European Commission

Addendum

VOLUME 1

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

Version history page

Date	Version history
April 2015	Initial version

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- *Active substance* –

Statement of subject matter and purpose for which this report has been prepared and background information on the application

1 Statement of subject matter and purpose for which this report has been prepared and background information on the application

1.1 Context in which the draft assessment was prepared.

1.1.1 Purpose for which the draft assessment report was prepared

This addendum to the Draft Assessment Report (DAR) is prepared for an extension of the conditions of approval for the active substance abamectin. Abamectin is currently approved as insecticide, acaricide. Abamectin is now applied for as nematicide.

1.1.2 Arrangements between rapporteur Member State and co-rapporteur Member State

Not applicable.

1.1.3 EU Regulatory history for use in Plant Protection Products

Abamectin is approved since 1 May 2009 (Commission Regulation 2008/107/EC; Commission Implementing Regulation (EU) No 540/2011). The current expiry date is 30 April 2019.
The EFSA conclusion (EFSA Scientific Report (2008) 147) is finalised on 29 May 2008 and provides endpoints agreed during the first inclusion evaluation. The Review Report (SANCO/138/08 –final) is dated 11 July 2008.
Confirmatory data have been submitted for abamectin. These were considered and in November 2012 the Standing Committee on Food Chain and Animal Health took note of the revised Review Report (SANCO/138/08 – final dated 20 November 2012).

1.1.4 Evaluations carried out under other regulatory contexts

Not applicable. Not taken into consideration for this evaluation.

1.2 Applicant(s) information

1.2.1 Name and address of applicant for amendment of the conditions of approval of the active substance

Name: Syngenta Crop Protection AG
Address: CH 4002 – Basel
Switzerland
Contact: [redacted]
Syngenta Crop Protection AG
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Telephone number: [redacted]
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1.2.2 Producers of the active substance

Refer to original DAR. The producer of the active substance did not change.

1.2.3 Information relating to the collective provisions of dossiers

Not applicable.

1.3 Identity of the active substance

Refer to original DAR. The identity of the active substance did not change.

1.4 Information on the plant protection product

1.4.1 Applicant

Name: Syngenta Crop Protection AG
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1.4.2 Producer of the plant protection product

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Fax number: [redacted]
E-mail: [redacted]

1.4.3 Trade name or proposed trade name and producer's development code number of the plant protection product

Trade name	Tervigo
Syngenta internal code number	A12115I

1.4.4 Detailed quantitative and qualitative information on the composition of the plant protection product

Abamectin content (typical purity of 92%)

Technical active substance	21.7 g/L	1.81%w/w
Pure active substance	20 g/L	1.67%w/w

1.4.5 Type and code of the plant protection product

Suspension concentrate (SC).

1.4.6 Function

Nematicide.

1.4.7 Field of use envisaged

For the use as a nematicide as a soil drip (soilbound application) for the control of root-knot nematodes (*Meloidogyne* spp.) in tomato, eggplant, pepper, cucurbits - edible peel (cucumber, zucchini, etc), cucurbits - inedible peel (melon, watermelon, squash) and green beans .

1.4.8 Effects on harmful organisms

In foliar use, main activity is triggered by ingestion, but in nematodes control, due to the difference of pest behaviour and their life cycles, contact activity in the soil solution is the main source of pest control. Treated pests rapidly become paralyzed and eventually die: although feeding stops almost immediately, it can take up to 2-4 days for death to occur. The screening tests with nematodes showed the irreversible stop of the activity after 24 h.

1.5 Detailed uses of the plant protection product (to be included for each preparation for which documentation was submitted).

1.5.1 Details of representative uses

The product is intended for the use as a nematicide as a soil drip (soilbound application) for the control of root-knot nematodes (*Meloidogyne* spp.) in tomato, eggplant, pepper, cucurbits - edible peel (cucumber, zucchini, etc), cucurbits - inedible peel (melon, watermelon, squash) and green beans.

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	
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:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*eg.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) eg. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(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
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

1.5.2 Further information on representative uses

Refer to GAP table.

1.5.3 Details of other uses applied for to support the setting of MRLs for uses beyond the representative uses

Not applicable.

1.5.4 Overview on authorisations in EU Member States

Not applicable.

Volume 1

Level 2

- *Abamectin* –

Summary of active substance hazard and of product risk assessment

2 Summary of active substance hazard of product risk assessment

2.1 Identity

2.1.1 Summary of identity

No new data on abamectin was evaluated. Please refer to the original DAR.

The new representative product A12115I, is a suspension concentrate (SC), containing 20 g/L pure active substance.

2.2 Physical and chemical properties

2.2.1 Summary of physical and chemical properties of the active substance

No new data on abamectin was evaluated. Please refer to the original DAR.

2.2.2 Summary of physical and chemical properties of the plant protection product

A12115I is a black/red liquid with no particular odour. It does not require classification regarding it's physical and chemical properties. Its density is 1.198g/cm^3 and its pH is 7.8, with an alkalinity of 0.16%, expressed as NaOH. Its viscosity is non-Newtonian and ranges between 70 and 436 mPa.s depending on temperature and shear rate. The product should be considered surface active, based on a surface tension of 37.2 mN/m at 20°C.

HDPE and PET are considered acceptable packaging types for A12115I, based on the shelf-life data provided. The product remained physically and chemically stable for 2 years at ambient temperatures in both packaging types. In addition, the product is stable at low temperatures and for 2 weeks at 54°C. It's technical properties indicate the product can be used as intended.

2.3 Data on application and efficacy

2.3.1 Summary of effectiveness

At the proposed rate of 5 l/ha Tervigo (A12115I) is effective against the root-knot nematode (Meloidogyne spp.). As root-knot nematodes are causing the damage throughout the season and hatching occurs during an extended period, several applications of A12115I at 5 L/ha should be used to efficiently control the pest. For eggplant, pepper, melon, watermelon, cucumber, zucchini and green bean the recommended and maximum number of applications for the whole season control is 4, while on tomato the maximum number of application per season is 6 . For tomato the applicants asks for six applications because tomato is a crop where farmers make long growing cycles (much more often than in other fruiting vegetable crops). The product Tervigo is not a soil sterilant, so I doesn't kill inactive stage of the nematodes (eggs), it kills only active larval stages. Tervigo gives protection for about 14 days (best case). With 4 applications of Tervigo plant is protected for about 50 days. Larva which hatch after this period are not affected by Tervigo. For short cycle crops infection at this late stage (up to 120 days) will not affect the yield, since the time period for population growth and galling

development is not long enough (farmer finishes the growing). In the crop cycles of 6 months or more (which is quite often for tomato) infection in that late period can affect the late harvesting.

Trials only have been conducted in the Mediterranean EPPO zone. For approval of the active substance these trials show that the proposed dose rate is sufficiently effective. The main goal of evaluation of efficacy for registration of an active substance is to check if the requested dose rates are realistic, this is important for determination of the risk envelope for the other aspects.
For the purpose of creating a realistic GAP (table of uses) for registration of the active substance the submitted efficacy data can be considered sufficient. For registration of the product additional trials or argumentation would be required to justify that the product is also is also effective under other conditions (eg. other EPPO zones).

2.3.2 Summary of information on the development of resistance

A12115I is a non fumigant nematicide. Application by drip irrigation system means that the product is applied in a row strip. A large part of the inter row area stays without the presence of the product, which means that this area is a kind of a buffer zone which prevents the occurrence of the resistance of nematode population to A12115I.

The evaluation for resistance risk and resistance management strategies will done in more detail during product registration.

2.3.3 Summary of adverse effect on treated crops

No phytotoxicity symptoms caused by A12115I at the proposed use rate of 5 l/ha were recorded in any trial.

2.3.4 Summary of observations on other undesirable or unintended side-effects

None.

2.4 Further information

2.4.1 Summary of methods and precautions concerning handling, storage, transport or fire

All relevant data was provided. Please refer to volume 3, B4, for more information.

2.4.2 Summary of procedures for destruction or decontamination

All relevant data was provided. Please refer to volume 3, B4, for more information.

2.4.3 Summary of emergency measures in case of an accident

All relevant data was provided. Please refer to volume 3, B4, for more information.

2.5 Methods of analysis

2.5.1 Methods used for the generation of pre-authorisation data

2.5.2 Methods for post control and monitoring purposes

A suitable analytical method for the preparation was provided, based on HPLC-UV.

No new data on residue analytical methods was considered. Please refer to the original DAR.

2.6 Effects on human and animal health

2.6.1 Summary of absorption, distribution, metabolism and excretion in mammals

Not applicable. Please refer to the original DAR.

2.6.2 Summary of acute toxicity

Not applicable. Please refer to the original DAR.

2.6.3 Summary of short-term toxicity

Not applicable. Please refer to the original DAR.

2.6.4 Summary of genotoxicity

Not applicable. Please refer to the original DAR.

2.6.5 Summary of long-term toxicity and carcinogenicity

Not applicable. Please refer to the original DAR.

2.6.6 Summary of reproductive toxicity

Not applicable. Please refer to the original DAR.

2.6.7 Summary of neurotoxicity

Not applicable. Please refer to the original DAR.

2.6.8 Summary of further toxicological studies on the active substance

Not applicable. Please refer to the original DAR.

2.6.9 Summary of toxicological data on impurities and metabolites

Not applicable. Please refer to the original DAR.

2.6.10 Summary of medical data and information

Not applicable. Please refer to the original DAR.

2.6.11 Toxicological end point for assessment of risk following long-term dietary exposure – ADI

No new data on abamectin was considered. Please refer to the original DAR.

The ADI for the original inclusion was concluded to be 0.0025 mg/kg bw/day based on the 18 and 53 week dog study.

2.6.12 Toxicological end point for assessment of risk following acute dietary exposure – ARfD (acute reference dose)

No new data on abamectin was considered. Please refer to the original DAR.

The ARfD for the original inclusion was concluded to be 0.005 mg/kg bw/day based on the acute neurotoxicity study in rat.

2.6.13 Toxicological end point for assessment of occupational, bystander and residents risks – AOEL

No new data on abamectin was considered. Please refer to the original DAR.

The AOEL for the original inclusion was concluded to be 0.0025 mg/kg bw/day based on the 18 and 53 week dog study.

2.6.14 Summary of product and risk assessment

A12115I containing 20 g/L abamectin has a low toxicity in respect of acute oral, dermal and inhalation toxicity and is not irritating to the rabbit skin or eye and is not a skin sensitiser. The classification according to Regulation (EC) 1272/2008 as amended, is given in the table below.

Table 2.6.14-1: Summary of acute toxicological data obtained with A12115I

Parameter [Reference]	Species	Result	Classification according to Regulation (EC) 1272/2008 as amended
Acute oral MLD [redacted 2009a]	Rat	LD_{50} = 1086 mg/kg (female)	Acute Tox. 4, H302 (Harmful if swallowed)
Acute dermal MLD [redacted 2010]	Rat	LD_{50} > 5000 mg/kg	No classification
Acute inhalation MLC [redacted 2009]	Rat	LC_{50} >1.02mg/L	Acute Tox. 4, H332 (Harmful if inhaled)
Acute skin irritation [redacted 2009b]	Rabbit	Not irritant	No classification
Acute eye irritation [redacted 2009c]	Rabbit	Slightly irritating	No classification
Skin sensitisation [redacted 2009d]	Guinea Pig	Not a sensitiser (modified Buehler)	No classification

The product A12115I is an SC formulation intended to be used as a soil drip irrigation in greenhouses. As the method of application is by soil drip and not a foliar spray, then there will not be any exposure

to the operator during the application. The only point where exposure is a possibility is during mixing and loading of the tank.

Exposures and risk assessments are specified in Table 2.6.14-2.

Table 2.6.14-2 Operator exposure and risk assessment

Application method	Model	Total systemic exposure (mg/kg bw/day)[1]	% of AOEL
Hand-held application, high crops	German model	0.00034371	13.75

[1] Systemic exposure based on dermal absorption of 10%, and respiratory absorption of 100% for the concentrate during mixing and loading of A12115I.

As the product is intended to be used in by soil drip in greenhouse bystander and resident exposure is not relevant.

For the worker since the product is applied by soil drip irrigation there will be no residue on the leaf surface and therefore there is no worker re-entry exposure scenario.

Conclusions on risk assessments for operators, bystanders and workers

Operator

- Using the German model, safe uses were identified for operators, without PPE, for:
  - Soil drip in pepper, aubergine, tomato, cucurbits, green beans in greenhouses

Bystander and residents

There is no risk of residential exposure or to the bystander as there is no likelihood of incidental short-term exposure to A12115I

Worker

There is no risk anticipated for the worker when re-entering crops treated with A12115I by soil drip irrigation.

2.7 Residues

2.7.1 Summary of storage stability of residues

Storage stability of avermectin B1a, avermectin B1b and avermectin B1a delta-8,9-Z-isomer was proven in high acid (orange peel), high oil (sunflower seed), high protein (runner bean), high starch (potato), high water (tomato) matrices for at least 24 months (orange peel 12 months) when stored at -18°C.

2.7.2 Summary of metabolism, distribution and expression of residues in plants, poultry, lactating ruminants, pigs and fish

No new additional metabolism studies were submitted for the extension of approval, since the metabolism studies in the dossier evaluated during the peer review contain sufficient information to elucidate the metabolic route in fruit and fruiting vegetables and in leafy vegetables.

Metabolism studies and feeding studies in livestock are not necessary, since the crops in the intended use are generally not used as livestock feed.

2.7.3 Definition of the residue

The residue definition for risk assessment and monitoring is defined as the combination of avermectin B1a, avermectin B1a δ-8,9 isomer and avermectin B1b, expressed as avermectin B1a.

2.7.4 Summary of residue trials in plants and identification of critical GAP

In protected tomato, peppers, cucumbers and green beans two acceptable supervised residue trials are available. In protected melons, three acceptable supervised residue trials are available. No detectable residues above the LOQ of 0.002 mg/kg (per analyte) were found in any of the crops.
The trials can be used as bridging studies to show that the foliar treatment with abamectin as an acaricide is worst case compared to the drip irrigation treatment and that the foliar treatment drives the MRL.

2.7.5 Summary of feeding studies in poultry, ruminants, pigs and fish

Livestock and fish feeding studies are not available and not required.

2.7.6 Summary of effects on processing

No new processing studies were submitted. A nature of residues study was evaluated during the peer review of abamectin. Processing studies are considered not necessary since residues are below the LOQ of 0.002 mg/kg.

2.7.7 Summary of residues in rotational crops

No new additional studies in rotational crops were submitted for the extension of approval, in the dossier evaluated during the peer review it was sufficiently proven that residues of abamectin in rotational crops are not to be expected.

2.7.8 Summary of other studies

No other studies were submitted.

2.7.9 Estimation of the potential and actual exposure through diet and other sources

The maximum TMDI for abamectin for the crops in the intended use and the existing EU-MRLs is 4.8% for WHO Cluster Diet B and the maximum IESTI is 63% for peppers.

2.7.10 Proposed MRLs and compliance with existing MRLs

For the supported uses of abamectin as a nematicide, no new MRLs are proposed, since the existing use as an acaricide drives the MRL. MRls have been set in reg 9EC) 396/2005. Art 6 MRL applications are ongoing and recently, the reasoned opinion on the review of existing MRLs for abamectin in the framework of art 12 of Reg 9EC) 396/2005 wa spublished (EFSA Journal 2014;12(9):3823 [84 pp.].).

2.7.11 Proposed import tolerance and compliance with existing import tolerances

Import tolerances are currently not proposed for abamectin.

2.8 Fate and behaviour in the environment

2.8.1 Summary of fate and behaviour in soil

Not applicable. Please refer to the original DAR.

2.8.2 Summary of fate and behaviour in water and sediment

Not applicable. Please refer to the original DAR.

2.8.3 Summary of fate and behaviour in air

Not applicable. Please refer to the original DAR.

2.8.4 Summary of monitoring data concerning fate and behaviour of the active substance, metabolites, degradation and reaction products

Not applicable. Please refer to the original DAR.

2.8.5 Definition of the residue in the environment requiring further assessment

Not changed. Please refer to the original DAR.

2.8.6 Summary of exposure calculations and product assessment

PECsoil

PECsoil calculations are required in the EFSA Guidance Document on ranking and clustering for protected crops [1](March 2014) for walk-in tunnels as if it were open field.

PECsoil calculations are based on the maximum field DT50 of the substance of 1.8 days (first order kinetics).

Table 2.8.6-1 PECsoil calculations for the representative uses (walk-in tunnels)

[1] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

Crop	Number of applications	Maximum use rate [g a.s./ha]	Minimum application interval (days)	Earliest growth stage at application	Crop interception [%]	Effective soil exposure rate per application [g a.s./ha]	PECS [mg a.s./kg]
Green Beans	2	100	10	BBBCH12	0	100	0.136
	4					100	0.136
Fruiting Vegetables	2				0	100	0.136
	6					100	0.136
Cucurbits*	2				0	100	0.136
	4					100	0.136

* also covering for the pepper/aubergine crop

The indicated number of applications does not entirely match the Table of Intended uses (6 applications + 4 applications in a second crop cycle). RMS therefore additionally assessed PECsoil for 10 applications (with a ten day interval). This gave the same result of **0.136 mg/kg** abamectin in soil, relevant for use in the ecotoxicological risk assessment. A PECplateau assessment is not relevant. No soil exposure assessment for the metabolites is considered necessary since their risk to soil organisms is covered by the parent assessment.

PECgw

The FOCUS simulation models FOCUS-PEARL (v 4.4.4) and FOCUS-PELMO (v 5.5.3) were used for the leaching assessment.

Abamectin is intended for indoor application to beans and tomatoes at BBCH 12-89, *via* drip irrigation to the soil surface. Up to six applications of abamectin, each at an application rate of 100 g a.s./ha, can be made to a single crop, and two crop cycles are possible in a given year. As a worst-case representation of this use pattern, a single application of abamectin was simulated at the maximum annual application rate of 1200 g a.s./ha. Additional simulations were also performed using an exaggerated annual application rate of 1 × 5000 g a.s./ha. RMS notes that in principle for groundwater asessments it is not always worst-case to pool all applications together instead of modelling a series of applications at different application dates. However, for this substance and its metabolites this is considered acceptable.

Both early-season and late-season applications were simulated, at approximately BBCH 12 and BBCH 89, respectively. The current versions of the FOCUS groundwater models are unable to simulate application *via* drip irrigation, therefore 'incorporation' was selected as the application method in the FOCUS-PEARL interface, and the incorporation depth was set to 10 cm. An application depth of 10 cm was also defined in the FOCUS-PELMO interface.

The agreed modelling endpoints were used, with the exception of a moisture correction for the DT50 values. Full details on this normalisation is given in Volume 3. It is noted that this in fact leads to the derivation of new Annex II endpoints, which is not within the scope of this application for extension of

the approval. In this particular case the RMS is confident that the changes to the endpoints do not compromise the conclusion on the risk for leaching.

See Table 2.8.6-2 for input values. For all substances a crop uptake factor of 0 was used. Q10 was 2.58.

Table 2.8.6-2 Summary of input parameters for abamectin, NOA448111, NOA448112, NOA457464 and NOA457465 for the leaching simulation models FOCUS-PEARL (v 4.4.4) and FOCUS-PELMO (v 5.5.3)

Physical chemistry properties			
	Molecular weight [g/mol]	**Water solubility at 25°C [mg/L]**	**Vapour pressure at 20°C [Pa]**
Abamectin	873.1	1.21	0
NOA448111	887.1	51 (at 20°C)	0
NOA448112	889.1	13.8 (at 20°C)	0
NOA457464	905.1	1.21	0
NOA457465	902.1	1.21	0
Degradation in soil			
	DT_{50} laboratory soil [d]	**Molar formation fraction[-] source to sink relation [-]**	**Transformation rate [a] [-]**
Abamectin	18.3	0.23 to NOA448111 0.30 to NOA448112 (0.47 to CO_2)	0.008712 to NOA448111 0.011363 to NOA448112 (0.017802 to CO_2)
NOA448111	28.8	0.85 to NOA457465 (0.15 to CO_2)	0.020457 to NOA457465 (0.003610 to CO_2)
NOA448112	22.7	0.58 to NOA457464 (0.42 to CO_2)	0.017710 to NOA457464 (0.012825 to CO_2)
NOA457464	43.4	NA	0.015971 to CO_2
NOA457465	74.1	NA	0.009354 to CO_2
Sorption to soil			
	K_{FOC} [L/kg]	**K_{FOM} [L/kg]**	**Freundlich exponent 1/n [-]**
Abamectin	5638	3270	0.95
NOA448111	3997	2318	0.83
NOA448112	1943	1127	0.87
NOA457464	1738	1008	0.91
NOA457465	3908	2267	0.94

[a] for PELMO; (ln(2) / DT_{50}) * FFm

For the active substance, abamectin, and the metabolites NOA448111, NOA448112, NOA457464 and NOA457465, the overall maximum PEC_{GW} in leachate at 1 m soil depth does not exceed 0.001 µg/L.

PECsw/sed

In line with EFSA Guidance Document on ranking and clustering for protected crops [2](March 2014) the approach described for walk-in tunnels was followed by the applicant.
Simulations were only considered for drainage scenarios. Four and six drip irrigation applications each at a rate of 100 g a.s./ha, from approximately BBCH 12 and with an interval of 10 days were considered. Drip irrigation application (incorporation) was considered as the application method in all simulations. Details on application windows and the approach to deal with a second crop cycle (alteration of crop development dates to match agronomic practice) are described in Volume 3.
The approach used to simulate two crop cycles seems valid to the RMS. In the FOCUS sws guidance document it is indicated (paragraph 5.2.3) that when two crops per year are grown these are run separately and the one producing the highest PEC value is used for further assessment. In that regard the approach chosen by the notifier is conservative.

See Table 2.8.6-3 for input values.

Table 2.8.6-3 Summary of input parameters for abamectin used in FOCUS Step 3 simulations

Physical chemistry properties			
	Molecular weight [g/mol]	**Water solubility at 25°C [mg/L]**	**Vapour pressure at 25°C [Pa]**
Abamectin	873.1	1.21	3.7×10^{-6}
Degradation in soil			
	DT_{50} field soil [d]	**DT_{50} laboratory soil [d]**	**Formation fraction[-] [a]**
Abamectin	NA	28.7	NA
Degradation in water/sediment systems			
	Whole System DT_{50} [d]	**Water phase DT_{50} [d]**	**Sediment phase DT_{50} [d]**
Abamectin	89	1000	89
Sorption to soil			
	K_{FOC} [L/kg]	**K_{FOM} [L/kg]**	**Freundlich exponent 1/n [-]**
Abamectin	5638	3270	0.94

[2] EFSA Guidance Document on clustering and ranking of emissions of active substances of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. EFSA Journal 2014;12(3):3615, 43 pp., doi:10.2903/j.efsa.2014.3615

Crop parameters			
	Crop uptake factor [-]	**Foliar extraction coefficient [1/cm] [b]**	**Foliar DT_{50} [d]**
Abamectin	0	0.5	10

NA – not applicable
[a] for metabolite simulations
[b] for FOCUS-PRZM; 0.05 mm^{-1} for FOCUS-MACRO

The global maximum PEC_{SW} and PEC_{SED} values generated by the simulations at Step 3, along with the exact application dates, are given in Tables 2.8.6-4 - 7. For time weighted average values please refer to Volume 3.

Table 2.8.6-4 Global maximum Predicted Environmental Concentrations of abamectin at Step 3 for 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

Table 2.8.6-5 Global maximum Predicted Environmental Concentrations of abamectin at Step 3 for 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

Table 2.8.6-6 Global maximum Predicted Environmental Concentrations of abamectin at Step 3 for early 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	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

Table 2.8.6-7 Global maximum Predicted Environmental Concentrations of abamectin at Step 3 for 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

The result shows that for this scenario abamectin does not enter the surface water by drainage which is understandable from its sorption properties. It is noted that the D6 scenario has a very specific drain flow timing, irrespective of the date of application. When looking at the scenario description in the

FOCUS sws guidance (paragraph 6.2.2) it becomes clear that drainflow only occurs between January and April, with the highest drainflow occurring in January. The fact that only D6 is modelled (since it is the only scenario available for fruiting vegetables) with drain events very far away from the time of application creates a rather small basis for the assessment. For instance the D2 and D3 scenarios show a much more diverse drain event pattern. However based on the substance properties (quick degradation, high sorption) the RMS is content that the exposure assessment is covered by the submitted modelling.
It is noted that no surface water exposure assessment for the metabolites was submitted. This is not considered necessary since their risk to aquatic organisms is covered by the parent assessment.

PECair
No additional assessment was required for the extension of the approval.

2.9 Effects on non-target species

2.9.1 Summary of effects on birds and other terrestrial vertebrates
Not applicable. Please refer to the original DAR.

2.9.2 Summary of effects on aquatic organisms
Not applicable. Please refer to the original DAR.

2.9.3 Summary of effects on arthropods
Not applicable. Please refer to the original DAR.

2.9.4 Summary of effects on non-target soil meso- and macrofauna
Not applicable. Please refer to the original DAR.

2.9.5 Summary of effects on soil nitrogen transformation
Not applicable. Please refer to the original DAR.

2.9.6 Summary of effects on terrestrial non-target higher plants
Not applicable. Please refer to the original DAR.

2.9.7 Summary of effects on other terrestrial organisms (flora and fauna)
Not applicable. Please refer to the original DAR.

2.9.8 Summary of effects on biological methods for sewage treatment
Not applicable. Please refer to the original DAR.

2.9.9 Summary of product exposure and risk assessment

2.9.9.1 Risk assessment for birds

Acute, short-term and (sub-)chronic dietary toxicity data

An overview of avian toxicity data for abamectin and the formulation A12115I is given in Table 2.9.9.1-01 and -02.

Table 2.9.9.1-01: EU Conclusions - Toxicity to birds of abamectin

Study	Test species	EU agreed endpoints (EFSA Scientific report No. 147 (2008))	Proposed endpoint[1]
Acute toxicity	*Anas platyrhynchos*	LD_{50} : ≤ 77 mg/kg/bw/day	LD_{50} : 26 mg/kg bw/day
Dietary toxicity (short-term)	*Anas platyrhynchos*	LC_{50} : 48.6 mg/kg/bw/day	-
Reproductive toxicity (long-term)	*Anas platyrhynchos* (males)	NOEC: 1.33 mg/kg/bw/day	-

[1] Since Annex I submission new calculations have been performed and as a result there is a new endpoint which is agreed by the EU experts and used in the risk assessment.

Table 2.9.9.1-02: Summary of avian toxicity endpoints for A12115I

Study type	Test substance	Species	Endpoint	Value
Acute oral toxicity	A12115I	Northern Bobwhite *(Colinus virginianus)*	14 d LD_{50}	>2000 mg A12115I/kg bw

Risk assessment

Since the application is indoors, no exposure of birds 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.

Exposure via drinking water (surface water)

The risk from exposure through drinking surface water is calculated for a small bird with body weight 10 g and a DWI (daily water intake) of 2.7 g/d. Surface water concentrations are calculated in section B.8. The PECsw is very low: < 0.0001 µg/L. Hence, a low risk is expected via this route.

Indirect exposure via contaminated fish

The concentration in fish is calculated according to the Guidance Document on risk assessment for birds and mammals (2009) as:

PEC_{fish} = 21-days TWA-PEC_{SW} x BCF.

Because the PECsw is very low (< 0.0001 µg/L) a low risk is expected via this route.

2.9.9.2 Risk assessment for aquatic organisms

An overview of aquatic toxicity data for abamectin is given in Table 2.9.9.2-01 (active substance and metabolites) and -02 (formulation A12115l).

Table 2.9.9.2-01: EU Conclusions - Toxicity to aquatic organisms of abamectin, metabolite NOA 427011, metabolite NOA 448112 and metabolite NOA 426289

Test substance	Test species	Test Type/Duration	EU agreed endpoints (EFSA Scientific report No. 147 (2008)) µg as/L
Acute toxicity to fish			
abamectin	*Oncorhynchus mykiss*	96 hr (static)	Mortality, LC_{50}: 3.6 (nom)
abamectin	*Oncorhynchus mykiss*	96 hr (flow-through; modified exposure test)	Mortality, LC_{50}: 8.7 (nom)
Vertimec 018EC	*Oncorhynchus mykiss*	96 hr (flow-through)	Mortality, LC_{50}: 2.3 (nom)
8,9-Z-avermectin B_{1a} (NOA 427011)	*Oncorhynchus mykiss*	96 hr (flow-through)	Mortality, LC_{50}: 5.1 (mm)
8a-hydroxyavermectin B_{1a} (NOA 448112)	*Oncorhynchus mykiss*	96 hr (semi-static)	Mortality, LC_{50}: 520 (mm)
Chronic toxicity to fish			
abamectin	*Oncorhynchus mykiss*	28 day (flow-through)	NOEC: 0.52 (mm)
Acute toxicity to aquatic invertebrates			
abamectin	*Daphnia pulex*	48 h (static)	Mortality, EC_{50}: 0.12 (mm)
Vertimec 018 EC	*Daphnia magna*	48 h (flow-through)	Mortality, EC_{50}: 0.59 (mm)
8,9-Z]-avermectin B_{1a} (NOA 427011)	*Daphnia magna*	48 h (static)	Mortality, EC_{50}: 0.082 (mm)
8a-hydroxyavermectin B_{1a} (NOA 448112)	*Daphnia magna*	48 h (static)	Mortality, EC_{50}: 1.6 (mm)
4”-oxoavermectin B_{1a} (NOA 426289)	*Daphnia magna*	48 h (static)	Mortality, EC_{50}: 0.28 (nom)
Chronic toxicity to aquatic invertebrates			
abamectin	*Daphnia magna*	21 day (flow-through)	Reproduction NOEC: 0.010 (nom)
Toxicity to algae			
Vertimec 018 EC	*Pseudokirchneriella subcapitata*	72 h (static)	Biomass: E_bC_{50}: >1590 (nom) Growth rate: E_rC_{50}: >1590 (nom)
8,9-Z]-avermectin B_{1a} (NOA 427011)	*Pseudokirchneriella subcapitata*	72 h (static)	Biomass: E_bC_{50}: >9000 (nom) Growth rate: E_rC_{50}: >9000 (nom)
8a-hydroxyavermectin B_{1a}	*Pseudokirchneriella subcapitata*	72 h (static)	Biomass: E_bC_{50}: >6100 (mm) Growth rate: E_rC_{50}: >6100

Test substance	Test species	Test Type/Duration	EU agreed endpoints (EFSA Scientific report No. 147 (2008)) µg as/L
(NOA 448112)			(mm)
Toxicity to Higher Plants			
Insecticide - Not applicable 14 d EC_{50}: 3900			
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 B_{1a} to aquatic invertebrates is considered to be covered by the mesocosm studies. The risk to fish needs to be addressed.			"It was concluded by the meeting that the NOEC from this study (0.2 µg a.s./L) can be used for risk assessment of ditches and streams. The experts recommended a safety factor of 2 to address uncertainty with regard to differences in species sensitivity. Frequency of application should not be of influence on the NOEC-value and the endpoint of the study with one application can also be used for the risk assessment of uses with three applications. The NOEAEC of 0.049 µg a.s./L from the study with a conventional static system (3 applications of the test substance) together with a safety factor of 3 was agreed upon and should be used for ponds and the glasshouse applications."

* Since Annex I submission/inclusion new studies/calculations for the active substance have been performed and as a result there are new end-points which are used in the risk assessment.
Nom: Nominal
mm : mean measured concentrations

Table 2.9.9.2-02: Endpoints for formulation A12115l

Test substance	Test species	Test Type/Duration	Endpoint µg as/L
A12115l	*Oncorhynchus mykiss*	96 hr (static)	LC50: 5.86 (mean measured)
A12115l	*Daphnia magna*	48 h (static)	EC50: 0.00759 (mean measured)
A12115l	*Pseudokirchneriella subcapitata*	72 h (static)	EC50 > 0.781 (mean measured)

Risk assessment

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 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.

The risk of metabolites which are formed in water are covered by the risk assessment of the parent.

2.9.9.3 Risk assessment for other terrestrial vertebrates than birds

An overview of mammalian toxicity data for abamectin and the formulation A12115I is given in Table 2.9.9.3-01 and -02.

Table 2.9.9.3-01: EU Conclusions - Toxicity to mammals of abamectin

Study	**Test species**	**EU agreed endpoints (EFSA Scientific report No. 147 (2008))**
Acute toxicity	Rat	LD50 = 8.7 mg/kg bw
Long-term toxicity	Rat	NOEC = 0.12 mg/kg bw/d

Table 2.9.9.3-02: Toxicity to mammals of formulation A12115I

Study	**Test species**	**EU agreed endpoints (EFSA Scientific report No. 147 (2008))**
Acute toxicity	Rat	LD50 = 1086 mg A12115I /kg bw

Risk assessment

Since the application is indoors, no exposure of 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.

Exposure via drinking water

The risk from exposure through drinking from surface water is calculated for a small mammal with body weight 10 g and a DWI (daily water intake) of 1.57 g/d. Surface water concentrations are calculated in section B.8. The PECsw is very low: < 0.0001 µg/L. Hence, a low risk is expected via this route.

Indirect exposure via contaminated fish

The concentration in fish is calculated according to the Guidance Document on risk assessment for birds and mammals (2009) as:

PEC_{fish} = 21-days TWA-PEC_{SW} x BCF.

Because the PECsw is very low (< 0.0001 µg/L) a low risk is expected via this route.

2.9.9.4 Risk assessment for bees

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.

2.9.9.5 Risk assessment for other non-target arthropods

The notifier argues that the proposed indoor drip use will result in negligible exposure through overspray and through contact with residues on plants. Hence, the risk for foliar non-target arthropods is negligible and only the risk to soil dwelling non-target arthropods is relevant. The RMS can agree with this argument.
Below the risk by exposure to soil is assessed.

For abamectin only toxicity data for the beetle *Poecilus cupreus* are available (see table below).

Table 2.9.9.5-01: Toxicity of abamectin to *Poecilus cupreus*

Species	Test Type	Vertimec 018EC Treatment Rates	Endpoints
Poecilus cupreus (Ground beetle)	Laboratory, inert sand substrate	1.2 - 58 g a.s./ha	0% mortality at all rates LR_{50}>58 g a.s./ha
	Lab/semi-field	2 x 5.4 g a.s./ha 2 x 27 g a.s./ha	<50% corrected mortality after 2nd application <50% effect on fecundity after 2nd application

Risk assessment

A12115I is applied at a maximum rate of 100 g as/ha. This dose rate must be multiplied with the MAF. For soil residues, a DT50 of 0.65 days is used. That means that there will be no build-up of the active substance between the applications. Hence the MAF is assumed to be 1.

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. Furthermore it is not considered sufficient to test only one soil species, which is also known as fairly insensitive, when the use is directly on soil. A test on *Folsomia candida* or *Hypoaspis aculeifer* is required.

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, the requirement mentioned above can be considered as a requirement on Member State level.

2.9.9.6 Risk assessment for earthworms and other soil non-target macro-organisms

Acute earthworm studies have been performed with abamectin, the formulation A12115I and metabolites [8,9-Z]-avermectin B_{1a} (NOA 427011) and 8a-hydroxy-avermectin B_{1a} (NOA 448112). A sub-lethal test was performed with the formulation Vertimec 0.18 EC. For A12115I no chronic test is available.The results of the studies are summarised in Table 2.9.9.6-01 and 2.9.9.6-02.

Table 2.9.9.6-01. Summary of earthworm toxicity studies with (formulations of) abamectin

Test substance	Species	Soil type	OM	T	Duration	Criterion	Value
			[%]	[°C]	[d]		[mg as/kg]
abamectin	*Eisenia fetida*	artificial	10	25	28	14-d LC_{50}	33
abamectin	*Eisenia fetida*	artificial	10	25	28	14-d LC_{50}	> 55
A12115I	*Eisenia fetida*	artificial	10	20	14	LC_{50}	> 100
Vertimec 0.18 EC	*Eisenia fetida*	artificial	10	20	56	NOEC	≥ 0.72

Table 2.9.9.6-02. Summary of earthworm toxicity studies with metabolites of abamectin

Test substance	Species	Soil type	OM	T	Duration	Criterion	Value
			[%]	[°C]	[d]		[mg/kg]
NOA 427011	*Eisenia fetida*	artificial	10	20	14	LC_{50}	50
NOA 448112	*Eisenia fetida*	artificial	10	20	14	LC_{50}	321

The two studies with abamectin were 28-day studies that were not performed according to OECD 207 or equivalent guidelines. The mortality figures after 14 days have been used to estimate the LC_{50}. Actual concentrations were measured in the second study with abamectin. The results indicate that degradation in artificial soil is slower than in natural soil with 62 - 72 % of nominal present after 28 days at 25 °C. The toxicity of abamectin in the second study was less than expected on the basis of the first study where an LC_{50} of 33 mg/kg was found. Degradation and a delay in burrowing time may have caused differences in actual exposure between studies. Abamectin caused a delay in burrowing time at levels of 23 mg/kg (nominal) and higher, a similar effect was observed for the [8,9-Z]-isomer, where burrowing was delayed at 12 mg/kg and higher.

Risk assessment

Abamectin

The acute risk assessment for earthworms is based on the highest initial PEC_S of 0.136 mg/kg (see Section B.8.3). Because the log K_{OW} of abamectin is > 2, the toxicity values are corrected to the default OM content of 5 % for agricultural soil. The lowest LC_{50} is 33 mg/kg at 10 % OM, equivalent to 16.5 mg/kg at 5 % OM. The resulting TER is 121, which is higher than the trigger of 10 and an acute risk is not expected.

The long-term NOEC is ≥ 0.72 mg/kg at 10 % OM, which is equivalent to ≥ 0.36 mg/kg at 5 % OM. At the highest initial PEC_S (0.136 mg/kg soil), the TER is **≥2.6**, indicating that there is a possible long-term risk for earthworms. This possible risk should be addressed by the notifier.

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, the requirement mentioned above can be considered as a requirement on Member State level.

Metabolites

For NOA 427011 and NOA448112, no PEC_S was calculated. As a worst case, the maximum initial PEC_S of abamectin can be used for risk assessment. The LC_{50} for NOA 427011 is 50 mg/kg at 10 % OM, equivalent to 25 mg/kg at 5 %. The resulting TER is 184, indicating a low risk for earthworms. The LC50 for NOA 448112 is 321 mg/kg at 10 % OM, equivalent to 161 mg/kg at 5 % OM. The TER is 1184, indicating a low risk.

For the other metabolites, NOA 448111, NOA 457464 and NOA 457465, no toxicity data are available. In view of the LC_{50} for NOA 448112, it can be assumed that toxicity of these metabolites will also not be higher than that of the parent. With PEC_S for these compound being lower than the PEC_S of NOA 448112, a risk is not expected and further information is not considered necessary.

2.9.9.7 Risk assessment for soil micro-organisms

A summary of the available effect data on soil micro-organisms is given in the table below.

Table 2.9.9.7-01 Effect data of abamectin and metabolites on soil micro-organisms

Nitrogen mineralisation	**abamectin**: < 25 % effect after 28 days at 0.347 mg/kg (equivalent to 216 g as/ha at 5 cm depth assuming soil bulk density 1500 kg/m^3) **NOA 427011 ([8,9-Z]-avermectin B_{1a})**: < 25 % effect after 28 days at 0.40 mg/kg **NOA 448112 (8a-hydroxy-avermectin B_{1a})**: < 25 % effect after 28 days at 0.66 mg/kg
Carbon mineralisation	**abamectin**: < 25 % effect after 28 days at 0.347 mg/kg (equivalent to 216 g as/ha at 5 cm depth assuming soil bulk density 1500 kg/m^3) **NOA 427011 ([8,9-Z]-avermectin B_{1a})**: < 25 % effect after 28 days at 0.40 mg/kg **NOA 448112 (8a-hydroxy-avermectin B_{1a})**: < 25 % effect after 28 days at 0.66 mg/kg

Risk assessment

Abamectin was found to have no unacceptable effects (< 25% compared to the control group) on soil nitrification at up to 0.347 mg product/kg. This concentration is 2.5 times higher than the maximum soil PEC of 0.136 mg a.s./kg, indicating an acceptable level of risk; no further evaluation is considered necessary.

For NOA 427011 and NOA448112, no PEC_S was calculated. As a worst case, the maximum initial PEC_S of abamectin can be used for risk assessment.
Metabolite NOA 427011 was found to have no unacceptable effects (< 25% compared to the control group) on soil nitrification at up to 0.40 mg a.s./kg, respectively. This concentration is nearly 3 times higher than the maximum soil PEC of 0.136 mg a.s./kg for the parent, indicating an acceptable level of risk.

Metabolite NOA448112 was found to have no unacceptable effects (< 25% compared to the control group) on soil nitrification at up to 0.66 mg a.s./kg, respectively. This concentration is nearly 5 times higher than the maximum soil PEC of 0.136 mg a.s./kg for the parent, indicating an acceptable level of risk.

Although the toxicity of soil metabolites NOA448111, NOA457464 and NOA457465 to soil micro-organisms has not been measured, the soil PECs were lower than for NOA448112 and exposure to the soil of these metabolites of abamectin will clearly be far lower than that for the parent due to their formation percentages.
Furthermore, although the toxicity of these metabolites to soil microorganisms has not been measured, the toxicity to aquatic organisms of those investigated is significantly lower than that of abamectin (see Point IIIA 10.2) and it is very unusual that the toxicity of a metabolite is more than ten times greater than that of the parent. On this basis, the risk from metabolites NOA448111, NOA457464 and NOA457465 is also considered to be acceptable.

2.9.9.8 Risk assessment for terrestrial non-target plants

A summary of the available toxicity data on terrestrial non-target plants is given in the table below.

Table 2.9.9.8-01 Toxicity data of Vertimec 0.18 EC on terrestrial non-target plants

herbicide profiling test	**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)

Risk assessment

Effects on non-target plants are of concern in the off-field environment, where they may be exposed to drift. The proposed uses of A12115I as an indoor soil drip will result in negligible exposure to the off-field environment. Hence, the risk to terrestrial non-target plants is acceptable.

2.9.9.9 Biological methods of sewage treatment

Emission of abamectin to sewage treatment plants may occur following the proposed use of A12115I in glasshouses. Based on the results of the activated sludge respiration test, with EC_{20}, EC_{50} and EC_{80} > 100 mg/L, no effect on biological methods of sewage treatment are expected.

2.10 Classification and labelling

No new data has been submitted which affects the harmonized classification and labelling of abamectin.

After Annex I approval abamectin has been included in Annex VI to Regulation (EC) No 1272/2008. The harmonized classification and labelling of abamectin is:

Signal word:	Danger
Hazard statements:	H300, H330, H361d, H372 (nervous system), H410

2.11 Relevance of metabolites in groundwater

None of the groundwater metabolites exceed 0.1 µg/L Therefore, no further relevance assessment is required.

2.12 Consideration of isomeric composition in the risk assessment

Not applicable.

2.13 Residue definitions

2.13.1 Definition of residues for exposure/risk assessment

To be specified for the following matrices:

Food of plant origin: not changed

Food of animal origin: not changed

Soil: not changed

Groundwater: not changed

Surface water: not changed

Sediment: not changed

Air: not changed

2.13.2 Definition of residues for monitoring

To be specified for the following matrices:

Food of plant origin: not changed

Food of animal origin: not changed

Soil: not changed

Groundwater: not changed

Surface water: not changed

Sediment: not changed

Air: not changed

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Summary and consideration with respect to the approval criteria of Regulation (EC) No 1107/2009

Identification of data gaps, proposed conditions, risk management measures, issues that could not be finalized and critical areas of concern

Proposed decisions

3 Proposed decision with respect to the application

3.1 Proposed decision

[redacted]