° 283/2013, Annex Part A, point 7.3.1)

Direct photolysis in air	Not studied - no data requested
Photochemical oxidative degradation in air	No data
Volatilisation	from plant surfaces (BBA guideline): predicted negligible
	from soil surfaces (BBA guideline): predicted negligible
Metabolites	none

Residues requiring further assessment (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.1)

Environmental occurring residues requiring further assessment by other disciplines (toxicology and ecotoxicology) and or requiring consideration for groundwater exposure	Soil: Indoxacarb, IN-JT333, IN-KG433, IN-KT413, IN JU873, IN-ML438, IN-MK638, IN-KB687, IN-MK643, and IN-U8E24. Surface water: Indoxacarb, IN-JT333, IN-KG433, IN-KT413, IN JU873, IN-ML438, IN MK638, IN-KB687, IN-MK643, IN-MP819, IN-MS775, IN U8E24, and IN-UYG24. Sediment: Indoxacarb, IN-JT333, IN-KG433, IN-KT413, IN-KB687, IN-MP819, and IN-MS775, Ground water: Indoxacarb, IN-JT333, IN-KG433, IN-KT413, IN JU873, IN-ML438, IN-MK638, IN-KB687, IN-MK643, and IN-U8E24. Air: -

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Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2)

See section 5, Ecotoxicology

Monitoring data, if available (Regulation (EU) N° 283/2013, Annex Part A, point 7.5

Soil (indicate location and type of study)	No data
Surface water (indicate location and type of study)	No data
Ground water (indicate location and type of study)	No data
Air (indicate location and type of study)	No data

PEC soil (Regulation (EU) N° 284/2013, Annex Part A, points 9.1.3 / 9.3.1)

Parent	DT_{50} (d): 231 days
Method of calculation	Kinetics: DFOP, DT_{50} calculated from k2 parameter Field or Lab: representative worst case from lab studies
Application data	Crop: Maize, Lettuce Depth of soil layer: 5cm for Actual concentration, mixing depth of 20cm for background plateau concentration Soil bulk density: 1.5g/cm^3 % plant interception: 50%/75% for maize (BBCH 34-77), 25% for lettuce (BBCH 13-49). Number of applications: 2 for maize, 4 for lettuce Interval (d): as worst-case the calculations were based on a single application of the total applied dose of parent active substance. Application rate(s): 37.5 g a.s./ha Since the highest PECs (0.150 mg/kg) will arise from the use on lettuce, only this crop group was considered for short and long term risk assessment.

Maize

$PEC_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial			0.038	
Plateau	0.042 mg/kg after 3			

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PEC$_{(s)}$ (mg/kg)	Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
concentration	yr			

Lettuce

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.150	-
Short term	24h			0.149	0.150
	2d			0.149	0.149
	4d			0.147	0.149
Long term	7d			0.147	0.148
	28d			0.138	0.144
	50d			0.129	0.139
	100d			0.111	0.130
Plateau concentration		0.169 mg/kg after 4 yr			

Metabolite IN-JT333	
Method of calculation	Molecular weight relative to the parent: 0.89 DT_{50} (d): 147.5 days Kinetics: DFOP, DT_{50} calculated from k2 parameter Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 6.97 g/ha (assumed IN-JT333 is formed at a maximum of 18.6 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.006	-
Short term	24h			0.006	0.006

List of end points

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	2d			0.006	0.006
	4d			0.006	0.006
Long term	7d			0.006	0.006
	28d			0.005	0.006
	50d			0.005	0.006
	100d			0.004	0.005
Plateau concentration		0.007 mg/kg after 2 yr			

Lettuce

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.025	-
Short term	24h			0.025	0.025
	2d			0.025	0.025
	4d			0.024	0.025
Long term	7d			0.024	0.024
	28d			0.022	0.023
	50d			0.020	0.022
	100d			0.016	0.020
Plateau concentration		0.026 mg/kg after 2 yr			

Metabolite IN-JU873 Method of calculation	Molecular weight relative to the parent: 0.867 DT_{50} (d): 103.5 days Kinetics: DFOP, DT_{50} calculated from k2 parameter Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 4.84 g/ha (assumed IN-JU873 is formed at a maximum of 12.9 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

List of end points

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$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
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
	28d			0.003	0.004
	50d			0.003	0.004
	100d			0.002	0.003
Plateau concentration		0.004 mg/kg after 2 yrs			

Lettuce

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.017	-
Short term	24h			0.017	0.017
	2d			0.017	0.017
	4d			0.016	0.017
Long term	7d			0.016	0.016
	28d			0.014	0.015
	50d			0.012	0.014
	100d			0.009	0.012
Plateau concentration		0.017 mg/kg after 2 yr			

Metabolite IN-ML438	
Method of calculation	Molecular weight relative to the parent: 0.717 DT_{50} (d): 186.5 days Kinetics: DFOP, DT_{50} calculated from k2 parameter Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 3.64 g/ha (assumed IN-ML438 is formed at a maximum of 9.7 % of the applied dose)

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As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.003	-
Short term	24h			0.003	0.003
	2d			0.003	0.003
	4d			0.003	0.003
Long term	7d			0.002	0.003
	28d			0.002	0.002
	50d			0.002	0.002
	100d			0.002	0.002
Plateau concentration		0.003 mg/kg after 2 yrs			

Lettuce

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.003	-
Short term	24h			0.003	0.003
	2d			0.003	0.003
	4d			0.003	0.003
Long term	7d			0.002	0.003
	28d			0.002	0.002
	50d			0.002	0.002
	100d			0.002	0.002
Plateau concentration		0.003 mg/kg after 2 yrs			

Metabolite IN-KG433 Method of calculation	Molecular weight relative to the parent: 0.98 DT_{50} (d): 17.4 days

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	Kinetics: FOMC, DT_{50} calculated from DT_{90}/3.32 Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 14.9 g/ha (assumed IN-KG433 is formed at a maximum of 39.7 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.015	-
Short term	24h			0.014	0.015
	2d			0.014	0.014
	4d			0.013	0.014
Long term	7d			0.011	0.013
	28d			0.005	0.009
	50d			0.002	0.006
	100d			<0.001	0.004
Plateau concentration		-			

Lettuce

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.059	-
Short term	24h			0.056	0.057
	2d			0.054	0.056
	4d			0.050	0.054
Long term	7d			0.044	0.051
	28d			0.019	0.035
	50d			0.008	0.025
	100d			0.001	0.014

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Plateau concentration	-

Metabolite IN-MK643 Method of calculation	Molecular weight relative to the parent: 0.41 DT_{50} (d): 314.2 days Kinetics: SFO Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 4.5 g/ha (assumed IN-MK643 is formed at a maximum of 12.0 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.002	-
Short term	24h			0.002	0.002
	2d			0.002	0.002
	4d			0.002	0.002
Long term	7d			0.002	0.002
	28d			0.002	0.002
	50d			0.002	0.002
	100d			0.001	0.002
Plateau concentration		0.002 mg/kg after 2 yrs			

Lettuce

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.007	-
Short term	24h			0.007	0.007
	2d			0.007	0.007
	4d			0.007	0.007

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Long term	7d			0.007	0.007
	28d			0.007	0.007
	50d			0.007	0.007
	100d			0.006	0.007
Plateau concentration		0.009 mg/kg after 2 yrs			

Metabolite IN-MK638 Method of calculation	Molecular weight relative to the parent: 0.415 DT_{50} (d): 17.3 days Kinetics: SFO Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 10.5 g/ha (assumed IN-MK638 is formed at a maximum of 28.1 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.004	-
Short term	24h			0.004	0.004
	2d			0.004	0.004
	4d			0.004	0.004
Long term	7d			0.003	0.004
	28d			0.001	0.003
	50d			<0.001	0.002
	100d			<0.001	0.001
Plateau concentration		-			

Lettuce

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Rapporteur Member State	Month and year	Active Substance (Name)
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PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.018	-
Short term	24h			0.017	0.018
	2d			0.016	0.017
	4d			0.015	0.016
Long term	7d			0.006	0.010
	28d			0.002	0.008
	50d			<0.001	0.004
	100d			0.006	0.010
Plateau concentration		-			

Metabolite IN-KT413 Method of calculation	Molecular weight relative to the parent: 0.973 DT_{50} (d): 10.34 days Kinetics: DFOP, DT_{50} calculated from k2 parameter Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 6.9 g/ha (assumed IN-KT413 is formed at a maximum of 18.4 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.007	-
Short term	24h			0.006	0.007
	2d			0.006	0.006
	4d			0.005	0.006
Long term	7d			0.004	0.006
	28d			0.001	0.003
	50d			<0.001	0.002

	100d			<0.001	<0.001
Plateau concentration		-			

Lettuce

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.027	-
Short term	24h			0.025	0.026
	2d			0.023	0.025
	4d			0.020	0.024
Long term	7d			0.017	0.021
	28d			0.004	0.012
	50d			<0.001	0.007
	100d			<0.001	0.004
Plateau concentration		-			

Metabolite IN-KB687 Method of calculation	Molecular weight relative to the parent: 0.445 DT_{50} (d): 0.67 days Kinetics: SFO Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 8.25 g/ha (assumed IN-KB687 is formed at a maximum of 22.0 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.004	-
Short term	24h			0.001	0.002
	2d			<0.001	0.002

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	4d			<0.001	0.001
Long term	7d			<0.001	0.001
	28d			<0.001	<0.001
	50d			<0.001	<0.001
	100d			<0.001	<0.001
Plateau concentration		-			

Lettuce

$PEC_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.015	
Short term	24h			0.06	0.009
	2d			<0.001	0.006
	4d			<0.001	0.003
Long term	7d			<0.001	0.002
	28d			<0.001	<0.001
	50d			<0.001	<0.001
	100d			<0.001	<0.001
Plateau concentration		-			

Metabolite IN-U8E24 Method of calculation	Molecular weight relative to the parent: 0.905 DT_{50} (d): 1000 days Kinetics: - (default value) Field or Lab: representative worst case from lab studies
Application data	Application rate assumed: 5.175 g/ha (assumed IN-U8E24 is formed at a maximum of 13.8 % of the applied dose) As a worst-case the calculations were based on a single application of the total applied dose of parent active substance (2 application for maize and 4 for lettuce)

Maize

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
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
	28d			0.005	0.005
	50d			0.005	0.005
	100d			0.005	0.005
Plateau concentration		0.022 mg/kg after 12 yrs			

Lettuce

PEC$_{(s)}$ (mg/kg)		Single application Actual	Single application Time weighted average	Multiple application Actual	Multiple application Time weighted average
Initial				0.019	-
Short term	24h			0.019	0.019
	2d			0.019	0.019
	4d			0.019	0.019
Long term	7d			0.019	0.019
	28d			0.018	0.019
	50d			0.018	0.019
	100d			0.018	0.019
Plateau concentration		0.035 mg/kg after 12 yrs			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

PEC ground water (Regulation (EU) N° 284/2013, Annex Part A, point 9.2.4.1)

Method of calculation and type of study (*e.g.* modelling, field leaching, lysimeter)	For FOCUS gw modelling, values used – Modelling using FOCUS model(s), with appropriate FOCUSgw scenarios, according to FOCUS guidance. Model(s) used: PELMO 5.5.3 and PEARL 4.4.4 Crop: Maize and Cabbage <u>INDOXACARB</u> Crop uptake factor: 0 Water solubility (mg/L): 0.2 at pH 7 and 20°C Vapour pressure: 9.8 x 10^{-9} Pa at 20°C Geometric mean parent $DT_{50\ lab}$: 32.4 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). K_{OC}: 5125 mL/g, arithmetic mean $^1/_n$= 1 (default). <u>Metabolite IN-JT333</u> Crop uptake factor: 0 Water solubility (mg/L): 0.2 at pH 7 and 20°C Vapour pressure: 9.8 x 10^{-9} Pa at 20°C Geometric mean $DT_{50\ lab}$: 16.4 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). Formation fraction : 1 from indoxacarb (default conservative value) K_{OC}: arithmetic mean 17300 mL/g, arithmetic mean $^1/_n$= 1 (default). <u>Metabolite IN-JU873</u> Crop uptake factor: 0 Water solubility (mg/L): 0.2 at pH 7 and 20°C Vapour pressure: 9.8 x 10^{-9} Pa at 20°C Geometric mean $DT_{50\ lab}$: 32.1 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). Formation fraction : 1 from IN-JT333 and 1 from IN-KG433 (default conservative values) K_{OC}: arithmetic mean 7637 mL/g, arithmetic mean $^1/_n$= 1 <u>Metabolite IN-ML438</u> Crop uptake factor: 0 Water solubility (mg/L): 0.2 at pH 7 and 20°C

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Vapour pressure: 9.8 x 10^{-9} Pa at 20°C

Geometric mean $DT_{50\ lab}$: 73.7 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).

Formation fraction : 1 from IN-JU873 (default conservative value)

K_{OC}: arithmetic mean 19601 mL/g, arithmetic mean $^{1}/_{n}$= 1 (default value)

Metabolite IN-KG433

Crop uptake factor: 0

Water solubility (mg/L): 0.2 at pH 7 and 20°C

Vapour pressure: 9.8 x 10^{-9} Pa at 20°C

Geometric mean $DT_{50\ lab}$: 4.2 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).

Formation fraction : 1 from Indoxacab (default conservative value)

K_{OC}: arithmetic mean 314 mL/g, arithmetic mean $^{1}/_{n}$= 0.92

Metabolite IN-MK643

Crop uptake factor: 0

Water solubility (mg/L): 0.2 at pH 7 and 20°C

Vapour pressure: 9.8 x 10^{-9} Pa at 20°C

Geometric mean $DT_{50\ lab}$: 169.5 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).

Formation fraction : 1 from ML-438 (default conservative value)

K_{OC}: arithmetic mean 269 mL/g, arithmetic mean $^{1}/_{n}$= 0.81

Metabolite IN-MK638

Crop uptake factor: 0

Water solubility (mg/L): 0.2 at pH 7 and 20°C

Vapour pressure: 9.8 x 10^{-9} Pa at 20°C

Geometric mean $DT_{50\ lab}$: 8.7 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7).

Formation fraction : 1 from KT413 (default conservative value)

K_{OC}: arithmetic mean 151 mL/g, arithmetic mean $^{1}/_{n}$= 0.84

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

	Metabolite IN-KT413 Crop uptake factor: 0 Water solubility (mg/L): 0.2 at pH 7 and 20°C Vapour pressure: 9.8 x 10^{-9} Pa at 20°C Geometric mean $DT_{50\ lab}$: 1.7 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). Formation fraction : 1 from Indoxacarb (default conservative value) K_{OC}: arithmetic mean 344 mL/g, arithmetic mean $^1/_n$= 0.95 Metabolite IN-KB687 Crop uptake factor: 0 Water solubility (mg/L): 0.2 at pH 7 and 20°C Vapour pressure: 9.8 x 10^{-9} Pa at 20°C Maximum $DT_{50\ lab}$: 0.67 d (normalisation to pF2, 20 °C with Q10 of 2.58 and Walker equation coefficient 0.7). Formation fraction : 1 from IN-KG433 (default conservative value) K_{OC}: arithmetic mean 237 mL/g, arithmetic mean $^1/_n$= 0.85 Metabolite IN-U8E24 Crop uptake factor: 0 Water solubility (mg/L): 0.2 at pH 7 and 20°C Vapour pressure: 9.8 x 10^{-9} Pa at 20°C Single value, $DT_{50\ lab}$: no reliable data – data gap Formation fraction : 1 from IN-KT413 (default conservative value) K_{OC}: no reliable data – data gap
Application rate	Gross application rate: 37.5 g/ha. Crop growth stage: Maize BBCH 34-77, Lettuce BBCH 13-49 Canopy interception %: Maize 50%/75%, Lettuce 35% Application rate net of interception: Maize 18.75/9.375 g/ha, Lettuce 28.125 g/ha. No. of applications: Maize 2, lettuce 4 Time of application (absolute or relative application dates): Maize 1st application 25 days after emergence Lettuce:1st application 7 days after emergence for early

and late cycle.

MAIZE

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	Metabolites (µg/L)								
			IN-JT333	IN-JU873	IN-ML438	IN-KG433	IN-MK643	IN-MK638	IN-KT413	IN-KB687	IN-U8E24
FOCUS PEARL 4.4.4 / Maize	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	Data gap
	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	

	Scenario	Parent (µg/L)	Metabolites (µg/L)								
			IN-JT333	IN-JU873	IN-ML438	IN-KG433	IN-MK643	IN-MK638	IN-KT413	IN-KB687	IN-U8E24
FOCUS PELMO 5.5.3 / Maize	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	Data gap
	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	

CABBAGE, early season

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	Metabolites (µg/L)								
			IN-JT333	IN-JU873	IN-ML438	IN-KG433	IN-MK643	IN-MK638	IN-KT413	IN-KB687	IN-U8E24
FOCUS PEARL 4.4.4 / Cabbage early	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	Data gap
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	0.003	<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	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

	Scenario	Parent (µg/L)	Metabolites (µg/L)								
			IN-JT333	IN-JU873	IN-ML438	IN-KG433	IN-MK643	IN-MK638	IN-KT413	IN-KB687	IN-U8E24
FOCUS PELMO 5.5.3 / Cabbage early	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	Data gap
	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	0.002	<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	

CABBAGE, late season

PEC(gw) - FOCUS modelling results (80th percentile annual average concentration at 1m)

	Scenario	Parent (µg/L)	Metabolites (µg/L)								
			IN-JT333	IN-JU873	IN-ML438	IN-KG433	IN-MK643	IN-MK638	IN-KT413	IN-KB687	IN-U8E24
FOCUS PEARL 4.4.4 / Cabbage late	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	Data gap
	Hamburg	<0.001	<0.001	<0.001	<0.001	<0.001	0.003	<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	

	Scenario	Parent (µg/L)	Metabolites (µg/L)								
			IN-JT333	IN-JU873	IN-ML438	IN-KG433	IN-MK643	IN-MK638	IN-KT413	IN-KB687	IN-U8E24
FOCUS PELMO 5.5.3 / Cabbage	Châteaudun	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	Data gap
	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	

PEC surface water and PEC sediment (Regulation (EU) N° 284/2013, Annex Part A, points 9.2.5 / 9.3.1)

Parent Parameters used in FOCUSsw step 1 and 2	Version control no. of FOCUS calculator: STEP 1-2 ver. 2-1 Molecular weight (g/mol): 528 K_{OC} (mL/g): 5125 DT_{50} soil (d): 32.1days (Lab.) DT_{50} water/sediment system (d): 5.8 d (geomean from sediment water studies)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

	DT_{50} water (d): 5.8 d DT_{50} sediment (d): 5.8 d Crop interception (%): Maize 50% (average) Lettuce 25% (minimal)
Parameters used in FOCUSsw step 3 (if performed)	Version control no.'s of FOCUS software: SWASH ver. 3.1, MACRO ver. 4.4.2, PRZM ver. 3.1.1, and TOXSWA ver. 3.3.1 Water solubility (mg/L): 0.2 Vapour pressure: 9.8 x 10^{-9} Pa at 20°C Kom (mL/g): 5125 1/n: 1 (default) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0
Application rate	Crop and growth stage: Maize BBCH 34-77, Lettuce 13-49 Number of applications: Maize 2 applications, Lettuce 4 applications. Interval (d): Maize 20 days, Lettuce 7 days Application rate(s): 37.5 g a.s./ha Application window: *Step 1&2* Maize : NEU & SEU: March-May, as worst-case covering March-May & June-Sept Lettuce : NEU: Oct-Feb as worst-case covering Oct-Feb, March-May & June-Sept SEU : March-May as worst-case covering Oct-Feb, March-May & June-Sept *Step 3&4* Maize : 30 days (single) or 50 days (multiple) from emergence date + 25 days, Lettuce : 30 days (single) or 51 days (multiple) from emergence date + 7 days

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Maize

STEP 1 – March-May & June-Sept – Single and multiple applications

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0 h	1.941		81.782	
	21 d				

STEP 2 - March-May

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.345			
	21 d				
Southern EU	0 h	0.345			
	21 d				

STEP 2 - June-sept

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.345			
	21 d				
Southern EU	0 h	0.345			
	21 d				

STEP 3 – (single application)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	**0.195**		0.104	
D4	pond	0 h	0.008		0.025	
D4	stream	0 h	**0.170**		0.014	
D5	pond	0 h	0.008		0.024	
D5	stream	0 h	0.180		0.012	
D6	ditch	0 h	0.193		0.055	
R1	pond	0 h	0.011		0.042	
R1	stream	0 h	0.136		**0.315**	
R2	stream	0 h	**0.182**		**0.651**	
R3	stream	0 h	**0.192**		0.253	
R4	stream	0 h	0.134		**0.667**	

STEP 3 – (Multiple applications)

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	**0.170**		0.100	
D4	pond	0 h	0.010		0.033	
D4	stream	0 h	0.148		0.015	
D5	pond	0 h	0.010		0.029	
D5	stream	0 h	0.165		0.043	
D6	ditch	0 h	**0.171**		0.141	
R1	pond	0 h	0.014		0.083	
R1	stream	0 h	0.117		**0.316**	
R2	stream	0 h	0.157		**0.651**	
R3	stream	0 h	0.165		**0.715**	
R4	stream	0 h	0.159		**0.667**	

STEP 4 – (single application) – 10m VFS

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	0.034		0.018	
D4	pond	0 h	0.005		0.016	
D4	stream	0 h	0.038		0.003	
D5	pond	0 h	0.005		0.015	
D5	stream	0 h	0.040		0.003	
D6	ditch	0 h	0.034		0.010	
R1	pond	0 h	0.006		0.021	
R1	stream	0 h	0.033		0.060	
R2	stream	0 h	0.041		0.103	
R3	stream	0 h	0.043		0.047	
R4	stream	0 h	0.061		0.147	

STEP 4 – (Multiple application) – 10m VFS

FOCUS STEP 4 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3	ditch	0 h	0.028		0.016	
D4	pond	0 h	0.006		0.021	
D4	stream	0 h	0.031		0.003	
D5	pond	0 h	0.006		0.018	
D5	stream	0 h	0.035		0.009	
D6	ditch	0 h	0.028		0.023	
R1	pond	0 h	0.008		0.035	
R1	stream	0 h	0.040		0.060	
R2	stream	0 h	0.033		0.103	
R3	stream	0 h	0.056		0.127	
R4	stream	0 h	0.072		0.147	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Metabolite IN-JT333 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 470 Soil or water metabolite: soil and water metabolite Koc (mL/g): 17300 DT_{50} soil (d): 16.4 days DT_{50} water/sediment system (d): 60.4 d (geometric mean from sediment water studies) DT_{50} water (d): 60.4 d DT_{50} sediment (d): 60.4 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 25.7 % Soil: 18.6 %
Parameters used in FOCUSsw step 3 (if performed)	Water solubility (mg/L): 0.2 Vapour pressure: 9.8×10^{-9} Pa at 20°C Kom/Koc (mL/g): 17300 1/n: 1 (default) Q10=2.58, Walker equation coefficient 0.7 Crop uptake factor: 0 Metabolite kinetically generated in simulation (yes): Formation fraction in soil (k_f/k_{dp}): 1 from parent Formation fraction in sediment water (k_f/k_{dp}): not performed
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

Maize

Step 1 – March-may & Jun- sept - Single application

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	0.165		15.267	

Step 1 – March-may & Jun- sept - Multiple application

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	0.330		30.535	

Step 2 – March-may & Jun- sept - Single application

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.079		1.156	
Southern EU	0 h	0.079		1.467	

Step 2 – March-may & Jun- sept - Multiple application

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.073		1.737	
Southern EU	0 h	0.073		2.184	

Lettuce

Step 1 – Oct-feb, March-may & Jun- sept - Single application

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	0.165		15.267	

Step 1 – Oct-feb, March-may & Jun- sept - Multiple application

FOCUS STEP 1 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
	0h	0.660		61.069	

Step 2 – March-may & Jun- sept - Single application

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.079			
Southern EU	0 h	0.079			

Step 2 – March-may & Jun- sept - Multiple application

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

FOCUS STEP 2 Scenario	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
		Actual	TWA	Actual	TWA
Northern EU	0 h	0.071		1.737	
Southern EU	0 h	0.071		2.184	

Step 3- Single application

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 (1^{st})	ditch	0 h	<0.001		0.412	
D3,(2^{nd})	ditch	0 h	<0.001		0.412	
D4 (1^{st})	stream	0 h	<0.001		0.050	
D4(1^{st})	stream	0 h	<0.001		0.000	
D6 (1^{st})	ditch	0 h	<0.001		0.412	
R1 (1^{st})	pond	0 h	<0.001		0.050	
R1(2^{nd})	pond	0 h	0.001		0.050	
R1(1^{st})	stream	0 h	0.001		0.124	
R1(2^{nd})	stream	0 h	0.001		0.143	
R2 (1^{st})	stream	0 h	0.000		0.050	
R2(2^{nd})	stream	0 h	0.000		0.540	
R3 (1^{st})	stream	0 h	0.001		0.075	
R3 (2^{nd})	stream	0 h	0.001		0.054	
R4(1^{st})	stream	0 h	0.002		0.030	
R4 (2^{nd})	stream	0 h	0.002		0.022	

Step 3- Multiple application

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

FOCUS STEP 3 Scenario	Water body	Day after overall maximum	PEC_{SW} (µg/L)		PEC_{SED} (µg/kg)	
			Actual	TWA	Actual	TWA
D3 (1^{st})	ditch	0 h	<0.001		1.112	
D3,(2^{nd})	ditch	0 h	<0.001		1.112	
D4 (1^{st})	stream	0 h	<0.001		0.125	
D4(1^{st})	stream	0 h	<0.001		0.000	
D6 (1^{st})	ditch	0 h	0.001		1.112	
R1 (1^{st})	pond	0 h	0.002		0.125	
R1(2^{nd})	pond	0 h	0.002		0.125	
R1(1^{st})	stream	0 h	0.004		0.695	
R1(2^{nd})	stream	0 h	0.004		0.511	
R2 (1^{st})	stream	0 h	0.002		0.182	
R2(2^{nd})	stream	0 h	0.001		1.523	
R3 (1^{st})	stream	0 h	0.005		0.448	
R3 (2^{nd})	stream	0 h	0.004		0.216	
R4(1^{st})	stream	0 h	0.006		0.158	
R4 (2^{nd})	stream	0 h	0.006		0.080	

Metabolite IN-JU873 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 470 Soil or water metabolite: soil metabolite Koc (mL/g): 13167 DT_{50} soil (d): 32.1 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 0.00001 % Soil: 12.9 %
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Main routes of entry	Drift, drainage and run-off
Metabolite IN-ML438 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 458 Soil or water metabolite: soil and water metabolite Koc (mL/g): 19601 DT_{50} soil (d): 73.7 days DT_{50} water/sediment system (d): 213.1 d (geometric mean from sediment water studies) DT_{50} water (d): 213.1 d DT_{50} sediment (d): 213.1 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 3.6 % Soil: 9.7 %
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	
Metabolite IN-KG433 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 516 Soil or water metabolite: soil and water metabolite Koc (mL/g): 314 DT_{50} soil (d): 4.2 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 7.7% Soil: 39.7%
Parameters used in FOCUSsw step 3 (if performed)	Not performed.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

Metabolite IN-MK643 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 218 Soil or water metabolite: soil metabolite Koc (mL/g): 269 DT_{50} soil (d): 169.5 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 0.0001% Soil: 12.0%
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Metabolite IN-MK638 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 220 Soil or water metabolite: soil and water metabolite Koc (mL/g): 151 DT_{50} soil (d): 8.7 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 26.9 % Soil: 28.1 %
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

Metabolite IN-KT413 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 514 Soil or water metabolite: soil and water metabolite Koc (mL/g): 344 DT_{50} soil (d): 1.7 days DT_{50} water/sediment system (d): 28.2 d (geometric mean from sediment water studies) DT_{50} water (d): 28.2 d DT_{50} sediment (d): 28.2 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 90.8 % Soil: 218.4 %
Parameters used in FOCUSsw step 3 (if performed)	Not performed.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

Metabolite IN-MP819 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 470 Soil or water metabolite: water metabolite Koc (mL/g): 19601 DT_{50} soil (d): 0.0001 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 21.3 % Soil: 0.0001%
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Metabolite IN-MS775 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 412 Soil or water metabolite: water metabolite Koc (mL/g): 19601 DT_{50} soil (d): 0.0001 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 14.7 % Soil: 0.0001%
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

Metabolite IN-KB687 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 235 Soil or water metabolite: soil and water metabolite Koc (mL/g): 237 DT_{50} soil (d): 0.67days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 28.7 % Soil: 22.0%
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Metabolite IN-U8E24 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 478 Soil or water metabolite: soil and water metabolite Koc (mL/g): 0 DT_{50} soil (d): 1000 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 24.3 % Soil: 13.8 %
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent
Main routes of entry	Drift, drainage and run-off

Metabolite IN-UYG24 Parameters used in FOCUSsw step 1 and 2	Molecular weight: 318 Soil or water metabolite: water metabolite Koc (mL/g): 64 DT_{50} soil (d): 0.0001 days DT_{50} water/sediment system (d): 1000 d (default) DT_{50} water (d): 1000 d DT_{50} sediment (d): 1000 d Crop interception (%):Maize 50% (average) Lettuce 25% (minimal) Maximum occurrence observed Total Water and Sediment: 31.6 % Soil: 0.0001%
Parameters used in FOCUSsw step 3 (if performed)	Not performed.
Application rate	Crop and growth stage: as for parent Number of applications: as for parent Interval (d): as for parent Application rate(s): as for parent Application window: as for parent

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Main routes of entry	Drift, drainage and run-off

MAIZE
PECsw

Metabolite	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)
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

PECsed

Metabolite	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)
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

Lettuce

PECsw

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Metabolite	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)
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

PECsed

Metabolite	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)
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.

Estimation of concentrations from other routes of exposure (Regulation (EU) N° 284/2013, Annex Part A, point 9.4)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 4 Environmental fate and behaviour

Method of calculation	Not required

PEC

Maximum concentration	Not required

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Ecotoxicology

Effects on birds and other terrestrial vertebrates (Regulation (EU) N° 283/2013, Annex Part A, point 8.1 and Regulation (EU) N° 284/2013, Annex Part A, point 10.1)

Species	Test substance	Time scale	End point	Toxicity (mg/kg bw per day)
Birds				
Colinus virginianus	DPX-KN128 (in DPX-MP062 (75:25))	Acute	LD_{50}	73.5 mg DPX-KN128/kg bw
Colinus virginianus	Preparation Indoxacarb 150 g/L EC	Acute	LD_{50}	89 mg DPX-KN128/kg bw
Colinus virginianus	IN-JT333	Acute	LD_{50}	1750 mg IN-JT333/kg bw
Colinus virginianus	DPX-KN128 (in DPX-MP062 (75:25))	Long-term	LD_{50}/10	7.35 mg DPX-KN128/kg bw/d
Colinus virginianus	DPX-MP062 (75:25)	Long-term	NOAEL	75.7 mg DPX-MP062/kg bw/d
Anasplatyrhynchos	DPX-MP062 (75:25)	Long-term	NOAEL	105 mg DPX-MP062/kg bw/d
Mammals				
rat	DPX- KN128	Acute	LD_{50}	179 mg/kg bw (females)
rat	Preparation Indoxacarb 150 g/L EC	Acute	LD_{50}	146.4 mg DPX-KN128 /kg bw
rat	IN-JT333	Acute	LD_{50}	39 mg IN-JT333/kg bw (females)
rat	DPX-KN128 (in DPX-JW062 (50:50))	Long-term [*for screening step*]	NOAEL	0.6 mg DPX-KN128 /kg bw/d
rat	DPX-KN128 (in DPX-JW062 (50:50))	Long-term [*for first tier risk assessment*]	NOAEL [*amend as appropriate*]	0.68 mg DPX-KN128 /kg bw/d
Endocrine disrupting properties (Annex Part A, points 8.1.5) *None*				
Additional higher tier studies (Annex Part A, points 10.1.1.2): *None*				
Terrestrial vertebrate wildlife (birds, mammals, reptile and amphibians) (Annex Part A, points 8.1.4, 10.1.3): *No data*				

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Toxicity/exposure ratios for terrestrial vertebrates (Regulation (EU) N° 284/2013, Part A, Annex point 10.1)

Maize at 37.5 g a.s./ha [2 applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	6.55	11.2	10
All	Small omnivorous bird	Long-term	1.67	**4.4**	5
Tier 1 (Birds)					
Maize BBCH 30-39	Medium granivorous bird "game bird"	Long-term	0.04	189.6	5
Maize BBCH >40	Medium granivorous bird "game bird"	Long-term	0.02	355.6	5
Maize BBCH 30-39	Small omnivorous bird “lark”	Long-term	0.14	52.7	5
Maize BBCH >40	Small omnivorous bird “lark”	Long-term	0.07	105.4	5
Maize BBCH 30-39	Medium herbivorous/granivorous bird "pigeon"	Long-term	0.29	25.0	5
Maize BBCH >40	Medium herbivorous/granivorous bird "pigeon"	Long-term	0.15	49.9	5
Maize BBCH ≥20	Small insectivorous bird “wagtail”	Long-term	0.12	59.3	5
Higher tier (birds):					
Not required					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	5.63	26	10
All	Small herbivorous mammal	Long-term	1.87	**0.32**	5
Tier 1 (Mammals)					
Maize BBCH ≥20	Small insectivorous mammal “shrew”	Long-term	0.05	13.9	5
Maize BBCH 30-39	Small herbivorous mammal "vole”	Long-term	0.94	**0.7**	5
Maize BBCH ≥40	Small herbivorous mammal "vole”	Long-term	0.47	**1.5**	5
Maize BBCH 30-39	Small omnivorous mammal “mouse”	Long-term	0.10	6.7	5
Maize BBCH ≥40	Small omnivorous mammal “mouse”	Long-term	0.05	13.9	5
Higher tier (Mammals): No valid refinement parameters available					
Further refinement required.					

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.23	31.8	5
Earthworm-eating mammals	Long-term	0.28	2.41	5
Fish-eating birds	Long-term	0.00	8059	5

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Fish-eating mammals		Long-term	0.00	835	5
Higher tier: No valid refinement parameters available for earthworm-eating mammals. Further refinement required. Metabolites: Risk assessment required.					

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	-	Not required	10
Puddle scenario, Screening step Application rate (64 g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed					
Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	-	-	10
Puddle scenario	Birds	Long-term	-	-	5
Puddle scenario	Mammals	Long-term	-	-	5

Lettuce at 37.5 g a.s./ha [4 applications]

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Screening Step (Birds)					
All	Small omnivorous bird	Acute	10.72	**6.9**	10
All	Small omnivorous bird	Long-term	2.83	**2.6**	5

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Birds)					
Leafy vegetables BBCH 10-49	Small granivorous bird “finch”	Acute	1.9	39.7	10
Leafy vegetables BBCH ≥50	Small granivorous bird “finch”	Acute	0.6	132.8	10
Leafy vegetables BBCH 10-49	Small omnivorous bird “lark”	Acute	1.6	45.4	10
Leafy vegetables BBCH ≥50	Small omnivorous bird “lark”	Acute	0.5	151.2	10
Leafy vegetables BBCH 10-19	Medium herbivorous/granivorous bird “pigeon”	Acute	6.1	12.0	10
Leafy vegetables BBCH 10-19	Small insectivorous bird “wagtail”	Acute	1.8	40.6	10
Leafy vegetables BBCH ≥20	Small insectivorous bird “wagtail”	Acute	1.7	43.2	10
Leafy vegetables BBCH 10-49	Small granivorous bird "finch"	Long-term	0.55	13.3	5
Leafy vegetables BBCH >50	Small granivorous bird "finch"	Long-term	0.17	44.2	5
Leafy vegetables BBCH 10-49	Small omnivorous bird “lark”	Long-term	0.48	15.4	5
Leafy vegetables BBCH >50	Small omnivorous bird “lark”	Long-term	0.14	50.9	5
Leafy vegetables Leaf development BBCH 10-19	Medium herbivorous/granivorous bird "pigeon"	Long-term	1.00	7.3	5
Leafy vegetables BBCH 10-19	Small insectivorous bird “wagtail”	Long-term	0.49	14.9	5
Leafy vegetables BBCH >20	Small insectivorous bird “wagtail”	Long-term	0.42	17.3	5
Higher tier (birds):					
Not required					
Screening Step (Mammals)					
All	Small herbivorous mammal	Acute	9.21	15.9	10
All	Small herbivorous mammal	Long-term	3.16	**0.19**	5

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Tier 1 (Mammals)					
Leafy vegetables BBCH 10-19	Small insectivorous mammal “shrew”	Long-term	0.19	**3.7**	5
Leafy vegetables BBCH ≥20	Small insectivorous mammal “shrew”	Long-term	0.08	8.2	5
Leafy vegetables BBCH 40-49	Small herbivorous mammal "vole”	Long-term	3.1	**0.2**	5
Leafy vegetables BBCH ≥50	Small herbivorous mammal "vole”	Long-term	0.96	**0.7**	5
Leafy vegetables all seasons	Large herbivorous mammal "Lagomorph”	Long-term	0.63	**1.1**	5
Leafy vegetables BBCH 10-49	Small omnivorous mammal “mouse”	Long-term	0.35	**2.0**	5
Leafy vegetables BBCH ≥50	Small omnivorous mammal “mouse”	Long-term	0.10	6.8	5
Higher tier (Mammals): No valid refinement parameters available					
Further refinement required.					

Risk from bioaccumulation and food chain behaviour[*indicate when not relevant* i.e *if Log kow≤3]*

Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Earthworm-eating birds	Long-term	0.93	7.9	5
Earthworm-eating mammals	Long-term	1.13	**0.60**	5
Fish-eating birds	Long-term	0.00	2128	5
Fish-eating mammals	Long-term	0.00	220	5

Higher tier: No valid refinement parameters available for earthworm-eating mammals. Further refinement required.
Metabolites: Risk assessment required.

Risk from consumption of contaminated water

Scenarios	**Indicator or focal species**	**Time scale**	**PEC_{dw}xDWR**	**TER**	**Trigger**
Leaf scenario	Birds	acute	17.25	**4.3**	10

Higher tier (Leaf scenario): Mitigation measures necessary

Puddle scenario, Screening step

Application rate (126.1g a.s./ha)/relevant endpoint <3000 (koc≥500 L/kg), TER calculation not needed

Puddle scenario	Birds	acute	-	-	10
Puddle scenario	Mammals	acute	-	-	10

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 5 Ecotoxicology

Growth stage	Indicator or focal species	Time scale	DDD (mg/kg bw per day)	TER	Trigger
Puddle scenario	Birds	Long-term	-	-	5
Puddle scenario	Mammals	Long-term	-	-	5

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Toxicity data for all aquatic tested species (Regulation (EU) N° 283/2013, Annex Part A, points 8.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.2)*

* This section does not yet reflect the new EFSA Guidance Document on aquatic organisms which has been noted in the meeting of the Standing Committee on Plants, Animals, Food and Feed on 11 July 2014.

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Laboratory tests				
Fish				
Oncorhynchus mykiss	DPX-KN128	Acute 96 hr (flow-through)	Mortality, LC_{50}	>0.17 mg a.s./L (mm)
Lepomis macrochirus	DPX-MP062 (79:21 mixture DPX-KN128/IN-KN127)	Acute 96 hr (flow-through)	Mortality, LC_{50}	0.90 mg DPX-MP062/L (mm)
Oncorhynchus mykiss	Indoxacarb 150 g/L EC	Acute 96 hr (static)	Mortality, LC_{50}	7 mg prep./L (0.84 mg a.s./L) (nom)
Pimephales promelas	DPX-KN128	Chronic 28 days (flow-through)	NOEC (ELS)	0.0675 mg/L (mm)
Oncorhynchus mykiss	DPX-MP062 (79:21 mixture DPX-KN128/IN-KN127)	Chronic 90 days (flow-through)	NOEC (ELS)	0.15 mg DPX-MP062/L (mm)
Pimephales promelas	IN-JT333	Chronic 28 days (flow-through)	NOEC (ELS) EC10	0.00242 mg/L (mm) 0.00249 mg/L (mm)
Oncorhynchus mykiss	IN-JT333	96 hr (flow-through)	Mortality, LC_{50}	0.029 mg/L (mm)
Oncorhynchus mykiss	IN-KN124	96 hr (semi-static)	Mortality, LC_{50}	>0.0931 mg/L (mm)
Oncorhynchus mykiss	IN-KN125	96 hr (semi-static)	Mortality, LC_{50}	0.0105 mg/L (mm)
Oncorhynchus mykiss	IN-JU873	96 hr (semi-static)	Mortality, LC_{50}	>0.441 mg/L (mm)
Oncorhynchus mykiss	IN-KG433	96 hr (flow-through)	Mortality, LC_{50}	>0.22 mg/L (mm)
Oncorhynchus mykiss	IN-KT413	96 hr (static)	Mortality, LC_{50}	>1.06 mg/L (mm)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Oncorhynchus mykiss	IN-MK638	96 hr (static)	Mortality, LC_{50}	28 mg/L (mm)
Oncorhynchus mykiss	IN-MK643	96 hr (static)	Mortality, LC_{50}	6.99 mg/L (mm)
Oncorhynchus mykiss	IN-KB687	96 hr (static)	Mortality, LC_{50}	11.9 mg/L (mm)
Oncorhynchus mykiss	IN-MP819	96 hr (flow-through)	Mortality, LC_{50}	>0.368 mg/L (mm)
Oncorhynchus mykiss	IN-MS775	96 hr (static)	Mortality, LC_{50}	>0.00396 mg/L (mm)
Oncorhynchus mykiss	IN-U8E24	96 hr (static)	Mortality, LC_{50}	46.5 mg/L (mm)
Oncorhynchus mykiss	IN-UYG24	96 hr (static)	Mortality, LC_{50}	>115 mg/L (mm)
Aquatic invertebrates				
Daphnia magna	DPX-KN128	48 h (flow-through)	Mortality, EC_{50}	>0.17 mg/L (mm)
Mysidopsis bahia	DPX-KN128	96 h (flow-through)	Mortality, EC_{50}	>0.126 mg/L (mm)
Daphnia magna	Indoxacarb 150 g/L EC	48 h (static)	Mortality, EC_{50}	1.38 prod./L (0.22 mg a.s./L) (ini)
Mysidopsis bahia	Indoxacarb 150 g/L EC	96 hr (static)	Mortality, LC_{50}	5.0 mg prep./L (0.75 mg a.s./L) (ini)
Daphnia magna	DPX-KN128	21 d (semi-static)	Reproduction and development, NOEC	0.0351 mg/L (mm)
Mysidopsis bahia	DPX-MP062 (79:21 mixture DPX-KN128/IN-KN127)	28 days (flow-through)	Reproduction and development, NOEC	0.0184 mg DPX-MP062/L (mm) (equivalent to 0.0145 mg DPX-KN128/L)
Daphnia magna	IN-KT413	21 d (semi-static)	Reproduction and development, NOEC	3.9 mg/L (mm)
Daphnia magna	IN-JT333	48 h (semi-static)	Mortality, EC_{50}	>0.029 mg/L (mm)
Mysidopsis bahia	IN-JT333	96 h (semi-static)	Mortality, EC_{50}	0.07 mg/L (mm)
Daphnia magna	IN-KN124	48 h (semi-static)	Mortality, EC_{50}	>0.106 mg/L (mm)
Daphnia magna	IN-KN125	48 h (semi-static)	Mortality, EC_{50}	>0.121 mg/L (mm)
Daphnia magna	IN-JU873	48 h (semi-static)	Mortality, EC_{50}	0.379 mg/L (mm)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Mysidopsis bahia	IN-JU873	96 h (semi-static)	Mortality, EC_{50}	>1.47 mg/L (mm)
Daphnia magna	IN-KG433	48 h (static)	Mortality, EC_{50}	>0.23 mg/L (mm)
Daphnia magna	IN-KT413	48 h (static)	Mortality, EC_{50}	>0.967 mg/L (mm)
Mysidopsis bahia	IN-KT413	96 h (static)	Mortality, EC_{50}	2.8 mg/L (mm)
Daphnia magna	IN-MK638	48 h (static)	Mortality, EC_{50}	80 mg/L (mm)
Mysidopsis bahia	IN-MK638	96 h (static)	Mortality, EC_{50}	41.1 mg/L (mm)
Daphnia magna	IN-MK643	48 h (static)	Mortality, EC_{50}	34.1 mg/L (mm)
Mysidopsis bahia	IN-MK643	96 h (static)	Mortality, EC_{50}	16.4 mg/L (mm)
Daphnia magna	IN-KB687	48 h (static)	Mortality, EC_{50}	7.83 mg/L (mm)
Mysidopsis bahia	IN-KB687	96 h (semi-static)	Mortality, EC_{50}	7.2 mg/L (mm)
Daphnia magna	IN-MP819	48 h (flow-through)	Mortality, EC_{50}	0.06 mg/L (mm)
Daphnia magna	IN-MS775	48 h (static)	Mortality, EC_{50}	>0.00567 mg/L (mm)
Daphnia magna	IN-U8E24	48 h (static)	Mortality, EC_{50}	>12 mg/L (nom)
Daphnia magna	IN-UYG24	48 h (static)	Mortality, EC_{50}	>120 mg/L (nom)
Sediment-dwelling organisms				
Chironomus riparius (spiked water)	DPX-KN128	28 d (static)	EC10	0.00168 mg/L (mm)
Chironomus riparius (spiked water)	DPX-KN128	28 d (static)	NOEC development rate	0.00292 mg a.s./kg dry sediment (mm) 0.0018 mg a.s./L (mm)
Chironomus riparius (spiked water)	IN-KT413	28 d (static)	NOEC development rate EC10 (development time)	0.024 mg/L (mm) 0.088 mg/L (mm)
Chironomus riparius (spiked sediment)	IN-JT333	28 d (static)	NOEC development rate	0.096 mg/kg dry sediment (mm)
Chironomus riparius (spiked sediment)	IN-KG433	28 d (static)	NOEC emergence ratio	0.17 mg/kg dry sediment (ini)
Chironomus riparius (spiked sediment)	IN-KT413	28 d (static)	NOEC development rate	7.5 mg/kg dry sediment (mm)

List of end points

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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Chironomus riparius (spiked sediment)	IN-MP819	28 d (static)	NOEC emergence, development rate	86.2 mg/kg dry sediment (mm)
Chironomus riparius (spiked sediment)	IN-MS775	28 d (static)	NOEC emergence ratio	2.2 mg/kg dry sediment (mm)
Algae				
Pseudokirchneriella subcapitata	DPX-KN128	72/96 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>0.0793 mg/L (mm) 0.0793 mg/L (mm) >0.0793 mg/L (mm) 0.0793 mg/L (mm) >0.0793 mg/L (mm) 0.0793 mg/L (mm)
Pseudokirchneriella subcapitata	Indoxacarb 150 g/L EC	72 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb	>16 mg/L (nom) 1.8 mg/L (nom) 12.5 mg/L (nom) 1.8 mg/L (nom)
Pseudokirchneriella subcapitata	IN-JT333	72/96/120 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb	>0.0075 mg/L (mm) 0.0075 mg/L (mm) >0.0075 mg/L (mm) 0.0075 mg/L (mm)
Pseudokirchneriella subcapitata	IN-KN124	72/96 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>0.0478 mg/L (mm) 0.0478 mg/L (mm) >0.0478 mg/L (mm) 0.0478 mg/L (mm) >0.0478 mg/L (mm) 0.0478 mg/L (mm)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Pseudokirchneriella subcapitata	IN-KN125	72/96 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>0.0508 mg/L (mm) 0.0508 mg/L (mm) >0.0508 mg/L (mm) 0.0508 mg/L (mm) >0.0508 mg/L (mm) 0.0508 mg/L (mm)
Pseudokirchneriella subcapitata	IN-JU873	72 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>0.265 mg/L (mm) 0.0332 mg/L (mm) >0.265 mg/L (mm) 0.0332 mg/L (mm) >0.265 mg/L (mm) 0.0332 mg/L (mm)
Pseudokirchneriella subcapitata	IN-KT413	72 h (static)	Growth rate: 72 h E_rC_{50}	>105 mg/L (mm)
Pseudokirchneriella subcapitata	IN-MK638	72 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	37.2 mg/L (mm) 0.641 mg/L (mm) 7.55 mg/L (mm) 0.641 mg/L (mm) 7.45 mg/L (mm) 0.641 mg/L (mm)
Pseudokirchneriella subcapitata	IN-MK643	72 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	59.7 mg/L (mm) 3.40 mg/L (mm) 31.8 mg/L (mm) 3.40 mg/L (mm) 31.8 mg/L (mm) 3.40 mg/L (mm)
Pseudokirchneriella subcapitata	IN-KB687	72 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>2.26 mg/L (mm) 0.0679 mg/L (mm) 1.41 mg/L (mm) 0.0227 mg/L (mm) 1.39 mg/L (mm) 0.0227 mg/L (mm)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Group	Test substance	Time-scale (Test type)	End point	Toxicity[1]
Pseudokirchneriella subcapitata	IN-MP819	72 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>0.358 mg/L (mm) 0.358 mg/L (mm) >0.358 mg/L (mm) 0.358 mg/L (mm) >0.358 mg/L (mm) 0.358 mg/L (mm)
Pseudokirchneriella subcapitata	IN-MS775	72 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>0.052 mg/L (mm) 0.052 mg/L (mm) >0.052 mg/L (mm) 0.052 mg/L (mm) >0.052 mg/L (mm) 0.052 mg/L (mm)
Pseudokirchneriella subcapitata	IN-U8E24	72/96 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	55.2 mg/L (mm) 6.1 mg/L (mm) 31.3 mg/L (mm) 6.1 mg/L (mm) 32.6 mg/L (mm) 6.1 mg/L (mm)
Pseudokirchneriella subcapitata	IN-UYG24	72/96 h (static)	Growth rate: 72 h E_rC_{50} NOECr Biomass: 72 h E_bC_{50} NOECb Yield: 72 h E_yC_{50} NOECy	>106 mg/L (mm) 27.4 mg/L (mm) 74.5 mg/L (mm) 6.64 mg/L (mm) 73.0 mg/L (mm) 6.64 mg/L (mm)
Further testing on aquatic organisms *none*				
Potential endocrine disrupting properties (Annex Part A, point 8.2.3) *[list evidence/indication on the potential for endocrine disrupting properties]*				
none				

[1] (nom) nominal concentration; (mm) mean measured concentration; (ini) initial measured concentration; prep.: preparation; a.s.: active substance

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Bioconcentration in fish (Annex Part A, point 8.2.2.3)

	Active substance	Metabolite1	Metabolite2	Metabolite3
$logP_{O/W}$	4.65			
Steady-state bioconcentration factor (BCF) (total wet weight/normalised to 5% lipid content)	77.3 L/Kg (measured) *			
Uptake/depuration kinetics BCF (total wet weight/normalised to 5% lipid content)	-			
Annex VI Trigger for the bioconcentration factor	-			
Clearance time (days) (CT_{50})	-			
(CT_{90})	-			
Level and nature of residues (%) in organisms after the 14 day depuration phase	-			
Higher tier study				
-				

* DPX-KN128

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Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
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The relevant guidance was the Guidance Document on Aquatic Ecotoxicology[7] and the updated guidance of EFSA (2013)[8].

Use on maize:

FOCUS$_{sw}$ step 1-3 - TERs for indoxacarb – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**
		Oncorhynchus mykiss	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC10
		>170 µg/L	67.5 µg/L	>126 µg/L	14.5 µg/L	>79.3 µg/L	1.68 µg/L
FOCUS Step 1	1.941	87	34	64	**7**	40	**0.87**
FOCUS Step 2							
North Europe	0.345	492		365	42		**4.87**
South Europe	0.546	311		230	26		**3.08**

[7] SANCO/3268/2001 rev. 4 Final (17 October 2002)

[8] EFSA PPR Panel (EFSA Panel on Plant Protection Products and their Residues), 2013. Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013;11(7):3290, 186 pp. doi:10.2903/j.efsa.2013.3290. Available online: www.efsa.europa.eu/efsajournal

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
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FOCUS Step 3					
Single application					
D3, ditch	0.195	871	646	74	**8.62**
D4, pond	0.008	21250	15750	1812	210
D4, stream	0.170	1000	741	85	**9.88**
D5, pond	0.008	21250	15750	1812	210
D5, stream	0.180	944	700	80	**9.33**
D6, ditch	0.193	880	652	75	**8.70**
R1, pond	0.011	15454	11454	1318	152
R1, stream	0.136	1250	926	106	12
R2, stream	0.182	934	692	79	**9.23**
R3, stream	0.192	885	656	75	**8.75**
R4, stream	0.134	1268	940	108	12
Multiple applications					
D3, ditch	0.170	1000	741	85	**9.88**
D4, pond	0.010	17000	12600	1450	168

D4, stream	0.148	1148		851	97		11.35
D5, pond	0.010	17000		12600	1450		168
D5, stream	0.165	1030		763	87		10.18
D6, ditch	0.171	994		736	84		**9.82**
R1, pond	0.014	12142		9000	1035		120
R1, stream	0.117	1452		1076	123		14.36
R2, stream	0.157	1082		802	92		10.70
R3, stream	0.165	1030		763	87		10.18
R4, stream	0.159	1069		792	91		10.57
Trigger		100	10	100	10	10	10

FOCUS$_{sw}$ step 4 - TERs indoxacarb – Maize at 37.5 g a.s./ha [2 applications]

Organisms *Chironomus riparius***:**

Toxicity endpoint: 1.68 µg/L

Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4					
Single application					

D3, ditch	10	10	0.034	49	10
D4, stream	10	10	0.038	44	10
D5, stream	10	10	0.040	42	10
D6, ditch	10	10	0.034	49	10
R2, stream	10	10	0.041	41	10
R3, stream	10	10	0.043	39	10
Multiple applications					
D3, ditch	10	10	0.028	60	10
D6, ditch	10	10	0.028	60	10

Sediment exposure

FOCUS$_{sed}$ step 1-3 - TERs for indoxacarb – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg/kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		2.92 µg/kg sed
FOCUS Step 1	81.782	**0.04**
FOCUS Step 2		
North Europe	14.279	**0.20**

South Europe	27.299	**0.11**
FOCUS Step 3		
Single application		

D3, ditch	0.104	28
D4, pond	0.025	116
D4, stream	0.014	208
D5, pond	0.024	121
D5, stream	0.012	243
D6, ditch	0.055	53.
R1, pond	0.042	69
R1, stream	0.315	**9.27**
R2, stream	0.651	**4.49**
R3, stream	0.253	11.54
R4, stream	0.667	**4.38**
Multiple applications		
D3, ditch	0.100	29
D4, pond	0.033	88
D4, stream	0.015	194
D5, pond	0.029	100
D5, stream	0.043	67

D6, ditch	0.141	20
R1, pond	0.083	35
R1, stream	0.316	**9.24**
R2, stream	0.651	**4.49**
R3, stream	0.715	**4.08**
R4, stream	0.667	**4.38**
Trigger		10

FOCUS$_{sed}$ step 4 - TERs indoxacarb – Maize at 37.5 g a.s./ha [2 applications]

Organisms *Chironomus riparius***:**

Toxicity endpoint: 2.92 µg/kg sed

Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsed (µg/kg sed)**	**TER**	**Trigger**
FOCUS Step 4					
Single application					

R1, stream	10	10	0.060	48	10
R2, stream	10	10	0.103	28	10
R3, stream	10	10	0.047	62	10
Multiple applications					
R1, stream	10	10	0.060	48	10
R2, stream	10	10	0.103	28	10
R3, stream	10	10	0.127	22	10
R4, stream	10	10	0.147	19	10

TER for metabolites (use on maize)

IN-JT333

FOCUS$_{sw}$ step 1-2 - TERs for IN-JT333 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Pimephales promelas*	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	NOEC	EC_{50}	EC_{50}
		10.5	2.42	>29	>7.5
FOCUS Step 1	0.330	**31**	**7.33**	**87**	22
FOCUS Step 2					
North Europe	0.079	132	30	367	94

South Europe	0.079	132	30	367	94
Trigger		100	10	100	10

FOCUS$_{sed}$ step 1-3 - TERs for IN-JT333 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		96 µg/kg sed
FOCUS Step 1	30.535	**3.14**
FOCUS Step 2		
North Europe	2.633	36
South Europe	4.428	21
Trigger		10

IN-JU873

FOCUS$_{sw}$ step 1-2 - TERs for IN-JU873 – Maize at 37.5 g a.s./ha [2 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		441	379	>265
FOCUS Step 1	0.151	2920	2509	1754
FOCUS Step 2				
North Europe	0.011	40090	34454	24090
South Europe	0.023	19173	16478	11521
Trigger		100	100	10

IN-KG433

$FOCUS_{sw}$ step 1-2 - TERs for IN-KG433 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>220	1.45*	7.92*
FOCUS Step 1	6.889	**31**	**0.21**	**1.15**
FOCUS Step 2				
North Europe	0.219	1004	**6.62**	36
South Europe	0.402	547	**3.61**	19
Trigger		100	100	10

* As no reliable value is available for aquatic invertebrates and algae, the toxicity of the parent compound divided by 10 was used for TER calculations.

$FOCUS_{sed}$ step 1-2 - TERs for IN-KG433 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		170 µg/kg sed

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

FOCUS Step 1	21.568	**7.88**
FOCUS Step 2		
North Europe	0.675	251
South Europe	1.250	136
Trigger		10

IN-KT413

FOCUS$_{sw}$ step 1-2 - TERs for IN-KT413 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**
		Oncorhynchus mykiss	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*
		LC_{50}	EC_{50}	NOEC	EC_{50}	NOEC
		>1060	967	3900	105000	24
FOCUS Step 1	3.679	288	262	1060	28540	**6.52**
FOCUS Step 2						

North Europe	0.396	2676	2441	9848	265151	60
South Europe	0.396	2676	2441	9848	265151	60
Trigger		100	100	10	10	10

FOCUS$_{sed}$ step 1-2 - TERs for IN-KT413 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		7500 µg/kg sed
FOCUS Step 1	11.707	640
FOCUS Step 2		
North Europe	1.006	7455
South Europe	1.107	6775
Trigger		10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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IN-MK638

FOCUS$_{sw}$ step 1-2 - TERs for IN-MK638 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		28000	41100	37200
FOCUS Step 1	2.463	11368	16686	15103
FOCUS Step 2				
North Europe	0.166	168674	247590	224096
South Europe	0.272	102941	151102	136764
Trigger		100	100	10

IN-MK643

FOCUS$_{sw}$ step 1-2 - TERs for IN-MK643 – Maize at 37.5 g a.s./ha [2 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		6990	16400	59700
FOCUS Step 1	0.912	7664	17982	65460
FOCUS Step 2				
North Europe	0.086	81279	190697	694186
South Europe	0.173	40404	94797	345086
Trigger		100	100	10

IN-KB687

$FOCUS_{sw}$ step 1-2 - TERs for IN-KB687 – Maize at 37.5 g a.s./ha [2 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		11900	7200	>2260
FOCUS Step 1	1.950	6102	3692	1158
FOCUS Step 2				
North Europe	0.071	167605	101408	31830
South Europe	0.071	167605	101408	31830
Trigger		100	100	10

IN-MP819

$FOCUS_{sw}$ step 1-2 - TERs for IN-MP819 – Maize at 37.5 g a.s./ha [2 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>368	60	>358
FOCUS Step 1	0.178	2067	337	2011
FOCUS Step 2				
North Europe	0.083	4433	722	4313
South Europe	0.083	4433	722	4313
Trigger		100	100	10

$FOCUS_{sed}$ step 1-2 - TERs for IN-MP819 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

		NOEC
		86200 µg/kg sed
FOCUS Step 1	3.764	22901
FOCUS Step 2		
North Europe	1.024	84179
South Europe	1.024	84179
Trigger		10

IN-MS775

FOCUS$_{sw}$ step 1-2 - TERs for IN-MS775 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>3.96	>5.67	>52

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

FOCUS Step 1	0.079	**50**	**71**	658
FOCUS Step 2				
North Europe	0.040	>99	141	1300
South Europe	0.040	>99	141	1300
Trigger		100	100	10

FOCUS$_{sed}$ step 1-2 - TERs for IN-MS775 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		2200 µg/kg sed
FOCUS Step 1	0.571	3852
FOCUS Step 2		
North Europe	0.49	4489

South Europe	0.49	4489
Trigger		10

IN-U8E24

FOCUS$_{sw}$ step 1-2 - TERs for IN-U8E24 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		46500	>12000	55200
FOCUS Step 1	3.546	13113	3384	15567
FOCUS Step 2				
North Europe	0.637	72998	18838	86656
South Europe	1.141	40754	10517	48379
Trigger		100	100	10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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IN-UYG24

FOCUS$_{sw}$ step 1-2 - TERs for IN-UYG24 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>115000	>120000	>106000
FOCUS Step 1	0.131	877863	916031	809160
FOCUS Step 2				
North Europe	0.107	1074766	1121495	990654
South Europe	0.107	1074766	1121495	990654
Trigger		100	100	10

IN-ML438

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

FOCUS$_{sw}$ step 1-2 - TERs for IN-ML438 – Maize at 37.5 g a.s./ha [2 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>17*	>12.6*	>7.93*
FOCUS Step 1	0.082	207	154	97
FOCUS Step 2				
North Europe	0.009	1889	1400	881
South Europe	0.012	1417	1050	661
Trigger		100	100	10

*No toxicity data is available for this metabolite. The toxicity of the active substance divided by 10 was used as surrogate.

Use on lettuce:

FOCUS$_{sw}$ step 1-3 - TERs for indoxacarb – Lettuce at 37.5 g a.s./ha [4 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**
		Oncorhynchus mykiss	*Pimephales promelas*	*Mysidopsis bahia*	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*
		LC_{50}	NOEC	EC_{50}	NOEC	EC_{50}	EC10
		>170 µg/L	67.5 µg/L	>126 µg/L	14.5 µg/L	>79.3 µg/L	1.68 µg/L
FOCUS Step 1	7.763	**21**	**8.70**	**16.23**	**1.87**	10.22	**0.22**
FOCUS Step 2							
North Europe	1.547	109	43	**81**	**9.37**		**1.09**
South Europe	1.547	109	43	**81**	**9.37**		**1.09**
FOCUS Step 3							
Single application							

D3, ditch (1st)	0.237	531	61	**7.09**
D3, ditch (2nd)	0.237	531	61	**7.09**
D4, pond (1st)	0.008	15750	1812	210
D4, stream (1st)	0.189	666	76	**8.89**
D6, ditch (1st)	0.232	543	62	**7.24**
R1, pond (1st)	0.013	9692	1115	129
R1, pond (2nd)	0.017	7411	852	98
R1, stream (1st)	0.156	807	92	10.77
R1, stream (2nd)	0.157	802	92	10.70
R2, stream (1st)	0.206	611	70	**8.16**
R2, stream (2nd)	0.21	600	69	**8.00**
R3, stream (1st)	0.219	575	66	**7.67**
R3, stream (2nd)	0.22	572	65	**7.64**
R4, stream (1st)	0.156	807	92	10.77
R4, stream (2nd)	0.155	812	93	10.84
Multiple applications				
D3, ditch (1st)	0.160	787	90	10.50

D3, ditch (2nd)	0.160		787	90		10.50
D4, pond (1st)	0.008		15750	1812		210
D4, stream (1st)	0.127		992	114		13.23
D6, ditch (1st)	0.159		792	91		10.57
R1, pond (1st)	0.062		2032	233		27
R1, pond (2nd)	0.032		3937	453		52
R1, stream (1st)	0.165		763	87		10.18
R1, stream (2nd)	0.207		608	70		**8.12**
R2, stream (1st)	0.139		906	104		12.09
R2, stream (2nd)	0.141		893	102		11.91
R3, stream (1st)	0.149		845	97		11.28
R3, stream (2nd)	0.265		475	54		**6.34**
R4, stream (1st)	0.370		340	39		**4.54**
R4, stream (2nd)	0.250		504	58		**6.72**
Trigger		100	10	100	10	10	10

FOCUS$_{sw}$ step 4 - TERs indoxacarb – Lettuce at 37.5 g a.s./ha [4 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Organisms *Chironomus riparius***:**

Toxicity endpoint: 1.68 µg/L

Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsw (µg/L)**	**TER**	**Trigger**
FOCUS Step 4*					
Single application					
D3, ditch (1st)	10	10	Not available	-	10
D3, ditch (2nd)	10	10	Not available	-	10
D4, stream (1st)	10	10	Not available	-	10
D6, ditch (1st)	10	10	Not available	-	10
R2, stream (1st)	10	10	0.040	42	10
R2, stream (2nd)	10	10	0.041	40	10
R3, stream (1st)	10	10	0.088	19	10
R3, stream (2nd)	10	10	0.071	23	10
Multiple applications					
R1, stream (2nd)	10	10	0.080	21	10
R3, stream (2nd)	10	10	0.077	21	10
R4, stream (1st)	10	10	0.175	**9.60**	10
R4, stream (2nd)	10	10	0.127	13.23	10
Single application	20	20			
D3, ditch (1st)	20	20	0.018	93	10
D3, ditch (2nd)	20	20	0.018	93	10
D4, stream (1st)	20	20	0.019	88	10
D6, ditch (1st)	20	20	0.017	98	10
Multiple applications					
R4, stream (1st)	20	20	0.092	18	10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Sediment exposure

FOCUS$_{sed}$ step 1-3 - TERs for indoxacarb – Lettuce at 37.5 g a.s./ha [4 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Scenario	**PEC global max (µg /kg sediment)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		2.92 µg/kg sed
FOCUS Step 1	327.128	**0.01**
FOCUS Step 2		
North Europe	78.497	**0.04**
South Europe	78.497	**0.04**
FOCUS Step 3		
Single application		
D3, ditch (1st)	0.160	18
D3, ditch (2nd)	0.160	18
D4, pond (1st)	0.014	208
D4, stream (1st)	0.127	22
D6, ditch (1st)	0.159	18

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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R1, pond (1st)	0.057	51
R1, pond (2nd)	0.084	34
R1, stream (1st)	0.215	13
R1, stream (2nd)	0.177	16
R2, stream (1st)	0.139	21
R2, stream (2nd)	0.141	20
R3, stream (1st)	0.277	10.54
R3, stream (2nd)	0.169	17
R4, stream (1st)	0.385	**7.58**
R4, stream (2nd)	0.280	10.43
Multiple applications		
D3, ditch (1st)	0.139	21
D3, ditch (2nd)	0.130	22
D4, pond (1st)	0.050	58
D4, stream (1st)	0.007	417
D6, ditch (1st)	0.069	42
R1, pond (1st)	0.218	13

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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R1, pond (2nd)	0.551	**5.30**
R1, stream (1st)	3.168	**0.92**
R1, stream (2nd)	2.164	**1.35**
R2, stream (1st)	2.640	**1.11**
R2, stream (2nd)	2.572	**1.14**
R3, stream (1st)	1.217	**2.40**
R3, stream (2nd)	0.984	**2.97**
R4, stream (1st)	0.975	**2.99**
R4, stream (2nd)	0.453	**6.45**
Trigger		10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

FOCUS$_{sed}$ step 4 - TERs indoxacarb – Lettuce at 37.5 g a.s./ha [4 applications]

Organisms *Chironomus riparius***:**

Toxicity endpoint: 2.92 µg/kg sed

Mitigation options	**[x] m non-spray buffer zone (corresponding to ≤ 95 % drift reduction)**	**[x] m vegetated buffer strip (corresponding to ≤ 90 % run-off reduction)**	**PECsed (µg/kg sed)**	**TER**	**Trigger**
FOCUS Step 4*					
Single application					
R4, stream (1st)	10	10	0.124	23	10
Multiple applications					
R1, pond (2nd)	10	10	0.229	12	10
R1, stream (1st)	10	10	0.501	**5.83**	10
R1, stream (2nd)	10	10	0.369	**7.91**	10
R2, stream (1st)	10	10	0.428	**6.82**	10
R2, stream (2nd)	10	10	0.399	**7.32**	10
R3, stream (1st)	10	10	0.202	14	10
R3, stream (2nd)	10	10	0.177	16	10
R4, stream (1st)	10	10	0.263	11.10	10
R4, stream (2nd)	10	10	0.117	24	10
Multiple applications					
R1, stream (1st)	20	20	0.175	16	10
R1, stream (2nd)	20	20	0.136	21	10
R2, stream (1st)	20	20	0.152	19	10
R2, stream (2nd)	20	20	0.137	21	10

TER for metabolites (use on lettuce)

IN-JT333

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

FOCUS$_{sw}$ step 1-3 - TERs for IN-JT333 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**fish chronic**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Pimephales promelas*	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	NOEC	EC_{50}	EC_{50}
		10.5	2.42	>29	>7.5
FOCUS Step 1	0.660	**15**	**3.67**	**43.94**	11.36
FOCUS Step 2					
North Europe	0.079	132	30	367	94
South Europe	0.079	132	30	367	94
Trigger		100	10	100	10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

FOCUS$_{sed}$ step 1-3 - TERs for IN-JT333 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		96 µg/kg sed
FOCUS Step 1	61.069	**1.57**
FOCUS Step 2		
North Europe	11.481	**8.36**
South Europe	11.481	**8.36**
FOCUS Step 3		
Single application		
D3, ditch (1st)	0.412	233
D3, ditch (2nd)	0.412	233
D4, pond (1st)	0.050	1920
D4, stream (1st)	0.000	96000

D6, ditch (1st)	0.412	233
R1, pond (1st)	0.050	1920
R1, pond (2nd)	0.050	1920
R1, stream (1st)	0.124	774
R1, stream (2nd)	0.143	671
R2, stream (1st)	0.050	1920
R2, stream (2nd)	0.540	177
R3, stream (1st)	0.075	1280
R3, stream (2nd)	0.054	1777
R4, stream (1st)	0.030	3200
R4, stream (2nd)	0.022	4363
Multiple applications		
D3, ditch (1st)	1.112	86
D3, ditch (2nd)	1.112	86
D4, pond (1st)	0.125	768
D4, stream (1st)	0.000	96000
D6, ditch (1st)	1.112	86

R1, pond (1st)	0.125	768
R1, pond (2nd)	0.125	768
R1, stream (1st)	0.695	138
R1, stream (2nd)	0.511	187
R2, stream (1st)	0.182	527
R2, stream (2nd)	1.523	63
R3, stream (1st)	0.448	214
R3, stream (2nd)	0.216	444
R4, stream (1st)	0.158	607
R4, stream (2nd)	0.080	1200
Trigger		10

IN-JU873

FOCUS$_{sw}$ step 1-2 - TERs for IN-JU873 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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		LC_{50}	EC_{50}	EC_{50}
		441	379	>265
FOCUS Step 1	0.302	1460	1254	877
FOCUS Step 2				
North Europe	0.067	6582	5656	3955
South Europe	0.067	6582	5656	3955
Trigger		100	100	10

IN-KG433

$FOCUS_{sw}$ step 1-2 - TERs for IN-KG433 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>220	1.45*	7.92*

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

FOCUS Step 1	13.778	**15**	**0.11**	**0.57**
FOCUS Step 2				
North Europe	0.820	268	**1.77**	**9.66**
South Europe	0.820	268	**1.77**	**9.66**
Trigger		100	100	10

* As no reliable value is available for aquatic invertebrates and algae, the toxicity of the parent compound divided by 10 was used for TER calculations.

FOCUS$_{sed}$ step 1-2 - TERs for IN-KG433 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		170 µg/kg sed
FOCUS Step 1	43.136	**3.94**
FOCUS Step 2		

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

North Europe	2.557	66
South Europe	2.557	66
Trigger		10

IN-KT413

FOCUS$_{sw}$ step 1-2 - TERs for IN-KT413 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Aquatic invertebrates prolonged**	**Algae**	**Sed. dweller prolonged**
		Oncorhynchus mykiss	*Daphnia magna*	*Daphnia magna*	*Pseudokirchneriella subcapitata*	*Chironomus riparius*
		LC_{50}	EC_{50}	NOEC	EC_{50}	NOEC
		>1060	967	3900	105000	24
FOCUS Step 1	7.359	144	131	529	14268	**3.26**
FOCUS Step 2						
North Europe	0.545	1944	1774	7155	192660	44

South Europe	0.545	1944	1774	7155	192660	44
Trigger		100	100	10	10	10

FOCUS$_{sed}$ step 1-2 - TERs for IN-KT413 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		7500 µg/kg sed
FOCUS Step 1	23.414	320
FOCUS Step 2		
North Europe	1.672	4485
South Europe	1.672	4485
Trigger		10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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IN-MK638

FOCUS$_{sw}$ step 1-2 - TERs for IN-MK638 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		28000	41100	37200
FOCUS Step 1	4.927	5682	8341	7550
FOCUS Step 2				
North Europe	0.764	36649	53795	48691
South Europe	0.645	43410	63720	57674
Trigger		100	100	10

IN-MK643

FOCUS$_{sw}$ step 1-2 - TERs for IN-MK643 – Lettuce at 37.5 g a.s./ha [4 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		6990	16400	59700
FOCUS Step 1	1.825	3830	8986	32712
FOCUS Step 2				
North Europe	0.516	13546	31782	115697
South Europe	0.516	13546	31782	115697
Trigger		100	100	10

IN-KB687

$FOCUS_{sw}$ step 1-2 - TERs for IN-KB687 – Lettuce at 37.5 g a.s./ha [4 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		11900	7200	>2260
FOCUS Step 1	3.901	3050	1845	579
FOCUS Step 2				
North Europe	0.103	115533	69902	21941
South Europe	0.103	115533	69902	21941
Trigger		100	100	10

IN-MP819

$FOCUS_{sw}$ step 1-2 - TERs for IN-MP819 – Lettuce at 37.5 g a.s./ha [4 applications]

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>368	60	>358
FOCUS Step 1	0.357	1030	168	1002
FOCUS Step 2				
North Europe	0.083	4433	722	4313
South Europe	0.083	4433	722	4313
Trigger		100	100	10

$FOCUS_{sed}$ step 1-2 - TERs for IN-MP819 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

		NOEC
		86200 µg/kg sed
FOCUS Step 1	7.528	11450
FOCUS Step 2		
North Europe	1.564	55115
South Europe	1.564	55115
Trigger		10

IN-MS775

FOCUS$_{sw}$ step 1-2 - TERs for IN-MS775 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>3.96	>5.67	>52

FOCUS Step 1	0.158	**25**	35	329
FOCUS Step 2				
North Europe	0.040	>99	141	1300
South Europe	0.040	>99	141	1300
Trigger		100	100	10

FOCUS$_{sed}$ step 1-2 - TERs for IN-MS775 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg /kg sed)**	**Sed. dweller prolonged**
		Chironomus riparius
		NOEC
		2200 µg/kg sed
FOCUS Step 1	1.142	1926
FOCUS Step 2		
North Europe	0.749	2937

South Europe	0.749	2937
Trigger		10

IN-U8E24

FOCUS$_{sw}$ step 1-2 - TERs for IN-U8E24 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		46500	>12000	55200
FOCUS Step 1	7.09	6559	1693	7786
FOCUS Step 2				
North Europe	2.723	17077	4407	20272
South Europe	2.219	20955	5408	24876

Trigger	100	100	10

IN-UYG24

FOCUS$_{sw}$ step 1-2 - TERs for IN-UYG24 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Daphnia magna*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>115000	>120000	>106000
FOCUS Step 1	0.262	438931	458015	404580
FOCUS Step 2				
North Europe	0.16	718750	750000	662500
South Europe	0.16	718750	750000	662500
Trigger		100	100	10

List of end points

Rapporteur Member State	**Month and year**	Active substance and Plant Protection Product **(Name)**
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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IN-ML438

FOCUS$_{sw}$ step 1-2 - TERs for IN-ML438 – Lettuce at 37.5 g a.s./ha [4 applications]

Scenario	**PEC global max (µg L)**	**fish acute**	**Aquatic invertebrates**	**Algae**
		Oncorhynchus mykiss	*Mysidopsis bahia*	*Pseudokirchneriella subcapitata*
		LC_{50}	EC_{50}	EC_{50}
		>17*	>12.6*	>7.93*
FOCUS Step 1	0.164	104	**77**	48
FOCUS Step 2				
North Europe	0.035	486	360	227
South Europe	0.035	486	360	227
Trigger		100	100	10

*No toxicity data is available for this metabolite. The toxicity of the active substance divided by 10 was used as surrogate.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Effects on bees (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.1 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.1)*

* This section does reflect the new EFSA Guidance Document on bees which has not yet been noted by the Standing Committee on Plants, Animals, Food and Feed.

Species	Test substance	Time scale/type of endpoint	End point	toxicity
Apis mellifera	a.s.,	Acute	Oral toxicity (LD_{50})	0.232 µg/bee
Apis mellifera	preparation Indoxacarb 150 g/L EC	Acute	Oral toxicity (LD_{50})	0.11 µg a.s./bee, (0.69 µg prod./bee)
Apis mellifera	a.s.,	Acute	Contact toxicity (LD_{50})	0.0682 µg/bee
Apis mellifera	preparation Indoxacarb 150 g/L EC	Acute	Contact toxicity (LD_{50})	0.08 µg a.s./bee (0.50 µg prod./bee)
Bombus terrestris	a.s.,	Acute	Oral toxicity (LD_{50})	0.07 µg a.s./bee
Bombus terrestris	preparation Indoxacarb 150 g/L EC	Acute	Oral toxicity (LD_{50})	0.11 µg a.s./bee, (0.73 µg prod./bee)
Bombus terrestris	a.s.,	Acute	Contact toxicity (LD_{50})	0.25 µg a.s./bee
Bombus terrestris	preparation Indoxacarb 150 g/L EC	Acute	Contact toxicity (LD_{50})	0.32 µg a.s./bee (2.13 µg prod./bee)
Apis mellifera	a.s.,	Chronic	10 d-LC50	0.0649 µg/bee/day
Apis mellifera	preparation Indoxacarb 150 g/L EC	Chronic	10 d-LC50	0.0399 µg a.s./bee/day (0.266 µg prod./bee)
Apis mellifera	preparation Indoxacarb 150 g/L EC	Bee brood development	NOEClarvae	1.11 µg a.s./bee (7.4 µg prod./bee)
	a.s.,	Sub-lethal effects (behavioural and reproductive)	NOEC hypopharyngeal glands	-

Potential for accumulative toxicity: *yes/no*
Semi-field test (Cage and tunnel test) **Oomen Brood feeding testing**

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Honey bee	Indoxacarb technical (DPX-KN128)	Bee brood feeding study	100 µg a.s./kg	Effects on mortality. Brood index and termination rate of eggs and young larvae were affected
Honey bee	Indoxacarb technical (DPX-KN128)	Bee brood feeding study	100 µg a.s./kg	No adverse effects on any parameter tested.
Honey bee	Indoxacarb 150 g/L EC	Bee brood feeding study	100 µg a.s./kg 667 µg prod./kg	No adverse effects on any parameter tested.

Tunnel tests

Species	Test substance	Type	Dose	Endpoint/observation
Honey bee colonies	Indoxacarb 150 g/L EC	Bee brood study on flowering *Phacelia tanacetifolia* in Germany	50 g a.s./ha 333 g prod./ha	Transient effect on flight activity, behaviour and mortality Strong effect on the brood development No effect on colony size, pupal mortality
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on *Phacelia tanacetifolia* in Germany	55.5 g a.s./ha 370 mL prod./ha during bee flight	No harmful effects on honey bee mortality in 2 of the 3 tunnels, transient mortality in 1 tunnel. No harmful effects on flight intensity, brood development, and behaviour
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on *Phacelia tanacetifolia* in France	55.6 g a.s./ha 371 mL prod./ha during bee flight	No harmful effects on flight intensity and brood development, increased mortality at day of application and 1 day thereafter
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on *Phacelia tanacetifolia* in Germany	55.6 g a.s./ha 359 mL prod./ha during bee flight	No harmful effects on brood development, increased mortality at day of application and 1 day thereafter Transient effects on flight intensity and behaviour
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on flowering *Phacelia tanacetifolia* in Germany	37.5 g a.s./ha 250 mL prod./ha during bee flight	During bee flight: Transient increase in mortality (up to DAA2) when applied during daily bee flight. No effect on

			37.5 g a.s./ha 250 mL prod./ha after bee flight	colony strength and brood development. Slight effect on flight intensity and behaviour when applied during daily bee flight. After bee flight: No effect on mortality, flight intensity, colony strength and brood development when applied in evening after daily bee flight. Slight and transient effect on behaviour when applied in evening after daily bee flight.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on flowering *Phacelia tanacetifolia* in Germany	50 g a.s./ha 333 mL prod./ha after bee flight	Transient effect on mortality (up to DAA3), and on flight intensity (day after application) and behaviour. No effect on colony size but slight and transient effect on the amount of brood cells after treatment. Obvious effects on brood development, particularly on the eggs.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on flowering *Phacelia tanacetifolia* in Germany	37.5 g a.s./ha 250 mL prod./ha during bee flight	During bee flight: Increase of pupal mortality when applied during daily bee flight. Slight and transient effect on flight

			37.5 g a.s./ha 250 mL prod./ha after bee flight	intensity and behaviour. No adverse effect on mortality and colony size when applied during daily bee flight. Slight effect on the amount of brood. Obvious effects on the brood development (eggs and larvae). After bee flight: Slight and transient effect on flight intensity and behaviour when applied after daily bee flight. No adverse effect on mortality and colony size when applied after daily bee flight.. Possible effect on the amount of brood. Obvious effects on the brood development (eggs and larvae).
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on *Phacelia tanacetifolia* in France	50 g a.s./ha 333 mL prod./ha during bee flight 50 g a.s./ha 333 mL prod./ha after bee flight	During bee flight: Transient effects on mortality and foraging activity were observed when applied during daily bee flight. After bee flight: No harmful effects on honey bee mortality, foraging activity when applied after daily bee flight.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on *Phacelia tanacetifolia* in France	55.6 g a.s./ha 371 mL prod./ha during bee flight 55.6 g a.s./ha 371 mL prod./ha after bee flight	Increase of mortality on day of application when applied during flight. Effects on foraging during 4 days. After bee flight: Results considered not fully reliable.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on flowering maize in Germany	37.5 g a.s./ha 250 mL prod./ha during bee flight	During bee flight: Increase in honey bee mortality when applied during flight (up to 3 DAA). No effect on honey

			37.5 g a.s./ha 250 mL prod./ha after bee flight	bee flight activity, brood development and colony condition. Effects on behaviour. After bee flight: Slight increase in honey bee mortality when applied after flight (0DAA). No effect on honey bee flight activity, brood development and colony condition. Effects on behaviour.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on flowering *Phacelia tanacetifolia* in Germany	37.5 g a.s./ha 232.1 mL prod./ha during bee flight 37.5 g a.s./ha 232.1 mL prod./ha after bee flight	Study considered valid but to be used with caution. During bee flight: No effect on mortality, flight intensity, colony strength when applied during flight. Slight and transient effect on behaviour. After bee flight: Slight effect on mortality and behaviour when applied after flight. No effect on flight intensity, colony strength.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on wheat treated with artificial honeydew in France	55.6 g a.s./ha 375 mL prod./ha during bee flight 55.6 g a.s./ha 375 mL prod./ha 3 hours before bee flight	Study not reliable. Effects on mortality were however obvious.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on wheat treated with artificial honeydew in France	37.5 g a.s./ha 250 mL prod./ha during bee flight 37.5 g a.s./ha 250 mL prod./ha after bee flight	Not reliable for risk assessment.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on wheat treated with artificial honeydew in France	55.6 g a.s./ha 375 mL prod./ha during bee flight	Increase in honey bee mortality and flight intensity up to 5 DAA in both treatments. Mortality was

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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			55.6 g a.s./ha 375 mL prod./ha after bee flight	high in both cases.Changes in behaviour noted on the day of application when applied after bee flight and noted up to 2 DAA when applied during bee flight. No larvae was found at the end of the test in both cases.
Honey bee colonies	Indoxacarb 150 g/L EC	Semi-field study on oilseed rape in France	50 g a.s./ha during bee flight	<u>During bee flight:</u> Mortality was observed when applied during daily bee flight. No effect on flight activity. <u>After bee flight:</u> No effects on mortality and flight activity when applied after daily bee flight.
			50 g a.s./ha after bee flight	
Bumblebee colonies	Indoxacarb 150 g/L EC	Semi-field study on flowering *Phacelia tanacetifolia* in Germany	37.5 g a.s./ha 249.1 mL prod./ha in 400L water <u>after</u> bumblebee flight	Not considered valid for risk assessment.
Field tests				
Honey bee colonies	Indoxacarb 150 g/L EC	Field study on oilseed rape before flowering (BBCH <59) in Germany, <u>hives exposed from d 9 and d 14 after application</u> <u>Application before flowering</u>	25.5 g a.s./ha 170 mL prod./ha in 300 L water/ha	No harmful effects on honey bee mortality, flight intensity, brood development, and behaviour 9 and 14 days after application; no residue of a.s. in honey
Honey bee colonies	Indoxacarb 150 g/L EC	Field study on flowering oilseed rape (BBCH <61) in Germany, <u>hives exposed from d 4 and d 6 after application</u> <u>Application at the beginning of flowering</u>	25.5 g a.s./ha 170 mL prod./ha	No harmful effects on honey bee mortality, brood development, and behaviour 4 and 6 days after application; no residue of a.s. in honey

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Honey bee colonies	Indoxacarb 150 g/L EC	Field study on maize in Germany, colonies exposed in evening after flight Application at the beginning of flowering	37.5 g a.s./ha 250 mL prod./ha in 300 L water/ha	Increase of mortality cannot be excluded. Results on flight intensity inconclusive. No test item related impact on the behaviour, and brood development. Test not representative of an application on a flowering crop.

Risk assessment for – Maize at 37.5 g a.s./ha [2 applications]

Species	Test substance	Risk quotient	HQ	Trigger
Apis mellifera	a.s.	HQcontact	**550**	50
Apis mellifera	preparation Indoxacarb 150 g/L EC	HQcontact	**469**	50
Apis mellifera	a.s.	HQoral	**161**	50
Apis mellifera	preparation Indoxacarb 150 g/L EC	HQoral	**341**	50

Lettuce at 37.5 g a.s./ha [4 applications]

Species	Test substance	Risk quotient	HQ	Trigger
Apis mellifera	a.s.	HQcontact	**550**	50
Apis mellifera	preparation Indoxacarb 150 g/L EC	HQcontact	**469**	50
Apis mellifera	a.s.	HQoral	**161**	50
Apis mellifera	preparation Indoxacarb 150 g/L EC	HQoral	**341**	50

Effects on other arthropod species (Regulation (EU) N° 283/2013, Annex Part A, point 8.3.2 and Regulation (EU) N° 284/2013 Annex Part A, point 10.3.2)

Laboratory tests with standard sensitive species

Species	Test Substance	End point	Toxicity
Typhlodromus pyri	Indoxacarb 150 g/L EC	LR_{50}	220.5 g a.s./ha (1470 mL product/ha)
Aphidius rhopalosiphi	Indoxacarb 150 g/L EC	LR_{50}	5.1 g a.s./ha (34 mL product/ha)
Additional species			

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Species	Test Substance	End point	Toxicity
Not required			

First tier risk assessment for – Maize at 37.5 g a.s./ha [2 applications]

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Indoxacarb 150 g/L EC	*Typhlodromus pyri*	220.5	0.29	0.01	2
Indoxacarb 150 g/L EC	*Aphidius rhopalosiphi*	5.1	**12.5**	0.30	2

[1]off-field at 1 m distance

First tier risk assessment for – Lettuce at 37.5 g a.s./ha [4 applications]

Test substance	Species	Effect (LR_{50} g/ha)	HQ in-field	HQ off-field[1]	Trigger
Indoxacarb 150 g/L EC	*Typhlodromus pyri*	220.5	0.46	0.01	2
Indoxacarb 150 g/L EC	*Aphidius rhopalosiphi*	5.1	**19.9**	0.37	2

[1]off-field at 1 m distance

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

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Extended laboratory tests, aged residue tests

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
Aphidius rhopalosiphi	adult	Indoxacarb 150 g/L EC, apple leaves	48-h	4.4, 10.0, 23.0, 52.5, and 120 g a.s./ha	Mortality, reproduction	Mortality: -8.1%, 5.4%, 8.1%, 43.2%, 70.3% Reproduction: -17.1%, -15.4%, -70.1%, 48.7%, n.a.	≥52.5 g a.s./ha (≥350 mL product/ha)
Aphidius rhopalosiphi	adult	Indoxacarb 150 g/L EC, apple leaves	48-h	1-4 × 100 g a.s./ha (aged residue)	Mortality, reproduction	1st application: 97.5% mortality 4th application: 100% mortality After 28 d field aging: 13.2% mortality and 53.8% reduction in reproduction After 56 d field aging : 2.5% mortality and 37.6% reduction in reproduction	No effect ≥ 50 % after 56 d field aging.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
Chrysoperla carnea	Larvae and adult	Indoxacarb 150 g/L EC, apple leaves	6-11 days	6.9, 17.25, 43.2, 108, and 270.0 g a.s./ha	Mortality, reproduction	Mortality: 0.0%, 0.0%, 92.3%, 96.2%, 100.0% Reduction fecundity: 37.7%, 67.4%, n.a., n.a., n.a. Reduction fertility: 1.3%, 11.4%, n.a., n.a., n.a.	> 6.9 g a.s./ha (46 mL product/ha)
Chrysoperla carnea	Larvae and adult	Indoxacarb 150 g/L EC, apple leaves	48 hours	1-4 × 100 g a.s./ha (28 days aged residue)	Mortality, reproduction	1st application: not valid 4th application: 94% mortality After 28 field ageing: 8.8% mortality and no adverse effect on fecundity and hatching (fertilization)	No effect ≥ 50 % after 28 d field aging.

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
RMS = France Co-RMS = Spain	**2016-12**	**Indoxacarb**

Section 5 Ecotoxicology

Species	Life stage	Test substance, substrate	Time scale	Dose (g/ha)[1,2]	End point	% effect[3]	ER_{50}
Orius laevigatus	Larvae and adult	Indoxacarb 150 g/L EC, apple leaves	9-day	1-4 × 100 g a.s./ha	Mortality, reproduction	1st application: 22.2% mortality, and no adverse effect on fecundity and hatching 4th application: 9% mortality, 13.5% reduction in reproduction and 10.2% reduction in hatching	No effect ≥ 50 % at 1-4 × 100 g a.s./ha.

[1] indicate whether initial or aged residues
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation
[3] positive percentages relate to adverse effects

Risk assessment for – Maize at 37.5 g a.s./ha [2 applications] based on extended lab test

Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Aphidius rhopalosiphi	≥52.5 g a.s./ha	63.75	0.15
Chrysoperla carnea	> 6.9 g a.s./ha (46 mL product/ha)	63.75	0.15

[1]at 1 m distance (2D)

Risk assessment for – Lettuce at 37.5 g a.s./ha [4 applications] based on extended lab test

Species	ER_{50} (g/ha)	In-field rate	Off-field rate[1]
Aphidius rhopalosiphi	≥52.5 g a.s./ha	101.25	0.19
Chrysoperla carnea	> 6.9 g a.s./ha (46 mL product/ha)	101.25	0.19

[1]at 1 m distance (2D)

Semi-field tests

List of end points

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Section 5 Ecotoxicology

Extended-laboratory studies with residue ageing to assess the potential for recovery with *Aphidius rhopalosiphi, Chrysoperla carnea,* and *Orius laevigatus.* Four applications of 100 g a.s./ha of Indoxacarb 150 g/L EC were made at 10-day intervals to apple trees. Using a worst-case exposure scenario that exceeds all proposed uses described in the GAP (4 × 100 g a.s./ha was actually investigated in these studies) transient in-field effects may be expected for *Aphidius rhopalosiphi* and *Chrysoperla carnea*, but not for *Orius laevigatus*. However, when residues of Indoxacarb 150 g/L EC were aged under natural conditions, the effects on both mortality and reproduction in these non-target arthropods were reduced. Aging residues for 28 days after the fourth application resulted in 8.8% mortality and no adverse effect on both fecundity and hatching of *Chrysoperla carnea* when compared to controls. Aging residues for 28 days resulted in 13.2% mortality and 57.8% reduction in reproduction of *Aphidius rhopalosiphi.* A 56-day aging period resulted in 2.5% mortality and 37.6% reduction in reproduction.
Field studies
-
Additional specific test
-

Effects on non-target soil meso- and macro fauna; effects on soil nitrogen transformation (Regulation (EU) N° 283/2013, Annex Part A, points 8.4, 8.5, and Regulation (EU) N° 284/2013 Annex Part A, points 10.4, 10.5)

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Earthworms					
Eisenia fetida	DPX-KN128	5% peat in test soil, test item mixed into soil	Chronic 56 d	reproduction	56-d NOEC = 29.2 mg/kg dry soil EC10 = 23.95 mg a.s./kg dry soil
Eisenia fetida	Indoxacarb 150 g/L EC	10% peat in test soil, test item mixed into soil	Chronic 56 d	reproduction	56-d NOEC = 199.3 mg product/kg dry soil (29.9 mg a.s./kg dry soil) EC10 = 142.88 mg prep./kg dry soil (21.43 mg a.s./kg dry soil)
Eisenia fetida	IN-JT333	5% peat in test soil, test item mixed into soil	Chronic 56 d	Growth, reproduction, behaviour	56-d NOEC = 100 mg/kg dry soil EC10 = 54.86 mg/kg dry soil

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Eisenia fetida	IN-JT333	10% peat in test soil, test item mixed into soil	Chronic 56 d	reproduction	56-d NOEC = 2.5 mg/kg dry soil
Eisenia fetida	IN-JU873	5% peat in test soil, test item mixed into soil	Chronic 56 d	reproduction	56-d NOEC = 50 mg/kg dry soil EC10 = 89.12 mg/kg dry soil
Eisenia fetida	IN-KG433	5% peat in test soil, test item mixed into soil	Chronic 56 d	reproduction	56-d NOEC = 50 mg/kg dry soil EC10 = 55.3 mg/kg dry soil
Eisenia fetida	IN-KT413	5% peat in test soil, test item mixed into soil	Chronic 56 d	Growth, reproduction, behaviour	56-d NOEC = 100 mg/kg dry soil
Eisenia fetida	IN-MK638	5% peat in test soil, test item mixed into soil	Chronic 56 d	Growth	56-d NOEC = 50 mg/kg dry soil
Eisenia fetida	IN-MK643	5% peat in test soil, test item mixed into soil	Chronic 56 d	Growth, reproduction, behaviour	56-d NOEC = 25 mg/kg dry soil EC10 = 22.25 mg/kg dry soil
Eisenia fetida	IN-KB687	5% peat in test soil, test item mixed into soil	Chronic 56 d	reproduction	56-d NOEC = 50 mg/kg dry soil
Other soil macroorganisms					
Folsomia candida	DPX-KN128	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC = 125 mg/kg dry soil EC10 = 106.8 mg/kg dry soil

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Section 5 Ecotoxicology

Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Folsomia candida	Indoxacarb 150 g/L EC	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	28-d NOEC = 6.6 mg prep./kg dry soil (1 mg a.s./kg dry soil) EC10 = 14.86 mg prep./kg dry soil
Folsomia candida	IN-JT333	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC = 50 mg/kg dry soil EC10 = 64.17 mg/kg dry soil
Folsomia candida	IN-JU873	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC = 100 mg/kg dry soil
Folsomia candida	IN-KG433	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC = 6.25 mg/kg dry soil
Folsomia candida	IN-KT413	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC= 100 mg/kg dry soil
Folsomia candida	IN-MK638	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC= 25 mg/kg dry soil EC10 = 10.15 mg/kg dry soil
Folsomia candida	IN-MK643	10% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC= 10 mg/kg dry soil EC10 = 80.28 mg/kg dry soil
Folsomia candida	IN-KB687	5% peat in test soil, test item mixed into soil	Chronic 28 d	reproduction	NOEC= 6.25 mg/kg dry soil EC10 = 10.80 mg/kg dry soil

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Hypoaspis aculeifer	DPX-KN128	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 1000 mg/kg dry soil
Hypoaspis aculeifer	Indoxacarb 150 g/L EC	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 95.3 mg prep./kg dry soil (14.3 mg a.s./kg dry soil) EC10 = 137.2 mg prep./kg dry soil
Hypoaspis aculeifer	IN-JT333	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 100 mg/kg dry soil
Hypoaspis aculeifer	IN-JU873	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 100 mg/kg dry soil
Hypoaspis aculeifer	IN-KG433	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 100 mg/kg dry soil
Hypoaspis aculeifer	IN-KT413	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 100 mg/kg dry soil EC10 = 62.7 mg/kg dry soil
Hypoaspis aculeifer	IN-MK638	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 100 mg/kg dry soil
Hypoaspis aculeifer	IN-MK643	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 100 mg/kg dry soil

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Test organism	Test substance	Application method of test a.s./ OM[1]	Time scale	End point	Toxicity
Hypoaspis aculeifer	IN-KB687	5% peat in test soil, test item mixed into soil	Chronic 14 d	reproduction	NOEC = 3.125 mg/kg dry soil EC10 = 5.44 mg/kg dry soil

Higher tier testing (e.g. modelling or field studies)
No data required.

Nitrogen transformation	Indoxacarb 150 g/L EC	0.84, 4.17, and 8.35 mg formulated product/kg soil dry weight	<25% effect at day 28 at 8.35 mg formulated product/kg soil dry weight
Nitrogen transformation	DPX-MP062 (79:21 mixture DPX-KN128/IN-KN127)	250 g DPX-MP062/ha	<25% effect at day 28 at 250 g a.s./ha (0.333 mg DPX-MP062/kg soil dry weight).
Nitrogen transformation	IN-JT333	60 g IN-JT333/ha	<25% effect at day 28 at 60 g/ha (0.08 mg IN-JT333/kg soil dry weight).
Nitrogen transformation	IN-JU873	0.087 and 0.87 mg IN-JU873/kg soil dry weight	<25% effect at day 28 at 0.087 and 0.87 mg IN-JU873/kg soil dry weight
Nitrogen transformation	IN-KG433	0.076 mg IN-KG433/kg soil dry weight	<25% effect at day 28 at 0.076 mg IN-KG433/kg soil dry weight (14.87%) based on nitrogen levels 28% effect at day 28 at 0.076 mg IN-KG433/kg soil dry weight based on nitrogen transformation
Nitrogen transformation	IN-KT413	0.102 and 1.02 mg IN-KT413/kg soil dry weight	<25% effect at day 28 at 0.102 and 1.02 mg IN-KT413/kg soil dry weight
Nitrogen transformation	IN-MK638	0.042 and 0.42 mg IN-MK638/kg soil dry weight	<25% effect at day 28 at 0.042 and 0.42 mg IN-MK638/kg soil dry weight

List of end points

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Nitrogen transformation	IN-MK643	0.041 and 0.41 mg IN-MK643/kg soil dry weight	<25% effect at day 28 at 0.041 and 0.41 mg IN-MK643/kg soil dry weight
Nitrogen transformation	IN-KB687	0.13, 0.67, and 1.33 mg/kg soil dry weight	<25% effect at day 28 at up to 1.33 mg IN-KB687/kg soil dry weight

Toxicity/exposure ratios for soil organisms

Maize at 37.5 g a.s./ha [2 applications]

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Eisenia fetida	DPX-KN128	Chronic	0.042 (plateau)	570	5
Eisenia fetida	Indoxacarb 150 g/L EC	Chronic	0.042 (plateau)	255	5
Eisenia fetida	IN-JT333	Chronic	0.007 (plateau)	7837	5
Eisenia fetida	IN-JT333	Chronic	0.007 (plateau)	178	5
Eisenia fetida	IN-JU873	Chronic	0.004 (plateau)	12500	5
Eisenia fetida	IN-KG433	Chronic	0.015 (initial)	3333	5
Eisenia fetida	IN-KT413	Chronic	0.007 (initial)	14285	5
Eisenia fetida	IN-MK638	Chronic	0.004 (initial)	12500	5
Eisenia fetida	IN-MK643	Chronic	0.002 (plateau)	11125	5
Eisenia fetida	IN-KB687	Chronic	0.004 (initial)	12500	5
Eisenia fetida	IN-ML438	Chronic	0.003 (plateau)	798	5
Eisenia fetida	IN-U8E24	Chronic	0.022 (plateau)	109	5
Folsomia candida	DPX-KN128	Chronic	0.042 (plateau)	2542	5
Folsomia candida	Indoxacarb 150 g/L EC	Chronic	0.042 (plateau)	23.8	5

List of end points

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Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Folsomia candida	IN-JT333	Chronic	0.007 (plateau)	7142	5
Folsomia candida	IN-JU873	Chronic	0.004 (plateau)	25000	5
Folsomia candida	IN-KG433	Chronic	0.015 (initial)	416	5
Folsomia candida	IN-KT413	Chronic	0.007 (initial)	14285	5
Folsomia candida	IN-MK638	Chronic	0.004 (initial)	2537	5
Folsomia candida	IN-MK643	Chronic	0.002 (plateau)	2500	5
Folsomia candida	IN-KB687	Chronic	0.004 (initial)	1562	5
Folsomia candida	IN-ML438	Chronic	0.003 (plateau)	3560	5
Folsomia candida	IN-U8E24	Chronic	0.022 (plateau)	485	5
Hypoaspis aculeifer	DPX-KN128	Chronic	0.042 (plateau)	23809	5
Hypoaspis aculeifer	Indoxacarb 150 g/L EC	Chronic	0.042 (plateau)	340	5
Hypoaspis aculeifer	IN-JT333	Chronic	0.007 (plateau)	14285	5
Hypoaspis aculeifer	IN-JU873	Chronic	0.004 (plateau)	25000	5
Hypoaspis aculeifer	IN-KG433	Chronic	0.015 (initial)	6666	5
Hypoaspis aculeifer	IN-KT413	Chronic	0.007 (initial)	8957	5
Hypoaspis aculeifer	IN-MK638	Chronic	0.004 (initial)	25000	5
Hypoaspis aculeifer	IN-MK643	Chronic	0.002 (plateau)	50000	5
Hypoaspis aculeifer	IN-KB687	Chronic	0.004 (initial)	781	5
Hypoaspis aculeifer	IN-ML438	Chronic	0.003 (plateau)	33333	5
Hypoaspis aculeifer	IN-U8E24	Chronic	0.022 (plateau)	4545	5

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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[a] The toxicity endpoint has been divided by 2 since the log P_{ow} is >2 and peat content in artificial soil was of 10%.

[b] No log Pow value was indicated. The toxicity endpoint has been conservatively divided by 2 since the peat content in artificial soil was of 10%.

[c] No endpoint correction as substrate contained reduced amount of peat (5%).

[d] As a worst-case assumption the endpoint of the parent compound divided by 10 was used.

Lettuce at 37.5 g a.s./ha [4 applications]

Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Eisenia fetida	DPX-KN128	Chronic	0.169 (plateau)	142	5
Eisenia fetida	Indoxacarb 150 g/L EC	Chronic	0.169 (plateau)	63	5
Eisenia fetida	IN-JT333	Chronic	0.026 (plateau)	2110	5
Eisenia fetida	IN-JT333	Chronic	0.026 (plateau)	48	5
Eisenia fetida	IN-JU873	Chronic	0.017 (plateau)	2941	5
Eisenia fetida	IN-KG433	Chronic	0.059 (initial)	847	5
Eisenia fetida	IN-KT413	Chronic	0.027 (initial)	3703	5
Eisenia fetida	IN-MK638	Chronic	0.018 (initial)	2777	5
Eisenia fetida	IN-MK643	Chronic	0.009 (plateau)	2472	5
Eisenia fetida	IN-KB687	Chronic	0.015 (initial)	3333	5
Eisenia fetida	IN-ML438	Chronic	0.011 (plateau)	217	5
Eisenia fetida	IN-U8E24	Chronic	0.035 (plateau)	109	5
Folsomia candida	DPX-KN128	Chronic	0.169 (plateau)	632	5
Folsomia candida	Indoxacarb 150 g/L EC	Chronic	0.169 (plateau)	5.9	5
Folsomia candida	IN-JT333	Chronic	0.026 (plateau)	1923	5
Folsomia candida	IN-JU873	Chronic	0.017 (plateau)	5882	5

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
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Test organism	Test substance	Time scale	Soil PEC	TER	Trigger
Folsomia candida	IN-KG433	Chronic	0.059 (initial)	106	5
Folsomia candida	IN-KT413	Chronic	0.027 (initial)	3703	5
Folsomia candida	IN-MK638	Chronic	0.018 (initial)	564	5
Folsomia candida	IN-MK643	Chronic	0.009 (plateau)	555	5
Folsomia candida	IN-KB687	Chronic	0.015 (initial)	416	5
Folsomia candida	IN-ML438	Chronic	0.011 (plateau)	971	5
Folsomia candida	IN-U8E24	Chronic	0.035 (plateau)	305	5
Hypoaspis aculeifer	DPX-KN128	Chronic	0.169 (plateau)	5917	5
Hypoaspis aculeifer	Indoxacarb 150 g/L EC	Chronic	0.169 (plateau)	84	5
Hypoaspis aculeifer	IN-JT333	Chronic	0.026 (plateau)	3846	5
Hypoaspis aculeifer	IN-JU873	Chronic	0.017 (plateau)	5882	5
Hypoaspis aculeifer	IN-KG433	Chronic	0.059 (initial)	1694	5
Hypoaspis aculeifer	IN-KT413	Chronic	0.027 (initial)	2322	5
Hypoaspis aculeifer	IN-MK638	Chronic	0.018 (initial)	5555	5
Hypoaspis aculeifer	IN-MK643	Chronic	0.009 (plateau)	11111	5
Hypoaspis aculeifer	IN-KB687	Chronic	0.015 (initial)	208	5
Hypoaspis aculeifer	IN-ML438	Chronic	0.011 (plateau)	9091	5
Hypoaspis aculeifer	IN-U8E24	Chronic	0.035 (plateau)	2857	5

[a] The toxicity endpoint has been divided by 2 since the log P_{ow} is >2 and peat content in artificial soil was of 10%.

[b] No log Pow value was indicated. The toxicity endpoint has been conservatively divided by 2 since the peat content in artificial soil was of 10%.

[c] No endpoint correction as substrate contained reduced amount of peat (5%).

[d] As a worst-case assumption the endpoint of the parent compound divided by 10 was used.

List of end points

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Effects on terrestrial non target higher plants (Regulation (EU) N° 283/2013, Annex Part A, point 8.6 and Regulation (EU) N° 284/2013 Annex Part A, point 10.6)

Screening data

Not available.

Laboratory dose response tests

Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Zea mays (corn) *Avena sativa* (oat) *Allium cepa* (common onion) *Lolium perenne*, (perennial ryegrass) *Cucumis sativa* (cucumber) *Brassica napus*, (oilseed rape) *Pisum sativum* (pea) *Glycine max* (soybean) *Beta vulgaris* (sugar beet) *Lycopersicon esculentum* (tomato)	Indoxacarb 150 g/L EC	> 100 g a.s./ha	-	1.04	>96	5
Allium cepa (common onion) *Triticum aestivum* (wheat) *Sorghum bicolour* (sorghum) *Zea mays* (corn) *Beta vulgaris* (sugarbeet) *Brassica napus* (oilseed rape) *Cucumis sativa* (cucumber) *Glycine max* (soybean) *Lycopersicon esculentum* (tomato)	Indoxacarb 150 g/L EC	> 504 g a.s./ha	-	1.04	>485	5

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Species	Test substance	ER_{50} (g/ha)[2] vegetative vigour	ER_{50} (g/ha)[2] emergence	Exposure[1] (g/ha)[2]	TER	Trigger
Pisum sativum (pea)						
Extended laboratory studies : Semi-field and field test: Not required						

[1] Drift estimates based on 90th percentile values for field crops (BBA 2000) are used.
[2] for preparations indicate whether dose is expressed in units of a.s. or preparation

Effects on biological methods for sewage treatment (Regulation (EU) N° 283/2013, Annex Part A, point 8.8)

Test type/organism	end point
Activated sludge	EC50 >1000 mg DPX-MP062/L[1]
Pseudomonas sp	-

[1] Mixture containing approximately 75% DPX-KN128.

Monitoring data (Regulation (EU) N° 283/2013, Annex Part A, point 8.9 and Regulation (EU) N° 284/2013, Annex Part A, point 10.8)

Available monitoring data concerning adverse effect of the a.s.

-

Available monitoring data concerning effect of the PPP.

-

Definition of the residue for monitoring (Regulation (EU) N° 283/2013, Annex Part A, point 7.4.2) Ecotoxicologically relevant compounds[1]

Compartment	
soil	Parent (indoxacarb)
water	Parent (indoxacarb)
sediment	Parent (indoxacarb)
groundwater	Parent (indoxacarb)

[1] metabolites are considered relevant when, based on the risk assessment, they pose a risk comparable or higher than the parent

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Section 5 Ecotoxicology

Classification and labelling with regard to ecotoxicological data (Regulation (EU) N° 283/2013, Annex Part A, Section 10)

Substance	Indoxacarb
Harmonised classification according to Regulation (EC) No 1272/2008 and its Adaptations to Technical Process [Table 3.1 of Annex VI of Regulation (EC) No 1272/2008 as amended][9]:	Aquatic acute 1; H400 Aquatic chronic 1; H410
Peer review proposal[10] for harmonised classification according to Regulation (EC) No 1272/2008:	

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353, 31.12.2008, 1-1355.

[10] It should be noted that harmonised classification and labelling is formally proposed and decided in accordance with Regulation (EC) No 1272/2008. Proposals for classification made in the context of the evaluation procedure under Regulation (EC) No 1107/2009 are not formal proposals.

List of end points

Rapporteur Member State	Month and year	Microbial or Viral Agent (Name)
	2016-12	

Used compounds code(s)

Code/Trivial name*	IUPAC name/SMILES notation	Structural formula

* The compound code / trivial name in bold is the name used in the list of endpoints.