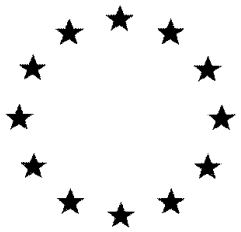
European Commission



List of Endpoints

Abamectin

Rapporteur Member State: The Netherlands

April 2015

Draft Assessment Report and Proposed decision of the Netherlands prepared in the context of the possible extension of the approval conditions of abamectin under Regulation (EC) 1107/2009

Contents

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

Chapter 2.1 Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name)	Open **Note:** All ratios within the given limits of the ISO name (subject to amendment of ISO 1750) are expected to give similar results for the physical/chemical properties.
Function (*e.g.* fungicide)	insecticide, acaricide, nematicide
Rapporteur Member State	The Netherlands

Identity (Annex IIA, point 1)

Chemical name (IUPAC)	**Avermectin B_{1a}** (10*E*,14*E*,16*E*,22*Z*)-(1*R*,4*S*,5'*S*,6*S*,6'*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-6'-[(*S*)-*sec*-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.$1^{4,8}$.$0^{20,24}$]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-*α*-L-*arabino*-hexopyranosyl)-3-*O*-methyl-*α*-L-*arabino*-hexopyranoside **Avermectin B_{1b}** (10*E*,14*E*,16*E*,22*Z*)-(1*R*,4*S*,5'*S*,6*S*,6'*R*,8*R*,12*S*,13*S*,20*R*,21*R*,24*S*)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.$1^{4,8}$.$0^{20,24}$]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'*H*-pyran)-12-yl 2,6-dideoxy-4-*O*-(2,6-dideoxy-3-*O*-methyl-*α*-L-*arabino*-hexopyranosyl)-3-*O*-methyl-*α*-L-*arabino*-hexopyranoside
Chemical name (CA)	abamectin: avermectin B_1 avermectin B_{1a}: 5-O-demethyl-avermectin A_{1a} avermectin B_{1b}: 5-O-demethyl-25-de(1- methylpropyl)-25-(1-methylethyl)-avermectin A_{1a}
CIPAC No	495 (abamectin)
CAS No	71751-41-2 (abamectin)

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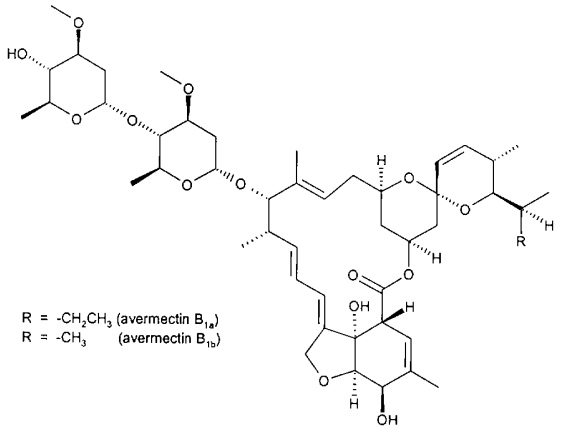
	65195-55-3 (avermectin B_{1a}) 65195-56-4 (avermectin B_{1b})
EEC No (EINECS or ELINCS)	265-610-3 (avermectin B_{1a}) 265-611-9 (avermectin B_{1b})
FAO Specification (including year of publication)	not applicable
Minimum purity of the active substance as manufactured (g/kg)	Open
Identity of relevant impurities (of toxicological, environmental and/or other significance) in the active substance as manufactured (g/kg)	None
Molecular formula	$C_{48}H_{72}O_{14}$ (avermectin B_{1a}) $C_{47}H_{70}O_{14}$ (avermectin B_{1b})
Molecular mass	873.1 g/mol (avermectin B_{1a}) 859.1 g/mol (avermectin B_{1b})
Structural formula	

Physical-chemical properties (Annex IIA, point 2)

Note: All ratios within the given limits of the ISO name (subject to amendment of ISO 1750) are expected to give similar results for the physical/chemical properties.

Melting point (state purity)	161.8-169.4 ºC (96.7%)
Boiling point (state purity)	Not determined, due to thermal decomposition during melting of abamectin.
Temperature of decomposition	thermal decomposition during melting of abamectin.
Appearance (state purity)	Technical : white powder (96.7%)
Vapour pressure (in Pa, state temperature)	< $3.7 * 10^{-6}$ Pa (at 25 ºC) (96.7%)
Henry's law constant (Pa m^3 mol^{-1})	< $2.7 * 10^{-3}$ Pa m^3 mol^{-1}
Solubility in water (g/L or mg/L, state pH and	1.21 ± 0.15 mg/L; pH 7.57 (25 ºC) (purity: 98.1%)

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temperature)	No pH dependence expected because of no dissociation
Solubility in organic solvents (in g/L or mg/L, state temperature)	Solubility at 25°C in g/L (96.7%): Acetone 72 g/L dichloromethane 470 g/L ethyl acetate 160 g/L hexane 0.110 g/L methanol 13 g/L octanol 83 g/L toluene 23 g/L
Surface tension	52.4 mN/m at 20°C (90% saturated solution)(96.7%)
Partition coefficient (log P_{OW}, state pH and temperature)	4.4 ± 0.3; pH 7.2 ±0 .1 (in aqueous phase), 20 ºC (96.7%) No pH dependence expected because of no dissociation
Dissociation constant	no dissociation in the pH-range from 1 to 12
UV / VIS absorption (max.) (if absorption >290 nm state ε at wavelength)	no absorption maximum observed between 280 and 750 nm At 244 nm: e=30717 l/mol*cm 239 nm: e=28332 253 nm: e=20156 (purity: not stated)
Flammability	not highly flammable (96.7%) no self-ignition before melting point (96.7%)
Explosive properties	not thermally, shock or friction sensitive (96.7%)
Oxidising properties	No oxidising properties (96.7%)

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Summary of representative uses evaluated (abamectin)*

Crop and/ or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					Type	Conc. of as	method kind	growth stage & season	number min max	interval between applications (min)	~~k~~g as/hL min max	water L/ha min max	kg as/ha min max		
(a)			(b)	(c)	(d-f)	(i)	(f-h)	(j)	(k)					(l)	(m)
Citrus	EU	Vertimec 018 EC	F	*Phyllocnistis citrella* *Panonychus citri* *Tetranychus urticae*	EC	18 g/L			1 - 3	7	0.00072–0.00135	1500-3000	0.0216	10	[2] [3][4]
Lettuce	EU	Vertimec 018 EC	F	*Liriomyza* sp.	EC	18 g/L			1 - 3	7	0.0018	1000	0.018	7	[1] [2][3][4]
Lettuce	EU	Vertimec 018 EC	G	*Liriomyza* sp.	EC	18 g/L			1 - 4	7	0.0009	1000	0.009	14	[3] [4]
Tomatoes	EU	Vertimec 018 EC	F	*Tetranychus urticae* *Liriomyza* sp.	EC	18 g/L			1 - 3	7	0.0009 – 0.0018	1200-2500	0.0216	3	[1][2][3][4]
Tomatoes	EU	Vertimec 018 EC	G	*Tetranychus urticae* *Liriomyza* sp.	EC	18 g/L			1 - 5	7	0.0009 – 0.0018	1200-2500	0.0216	3	[3][4]

[1] Additional information/data is needed in the section residues.
[2] Data gaps were identified in section ecotoxicology related to the long-term risk to birds and mammals.
[3] Data gaps were identified in section ecotoxicology related to the aquatic risk assessment and the relevance of an impurity
[4] The assessment of the exposure of groundwater by a metabolite is not finalised due to a data gap in the section environmental fate and behaviour

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Rapporteur Member State	Month and year	Active Substance (Name)
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Tradename: Tervigo
Development code A12115I
Active Ingredient: Abamectin

Crop and/ or situation (a)	Member State or Country	Product name	F G or 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 as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
Pepper	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	
Aubergine	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	
Tomato	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	6	10	0.5 - 1.0	10000 - 20000	100	0	
Cucurbits - edible peel (Cucumber, zucchini, etc)	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	
Cucurbits - inedible peel (Melon, Watermelon, Squash)	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	

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Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

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

Crop and/ or situation (a)	Member State or Country	Product name	F G or 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 as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
Green beans	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	

Remarks:

*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)	(i)	g/kg or g/l
(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(j)	Growth stage at 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
(c)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds		
(d)	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
(f)	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions

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Chapter 2.2 – Methods of Analysis

Analytical methods for the active substance (Annex IIA, point 4.1)

Technical as (principle of method)	**avermectin B_{1a}, avermectin B_{1b}**: HPLC-UV at 254 nm
Impurities in technical as (principle of method)	HPLC-UV at 254 nm GC-FID
Plant protection product (principle of method)	**avermectin B_{1a}, avermectin B_{1b}**: HPLC-UV at 254 nm

Analytical methods for residues (Annex IIA, point 4.2)

Residue definitions for monitoring purposes

Food of plant origin	Residue definition is sum of avermectin B_{1a}, avermectin B_{1a} 8,9-Z isomer, and avermectin B_{1b}, expressed as avermectin B_{1a}
Food of animal origin	Not required as no MRLs are set.
Soil	4-hydroxy-8a-oxo-avermectin B_{1a}.
Water	Open
Air	avermectin B_{1a}

Monitoring/Enforcement methods

Analytical methods for residues (Annex IIA, point 4.2)

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	HPLC-MS/MS method REM 198.02 with separate quantification of avermectin B_{1a}, avermectin B_{1a} 8,9-Z isomer, and avermectin B_{1b}. LOQ 0.002 mg/kg for tomato, orange and cotton seed. LOQ 0.01 mg/kg for green hops.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	No methods required. However a method was submitted (see also body fluids and tissues)
Soil (principle of method and LOQ)	HPLC-MS/MS after extraction with acetonitrile/water and clean-up on HLB SPE columns. Method validated on two soils. LOQ 0.5 µg/kg for individual compounds µg/kg (avermectin B_{1a}, avermectin B_{1b}, [8,9-Z]-avermectin

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	B_{1a} , 8a-oxo-avermectin B_{1a}, 8_a-hydroxy-avermectin $B_{1a,}$ 4,8a-dihydroxy-avermectin B1a and 4-hydroxy-8a-oxo-avermectin B_{1a}
Water (principle of method and LOQ)	Determination by LC-MS/MS after dilution with acetonitrile and clean-up on HLB SPE columns. Method validated on river water, ground water and drinking water. LOQ for individual compounds 0.05 µg/L (avermectin B_{1a}, avermectin B_{1b}, [8,9-Z]-avermectin B_{1a}, 4"-oxo-avermectin $B_{1a,}$ 3"-demethyl-avermectin B_{1a})
Air (principle of method and LOQ)	Determination by HPLC-UV (243 nm) after extraction with methanol. Method validated at spiking levels 0.1 and 10 µg/m^3. LOQ for individual compounds 0.1 µg/m^3 (avermectin B_{1a}, avermectin B_{1b})
Body fluids and tissues (principle of method and LOQ)	HPLC-MS/MS method REM 198.02 with separate quantification of avermectin B_{1a}, avermectin B_{1a} 8,9-Z isomer, and avermectin B_{1b}. LOQ 0.002 mg/kg for meat and blood

Classification and proposed labelling (Annex IIA, point 10)

with regard to physical and chemical data	No classification is proposed

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Mammalian toxicology

Chapter 2.3 Impact on Human and Animal Health

Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)

Rate and extent of oral absorption	Maximum blood concentration within 4-8 h. Approximately 86% of oral dose is absorbed (based on urinary excretion after oral or intravenous administration).
Distribution	Distributed throughout all major organs and tissues
Potential for accumulation	No potential for accumulation upon repeated oral administration
Rate and extent of excretion	Rapidly eliminated, almost exclusively via non-biliary excretion back into the intestine and eliminated with the faeces.
Metabolism in animals	Major pathways include demethylation, hydroxylation, cleavage of the oleandrosyl ring and oxidation reactions.
Toxicologically relevant compounds (animals and plants)	Parent and 8,9-Z isomer of avermectin B1a (photodegradation product)
Toxicologically relevant compounds (environment)	Parent and 8,9-Z isomer of avermectin B1a (photodegradation product)

Acute toxicity (Annex IIA, point 5.2)

Rat LD_{50} oral	8.7 mg/kg bw (oil vehicle)	**H300**
Rat LD_{50} dermal	> 330 mg/kg bw (highest dose tested); > 2000 mg/kg bw (rabbit)	
Rat LC_{50} inhalation	0.034 mg/L< LC_{50} <0.051 mg/L (4 h; nose only)	**H330**
Skin irritation	Not irritating	
Eye irritation	Not irritating	
Skin sensitisation	Non-sensitizing (M&K)	

Short term toxicity (Annex IIA, point 5.3)

Target / critical effect	Tremors, ataxia and mydriasis, liver, absent or decreased pupil reflex	
Relevant oral NOAEL	0.25 mg/kg bw/day (18-w and 53-w, dog)	**H372**
Relevant dermal NOAEL	No data – not required	
Relevant inhalation NOAEL	0.577 µg/L (30-d, rat)	

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Mammalian toxicology

Genotoxicity (Annex IIA, point 5.4)

	No genotoxic potential	

Long term toxicity and carcinogenicity (Annex IIA, point 5.5)

Target/critical effect	Rat: increased mortality (m), tremors Mouse: increased mortality (m), extramedullary hematopoiesis in the spleen (m), reduced bw gain	
Relevant NOAEL	1.5 mg/kg bw/day (104-wk rat) 4 mg/kg bw/day (94-wk mouse)	
Carcinogenicity	No carcinogenic potential	

Reproductive toxicity (Annex IIA, point 5.6)

Reproduction toxicity

Reproduction target / critical effect	Parent: no treatment-related effects Fertility: no effects Offspring: increased pup mortality, retarded pup growth, total litter loss, decreased lactation index	
Relevant parental NOAEL	0.4 mg/kg bw/day (highest dose tested)	
Relevant reproductive NOAEL	0.4 mg/kg bw/day (highest dose tested)	
Relevant offspring NOAEL	0.12 mg/kg bw/day (findings in young rats, not relevant for human risk assessment)	

Developmental toxicity

Developmental target / critical effect	Rat: cleft palate, lumbar rib and lumbar count variation (in the absence of maternal toxicity) Rabbit: cleft palate, omphaloceles, clubbed fore-feet and delayed ossification (at maternally toxic dose)	**H361 d**
Relevant maternal NOAEL	1.6 mg/kg bw/day (rat) 1.0 mg/kg bw/day (rabbit)	
Relevant developmental NOAEL	0.8 mg/kg bw/day (rat) 1.0 mg/kg bw/day (rabbit)	

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Mammalian toxicology

Neurotoxicity (Annex IIA, point 5.7)

Acute neurotoxicity	NOAEL 0.5 mg/kg bw (rat, reduced splay reflex)	
Repeated neurotoxicity	NOAEL 1.6 mg/kg bw/day (90-d rat: clinical signs, bw loss, macroscopy and histology stomach)	
Delayed neurotoxicity	Not required, not performed.	

Other toxicological studies (Annex IIA, point 5.8)

Mechanism studies	P-glycoprotein deficient animals (CF-1 mouse, neonatal rat) are more sensitive to abamectin. Since non-functional p-glycoprotein has not been identified in humans, and the supplementary studies show that only the –/– CF-1 mouse is more sensitive to abamectin toxicity, the studies with the unique polymorphic CF-1 mouse are not relevant for human risk assessment.
Studies performed on metabolites or impurities	Toxicity of the 8,9-Z isomer of avermectin B1a is lower or comparable to abamectin: oral LD_{50} 217 mg/kg bw (CD-1 mice) Developmental study with CD-1 mice: maternal NOAEL 3.0 mg/kg bw/d (highest dose), foetal NOAEL <0.75 mg/kg bw/d (cleft palate) Developmental study with rats: maternal NOAEL 1.0 mg/kg bw/day, foetal NOAEL 1.0 mg/kg bw/day (no effects at the highest dose) One generation study with rats: maternal and reproductive NOAEL 0.40 mg/kg bw/d (highest dose), offspring NOAEL 0.12 mg/kg bw/d (post-natal death) Ames test negative. The reference values derived for abamectin are applicable also for the 8,9-Z isomer.

Medical data (Annex IIA, point 5.9)

No adverse health effects from manufacturing. Severely poisoned patients showed an uneventful recovery from typical symptoms of avermectin toxicity.

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Mammalian toxicology

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI	0.0025 mg/kg bw/day	18 and 53-wk dog study	100
AOEL	0.0025 mg/kg bw/day	18 and 53-wk dog study	100
ARfD	0.005 mg/kg bw	acute neurotoxicity rat	100

Dermal absorption (Annex IIIA, point 7.3)

Vertimec 018EC (*in vitro* study)	1% of applied dose (*in vivo* study with monkey, and *in vitro* study with human skin)
EC formulation with avermectin B1a (*in vivo* study)	

Exposure scenarios (Annex IIIA, point 7.2)

Operator – use on citrus (% AOEL)		without PPE	with PPE
Mechanical upward spraying, field	UK-75th	20	12
	DE-GM	16	3
Manual upward spraying, field	DE-GM	34	5
Operator – use on lettuce			
Mechanical downward spraying, field	UK-75th	18	3
	DE-GM	9	<1
Manual downward spraying, field	UK-75th	46	10
Manual downward spraying, greenhouse	Dutch-90th	15	2
Operator – use on tomatoes			
Mechanical downward spraying, field	UK-75$^{th.}$	20	3
	DE-GM	11	<1
Mechanical upward spraying, field	UK-75th	23	15
	DE-GM	16	3
Manual upward spraying, field	DE-GM	34	5
Manual upward spraying, greenhouse	UK-75th/Mich 90th	129	7
	DE-GM/Mich 90th	130	6
	Dutch-90th	37	4

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Mammalian toxicology

Operator – use on pepper, aubergine, tomato, cucurbits, green beans Soil drip irrigation, greenhouse	DE - GM	14	
Workers	exposure up to 17% of the AOEL, without PPE (EUROPOEM II)		
Bystanders	exposure up to 2% of the AOEL (EUROPOEM II)		

Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)

	RMS/peer review proposal
Substance classified (name)	H300 "Fatal if swallowed" H330 "Fatal if inhaled" H361d "Suspected of damaging the unborn child." H372 "Causes damage to nervous system through prolonged or repeated exposure."

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Residues

Chapter 2.4 – Residues

Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)

Plant groups covered	fruit (citrus, tomato) leafy crops (celery, tomato) pulses/oilseeds (cotton)
Rotational crops	leafy crop (lettuce) roots and tubers (carrot, turnip) cereal (sorghum)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Standard hydrolysis studies in buffer solution available. Some degradation of abamectin is observed. The major degradation product is considered of the same toxicity as the parent.
Residue pattern in processed commodities similar to residue pattern in raw commodities	Not exactly the same from a chemical point of view. The same from a toxicological point of view
Plant residue definition for monitoring	Sum of avermectin B1a, avermectin B1a 8,9-Z isomer, and avermectin B1b, expressed as avermectin B1a
Plant residue definition for risk assessment	Sum of avermectin B1a, avermectin B1a 8,9-Z isomer, and avermectin B1b, expressed as avermectin B1a
Conversion factor (monitoring to risk assessment)	not applicable

Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)

Animals covered	Lactating goat
Time needed to reach a plateau in milk and eggs	Milk : 3 days Eggs : data not available
Animal residue definition for monitoring	Not necessary – covered by legal provisions in force for abamectin from veterinary uses
Animal residue definition for risk assessment	Not necessary – covered by legal provisions in force for abamectin from veterinary uses
Conversion factor (monitoring to risk assessment)	Not applicable
Metabolism in rat and ruminant similar (yes/no)	Very limited degradation by ruminants
Fat soluble residue: (yes/no)	yes

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Residues

Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)

	low levels of residues present, which constitute no consumer

Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 introduction)

commodities with high water content	3 years in watery matrices
commodities with high water and high acid content	2 years in fatty matrices, 14 months in acidic matrices

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

	Ruminant:	Poultry:	Pig:
	Conditions of requirement of feeding studies		
Expected intakes by livestock ≥ 0.1 mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)	No, supported uses not intended for livestock feed	No	No
Potential for accumulation (yes/no):	No	No	No
Metabolism studies indicate potential level of residues ≥ 0.01 mg/kg in edible tissues (yes/no)	n/a	No	No
	Residue levels in matrices : Mean (max) mg/kg		
Muscle	Not required	Not required	Not required
Liver	Not required	Not required	Not required
Kidney	Not required	Not required	Not required
Fat	Not required	Not required	Not required
Milk	Not required		
Eggs		Not required	

Summary of critical residues data (Annex IIA, point 6.3, Annex IIIA, point 8.2)

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a) (mg/kg)	Recommendation /comments	MRL (mg/kg)	STMR (b) (mg/kg)
Tomato	Northern EU (glasshouse)	<0.006 (2x)	Bridging studies for the use as a nematicide. Foliar use results in higher residue levels and drives the MRL. Two trials are	n.a.	n.a.

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Residues

Crop	Northern or Mediterranean Region	Trials results relevant to the critical GAP (a) (mg/kg)	Recommendation /comments	MRL (mg/kg)	STMR (b) (mg/kg)
			sufficient.		
Pepper	Northern EU (glasshouse)	<0.006 (2x)	Bridging studies for the use as a nematicide. Foliar use results in higher residue levels and drives the MRL. Two trials are sufficient.	n.a.	n.a.
Cucumber	Northern EU (glasshouse)	<0.006 (2x)	Bridging studies for the use as a nematicide. Foliar use results in higher residue levels and drives the MRL. Two trials are sufficient.	n.a.	n.a.
Melon	Southern EU (glasshouse)	<0.006 (2x)	Bridging studies for the use as a nematicide. Foliar use results in higher residue levels and drives the MRL. Two trials are sufficient.	n.a.	n.a.
Beans, fresh with pods	Southern EU (glasshouse)	<0.006 (2x)	Bridging studies for the use as a nematicide. Foliar use results in higher residue levels and drives the MRL. Two trials are sufficient.	n.a.	n.a.

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17
(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the critical GAP
(c) critical GAP on lettuce is in greenhouses application in Northern Europe, since the decrease of abamectine occurs through photolytic breakdown and is lowest in greenhouses/Northern zones.

Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)

ADI	0.0025 mg/kg bw/day
TMDI (% ADI)	4.8% WHO cluster diet B (EFSA Journal 2014;12(9):3823)
IEDI (% ADI)	Not applicable
Factors included in IEDI	Not applicable
ARfD	0.005 mg/kg bw
Acute exposure (% ARfD)	63%, peppers (EFSA Journal 2014;12(9):3823)

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Residues

Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)			
Crop/processed crop	Number of studies	Transfer factor	% Transference *
Not required			

* Calculated based on distribution in the different portions, parts, or products as determined through balance studies

Proposed MRLs (Annex IIA, point 6.7, Annex IIIA, point 8.6)

MRLs are not proposed for the use as a nematicide, since the use as an acaricide drives the MRL. MRLs have been set in Reg 9EC) 396/2005.

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Fate and behaviour in the environment

Chapter 2.5 – Fate and Behaviour in the Environment

The fate and behaviour of the B1b component of abamectin in soil water and air is expected to be comparable to that of the B1a component due to the small difference in the structure resulting from an ethyl or a methyl functional group substitution in a compound with a molecular mass of >850 (assessment of B1a is considered to cover B1b and both their consequent [8,9-Z] isomers)

Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1.1)

Mineralisation after 100 days	12.4 % of AR (91 d); [23-^{14}C] -avermectin B_{1a} 3.2% of AR (21weeks); [3,7,11,13,23-^{14}C]-avermectin B_{1a} (25ºC biometer flask)
Non-extractable residues after 100 days	39.1 % of AR (91 d), max. 44.1% after 196 d [23-^{14}C] -avermectin B_{1a}
Relevant metabolites - name and/or code, % of applied (range and maximum)	8a-hydroxy-avermectin B_{1a} (NOA 448112): 15.7 % of AR 8a-oxo-avermectin B_{1a} (NOA 448111):10.3 % of AR 4,8a-dihydroxy-avermectin B_{1a} (NOA 457464):9.3% of AR 8a-oxo-4-hydroxy-avermectin B_{1a} (NOA 457465): 9.9 % of AR unknown metabolite U8 > 5 % of AR on > 2 consecutive time points

Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.1.2)

Anaerobic degradation	$DT_{50, lab}$ (20°C, anaerobic): No reliable anaerobic study supplied. Information from partly aerobic/anaerobic experiments indicate that additional degradation under anaerobic conditions is negligible as compared to preceding aerobic degradation
Soil photolysis	mineralisation: 7.6 % after 28 d bound residues: 25.9 % after 28 d $DT_{50,photolysis}$: 12.9 d at 12 h L:D, 24.5 °C, corresponding with 21.7 d at 30 - 50 °N in summer **metabolites**: 8a-oxo-avermectin B_{1a} (NOA 448111): 5.7 % of AR 8a-hydroxy-avermectin B_{1a} (NOA 448112): 4.0 % of AR

Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)

Method of calculation	laboratory: first order kinetics for avermectin B_{1a}, simultaneous fit of formation and decline for

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	metabolites with Berkely-Madonna
Laboratory studies (range or median, with n value, with r^2 value)	$DT_{50, lab}$ (20°C, aerobic): **avermectin B_{1a}**: mean 28.7 d (range 11.2 - 65.7 d; n = 8; r^2 0.9471 - 0.9970) **NOA 448111**: mean 45.3 d (range 40.5 - 50.6 d; n = 4; r^2 0.86 - 0.94) **NOA 448112**: mean 35.8 d (range 26.8 - 75.4 d; n = 4; r^2 0.93 - 0.98) **NOA 457464**: mean 65.9 d (range 48.5 - 99.0 d; n = 3; r^2 0.97 - 0.99) **NOA 457465**: mean 112 d (range 59.8 - 173 d; n = 3; r^2 0.97 - 0.98) Geomean DT_{50} used for FOCUS modelling (20ºC, pF2-3.5) **avermectin B_{1a}**: geomean 28.7 d **NOA 448111**: geomean 45.3 d, arith.mean formation fraction 0.23 (from parent) **NOA 448112**: geomean 35.8 d, arith.mean formation fraction 0.30 (from parent) **NOA 457464**: geomean 65.9 d, arith.mean formation fraction 0.58 (from NOA 448112) **NOA 457465:** geomean 112 d, arith.mean formation fraction 0.85 (from NOA 448111)
	$DT_{90, lab}$ (20°C, aerobic): calculated as DT_{50} x 3.3 **avermectin B_{1a}**: 95.3 d **NOA 448111**: 150 d **NOA 448112**: 119 d **NOA 457464**: 219 d **NOA 464457**: 372 d
	$DT_{50, lab}$ (10°C, aerobic): **avermectin B_{1a}**: 50.6 d, calculated with Arrhenius equation and an activation energy of 54kJ $mol^{-1}$from DT_{50} at 8.6, 20 and 30 °C

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	$DT_{50, lab}$ (20°C, anaerobic): No reliable anaerobic study supplied. Information from partly aerobic/anaerobic experiments indicate that additional degradation under anaerobic conditions is negligible as compared to preceding aerobic degradation
	degradation in the saturated zone: no information available not required.
Field studies (state location, range or median with n value)	$DT_{50, field}$: **avermectin B_{1a}**: Vouvry, CH: 1.8 d (grass cover after application on bare soil, average temperature 16 °C) (n=1) **[8,9-Z]-avermectin B_{1a}** detected shortly after appl but no longer after 1 day Bavaria, D: < 1 d (grass cover after application on bare soil, average temperature 17 °C) (n=1) **[8,9-Z]-avermectin B_{1a}** analysed <LOQ **avermectin B_{1a} + [8,9-Z]-avermectin B_{1a}**: Bavaria, D:< 1 d (bare soil, average temperature 17 °C) (n=1) Analytical method UV detection, no distinction between parent and isomer Alsace, F:< 1 d (bare soil, average temperature 17 °C) (n=1) analytical method does not distinguish between parent and isomer Po Valley, I:< 1 d (bare soil, average temperature 13 °C) (n=1) analytical method does not distinguish between parent and isomer Champagne, F: < 1 d (bare soil, average temperature 13 °C) (n=1) analytical method does not distinguish between parent and isomer
	$DT_{90, field}$: < 1 d
Soil accumulation and plateau concentration	accumulation not expected in view of $DT_{50,field}$

Soil adsorption/desorption (Annex IIA, point 7.1.2)

K_F / K_{OC}	K_{OC}: **avermectin B_{1a}**: arith.mean 5638 L/kg (range 1495 - 7893 L/kg; 1/n 0.789 - 1.01; 7 soils) **NOA 448111**: arith.mean 3997 L/kg (range 3027 - 5052 L/kg; 1/n 0.826 - 0.835; 3 soils) **NOA 448112**: arith.mean 1943 L/kg (range 1098 - 3104 L/kg; 1/n 0.796 - 0.961; 3 soils) **NOA 457464**: arith.mean 1738 L/kg (range 1081 - 2412 L/kg; 1/n 0.890 - 0.944; 3 soils)

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	NOA 457465: arith.mean 3908 L/kg (range 2573 - 5813 L/kg; 1/n 0.791 - 1.01; 3 soils) Values to use ~~Used~~ for FOCUS modelling K_{Om}: parent, arithmetic mean 3270 L/kg, $^1/_n$= 0.941. NOA 448111, arith.mean 2318 L/kg, $^1/_n$= 0.829 NOA 448112, arith.mean 1127 L/kg, $^1/_n$= 0.871 NOA 457464, arith.mean 1008 L/kg, $^1/_n$= 0.912 NOA 457465, arith.mean 2267 L/kg, $^1/_n$= 0.941
K_D	K_F: **avermectin B_{1a}**: arith.mean 129 L/kg (range 18.2 - 334 L/kg; 7 soils) **NOA 448111**: arith.mean 81.7 L/kg (range 38.3 - 128 L/kg; 3 soils) **NOA 448112**: arith.mean 41.1 L/kg (range 15.9 - 78.9 L/kg; 3 soils) **NOA 457464**: arith.mean 35.4 L/kg (range 16.9 - 61.3 L/kg; 3 soils) **NOA 464457**: arith.mean 82.3 L/kg (range 32.7 - 148 L/kg; 3 soils)
pH dependance (yes / no) (if yes type of dependence)	no

Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)

Column leaching	no reliable information supplied
Aged residues leaching	Guideline: BBA IV, 4-2; OECD draft Precipitation: 200 mm Time period: 2 d Radioactivity in leachate 0.5 - 0.9 % of radioactivity applied after ageing, maximum of avermectin B_{1a} 0.2 % of aged residue, metabolites < 0.1 %. Total extractable radioactivity in soil column 85.1 - 92.9 % of aged residue, 44.8 - 36.6 % of aged residue present as avermectin B_{1a} in top 4 cm. Metabolites in 0 - 4 cm: NOA 448111 8.0 %, NOA 448112 14.0 - 14.2 %, NOA 457464 2.8 - 3.4 % and NOA 457465 1.6 - 2.3 % of aged residue, < 1 % in deeper layers.
Lysimeter/ field leaching studies	not submitted, not considered necessary

PEC (soil) (Annex IIIA, point 9.1.3)

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Fate and behaviour in the environment

parent

Method of calculation	DT_{50}: 1.8 d (worst case $DT_{50,field}$) first-order kinetics
Application rate	**Original inclusion** citrus: 3 x 21.6 g as/ha, interception 70 % lettuce (field): 3 x 18 g as/ha, interception 40 % lettuce (glass): 4 x 9 g as/ha, interception 40 % tomatoes (field): 3 x 21.6 g as/ha, interception 50 % tomatoes (glass): 5 x 21.6 g as/ha, interception 50 % spray interval 7 days **Extension of approval** Green beans 4x100 g a.s./ha, interception 0 (drip irrigation) Fruiting vegetables 6x100 g a.s./ha, interception 0 (drip irrigation) Cucurbits 4x100 g a.s./ha, interception 0 (drip irrigation)

Original inclusion

PEC_S (mg/kg) **citrus**		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.00864		0.0093	
short term	1	0.0043	0.0062	0.0044	0.0063
	2	0.0022	0.0047	0.0022	0.0047
	4	0.0005	0.0029	0.0005	0.0029
long term	7	0.0001	0.0018	0.0001	0.0018
	14	0.0000	0.0009	0.0000	0.0009
	21		0.0006		0.0006
	28		0.0004		0.0004
	56		0.0002		0.0002
	100		0.0001		0.0001

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Fate and behaviour in the environment

PEC_S (mg/kg) **lettuce (field) tomatoes (field and glasshouse)**[1]		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.0144		0.0154	
short term	1	0.0072	0.0104	0.0073	0.0105
	2	0.0036	0.0078	0.0036	0.0079
	4	0.0009	0.0049	0.0009	0.0049
long term	7	0.0001	0.0029	0.0001	0.0030
	14	0.0000	0.0015	0.0000	0.0015
	21		0.0010		0.0010
	28		0.0007		0.0007
	56		0.0004		0.0004
	100		0.0002		0.0002

1: Product of application rate and interception fraction is same for lettuce and tomatoes; because of low DT_{50}, number of applications does not change PEC_S.

PEC_S (mg/kg) **lettuce (glasshouse)**		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.0072		0.0077	
short term	1	0.0036	0.0052	0.0036	0.0052
	2	0.0018	0.0039	0.0018	0.0039
	4	0.0005	0.0024	0.0005	0.0025
long term	7	0.0001	0.0015	0.0001	0.0015
	14	0.0000	0.0007	0.0000	0.0007
	21		0.0005		0.0005
	28		0.0004		0.0004
	56		0.0002		0.0002
	100		0.0001		0.0001

Initial PECs for metabolites based on the sum of application rates and the maximum observed formation % from laboratory studies (conservative approach): formation % NOA 448111: 10.3% NOA 448112: 15.7% NOA 457464: 9.3% NOA 457465: 9.9%				
PEC_S (mg/kg)	**NOA 448111**	**NOA 448112**	**NOA 457464**	**NOA 457465**
citrus	0.004	0.003	0.004	0.004

List of end points

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Fate and behaviour in the environment

Tomato field	0.004	0.007	0.004	0.004
Tomato glasshouse	0.007	0.011	0.007	0.007
Lettuce field	0.003	0.005	0.003	0.003
Lettuce glasshouse	0.002	0.003	0.002	0.002

Extension of approval

Initial PECs [mg a.s./kg]	Abamectin	Metabolites
Green Beans	0.136	not assessed, risk covered by parent substance
	0.136	
Fruiting Vegetables	0.136	
	0.136	
Cucurbits*	0.136	
	0.136	

* also covering for the pepper/aubergine crop

Route and rate of degradation in water (Annex IIA, point 7.2.1)

Hydrolysis of active substance and relevant metabolites (DT_{50}, state pH and temperature)	**avermectin B_{1a}**: No hydrolysis at pH 4 -7, 25 °C pH 9, 60 °C: 4.9 d pH 9, 50 °C: 9.9 d pH 9, 25 °C: 213 d (extrapolated) pH 9, 20 °C: 380 d (calculated with Arrhenius equation) metabolites: 2-epi-avermectin B_{1a}: 25 % of AR at 50 and 60 °C 1,18 hydrolysed avermectin B_{1a}: 17.5 % of AR at 60 °C unknown: 15.6 % of AR at 60 °C
Photolytic degradation of active substance and relevant metabolites	**avermectin B_{1a}**: Xenon: 2 d, equivalent to 1.5 sunlight days at 30 - 50 °N natural summer sunlight 40 ºN: 1.3 d. metabolites: NOA 448111: 5.6 % of AR [8,9-Z]-avermectin B_{1a}: 8.2 % of AR, $DT_{50,photo}$ 5.8 sunlight days at 30 - 50 °N
Readily biodegradable (yes/no)	avermectin B_{1a} is *not readily biodegradable*

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Fate and behaviour in the environment

Degradation in water/sediment (range or median, with n value, with r^2 value, state temperature)	$DT_{50,\ water}$: **avermectin B_{1a}**: mean 2.4 d (20 °C; range 1.8 - 2.9 d; n = 2, first-order, r^2 0.945 - 0.953). Decline of concentrations in water column determined by rapid initial sorption. Value represents dissipation rather than degradation.
	$DT_{90,\ water}$: calculation from DT_{50} not applicable as DT_{50} is determined by sorption
	$DT_{50,\ whole\ system}$: **avermectin B_{1a}**: mean 89 d (20 °C; range 87 - 91 d; n = 2, first-order, r^2 0.965 - 0.991)
	$DT_{90,\ whole\ system}$: calculated as 3.3 x $DT_{50,system}$ **avermectin B_{1a}**: mean 294 d
Mineralisation	max. 0.1 - 3 % of AR (study end 100 d; n = 2) [23-^{14}C]-avermectin B_{1a}
Non-extractable residues	max. 20 - 23 % of AR (study end 100 d; n = 2) [23-^{14}C]-avermectin B_{1a}
Distribution in water / sediment systems (active substance)	**avermectin B_{1a}**: sediment: max. 78.1 - 82.8 % of AR after 14 d, 44.3 - 45.3 % of AR at study end after 100 d $DT_{50,sediment}$: mean 99 d (87 - 111 d; n = 2, first-order, r^2 0.942 - 0.987)
Distribution in water / sediment systems (metabolites)	water: metabolites < 1 % of AR sediment: NOA 448111 max. 1.9-2.8 % of AR (70 - 100 d) NOA 448112: max. 1.5-1.9 % of AR (35/70 - 70 d) NOA 426289 (4"-oxo-avermectin B_{1a}): max. 6.9 - 8.6 % of AR (70 - 100 d) NOA 445495 (3"-demethyl-avermectin B_{1a}): max. 1.7 - 2.0 % of AR (day 70)

PEC (surface water) (Annex IIIA, point 9.2.3)

parent

Method of calculation	**field applications:** FOCUS Surface Water - Step 3 SWASH 2.1 (9 April 2003), with MACRO 4.3b, PRZM 3.21.b and TOXSWA 2.1.1.F1. **glasshouse applications:** FOCUS Surface Water - Step 2 with modifications (no drainage and run-off, no crop interception, application rate changed so that total loading to water surface (in g/m^2) is equal to 0.1 % of the

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	application rate) **input:** DT_{50} for degradation in water: 89 d ($DT_{50,system}$ at 20 °C) DT_{50} for degradation in sediment: 1000 d (default) DT_{50} for degradation in soil: 1 d ($DT_{50,field}$) For the extension of approval: DT_{50} soil 28.7 days (geomean lab) sorption: K_{OM} 3270 L/kg
Application rate	**Original inclusion** citrus: 3 x 21.6 g as/ha, applic. window April-May lettuce (field): 3 x 18 g as/ha, 2 crops; May-June, lettuce (glass):4 x 9 g as/ha tomatoes (field): 3 x 21.6 g as/ha, applic. window April-May tomatoes (glass): 5 x 21.6 g as/ha spray interval 7 days **Extension of approval** Fruiting vegetables, 4 scenarios: Single crop 6x100 g a.s./ha, early, April-July Single crop 6x100 g a.s./ha, late, May-August Two crops 6x100 + 4x100 g a.s./ha, early, February-April + August-October Two crops 6x100 + 4x100 g a.s./ha, late, August-September + August-October spray interval 10 days
Main routes of entry	**Original inclusion** drift, drainage and run-off **Extension of approval** drainage

Highest PEC_{SW} for each combination of crop and type of waterbody

Original inclusion

citrus

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Fate and behaviour in the environment

PEC_{sw} (µg/L) ditch, D6		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.791	-	0.673	-
short-term	1	0.69	0.736	0.597	0.633
	2	0.612	0.691	0.535	0.599
	4	0.449	0.607	0.421	0.539
long term	7	0.21	0.481	0.237	0.448
	14	0.052	0.293	0.071	0.392
	21	0.027	0.207	0.039	0.339
	28	0.016	0.161	0.024	0.300
	42	0.007	0.111	0.011	0.25
	50	0.005	0.094	0.008	0.216
	100	0.001	0.048	0.002	0.113

PEC_{sw} (µg/L) stream, R4		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.590	-	0.432	-
short-term	1	0	0.069	0	0.088
	2	0	0.034	0	0.044
	4	0	0.017	0	0.022
long term	7	0	0.01	0.422	0.01
	14	0.008	0.005	0.422	0.002
	21	0	0.003	0	0.002
	28	0	0.003	0	0.007
	42	0	0.002	0	0.005
	50	0	0.001	0	0.004
	100	0	0.001	0	0.002

lettuce, field application

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PEC_{sw} (µg/L) ditch, D3, 1st crop		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.113	-	0.083	
short-term	1	0.05	0.086	0.038	0.064
	2	0.005	0.054	0.005	0.041
	4	0	0.029	0	0.021
long term	7	0	0.016	0	0.012
	14	0	0.008	0	0.012
	21	0	0.005	0	0.012
	28	0	0.004	0	0.009
	42	0	0.003	0	0.006
	50	0	0.002	0	0.005
	100	0	0.001	0	0.003

PEC_{sw} (µg/L) pond, R1, 1st crop		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.004	-	0.007	-
short-term	1	0.004	0.004	0.006	0.006
	2	0.004	0.004	0.006	0.006
	4	0.003	0.004	0.006	0.006
long term	7	0.003	0.003	0.005	0.006
	14	0.002	0.003	0.005	0.005
	21	0.002	0.003	0.004	0.005
	28	0.002	0.003	0.003	0.005
	42	0.001	0.002	0.003	0.004
	50	0.001	0.002	0.003	0.004
	100	0	0.001	0.001	0.003

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Fate and behaviour in the environment

PEC_{SW} (µg/L) stream, R3, 1st crop		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.105	-	0.077	
short-term	1	0	0.031	0	0.028
	2	0	0.015	0	0.014
	4	0	0.008	0	0.007
long term	7	0	0.004	0	0.004
	14	0	0.002	0	0.004
	21	0	0.002	0	0.003
	28	0	0.001	0	0.003
	42	0	0.001	0	0.002
	50	0	0.001	0	0.002
	100	0	0	0	0.001

lettuce, glasshouse application

PEC_{SW} (µg/L) Step 2		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.0030	-	0.0043	-
short-term	1	0.0012	0.0021	0.0025	0.0034
	2	0.0007	0.0016	0.002	0.0029
	4	0.0005	0.0011	0.0018	0.0024
long term	7	0.0005	0.0008	0.0017	0.0021
	14	0.0005	0.0006	0.0016	0.0019
	21	0.0004	0.0006	0.0016	0.0018
	28	0.0004	0.0005	0.0015	0.0017
	42	0.0004	0.0005	0.0013	0.0016
	50	0.0003	0.0005	0.0012	0.0016
	100	0.0002	0.0004	0.0008	0.0013

tomatoes, field application

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Fate and behaviour in the environment

PEC_{sw} (µg/L) ditch, D6		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.135	-	0.099	-
short-term	1	0.006	0.066	0.048	0.078
	2	0	0.034	0.006	0.05
	4	0	0.017	0.001	0.026
long term	7	0	0.01	0	0.015
	14	0	0.005	0	0.011
	21	0	0.003	0	0.009
	28	0	0.003	0	0.007
	42	0	0.002	0	0.004
	50	0	0.001	0	0.004
	100	0	0.001	0	0.002

PEC_{sw} (µg/L) stream, R3		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.127	-	0.092	-
short-term	1	0.001	0.047	0	0.034
	2	0	0.024	0	0.017
	4	0	0.012	0	0.009
long term	7	0	0.007	0	0.005
	14	0	0.0034	0	0.005
	21	0	0.002	0	0.005
	28	0	0.002	0	0.004
	42	0	0.001	0	0.003
	50	0	0.001	0	0.002
	100	0	0.001	0	0.001

tomatoes, glasshouse application

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC_{SW} (µg/L) Step 2		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.0072	-	0.0114	-
short-term	1	0.0029	0.0051	0.0071	0.0092
	2	0.0017	0.0037	0.0058	0.0078
	4	0.0012	0.0025	0.0052	0.0066
long term	7	0.0011	0.0019	0.0051	0.0060
	14	0.0011	0.0015	0.0048	0.0055
	21	0.0010	0.0014	0.0046	0.0052
	28	0.0010	0.0013	0.0043	0.0050
	42	0.0009	0.0011	0.0039	0.0047
	50	0.0008	0.0011	0.0036	0.0046
	100	0.0005	0.0009	0.0025	0.0038

Step 4 calculations for Citrus, Tomatoes (field) and Lettuce (field)

Results for citrus 1 and 3 applications, FOCUS Step 4

Buffer zone	Scenario	Water body	PEC_{SW} [µg/L]			PEC_{SW} [µg/L] 3 appl.	PEC_{SED} [µg/kg dw]			PEC_{SED} [µg/kg dw] 3 appl.
			max.	21-d TWA	28-d TWA	max	max.	21-d TWA	28-d TWA	Max.
5m	D6	ditch	0.534	0.140	0.108	0.461	1.274	0.062	0.981	2.310
	R4	stream	0.384	0.0021	0.0016	0.284	0.033	0.020	0.018	0.071
10m	D6	ditch	0.240	0.063	0.049	-	0.578	0.484	0.447	-
	R4	stream	0.173	0.0009	0.0007	-	0.015	0.009	0.008	-
12m	D6	ditch	0.176	0.046	0.036	-	0.425	0.356	0.329	-
	R4	stream	-	-	-	-	-	-	-	-
14m	D6	ditch	0.135	0.035	0.027	-	0.328	0.275	0.255	-
	R4	stream	0.097	0.0005	0.0004	-	0.008	0.005	0.005	-
18m	D6	ditch	0.088	0.023	0.018	-	0.215	0.180	0.167	-

Results for tomatoes 1 application, FOCUS Step 4

Buffer zone	Scenario	Water body	PEC_{SW} [µg/L]			PEC_{SED} [µg/kg dw]		
			max.	21-d TWA	28-d TWA	max.	21-d TWA	28-d TWA
2m	D6	ditch	0.080	0.002	0.0015	0.029	0.018	0.016
	R3	stream	0.085	0.0016	0.0012	0.023	0.016	0.015

Results lettuce 1 application 1st crop, FOCUS Step 4

Buffer zone	Scenario	Water body	PEC_{SW} [µg/L]			PEC_{SED} [µg/kg dw]		
			max.	21-d TWA	28-d TWA	max.	21-d TWA	28-d TWA
2m	D6	ditch	0.066	0.0009	0.0007	0.015	0.009	0.009
	R3	stream	0.069	0.0007	0.0005	0.010	0.006	0.006

Extension of approval

STEP 3 global maximum PECsw and PECsed for a.s. abamectin

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

Early applications to a single annual crop of fruiting vegetables

Application rate [g a.s./ha]	Scenario	Water body	Application dates	Date of global maximum	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Main route of entry to water body for max. PEC_{SW}
6 x 100	D6	Ditch	23-Apr-1986, 07-May-1986, 19-May-1986, 31-May-1986, 24-Jun-1986, 06-Jul-1986	19-Jan-87	<0.0001	<0.0001	Drainage

Late applications to a single annual crop of fruiting vegetables

Application rate [g a.s./ha]	Scenario	Water body	Application dates	Date of global maximum	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Main route of entry to water body for max. PEC_{SW}
6 x 100	D6	Ditch	31-May-1986, 24-Jun-1986, 06-Jul-1986, 17-Jul-1986, 27-Jul-1986, 06-Aug-1986	19-Jan-87	<0.0001	<0.0001	Drainage

Early applications to a first crop of fruiting vegetables followed by applications to a second fruiting vegetable crop

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

Application rate [g a.s./ha]	Scenario	Water body	Application dates	Date of global maximum	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Main route of entry to water body for max. PEC_{SW}
6 x 100[a] & 4 x 100[b]	D6	Ditch	27-Feb-1986, 13-Mar-1986, 23-Mar-1986, 02-Apr-1986, 12-Apr-1986, 22-Apr-1986, 11-Aug-1986, 21-Aug-1986, 31-Aug-1986, 06-Oct-1986	19-Jan-87	<0.0001	<0.0001	Drainage

[a] applications to first crop
[b] applications to second crop

Late applications to a first crop of fruiting vegetables followed by applications to a second fruiting vegetable crop

Application rate [g a.s./ha]	Scenario	Water body	Application dates	Date of global maximum	PEC_{SW} [µg/L]	PEC_{SED} [µg/kg]	Main route of entry to water body for max. PEC_{SW}
6 x 100[a] & 4 x 100[b]	D6	Ditch	07-May-1986, 19-May-1986, 31-May-1986, 24-Jun-1986, 06-Jul-1986, 17-Jul-1986, 11-Aug-1986, 21-Aug-1986, 31-Aug-1986, 06-Oct-1986	19-Jan-87	<0.0001	<0.0001	Drainage

[a] applications to first crop
[b] applications to second crop

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC (sediment)

Parent

Method of calculation	according to FOCUS Step 2; version 1.1 of STEP 1 -2 IN FOCUS
Application rate	**Original inclusion** **field applications:** FOCUS Surface Water - Step 3 SWASH 2.1 (9 April 2003), with MACRO 4.3b, PRZM 3.21.b and TOXSWA 2.1.1.F1. **glasshouse applications:** FOCUS Surface Water - Step 2 with modifications (no drainage and run-off, no crop interception, application rate changed so that total loading to water surface (in g/m^2) is equal to 0.1 % of the application rate) **input:** DT_{50} for degradation in water: 89 d ($DT_{50,system}$ at 20 °C) DT_{50} for degradation in soil: 1 d ($DT_{50,field}$) sorption: K_{OM} 3270 L/kg **Extension of approval** See PECsw

Highest PEC_{SED} for each combination of crop and type of waterbody

citrus

PEC_{SED} (µg/kg dwt)		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
ditch, D6					
initial	0	1.88	-	3.350	-
short-term	1	1.866	1.879	3.335	3.348
	2	1.831	1.875	3.284	3.343
	4	1.732	1.859	3.136	3.324
long term	7	1.5348	1.821	2.874	3.274
	14	1.26	1.695	2.349	3.1
	21	1.035	1.564	1.975	2.9
	28	0.875	1.445	1.676	2.761
	42	0.662	1.249	1.255	2.493

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC_{SED} (µg/kg dwt) ditch, D6		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
	50	0.571	1.16	1.083	2.345
	100	0.251	0.795	0.472	1.717

PEC_{SED} (µg/kg dwt) stream, R4		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.051	-	0.104	-
short-term	1	0.047	0.0504	0.101	0.103
	2	0.044	0.049	0.096	0.101
	4	0.039	0.045	0.091	0.099
long term	7	0.0324	0.041	0.083	0.095
	14	0.024	0.0344	0.071	0.089
	21	0.019	0.03	0.061	0.084
	28	0.016	0.027	0.053	0.079
	42	0.012	0.023	0.043	0.073
	50	0.01	0.021	0.038	0.07
	100	0.005	0.014	0.02	0.053

lettuce, field application

PEC_{SED} (µg/kg dwt) ditch, D3, 1st crop		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.076	-	0.115	-
short-term	1	0.073	0.075	0.111	0.114
	2	0.068	0.074	0.105	0.113
	4	0.06	0.071	0.095	0.108
long term	7	0.051	0.065	0.083	0.102
	14	0.037	0.056	0.063	0.089
	21	0.029	0.049	0.051	0.085

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC_{SED} (µg/kg dwt) ditch, D3, 1st crop		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
	28	0.024	0.043	0.043	0.079
	42	0.018	0.036	0.033	0.069
	50	0.015	0.033	0.029	0.065
	100	0.0084	0.022	0.015	0.046

PEC_{SED} (µg/kg dwt) pond, R1, 2nd crop		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.028	-	0.061	-
short-term	1	0.028	0.028	0.061	0.061
	2	0.028	0.028	0.061	0.061
	4	0.028	0.028	0.061	0.061
long term	7	0.028	0.028	0.061	0.061
	14	0.028	0.028	0.061	0.061
	21	0.027	0.027	0.061	0.061
	28	0.027	0.027	0.060	0.061
	42	0.027	0.027	0.059	0.061
	50	0.026	0.026	0.058	0.061
	100	0.022	0.022	0.049	0.059

PEC_{SED} (µg/kg dwt) stream, R2, 1st crop		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.007	-	0.039	-
short-term	1	0.007	0.007	0.038	0.038
	2	0.007	0.007	0.037	0.027
	4	0.007	0.007	0.036	0.027
long term	7	0.006	0.007	0.034	0.026
	14	0.006	0.006	0.032	0.025

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC_{SED} (µg/kg dwt) **stream, R2, 1st crop**	Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
21	0.005	0.006	0.031	0.024
28	0.005	0.006	0.029	0.023
42	0.004	0.005	0.026	0.021
50	0.004	0.005	0.025	0.020
100	0.003	0.004	0.017	0.016

lettuce, glasshouse application

PEC_{SED} (µg/kg dwt) **Step 2**		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.0183	-	0.0667	-
short-term	1	0.0182	0.0182	0.0665	0.0666
	2	0.0181	0.0182	0.0661	0.0665
	4	0.0178	0.0181	0.0651	0.0661
long term	7	0.0174	0.0179	0.0636	0.0653
	14	0.0165	0.0174	0.0603	0.0636
	21	0.0156	0.017	0.0571	0.062
	28	0.0148	0.0165	0.054	0.0604
	42	0.0133	0.0157	0.0484	0.0573
	50	0.0125	0.0152	0.0455	0.0556
	100	0.0084	0.0128	0.0308	0.0467

tomatoes, field application

PEC_{SED} (µg/kg dwt) **ditch, D6**		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.049	-	0.092	-
short-term	1	0.046	0.048	0.089	0.092
	2	0.043	0.047	0.084	0.09
	4	0.038	0.044	0.074	0.087

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC_{SED} (µg/kg dwt) ditch, D6		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
long term	7	0.032	0.041	0.063	0.081
	14	0.023	0.034	0.066	0.071
	21	0.018	0.032	0.053	0.067
	28	0.015	0.027	0.039	0.062
	42	0.01	0.022	0.028	0.053
	50	0.009	0.021	0.024	0.049
	100	0.004	0.013	0.01	0.034

PEC_{SED} (µg/kg dwt) stream, R4		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.067	-	0.602	-
short-term	1	0.066	0.066	0.595	0.599
	2	0.065	0.066	0.588	0.596
	4	0.063	0.065	0.584	0.591
long term	7	0.061	0.064	0.565	0.584
	14	0.057	0.061	0.536	0.568
	21	0.053	0.059	0.505	0.552
	28	0.053	0.057	0.478	0.537
	42	0.045	0.054	0.432	0.51
	50	0.042	0.052	0.402	0.495
	100	0.025	0.043	0.242	0.407

tomatoes, glasshouse application

PEC_{SED} (µg/kg dwt) Step 2		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
initial	0	0.0431	-	0.196	-
short-term	1	0.0430	0.0431	0.195	0.196
	2	0.0428	0.0430	0.194	0.195

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC_{SED} (µg/kg dwt) Step 2		Single application actual	Single application time weighted average	Multiple application actual	Multiple application time weighted average
	4	0.0421	0.0427	0.191	0.194
long term	7	0.0412	0.0423	0.187	0.192
	14	0.0390	0.0412	0.177	0.187
	21	0.0369	0.0401	0.167	0.182
	28	0.0350	0.0391	0.159	0.177
	42	0.0313	0.0371	0.142	0.168
	50	0.0295	0.0360	0.134	0.163
	100	0.0200	0.0302	0.0905	0.137

Extension of approval
See PECsw calculations

metabolite NOA 426289 (4"-oxo-avermectin B_{1a})

Method of calculation	Highest STEP 3 peak concentration of avermectin B_{1a} in sediment multiplied by maximum formation percentage 8.6 %

PEC_{SED} (µg/kg dwt) crop and scenario	Multiple applications actual
citrus, D6	0.288
lettuce, field, D3	0.01
lettuce, glasshouse, (Step 2)	0.0057
tomatoes, field, R4	0.052
tomatoes, glasshouse, (Step 2)	0.0169

PEC (groundwater) (Annex IIIA, point 9.2.1)

Method of calculation and type of study (*e.g.* modelling, monitoring, lysimeter)	**Model used**: PEARL version 2.2.2 **Scenarios**: citrus: Piacenza, Porto, Sevilla, Thiva, crop citrus lettuce: Chateaudun, Hamburg, Joikoinen, Kremsmünster, Porto, Sevilla, Thiva, crop cabbage tomatoes: Chateaudun, Piacenza, Porto, Sevilla,

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

	Thiva, crop tomatoes **avermectin B_{1a}**: geomean $DT_{50,lab}$ 28.7 d (pF2, 20 °C) for extension of approval: geomean $DT_{50,lab}$18.3 d mean K_{OM}: 3270 L/kg, 1/n= 0.9 **NOA 448111**: formation fraction 0.23 (from parent) mean k_{lab} 0.0153/d $DT_{50,lab}$ 45.3 d (pF2, 20 °C) for extension of approval: geomean $DT_{50,lab}$ 28.8 d mean K_{OM}: 2115 L/kg, 1/n= 0.9 **NOA 448112**: formation fraction 0.30 (from parent) mean k_{lab} 0.0194/d $DT_{50,lab}$ 35.7 d (pF2, 20 °C) for extension of approval: geomean $DT_{50,lab}$ 22.7 d mean K_{OM}: 1127 L/kg, 1/n= 0.9 **NOA 457464**: formation fraction 0.58 (from NOA 448112) mean k_{lab} 0.0105/d $DT_{50,lab}$ 66 d (pF2, 20 °C) for extension of approval: geomean $DT_{50,lab}$ 43.4 d mean K_{OM}: 1019 L/kg, 1/n= 0.9 **NOA 457465**: formation fraction 0.85 (from NOA 448111) mean k_{lab} 0.0062/d $DT_{50,lab}$ 112 d (pF2, 20 °C) for extension of approval: geomean $DT_{50,lab}$ 74.1 d mean K_{OM}: 1898 L/kg, 1/n= 0.9
Application rate	**Original inclusion** citrus: 3 x 21.6 g as/ha, April, int 7 d, no interception simulated lettuce (field): 3 x 18 g as/ha, May-June, int 7 d (1st crop), July-August, int 7 d (2nd crop), no interception simulated tomatoes (field): 3 x 21.6 g as/ha, April-May, int 7d, no interception **Extension of approval** for beans (field + vegetable) and tomato: 1 x 1200 g a.s (maximum annual application rate); 1 x 5000 g a.s (exaggerated annual application rate) For both crops no interception was assumed, incorporation at 10 cm was chosen as drip irrigation cannot be simulated. Application timing was chosen to reflect the extremes of the indoor growing season: early application at 1st of February late application at 15th of October

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

PEC_{GW} (µg/L)

Maximum concentration	all scenarios: < 0.001 µg/L (avermectin B_{1a}, avermectin B_{1b} and metabolites)
Average annual concentration	all scenarios: < 0.001 µg/L

Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)

Direct photolysis in air	no information supplied
Quantum yield of direct phototransformation	0.0287 (winter)
Photochemical oxidative degradation in air	$DT_{50,air}$ < 1 h estimated by Atkinson method (24 hours)
Volatilisation	from plant surfaces: no information supplied
	from soil: no information supplied

PEC_A (air)

Method of calculation	Based on vapour pressure of < 3.7×10^{-6} Pa, Henry's law constant of ≤ 2.7×10^{-3} Pa/m^3.mol (1.13×10^{-6} dimensionless), volatilisation is unlikely. Should abamectin volatilise, quick degradation will occur.

PEC_A

Maximum concentration	Negligible

Definition of the Residue (Annex IIA, point 7.3)

For which a risk assessment is triggered or groundwater exposure assessment is triggered.	**soil**: avermectin B_{1a} and avermectin B_{1b}, [8,9-Z]-avermectin B_{1a} (NOA 427011), 8a-oxo-avermectin B_{1a} (NOA 448111), 8a-hydroxy-avermectin B_{1a} (NOA 448112), 4,8a-dihydroxy-avermectin B_{1a} (NOA 457464), 4-hydroxy-8a-oxo-avermectin B_{1a} (NOA 457465). **Surface water**: avermectin B_{1a} and avermectin B_{1b}, [8,9-Z]-avermectin B_{1a} (NOA 427011) 8a-oxo-avermectin B_{1a} (NOA 448111), 8a-hydroxy-avermectin B_{1a} (NOA 448112), 4,8a-dihydroxy-avermectin B_{1a} (NOA 457464), 4-hydroxy-8a-oxo-avermectin B_{1a} (NOA 457465). **sediment**: avermectin B_{1a} and avermectin B_{1b}, and 4"-oxo-

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Fate and behaviour in the environment

	avermectin B_{1a} (NOA 426289) 8a-oxo-avermectin B_{1a} (NOA 448111), 8a-hydroxy-avermectin B_{1a} (NOA 448112), 4,8a-dihydroxy-avermectin B_{1a} (NOA 457464), 4-hydroxy-8a-oxo-avermectin B_{1a} (NOA 457465). **groundwater**: avermectin B_{1a} and avermectin B_{1b}, 8a-oxo-avermectin B_{1a} (NOA 448111), 8a-hydroxy-avermectin B_{1a} (NOA 448112), 4,8a-dihydroxy-avermectin B_{1a} (NOA 457464), 4-hydroxy-8a-oxo-avermectin B_{1a} (NOA 457465) **and U8.** **air**: avermectin B_{1a} and avermectin B_{1b} (by default)

Monitoring data, if available (Annex IIA, point 7.4)

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

Classification and proposed labelling (Annex IIA, point 10)

with regard to fate and behaviour data	Potential for R53

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Chapter 2.6 – Effects on Non-target Species

Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)

Species	Test substance	Time scale	End point (mg/kg bw/day)	End point (mg/kg feed)
Birds ‡				
Anas platyrhynchos	a.s.	Acute	LD_{50} ≤ 77	not relevant
	Preparation	Acute	NA	
Colinus virginianus	Preparation (A12115l)	Acute	>2000 mg A12115/kg bw	
	Metabolite 1	Acute	NA	
Anas platyrhynchos	a.s.	Short-term	LC_{50} 48.6	383
Anas platyrhynchos, males	a.s.	Long-term	NOEC 1.33	12
Colinus virginianus	Preparation (A12115l)			
Mammals ‡				
rat	a.s.	Acute	LD_{50} 8.7	not relevant
	Preparation	Acute	NA	
	Preparation (A12115l)	Acute	LD_{50} 1086 mg A12115l/kg bw	
	Metabolite 1	Acute	NA	
rat	a.s.	Long-term	NOEC 0.12	
Additional higher tier studies ‡				

Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)

Original inclusion

Crop and application rate: citrus (orchard scenario) / 3 x 0.0216 kg as/ha / exposure by food

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
insectivorous bird	Acute	1.2	66*	10

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
insectivorous bird	Short-term	0.65	75	10
insectivorous bird	Long-term	0.65	**2.0**	5
Higher tier refinement (Birds)				
insectivorous bird	Acute	NA	NA	10
insectivorous bird	Short-term	NA	NA	10
insectivorous bird	Long-term	0.19	7.0 (res)	5
Tier 1 (Mammals)				
small herbivorous mammal	Acute	4.3	**2.0**	10
small herbivorous mammal	Long-term	1.46	**0.08**	5
Higher tier refinement (Mammals)				
small herbivorous mammal	Acute	0.629	13.8 (res, DT_{50})	10

* An acute toxicity value of 77 mg/kg bw for birds has been used to calculate the acute TER for birds. However, vomiting was observed at all dose levels. Assuming that 2/3 of the dose is vomited the LD50 will be 26 mg/kg bw. Even with this conservative value the TER-value will be higher than 10 (lowest TER = 11 (tomatoes in field).

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Crop and application rate: lettuce (field; leafy crop scernario) / 3 x 0.018 kg as/ha / exposure by food

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
medium herbivorous bird	Acute	2.0	39*	10
insectivorous bird	Acute	0.97	79*	10
medium herbivorous bird	Short-term	1.1	44	10
insectivorous bird	Short-term	0.54	89	10
medium herbivorous bird	Long-term	0.58	**2.3**	5
insectivorous bird	Long-term	0.54	**2.5**	5
Higher tier refinement (Birds)				
medium herbivorous bird	Long-term	0.091	14.6 (res, DT_{50})	5
Tier 1 (Mammals)				
medium herbivorous mammal	Acute	0.75	11	10
mediumherbivorous mammal	Long-term	0.21	**0.56**	5

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Higher tier refinement (Mammals)				
medium herbivorous mammal	Acute	NA	NA	10
medium herbivorous mammal	Long-term		3.6 (res, DT_{50})	5

* An acute toxicity value of 77 mg/kg bw for birds has been used to calculate the acute TER for birds. However, vomiting was observed at all dose levels. Assuming that 2/3 of the dose is vomited the LD50 will be 26 mg/kg bw. Even with this conservative value the TER-value will be higher than 10 (lowest TER = 11 (tomatoes in field).

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)
[2] for cereals indicate if it is early or late crop stage
[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

Crop and application rate: tomatoes (field; leafy crop scernario) / 3 x 0.0216 kg as/ha / exposure by food

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
medium herbivorous bird	Acute	2.4	32*	10
insectivorous bird	Acute	1.2	66*	10
frugivorous bird	Acute	0.88	30	10
medium herbivorous bird	Short-term	1.3	37	10
insectivorous bird	Short-term	0.65	75	10
medium herbivorous bird	Long-term	0.70	**1.9**	5
insectivorous bird	Long-term	0.65	**2.0**	5
frugivorous birds	Long-term	0.14	9.5	5
Higher tier refinement (Birds)				
medium herbivorous bird	Long-term	0.038	39	5
Tier 1 (Mammals)				
medium herbivorous mammal	Acute	0.89	**9.7**	10
medium herbivorous mammal	Long-term	0.26	**0.47**	5
Higher tier refinement (Mammals)				
medium herbivorous mammal	Acute		acceptable**	10
medium herbivorous mammal	Long-term		acceptable**	5

* An acute toxicity value of 77 mg/kg bw for birds has been used to calculate the acute TER for birds. However, vomiting was observed at all dose levels. Assuming that 2/3 of the dose is vomited the LD50 will be 26 mg/kg bw. Even with this conservative value the TER-value will be higher than 10 (lowest TER = 11 (tomatoes in field).

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

** : it is assumed that tomato foliage, at the later growth stages when abamectin is applied, is unlikely to be eaten by herbivorous mammals

[1] in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

[2] for cereals indicate if it is early or late crop stage

[3] If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

All crops: exposure via drinking from surface water or puddles / leaf axils

Indicator species/Category[2]	Time scale	ETE	TER	Annex VI Trigger[3]
Tier 1 (Birds)				
small bird (puddles/leaf axils)	Acute	0.97	79*	10
small bird (surface water)	Acute	0.000214	252000*	10
Tier 1 (Mammals)				
small mammal (puddles/leaf axils)	Acute	0.57	15	10
small mammal (surface water)	Acute	0.00019	73000	10

* An acute toxicity value of 77 mg/kg bw for birds has been used to calculate the acute TER for birds. However, vomiting was observed at all dose levels. Assuming that 2/3 of the dose is vomited the LD50 will be 26 mg/kg bw. Even with this conservative value the TER-value will be higher than 10 (lowest TER = 11 (tomatoes in field).

All crops: exposure via eating of worms or fish

Indicator species/Category[2]	Time scale	ETE	TER[1]	Annex VI Trigger[3]
Tier 1 (Birds)				
worm-eating bird	Long-term	0.0025	532	10
fish-eating bird	Long-term	0.005	266	10
Tier 1 (Mammals)				
worm-eating mammal	Long-term	0.0025	48	10
fish-eating mammal	Long-term	0.005	24	10

Extension of approval

Since the application is indoors, no exposure of birds and mammals through consumption of residues on food items is expected. Exposure is possible by surface water after emission of the active substance from indoors to the surface water. Furthermore secondary poisoning by consuming fish is a possible route of exposure. Becasue the PECsw is very low (<0.0001 µg/L), a low risk is expected via these routes.

Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg as/L)
Laboratory tests ‡				

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg as/L)
Fish				
Oncorhynchus mykiss	abamectin	96 hr (static)	Mortality, LC_{50}	3.6 (nom)
Oncorhynchus mykiss	abamectin	96 hr (flow-through; modified exposure test)	Mortality, LC_{50}	8.7 (nom)
Oncorhynchus mykiss	Vertimec 018 EC	96 hr (flow-through)	Mortality, LC_{50}	2.3 (nom)
Oncorhynchus mykiss	A12115I	96 hr (static)	Mortality, LC_{50}	5.86 (mm)
Oncorhynchus mykiss	[8,9-Z]-avermectin B_{1a} (NOA 427011)	96 hr (flow-through)	Mortality, LC_{50}	5.1 (mm)
Oncorhynchus mykiss	8a-hydroxy-avermectin B_{1a} (NOA 448112)	96 hr (semi-static)	Mortality, LC_{50}	520 (mm)
Oncorhynchus mykiss	abamectin	28 d (flow-through)	NOEC	0.52 (mm)
Aquatic invertebrate				
Daphnia pulex	abamectin	48 h (static)	Mortality, EC_{50}	0.12 (mm)
Daphnia magna	Vertimec 018 EC	48 h (flow-through)	Mortality, EC_{50}	0.59 (mm)
Daphnia magna	A12115I	48 h (static)	Mortality, EC_{50}	0.00759 (mm)
Daphnia magna	[8,9-Z]-avermectin B_{1a}	48 h (static)	Mortality, EC_{50}	0.082 (mm)
Daphnia magna	8a-hydroxy-avermectin B_{1a}	48 h (static)	Mortality, EC_{50}	1.6 (mm)
Daphnia magna	4”-oxo-avermectin B_{1a} (NOA 426289)	48 h (static)	Mortality, EC_{50}	0.28 (nom)
Daphnia magna	abamectin	21 d (flow-through)	Reproduction, NOEC	0.010 (nom)
Sediment dwelling organisms				
Chironomus riparius	abamectin	28 d (static; water-spiked)	NOEC	0.081 (nom)
Chironomus riparius	abamectin	28 d (static; sediment spiked)	NOEC	3.3 µg/kg dwt (nom)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Group	Test substance	Time-scale (Test type)	End point	Toxicity[1] (µg as/L)
Algae				
Pseudokirchneriella subcapitata	Vertimec 018 EC	72 h (static)	Biomass: $E_bC_{50;}$ Growth rate: E_rC_{50}	> 1590 (nom)
Pseudokirchneriella subcapitata	A12115I	72 h (static)	Biomass: $E_bC_{50;}$ Growth rate: E_rC_{50}	>0.781 (mm)
Pseudokirchneriella subcapitata	[8,9-Z]-avermectin B_{1a}	72 h (static)	Biomass: E_bC_{50}; Growth rate: E_rC_{50}	> 9000 (nom)
Pseudokirchneriella subcapitata	8a-hydroxy-avermectin B_{1a}	72 h (static)	Biomass: E_bC_{50}; Growth rate: E_rC_{50}	> 6100 (mm)
Higher plant				
Indicate species.		14 d (static)	Fronds, EC_{50}	NA
	Preparation	14 d (static)	Fronds, EC_{50}	NA
	Metabolite 1	14 d (static)	Fronds, EC_{50}	NA
Microcosm or mesocosm tests NOEC: 1st study: 0.2 µg as/L, nominal concentration after single application, recirculation; NOEAEC-value not possible to derive 2nd study: 0.015 µg as/L; NOEAEC = 0.049 µg as/L, nominal concentration after three applications, no recirculation. It should be noted that Daphnids did not have sufficient abundance for statistical analysis and that it is thus not known whether at the NOEAEC-level Daphnids will be able to recover from possible effects. The similarity between the chronic Daphnia NOEC and the EAC (SF of 3 on the NOEAEC value) indicates however that Daphnia will probably not be affected. The risk of metabolite [8,9-Z]-avermectin B1a to aquatic invertebrates is considered to be covered by the mesocosm studies. The risk to fish needs to be addressed.				

[1] indicate whether based on nominal ($_{nom}$) or mean measured concentrations ($_{mm}$). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)

Original inclusion

FOCUS Step 3

Crop and application rate: citrus / 3 x 0.0216 kg as/ha

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
a.s.	Fish	3.6	Acute	0.791		**4.6**	100
a.s.	Fish	0.52	Chronic		0.224	**2.3**	10
a.s.	Aquatic invertebrates	0.12	Acute	0.791		**0.15**	100
a.s.	Aquatic invertebrates	0.010	Chronic		0.352	**0.03**	10
a.s.	Algae		Chronic	0.791		NA	10
a.s.	Higher plants[2]		Chronic	NA			10
a.s.	Sediment-dwelling organisms	0.081	Chronic	0.791		**0.10**	10
Vertimec 018 EC	Fish	2.3	Acute	0.791		**2.9**	100
Vertimec 018 EC	Aquatic invertebrates	0.59	Acute	0.791		**0.75**	100
Vertimec 018 EC	Algae	>1590	Chronic	0.791		>2010	10

[1] PEC_{SW} is highest actual PEC_{SW} (acute daphnids, fish and algae) or TWA-PEC_{SW} (chronic daphnids, fish) after single or multiple applications, selected from the different Step 3-scenarios for each crop. For glasshouse applications, Step 2-values are used.

[2] only required for herbicides

Crop and application rate: lettuce, field / 3 x 0.018 kg as/ha

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
a.s.	Fish	3.6	Acute	0.115		**31**	100
a.s.	Fish	0.52	Chronic		0.012	43	10
a.s.	Aquatic invertebrates	0.12	Acute	0.115		**1.0**	100
a.s.	Aquatic invertebrates	0.010	Chronic		0.029	**0.35**	10
a.s.	Algae		Chronic	0.115		NA	10
a.s.	Higher plants[2]		Chronic	NA			10
a.s.	Sediment-dwelling organisms	0.081	Chronic	0.115		**0.70**	10
Vertimec 018 EC	Fish	2.3	Acute	0.115		**21**	100

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
Vertimec 018 EC	Aquatic invertebrates	0.59	Acute	0.115		**5.3**	100
Vertimec 018 EC	Algae	>1590	Chronic	0.115		>13826	10

[1] PEC_{SW} is highest actual PEC_{SW} (acute daphnids, fish and algae) or TWA-PEC_{SW} (chronic daphnids, fish) after single or multiple applications, selected from the different Step 3-scenarios for each crop. For glasshouse applications, Step 2-values are used.

[2] only required for herbicides

Crop and application rate: lettuce, glasshouse / 4 x 0.009 kg as/ha

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
a.s.	Fish	3.6	Acute	0.0043		837	100
a.s.	Fish	0.52	Chronic		0.0017	306	10
a.s.	Aquatic invertebrates	0.12	Acute	0.0043		**28**	100
a.s.	Aquatic invertebrates	0.010	Chronic		0.0018	**5.6**	10
a.s.	Algae		Chronic	0.0043		NA	10
a.s.	Higher plants[2]		Chronic	NA			10
a.s.	Sediment-dwelling organisms	0.081	Chronic	0.0043		19	10
Vertimec 018 EC	Fish	2.3	Acute	0.0043		535	100
Vertimec 018 EC	Aquatic invertebrates	0.59	Acute	0.0043		137	100
Vertimec 018 EC	Algae	>1590	Chronic	0.0043		>3.7 x 10^5	10

[1] PEC_{SW} is highest actual PEC_{SW} (acute daphnids, fish and algae) or TWA-PEC_{SW} (chronic daphnids, fish) after single or multiple applications, selected from the different Step 3-scenarios for each crop. For glasshouse applications, Step 2-values are used.

[2] only required for herbicides

Crop and application rate: tomatoes, field / 3 x 0.0216 kg as/ha

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
a.s.	Fish	3.6	Acute	0.136		**26**	100
a.s.	Fish	0.52	Chronic		0.004	130	10

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
a.s.	Aquatic invertebrates	0.12	Acute	0.136		**0.88**	100
a.s.	Aquatic invertebrates	0.010	Chronic		0.009	**1.1**	10
a.s.	Algae		Chronic	0.136		NA	10
a.s.	Higher plants[2]		Chronic	NA			10
a.s.	Sediment-dwelling organisms	0.081	Chronic	0.136		**0.60**	10
Vertimec 018 EC	Fish	2.3	Acute	0.136		**17**	100
Vertimec 018 EC	Aquatic invertebrates	0.59	Acute	0.136		**4.3**	100
Vertimec 018 EC	Algae	>1590	Chronic	0.136		>11691	10

[1] PEC_{SW} is highest actual PEC_{SW} (acute daphnids, fish and algae) or TWA-PEC_{SW} (chronic daphnids, fish) after single or multiple applications, selected from the different Step 3-scenarios for each crop. For glasshouse applications, Step 2-values are used.

[2] only required for herbicides

Crop and application rate: tomatoes, glasshouse / 5 x 0.0216 kg as/ha

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
a.s.	Fish	3.6	Acute	0.0144		250	100
a.s.	Fish	0.52	Chronic		0.0052	100	10
a.s.	Aquatic invertebrates	0.12	Acute	0.0144		**11**	100
a.s.	Aquatic invertebrates	0.010	Chronic		0.0046	**2.2**	10
a.s.	Algae		Chronic	0.0144		NA	10
a.s.	Higher plants[2]		Chronic	NA			10
a.s.	Sediment-dwelling organisms	0.081	Chronic	0.0144		**5.6**	10
Vertimec 018 EC	Fish	2.3	Acute	0.0144		**202**	100
Vertimec 018 EC	Aquatic invertebrates	0.59	Acute	0.0144		**41**	100

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Test substance	Organism	Toxicity end point (µg as/L)	Time scale	PEC_i[1] (µg as/L)	PEC_{twa} (µg as/L)	TER	Annex VI Trigger[1]
Vertimec 018 EC	Algae	>1590	Chronic	0.0144		> 1.4 x 10^5	10

[1] PEC_{SW} is highest actual PEC_{SW} (acute daphnids, fish and algae) or TWA-PEC_{SW} (chronic daphnids, fish) after single or multiple applications, selected from the different Step 3-scenarios for each crop. For glasshouse applications, Step 2-values are used.

[2] only required for herbicides

Toxicity/exposure ratios based on the EAC-value (mesocosm without fish)

Crop	Waterbody	Scenario	highest PEC_{SW} [µg as/L]	EAC used [µg as/L]	TER EAC/PEC_{SW}	Annex VI trigger
citrus	ditch	D6, 1 application	0.791	~~0.6~~ 0.1*	~~0.75~~ **0.13**	1
		- 5 m bufferzone	0.534		**0.19**	
		- 10 m bufferzone	0.240		**0.42**	
		- 12 m bufferzone	0.176		**0.57**	
		- 14 m bufferzone	0.135		**0.74**	
		- 18 m bufferzone	0.088		1.14	
	stream	R4, 1 application	0.590	~~0.6~~ 0.1	~~1.0~~ **0.17**	1
		- 5 m bufferzone	0.384		**0.26**	
		- 10 m bufferzone	0.173		**0.57**	
		- 14 m bufferzone	0.097		1.03	
lettuce, field	ditch	D6, 1 application	0.115	~~0.6~~ 0.1	~~5.2~~ **0.87**	1
		- 2 m bufferzone	0.066		1.52	
	pond	D4, 3 applications	0.007	0.016**	2.3	1
		R1, 3 applications (1st crop)				
	stream	R3, 1 application (1st crop)	0.106	~~0.6~~ 0.1	~~5.7~~ **0.94**	1
		- 2 m bufferzone	0.069		1.45	
lettuce, glasshouse	ditch	Step 2, 4 applications	0.0043	0.016	3.7	1
tomatoes, field	ditch	D6, 1 application	0.136	~~0.6~~ 0.1	~~4.4~~ **0.74**	1
		- 2 m bufferzone	0.080		1.25	
	stream	R3, 1 application	0.127	~~0.6~~ 0.1	~~4.7~~ **0.79**	1
		- 2 m bufferzone	0.085		1.18	

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Crop	Waterbody	Scenario	highest PEC_{SW} [µg as/L]	EAC used [µg as/L]	TER EAC/PEC_{SW}	Annex VI trigger
tomatoes, glasshouse	ditch	Step 2, 5 applications	0.0144	0.016	1.1	1

* safety factor of 2 on the NOEC from 1st study
** safety factor of 3 on the NOEAEC from 2nd study

Toxicity/exposure ratios for fish, based on the LC50-value of the modified exposure test

Crop	Waterbody	highest PEC_{SW} [µg as/L]	Scenario	LC50 [µg as/L]	TER EAC/PEC_{SW}	Annex VI trigger
citrus	ditch	0.791	D6, 1 application	10.1	**11**	100
	ditch	0.430	D6, 1 application, 6m bufferzone	10.1	**20**	100
	stream	0.590	R4, 1 application	10.1	**15**	100
lettuce, field	ditch	0.115	D6, 1 application	10.1	**76**	100
	pond	0.007	D4, 3 applications R1, 3 applications (1st crop)	10.1	1243	100
	stream	0.106	R3, 1 application (1st crop)	10.1	**74**	100
lettuce, glasshouse	ditch	0.0043	Step 2, 4 applications	10.1	2023	100
tomatoes, field	ditch	0.136	D6, 1 application	10.1	**64**	100
	stream	0.127	R3, 1 application	10.1	**69**	100
tomatoes, glasshouse	ditch	0.0144	Step 2, 5 applications	10.1	604	100

Acute toxicity/exposure ratios for fish, based on the HC5-value of 0.31 µg a.s./L

Crop	Waterbody	Scenario	highest PEC_{SW} [µg as/L]	LC50 [µg as/L]	TER HC5/PEC_{SW}	Annex VI trigger
citrus	ditch	D6, 1 application - 10 m bufferzone	0.791 0.240	~~0.66~~ 0.31	~~**0.8**~~ **0.39** 1.1	1
	stream	R4, 1 application - 10 m bufferzone	0.590 0.173	~~0.66~~ 0.31	~~1.1~~ **0.53** 1.79	1
lettuce, field	ditch	D6, 1 application	0.115	~~0.66~~ 0.31	~~5.7~~ 2.7	1
	pond	D4, 3 applications R1, 3 applications (1st crop)	0.007	~~0.66~~ 0.31	~~94~~ 44	1
	stream	R3, 1 application (1st crop)	0.106	~~0.66~~ 0.31	~~6.2~~ 2.9	1

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Crop	Waterbody	Scenario	highest PEC_{SW} [µg as/L]	LC50 [µg as/L]	TER HC5/PEC_{SW}	Annex VI trigger
lettuce, glasshouse	ditch	Step 2, 4 applications	0.0043	~~0.66~~ 0.31	~~153~~ 72	1
tomatoes, field	ditch	D6, 1 application	0.136	~~0.66~~ 0.31	~~4.9~~ 2.3	1
	stream	R3, 1 application	0.127	~~0.66~~ 0.31	~~5.2~~ 2.4	1
tomatoes, glasshouse	ditch	Step 2, 5 applications	0.0144	~~0.66~~ 0.31	~~46~~ 21	1

Chronic toxicity-exposure ratios for fish using FOCUS Step 3 (field applications) and 2 (glasshouse uses) PIECvalues

Species	NOEC [µg as/L]	crop	PIECsw (ug/L)	TER
O. mykiss	0.52	citrus	0.791	**0.66**
		Lettuce (field)	0.115	**4.5**
		Lettuce (glasshouse)	0.0043	121
		Tomato (field)	0.136	**3.8**
		Tomato (glasshouse)	0.0114	46

Chronic toxicity-exposure ratios for fish from use of abamectin using FOCUS Step 4 (citrus), 3 (field applications) and 2 (glasshouse uses) PIEC values and a chronic HC5-value

Species	chronic HC5 [µg as/L]	crop	PIECsw (ug/L)	TER
O. mykiss	0.22	citrus citrus (12 m bufferzone)	0.791 0.176	**0.28** 1.25
		Lettuce (field)	0.115	1.9
		Lettuce (glasshouse)	0.0043	51
		Tomato (field)	0.136	1.6
		Tomato (glasshouse)	0.0114	19

Extension of approval

The exposure to surface water is very low: The PECsw < 0.0001 µg/L. The lowest endpoint available is the endpoint of the formulation A12115l for *Daphnia magna*: EC50 = 0.00759 µg as/L. With a safety factor of 100 the first tier RAC = 0.0000759 µg/L. The TER is then > 0.759, possibly below 1. The higher

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

tier RAC from the mesocosm study is 0.049 µg/L with a safety factor of 3 is 0.016 µg/L. This is much higher than the PECsw. Hence, there is an acceptable risk for aquatic organisms.

Bioconcentration				
	Active substance	Metabolite1	Metabolite2	Metabolite3
log $P_{O/W}$	4.4	NA	NA	NA
Bioconcentration factor (BCF)[1] ‡	69 L/kg wwt*			
Annex VI Trigger for the bioconcentration factor	100			
Clearance time (days) (CT_{50})	n.d.			
(CT_{90})	n.d.			
Level and nature of residues (%) in organisms after the 14 day depuration phase	0.32 µg/kg wwt			

[1] only required if log $P_{O/W}$ >3.
* based on total ^{14}C or on specific compounds

Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
a.s. ‡	no reliable information available	0.0022
Preparation	NA	NA
Preparation (A12115I)	0.00528	0.00198
Metabolite 1	NA	NA
Field or semi-field tests		
Residual toxicity to honeybees Acute toxicity residues of abamectin on citrus and alfalfa leaves to honeybees. Leaves sprayed at 0.0015 - 0.015 g as/L in California during summer, ageing for 0.5 - 72 hours, average temperature 24 - 27 °C. Mortality caused by 0.5 - 1 hour aged residues was 92 - 100 % at all concentrations, mortality decreased with increasing ageing time. The time needed to reduce mortality to 50 % was dependent of concentration and increased from 2.1 hours at 0.0015 g as/L to 41.3 hours at 0.015 g as/L. Minimum ageing time to reduce residual toxicity to < LD_{50} is estimated to be 39 hours for citrus and 43 hours for tomatoes after single spray at proposed concentration (0.0135 and 0.018 g as/L). Necessary waiting time to non-toxic residues 96 hours. Semi-field study with bumblebees Glasshouse test to determine the residual toxicity of Dynamec 1.8 EC (abamectin 18 g as/L) to bumblebees. Mini-hives introduced 6 to 48 hours after spraying tomato plants at 14.6 and 11.8 g as/ha. No significant effect on survival and pollination at both treatment levels, but trend for highest		

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Test substance	Acute oral toxicity (LD_{50} µg/bee)	Acute contact toxicity (LD_{50} µg/bee)
mortality to occur in the 6 and 12 hour aged treatments. Use of full size hives could result in significant differences in bee mortality. Exposure to residues within 6 - 12 hours after spraying could thus lead to a significant effect on bumblebee survival.		

Hazard quotients for honey bees (Annex IIIA, point 10.4)

Original inclusion

Crop and application rate: citrus, tomatoes (field): 3 x 0.0216 kg as/ha

Test substance	Route	Hazard quotient	Annex VI Trigger
a.s.	Contact	**9818**	50
a.s.	oral	NA	50
Preparation	Contact	NA	50
Preparation	oral	NA	50

Extension of approval

The exposure of bees is predominantly through contact and oral ingestion of the residues on crops. The proposed soil drip use indoors will result in negligible exposure to bees. Hence, the risk to bees is considered to be acceptable.

Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)

Species	Stage	Test Substance	Dose (g as/ha)	Aged (d)	Endpoint	Effect[1] (%)	Annex VI Trigger
Laboratory tests							
Poecilus cupreus	adults	Vertimec 018 EC	1.2	-	survival food consumption	0 0	30
			5.8	-	survival food consumption	0 0	30
			29	-	survival food consumption	0 0	30
			58	-	survival food consumption	0 0	30

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Poecilus cupreus	adults	Vertimec 018 EC	2 x 5.8		survival food consumption	-3.4 0	50
			2 x 5.8		survival food consumption	3.3 6.1	50
			2 x 5.8		survival food consumption	-3.4 -2.8	50
			2 x 29.2		survival food consumption	10.3 0	50
			2 x 29.2		survival food consumption	0 0	50
			2 x 29.2		survival food consumption	-3.4 -5.6	50
			2 x 5.8 + adjuvant		survival food consumption	0 -3.0	50
			2 x 5.8 + adjuvant		survival food consumption	0 15.2	50
			2 x 5.8 + adjuvant		survival food consumption	-3.4 5.6	50
			2 x 29.2 + adjuvant		survival food consumption	6.9 9.1	50
			2 x 29.2 + adjuvant		survival food consumption	0 -6.1	50
			2 x 29.2 + adjuvant		survival food consumption	0 -2.8	50

1: negative values indicate increase relative to control

Species	Stage	Test Substance	Dose (g as/ha)	Aged (d)	Endpoint	Effect[1] (%)	Annex VI Trigger
Laboratory tests (cont.)							
Typhlodromus pyri	proto-nymphs	Vertimec 018 EC	1.17	-	survival reproduction	88.2 100	50
			5.84	-	survival	97.9	50
			29.2	-	survival	100	50
			58.4	-	survival	100	50
			0.088	-	survival reproduction	4 27	50

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Typhlodromus pyri	proto-nymphs	Vertimec 018 EC	0.133	-	survival reproduction	13 34	50
			0.199	-	survival reproduction	11 52	50
			0.298	-	survival reproduction	24 72	50
			0.448	-	survival	59	50
Typhlodromus pyri	proto-nymphs	Vertimec 018 EC	4.33	-	survival	100	50
			4.33	1	survival reproduction	15 56.5	50
			4.33	6	survival reproduction	0 10.8	50
			22.4	0	survival	100	50
			22.4	1	survival	100	50
			22.4	6	survival reproduction	12 78.4	50
			22.4	15	survival reproduction	0 -6.7	50

1: negative values indicate increase relative to control

Species	Stage	Test Substance	Dose (g as/ha)	Aged (d)	Endpoint	Effect[1] (%)	Annex VI Trigger
Laboratory tests (cont.)							
Aphidius rhopalosiphi	adult	Vertimec 018 EC	0.58		survival	93.3	50
			5.84		survival	100	50
			29.2		survival	100	50
			58.4		survival	100	50
Aphidius rhopalosiphi	adult	Vertimec 018 EC	0.023		survival	0	50
			0.057		survival reproduction	0 7	50
			0.143		survival reproduction	3 67	50
			0.358		survival reproduction	40 94	50
			0.895		survival	80	50

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

			2.238		survival	97	50
Aphidius rhopalosiphi	adult	Vertimec 018 EC	4.32		survival	95	50
			22.4		survival	100	50
			4.32	1	survival reproduction	25 67	50
			22.4	1	survival	80	50
			4.32	6	survival reproduction	3 52	50
			22.4	6	survival reproduction	15 57	50
			4.32	16	survival reproduction	3 -9	50
			22.4	16	survival reproduction	11 -8	50
Orius laevigatus			1.2		survival reproduction	63.2 -8.3	50
			5.8		survival	90.8	50
			29.2		survival	97.7	50
			58.4		survival	100	50

1: negative values indicate increase relative to control

Species	Stage	Test Substance	Dose (g as/ha)	Aged (d)	Endpoint	Effect[1] (%)	Annex VI Trigger
Semi-field tests							
Aphidius colemani	adult	Vertimec 018 EC	0.20-0.73		activity reproduction	67 62	50
			2.48-9.11		activity reproduction	77 80	50
			0.20-0.73 2x		activity reproduction	13 39	50
			2.48-9.11 2x		activity reproduction	86 54	50
			0.20-0.73 4x		activity reproduction	34 0	50
			2.48-9.11 4x		activity reproductio	84 26	50

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

					n		
			0.20-0.73 4x		activity reproductio n	-9 29	50
			2.48-9.11 4x		activity reproductio n	32 -34	50
			0.20-0.73 4x		activity reproductio n	-40 6	50
			2.48-9.11 4x		activity reproductio n	3 -11	50
Orius laevigatus	nymp hs	Vertimec 018 EC	2.7		survival	49.2	50
			2.7	2	survival	16.9	50
			2.7	7	survival	13.2	50
			13.5		survival	58.7	50
			13.5	2	survival	45.8	50
			13.5	7	survival	26.5	50
			2.7 + paraffin oil		survival	38.1	50
			2.7 + paraffin oil	2	survival	8.5	50
			2.7 + paraffin oil	7	survival	8.8	50
			13.5 + paraffin oil		survival	63.5	50
			13.5 + paraffin oil	2	survival	49.2	50
			13.5 + paraffin oil	7	survival	35.3	50
			paraffin oil		survival	7.9	
			paraffin oil	2	survival	-13.6	
			paraffin oil	7	survival	16.2	

1: negative values indicate increase relative to control

Original inclusion

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Crop	Maximum single dose [g as/ha]	Number of applications	MAF[1]	Vegetation distribution factor	Drift[2] [%]	Exposure off-field[3] [g as/ha]	Required bufferzone to reach off-field exposure < 0.20 g a.s./ha
citrus	21.6	3	1.24	10	11.01	1.47	15 m
lettuce field	18	3	1.24	10	2.01	0.22	5 m
tomatoes field	21.6	3	1.24	10	2.01	0.27	5 m

1: MAF based on DT_{50} of 3 days and spray interval 7 days
2: drift value for late application to fruit crops used in accordance with FOCUS Surface water
3: off-field exposure value includes correction factor of 5 to be used in case of extended laboratory tests

Extension of approval

The LR50 for *Poecilus cupreus* is >58 g as/ha. That means that it is not clear if at a the dose of 100 gas/ha there will be effects >50% on this species or not. Also the available extended lab test has been done with too low dose rates. Hence, it is not clear yet if the risk for *Poecilus cupreus* is acceptable. Not in all Member States the soil in glasshouses is considered as a natural soil with a natural soil community. E.g. in The Netherlands no risk assessment is performed for soil organisms regarding glasshouse uses, because management practice includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community within glasshouses. Hence, refinement of the risk can be considered as a Member State issue.

Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5. Annex IIIA, points, 10.6 and 10.7)

Test organism	Test substance	Time scale	End point[1]
Earthworms			
	abamectin	Acute 14 days	LC_{50} 33 mg a.s./kg d.w.soil (10% OM) equivalent to 16.5 mg/kg at default OM content of 5 % for agricultural soil
	a.s. ‡	Chronic 8 weeks	NA
	Preparation	Acute	NA
	Preparation (A12115I)	Acute	LC50 >100 mg a.s./kg dw soil
	Vertimec 018 EC	Chronic	NOEC ≥ 0.72 mg as/kg (10 % OM, 56 d) equivalent to ≥ 0.36 mg as/kg at default OM content of 5 % for agricultural soil
	[8,9-Z]-avermectin B_{1a} (NOA 427011)	Acute	LC_{50} 50 mg/kg (10 % OM) equivalent to 25 mg/kg at default OM content of 5 % for agricultural soil

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Test organism	Test substance	Time scale	End point[1]
	8a-hydroxy-avermectin B_{1a} (NOA 448112)	Acute	LC_{50} 321 mg/kg (10 % OM) equivalent to 161 mg/kg at default OM content of 5 % for agricultural soil
Other soil macro-organisms			
Soil mite	a.s. ‡		NA
	Preparation		NA
	Metabolite 1		NA
Collembola			
	a.s. ‡	Chronic	NA
	Preparation		NA
	Metabolite 1		NA
Soil micro-organisms			
Nitrogen mineralisation	abamectin		< 25 % effect after 28 days at 0.347 mg/kg dw soil (equivalent to 216 g as/ha at 5 cm depth assuming soil bulk density 1500 kg/m^3)
	[8,9-Z]-avermectin B_{1a} (NOA 427011)		< 25 % effect after 28 days at 0.40 mg/kg dw soil
	8a-hydroxy-avermectin B_{1a} (NOA 448112)		< 25 % effect after 28 days at 0.66 mg/kg dw soil
Carbon mineralisation	abamectin		< 25 % effect after 28 days at 0.347 mg/kg dw soil (equivalent to 216 g as/ha at 5 cm depth assuming soil bulk density 1500 kg/m^3)
	[8,9-Z]-avermectin B_{1a} (NOA 427011)		< 25 % effect after 28 days at 0.40 mg/kg dw soil
	8a-hydroxy-avermectin B_{1a} (NOA 448112)		< 25 % effect after 28 days at 0.66 mg/kg dw soil
Field studies[2]			
Not required			

[1] indicate where end point has been corrected due to log Pow >2.0 (e.g. LC_{50corr})
[2] litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Toxicity/exposure ratios for earthworms, based on toxicity values at default OM content of 5% for agricultural soil

Original inclusion

Crop and application rate: citrus / 3 x 0.0216 kg as/ha

Test substance	Time scale	Soil PEC	TER	Trigger
abamectin	Acute	0.0093	1774	10
abamectin	Chronic	0.0093	≥ 39	5
metabolite NOA 427011 ([8,9-Z]-avermectin B_{1a})[1]	Acute	0.0093	2688	10
metabolite NOA 448112 (8a-hydroxy-avermectin B_{1a})	Acute	0.003	53667	10

3: for this metabolite no PEC_s was calculated as this metabolite was not identified in the soil biodegradation studies. Therefore, the maximum initial PEC_s is used for risk assessment

Crop and application rate: lettuce (field) / 3 x 0.018 kg as/ha

Test substance	Time scale	Soil PEC	TER	Trigger
abamectin	Acute	0.0154	1071	10
abamectin	Chronic	0.0154	≥ 23	5
metabolite NOA 427011 ([8,9-Z]-avermectin B_{1a})[3]	Acute	0.0154	1623	10
metabolite NOA 448112 (8a-hydroxy-avermectin B_{1a})	Acute	0.005	32200	10

1: for this metabolite no PEC_s was calculated as this metabolite was not identified in the soil biodegradation studies. Therefore, the maximum initial PEC_s is used for risk assessment

Crop and application rate: lettuce (glasshouse) / 4 x 0.009 kg as/ha

Test substance	Time scale	Soil PEC	TER	Trigger
abamectin	Acute	0.0077	2143	10
abamectin	Chronic	0.0077	≥ 47	5
metabolite NOA 427011 ([8,9-Z]-avermectin B_{1a})[1]	Acute	0.0077	3247	10
metabolite NOA 448112 (8a-hydroxy-avermectin B_{1a})	Acute	0.003	53667	10

1: for this metabolite no PEC_s was calculated as this metabolite was not identified in the soil biodegradation studies. Therefore, the maximum initial PEC_s is used for risk assessment

Crop and application rate: tomatoes (field) / 3 x 0.0216 kg as/ha

Test substance	Time scale	Soil PEC	TER	Trigger
abamectin	Acute	0.0154	1071	10

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Test substance	Time scale	Soil PEC	TER	Trigger
abamectin	Chronic	0.0154	≥ 23	5
metabolite NOA 427011 ([8,9-Z]-avermectin B_{1a})[1]	Acute	0.0154	1623	10
metabolite NOA 448112 (8a-hydroxy-avermectin B_{1a})	Acute	0.007	23000	10

1: for this metabolite no PEC_s was calculated as this metabolite was not identified in the soil biodegradation studies. Therefore, the maximum initial PEC_s is used for risk assessment

Crop and application rate: tomatoes (glasshouse) / 5 x 0.0216 kg as/ha

Test substance	Time scale	Soil PEC	TER	Trigger
abamectin	Acute	0.0154	1071	10
abamectin	Chronic	0.0154	≥ 23	5
metabolite NOA 427011 ([8,9-Z]-avermectin B_{1a})[1]	Acute	0.0154	1623	10
metabolite NOA 448112 (8a-hydroxy-avermectin B_{1a})	Acute	0.011	14636	10

1: for this metabolite no PEC_s was calculated as this metabolite was not identified in the soil biodegradation studies. Therefore, the maximum initial PEC_s is used for risk assessment

Extension of approval

Crop and application rate: soil drip application in tomato (glasshouse)/ 6 x 0.1 kg as/ha

Test substance	Time scale	Soil PEC	TER	Trigger
abamectin	Acute	0.136	121	10
abamectin	Chronic	0.136	**≥ 2.6***	5

* Not in all Member States the soil in glasshouses is considered as a natural soil with a natural soil community. E.g. in The Netherlands no risk assessment is performed for soil organisms regarding glasshouse uses, because management practice includes regular sterilisation of the soil, which prevents the formation of a natural soil organism community within glasshouses. Hence, refinement of the risk can be considered as a Member State issue.

Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)

Preliminary screening data

Vertimec 0.18 EC:

seedling emergence:
no effect on maize, wild oat, onion, sugar beet, oilseed rape and soybean at 50.6 g as/ha

vegetative vigour:
no effect on of maize, wild oat, onion, sugar beet and oilseed rape at 50.6 g as/ha
slight effect on vegetative vigour of soybean at 25.3 and 50.6 g as/ha (rating 8.5 and 8 out of 9)

List of end points

Rapporteur Member State	Month and year	Active Substance (Name)
The Netherlands	February 2008 April 2015	Abamectin

Ecotoxicology

Effects on biological methods for sewage treatment (Annex IIA 8.7)

Test type/organism	end point
Activated sludge	EC_{20}, EC_{50} and EC_{80} > 100 mg/L
Pseudomonas sp	NA

Ecotoxicologically relevant compounds (consider parent and all relevant metabolites requiring further assessment from the fate section)

Compartment	
soil	Avermectin B1a
water	Avermectin B1a, but data gap needs to be filled before can be finalised
sediment	Avermectin B1a, but data gap needs to be filled before can be finalised
groundwater	Avermectin B1a, fate data gap needs to be filled on U8 before can be finalised

Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)

	RMS/peer review proposal
Active substance	R50/53

	RMS/peer review proposal
Preparation	S60, S61