European Food Safety Authority

Peer Review Report on Abamectin

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April 2016

PEER REVIEW REPORT ON **ABAMECTIN** APRIL 2016

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Comments on the draft assessment report on Abamectin (Amendment to approval conditions)

RMS NL

End of commenting period: 04.08.2015 (APPL; MS; EFSA)

Date	Supplier	File
07.07.2015	FR	01 Abamectin comments on DAR_FR_2015_07_07.doc
03.08.2015	PL	02 Abamectin comments on DAR_PL_2015_08_03.doc
03.08.2015	EFSA	03 Abamectin comments on DAR_EFSA_2015_08_03.doc
04.08.2015	AT	04 Abamectin comments on DAR_AT_2015_08_04.doc
04.08.2015	DE	05 Abamectin comments on DAR_DE_2015_08_04.doc
04.08.2015	UNAF	06 Abamectin comments on DAR_UNAF_2015_08_04.doc

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 4, C.1.3.2, limits	FR: page 4, the limits should be 2.25% w/w instead of 2.26% and 2.08% w/w, instead of 2.09%. Please RMS, correct.	

Physical and chemical properties of the active substance			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, B.2.1	FR: No new study. No comment.	

Physical and chemical properties of the plant protection product			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, B.2.2	FR: page 4, point 2.5.3. It should be specified that the product is surface active. Please RMS, add.	
2	Vol. 3, B.2.2	FR: We consider that, to ease the review, it is useful to recall, before physico-chemical table, the maximum and minimum use concentrations, relevant impurities, claimed packaging and content of H304 Asp Cat. 1 classified co-formulants.	
3	Vol. 3, B.2.2	FR: It is not indicated, when required, whether the tests are performed at the minimal or the maximal concentration. Please RMS, specify.	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

Methods of analysis			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	Vol. 3, B.5	FR: No new study. No comment.	

Other comments			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
1	LOEP. Chapter 2.1. Identity	FR: page 4, please RMS, explain why minimum purity of the active substance is an open point.	
2	LOEP. Chapter 2.2. Methods of Analysis	FR: page 9, MRLs are set for animal products by Reg. (EU) No 508/2011. Please RMS, correct.	

Section 2 – Effects on human and animal health

2. Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3CP, B.6.1.3 Inhalation	FR: Please precise if the test article corresponds to the undiluted product or to the 50% (v/v) solution of product as indicated at the beginning of the chapter "generation of the test atmosphere". In case of a 50% (v/v) solution of Abamectin SC (A12115I), it would change the LC_{50} and would impact the classification of the preparation.	
(2)	Vol. 3CP, B.6.1.6 Skin sensitisation	FR: Please precise how the induction and challenge concentrations have been established.	

3. Residue data

Other comments			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 CA-B7, General	FR: No comment, we agree with the assessment	

4. Environmental fate and behaviour

FR: Not Reviewed

Section 5 - Ecotoxicology

5. Ecotoxicology

FR: Not Reviewed

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.1. The representative formulation	No comments. All presented information is sufficient for identification of the representative formulation.	

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		No data for comments.	

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.2. IIIA 2.5.3 ; page 5	According to provisions of Commission Regulation (EU) No 284/2013, the surface tension shall be determined at the highest concentration level being proposed for the representative formulation. It would be useful if RMS confirms that this test supports the requirement for that property.	
(2)	Vol. 3, B.2. IIIA 2.8.2 page 10 IIIA 2.8.3.1 page 10	For suspensibility and persistent foaming tests, if several concentrations are recommended, the highest and lowest concentrations within the scope of the method should be used.	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Physical, chemical and technical properties of the formulation (B.2.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		It would be useful if ZRMS confirms that the both tests support the minimum and maximum in-use concentrations being proposed for the evaluated product.	

Data of application (B.3)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3; B.3. the representative formulation	No comments.	

Further information (B.4)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3; B.4. the representative formulation	No comments.	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Methods of analysis (B.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.5.1.1 page 5 Representative formulation study 2	It would be beneficial for the evaluation if the more detailed description of the parameters evaluated in the method validation will be presented in the report. Additionally, the RMS statement is needed whether the end-points from the validation method fulfills the acceptance criteria presented in guidance SANCO/3030/99 rev.4. For completeness, the linearity in the validation should be reported in terms of the working range of concentrations used for the determination of the active substance in the representative formulation. For accuracy in the validation, it would be useful if RMS clarifies the type of samples used for recovery assessment. The recovery should be determined by replicate analysis of fortified samples (Samples should ideally be laboratory-prepared co-formulant mixes to which a known quantity of analyte is added). For precision, the acceptability of the % RSD may be assessed using the modified Horwitz equation (the proposed acceptable value of Horwitz x 0.67 should be included in the report as an acceptance criterion).	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

Other comments Volume 4 Annex C Confidential Information			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 4; C.1.3.3 page 7	It would be useful if the available toxicological data for each formulant being a part of the formulation will be presented in the report. Such an information on toxicological data can be a basis for resultant classification of the evaluated formulation.	

Section 2 - Mammalian toxicology (B.6)

2. Toxicology and metabolism data (Addendum, Volume 3 - Annex B.6)

No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General comment	Front page: It is not clear whether the data relate to the active substance abamectin as such or to the abamectin in plant protection product A12115l which is Syngenta trade code number of Tervigo (Addendum, Volume 1).	
(1)	B.6	We propose to clarify that in Addendum only the information on acute toxicity of formulation A12115l are included. Other data can be found in original DAR for active substance abamectin.	

Section 3 - Residues (B.7)

3. Residues (Addendum, Volume 3 - Annex B (A12115l))

No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	General comment	On the first page a code number A12115l is given. This is Syngenta trade code number of plant protection product Tervigo (Addendum, Volume 1), whereas the information provided relates to the active substance abamectin. Please verify.	
(2)	B.7.5	Invalid number of the table "Intended Good Agricultural Practices (GAP) for the abamectin as a nematocide in Europe"- the table should be numbered as Table 7.5.1	
(3)	B.7.6.2	In the description of study design two residue trials on tomato are mentioned, whereas conclusions refer to four trials.	
(4)	B.7.6.3	In the description of study design two residue trials on pepper are mentioned, whereas conclusions refer to four trials.	
(5)	B.7.6.4	In the description of study design two residue trials on cucumber are mentioned, whereas conclusions refer to four trials.	

Section 4 - Environmental fate and behaviour (B.8)

4. Environmental fate and behaviour (Addendum, Volume 3 - Annex B.8)

No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	B.8.6.2	It is likely that PECsw values calculated for other D scenarios (not only D6) could be also useful for risk assessment. Although it is not possible to calculate the PECsw values for fruiting vegetables, but maybe the substitute crops could be used instead of fruiting vegetables. However, if it is assumed that PECsw for other D scenarios would be lower than PECsw for D6, and the value for D6 scenario represents the worst case, the report should contain some information/ justification about that.	

5. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3.B.9, B.9.2.4 Summary of aquatic toxicity data	There is a mistake in the first sentence: instead of "*avian toxicity data*" should be "*aquatic toxicity data*".	
(2)	Vol.3 B.9, B.9.2.5 Risk assessment for aquatic organisms	From the sentence in first paragraph: "*The higher tier RAC from the mesocosm study is 0.049 µg/L with a safety factor of 3 is 0.016 µg/L*" is difficult to distinguish which the value is a RAC, is this equal 0.049 µg/L or 0.016 µg/L? This sentence should be rewrite to make it clear.	

Earthworms and other soil non-target organisms (macro and micro) (B.9.6, B.9.7 and B.9.8)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol.3. B.9. B.9.6.3 Risk assessment for earthworms	PL: The toxicity data for metabolites NOA 427011 and NOA448112 are available, therefore for completeness of the evaluation, the PEC_{soil} for these metabolites could be calculated and the risk assessment might be based on the corresponding values for metabolites.	
(2)	Vol.3. B.9. B.9.7.2 Risk assessment for soil micro-organisms	PL: Since the toxicity data for metabolites NOA 427011 and NOA448112 are available, therefore for completeness of the evaluation, the PEC_{soil} for these metabolites could be calculated and the risk assessment might be based on the corresponding values for metabolites..	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Data on application and efficacy			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.3, efficacy data package	EFSA: The efficacy data have not been evaluated	

2. Effects on human and animal health

Further toxicological studies			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3 Literature review	EFSA: a summary of the literature search conducted by the applicant is briefly summarised in B.6.15. Could the RMS clarify how relevance was assessed? Could the RMS clarify the search terms for abamectin metabolites? The assessment of the literature search appears to be incomplete since reliability assessment was not conducted or at least it was not included in the assessment report. Please note that EFSA could not find the applicant's document on the literature search in the dossier available to EFSA.	

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, Operator exposure	EFSA: Agreed with non-dietary exposure estimates during mixing/loading before drip irrigation in	

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		greenhouses according to the German BBA model. Could the RMS provide non-dietary exposure estimates during mixing/loading before drip irrigation in greenhouses according to the UK POEM model?	

3. Residue data

Metabolism, distribution and expression of residues in plants			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.7, Metabolism in plants	EFSA: Metabolism in plants has been investigated following foliar applications only, while the intended uses as nematicide refers to soil drip applications. Plant metabolism study using soil applications is requested.	
Other comments			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Addendum Vol. 3, B.7 References relied on,	EFSA: Regulation (EC) No 1107/2009 requires a search of the scientific peer-reviewed open literature to be included in all applications made under the regulation. This information is missing in section B.7 residues and should be provided.	

4. Environmental fate and behaviour

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)		EFSA: See comment in the PECsw section where it is identified that PECsw for the soil metabolites reaching levels that the EU peer review concluded trigger assessment, i.e. NOA448111, NOA448112, NOA457464 and NOA457465 need to be calculated. If these estimates (that are currently missing) were to indicate there might be residues in surface water at the point of drinking water extraction, then Regulation (EC) No 1107/2009 requires in its approval criteria that 'it shall have no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health, ….through drinking water (taking into account substances resulting from water treatment). So information on the effect of water treatment processes on the nature of residues when surface water is abstracted for drinking water might need to be considered. If residues at the point of drinking water extraction could not be excluded, in the first instance a consideration of the processes of ozonation and chlorination would appear appropriate.	

Section 4 - Environmental fate and behaviour

PEC in soil			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.8.3 PECsoil, page 5	EFSA: PEC in soil have not been calculated for the major soil metabolites. It is also noted the effects database regarding soil organisms is incomplete for the soil metabolites. Therefore the statement that PEC in soil for metabolites are not required because the risk assessment for the metabolites is covered by that for the active substance does not seem appropriate.	

PEC in surface water and ground water			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.8.6.1 PECgroundwater, pages 11-15 and 16-20	EFSA: The normalisations carried out for incubation soil moisture content are wrong / do not comply with FOCUS guidance. The incubation gravimetric soil moisture contents are available for each soil (are clearly described in the original DAR). Therefore FOCUS default MWHC values for each soil texture should not have been used as the basis for the calculations of the incubation soil moisture, rather the known moisture contents of the incubations should have been used for the moisture correction factors. If the correction factors are correctly calculated, the geometric means appropriate for use in FOCUS modelling are: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d	Soil / MWHC / incubation soil moisture / correction factor G loam / 66.84% / 26.74% / 26.74/25=>1 G silt loam / 67.9% / 27.16% / 27.16/26=>1 P loamy sand / 49.2% / 19.68% / 19.68/14=>1 18 sandy clay loam / 60.4% / 24.16% / 24.16/22=>1 M silty clay loam / 52.6% / 21.04% / 21.04/30^0.7=0.78 FC L sandy loam / 14.4% / 10.8% / 10.8/19^0.7=0.67 I sand / 1.54% / 1.155% / 1.155/12^0.7=0.19 H clay / 38.6% / 28.95% / 28.95/48^0.7=0.7

PEC in surface water and ground water			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		NOA457465 112.3 d. Consequently updated PECgw may need to be calculated. The above DT50 are all longer than those used in the available modelling. Note in any surface water modelling that would be provided in the future for these soils metabolites, EFSA considers the soil DT50 indicated in this comment would need to be used.	
(2)	Addendum Vol. 3, B.8.6.2 PECsurface water, pages 11-15 and 16-20	EFSA: PECsurface water have not been calculated for the soil metabolites that the peer review considered reached levels that triggered consideration. Namely NOA448111, NOA448112, NOA457464 and NOA457465. These metabolites were only present at very low levels in the sediment water systems. Therefore it is considered unlikely that microcosm / mesocosm study effect endpoints might be used to cover the risk for these compounds. Anyway endpoints from microcosm / mesocosms are low indicating toxicity from whatever compounds were present in these effects studies. Effects data where a metabolite was dosed only appears available for one of these metabolites (NOA448112, daphnia EC50 1.6µg/L) but this endpoint indicates, that at least NOA448112 is quite hazardous. Therefore to complete a risk assessment PECsw at step 3 and possibly step 4 for NOA448111, NOA448112, NOA457464 and NOA457465 would need to be provided, noting that they all have higher geomean soil DT50 and lower adsorption	

Section 4 - Environmental fate and behaviour

PEC in surface water and ground water			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		constants than the values used for the active substance abamectin in the available PECsw calculations for the nematicide uses. Therefore the available simulations for abamectin, do not 'cover' the exposure that may occur from these metabolites.	

Other comments incl. available monitoring data			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.8.10 References relied on, page 31	EFSA: Regulation (EC) No 1107/2009 requires a search of the scientific peer-reviewed open literature to be included in all applications made under the regulation. What is provided should follow the EFSA guidance on literature reviews, so follow a systematic review approach. There is no evidence from what is presented in the addendum to volume 3 B.8 that the applicant completed this task in relation to information on fate and behaviour in the environment.	

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.9.1.5 Risk assessment for birds	EFSA: according to the GAP, the application is performed indoor. However, no consideration is provided about later stage. Can the RMS confirm that the treated plants remain in indoor conditions after being treated (no transplanting to open field or removal of non-permanent structures)? Please note that this comment is relevant for other areas of the risk assessment where negligibility of exposure was claimed (i.e. mammals).	

Aquatic organisms			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.9.2.5 Risk assessment for aquatic organisms	EFSA: RMS claimed that the risk for the metabolites which are formed in water is covered by the risk assessment of the parent. However, the risk for soil metabolites isn't. There are 4 soil metabolites (namely NOA448111, NOA448112, NOA457464, and NOA457465) which are more persistent and more mobile than the parent. Furthermore, aquatic toxicity data are available for only one of them (NOA448112), which showed to be rather toxic to daphnids (EC50=1.6 μg/L). A full risk assessment for these metabolites should be carried out.	See also the relevant comment in the e-fate section

Section 5 - Ecotoxicology

Bees and non-target arthropods			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.9.5.2 Risk assessment for NTA	EFSA: we agree with the RMS that tests on other soil species, such as *Folsomia candida* and *Hypoaspis aculifer*, should be carried out for a more transparent risk assessment.	

Earthworms and other non-target soil macro- and mesofauna			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.9.6.3 Risk assessment for earthworms	EFSA: the maximum initial PECs for abamectin does not necessarily represent a worst-case for metabolites, as these are more persistent and may reach higher concentrations after 4-6 applications. See also the respective comment in the e-fate section.	
(2)	Addendum Vol. 3, B.9.6.3 Risk assessment for earthworms	EFSA: no toxicity data are available for 3 soil metabolites. In the Addendum, the toxicity of these metabolites was assumed to be equal to that of the parent. However, there are no data underpinning this assumption. Normally, when no data are available for metabolites, the risk assessment is carried out assuming that these are 10 times more toxic than the parent	

Section 5 - Ecotoxicology

Soil nitrogen transformation			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.9.7.2 Risk assessment for soil micro-organisms	EFSA: the maximum initial PECs for abamectin does not necessarily represent a worst-case for metabolites, as these are more persistent and may reach higher concentrations after 4-6 applications. See also the respective comment in the e-fate section.	

Terrestrial non-target higher plants			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		EFSA: no comment	

Other non-target terrestrial organisms (flora and fauna)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		EFSA: no comment	

Biological methods for sewage treatment			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		EFSA: no comment	

Section 5 - Ecotoxicology

Other comments incl. available monitoring data			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Addendum Vol. 3, B.9	EFSA: Regulation (EC) No 1107/2009 requires a search of the scientific peer-reviewed open literature to be included in all applications made under the regulation. What is provided should follow the EFSA guidance on literature reviews, so follow a systematic review approach. There is no evidence from what is presented in the addendum to volume 3 B.9 that the applicant completed this task in relation to information on ecotoxicology.	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. **Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis**

AT: not considered

2. Effects on human and animal health

AT: considered, but no comments are necessary

3. Residue data

AT: not considered

4. Environmental fate and behaviour

AT: considered, but no comments are necessary

5. Ecotoxicology

Aquatic organisms			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, IIIA, 10.2.2.1/01	AT: It is agreed that the endpoint should be recalculated, but we question whether it is completely correct to calculate the Probit analysis only with two concentrations (5.91µg a.s./L according to our calculations). However, the result may not change considerably.	
(2)	Vol. 3, IIIA, 10.2.2.2/01	AT: Reference and year of execution should probably be in line. It would be helpful to have the results presented within a table. As indicated in the first comment it is considered more correct to include all test concentrations (if possible) in the probit analysis. It might also be specified which software was used for the probit calculation.	

Earthworms and other non-target soil macro- and mesofauna			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol., B 9.6.2	AT: Significant, dose dependent effects on the mean biomass change were observed, but not discussed further in the risk assessment. Are these effects not considered to be of relevance?	

Section 1 – Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of analysis

1. General comments

Other comments			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 1, 3.1, Proposed decision	DE: The proposed decision that the extension of the conditions of approval for the active substance abamectin can be approved under Regulation (EC) No 1107/2009 is currently not supported, as no sufficient assessment of the soil metabolites with regard to the risks to consumers is presented. At least a case evaluation should be presented covering residue and toxicity aspects. For a further explanation, please refer to comment #1 on metabolism, distribution and expression of residues in plants in the residue section.	
(2)	Volume 1, 1.5.1 and Volume 3, CP B.8, A12115I	DE: In Volume 1 (DAR Addendum 01 Volume 1) it is stated (chapter 1.5.1) that the representative product is intended to be applied indoor as soil drip. In Volume 3 CP B.8 A12115I directly at the beginning it is stated that the addendum concerns the extension of the approval for the use of abamectin as nematicide in glasshouses only. It is further stated that the applicant narrowed the specific use down to an indoor drip irrigation on soil in walk-in tunnels. From our point of view the intended use for the extension of the approval should be clarified as the application in walk-in tunnels is something different as an application in glasshouses.	

2. Effects on human and animal health

Product exposure and risk assessment, including dermal absorption			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, CP B.6.4, Toxicological data co-formulants	DE: No information on the toxicological properties of the co-formulants is given. Please add.	
(2)	Vol. 3, CP B.6.4.1.1, Operator exposure	DE: A work rat of 4 ha for drip irrigation in greenhouses might be a more realistic worst-case than 1 ha. However, this has no impact on the outcome of the risk assessment.	
(3)	Vol. 3, CP B.6.4.3, Worker exposure	DE: Worker exposure might be relevant during harvesting of fruits that grow close to the soil such as melons since application can take place shortly before harvest. In that case, gloves are necessary for the worker.	
(4)	LoEP (dermal absorption)	DE: For completeness the dermal absorption value for Tervigo should be given in the LoEP as well.	

Other comments, incl comments on volume 4 (impurities, batches)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, CP B.6.6, Literature search	DE: It is appreciated that an up-to-date literature search was conducted. According to the evaluation, two articles were considered potentially relevant. Please state where in the addendum these articles are evaluated!	
(2)	Vol. 3, Table of Contents	DE: Please correct the numbering in the Table of Contents.	

3. Residue data

Storage stability of residues			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, CP B.7.6.7, Storage stability	DE: The level of detail in the storage data hardly allows for a profound assessment of the analyses (refers to all data). E.g., for the spike level of 0.05 mg/kg, the recovered 0.04 mg/kg are reported as either 80 % recovery or 67 % (runner bean; Table B.7.6.7-4). Unspecified recoveries of 66-90 % within the whole storage period embrace acceptable as well as unacceptable levels (Table B.7.6.7-3). More details could better support the claimed stability.	

Metabolism, distribution and expression of residues in plants			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, CP B.7.1, Metabolism, distribution and expression of residues in plants and Vol. 3, CP B.7.16, p. 44, Summary and evaluation of residue behaviour	DE: The metabolism studies available were all carried out as foliar spray. The intended uses as soil application (drip/drench) are therefore not covered by the data. Although the metabolite spectra in plant and soil metabolism studies are identical (except minor soil hydroxy-metabolites NOA 457464 and NOA 457465), large parts of the soil radioactivity are not covered by the residue analytical method, and the soil-plant transfer after drench application cannot be quantitatively assessed. Further uncertainty is caused by the low	

Metabolism, distribution and expression of residues in plants			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		identification rate in soil metabolism studies. No toxicological assessment of metabolites is noted. A case should be presented (minimum requirement) covering residue and toxicity aspects.	

4. Environmental fate and behaviour

Route and rate of degradation in soil			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 13, LoEP, DT_{50}, lab	DE: For PECgw new normalised DT_{50} values were used. These values should also be presented in the part 'Rate of degradation in soil'. The title 'extension of approval' could be used to make the difference to the 'original approval'.	

PEC in soil			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 10 Vol. 3 CP, B.8.3, PECsoil for metabolites	DE: In our opinion PEC_{soil} should be calculated for all relevant soil metabolites. In the LoEP from April 2015 in the part 'Definition of the Residue' it is stated that all soil metabolites are triggered for soil exposure assessment. Within the list of endpoints the unknown metabolite U8 is also listed as relevant soil metabolite but was not included in the part 'Definition of the Residue'. Please clarify if a PEC_{soil} calculation is required for the metabolite U8.	

Section 4 - Environmental fate and behaviour

Definition of the residues			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR addendum 13_List of endpoints_2015-04-14, Definition of residue	DE: In the provided list of endpoints within the paragraph `Route of degradation in soil´ the unknown metabolite U8 is listed as relevant soil metabolite, occurring with > 5 % of AR on > 2 consecutive time points. However, later on within the paragraph `Definition of residue´ this metabolite is not stated any more. Please clarify why no assessment is triggered for this metabolite.	

5. Ecotoxicology

Birds and other terrestrial vertebrates			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 11 Vol. 3 CP, B.9.1.5, Risk assessment for birds	DE: We agree with the RMS but only on the basis of the restriction to the indoor application as soil drip as presented in Vol. 1, chapter 1.5.1.	

Aquatic organisms			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 11 Vol. 3 CP, B.9.2.5, Risk assessment for aquatic organisms	DE: We agree with the RMS but only on the basis of the restriction to the indoor application as soil drip as presented in Vol. 1, chapter 1.5.1.	

Bees and non-target arthropods			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 11 Vol. 3 CP, B.9.5.2, Risk assessment for other non-target arthropods	DE: We agree with the opinion of the RMS that it is not clear if the risk for *P. cupreus* is acceptable. We also agree that it is not sufficient to test only one species and beside that one which is known to be really insensitive. Thus we also think that test on *Folsomia candida* and *Hypoaspis aculeifer* are required.	

Earthworms and other non-target soil macro- and mesofauna			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 11 Vol. 3 CP, B.9.6.3, Risk assessment for earthworms	DE: We agree with the RMS but only on the basis of the restriction to the indoor application as presented in Vol. 1, chapter 1.5.1 and in the case that the exposure of natural soil can be excluded. However if the application takes place as soil drip irrigation in walk-in tunnels as specified by the applicant it has to be expected that the tunnels are constructed on natural soil and hence an exposure of earthworms and other non-target soil organisms cannot be excluded. According to Vol. 3, Part B.8 PEC_{soil} calculation the application on soil in walk-in tunnels has to be regarded as an open field application. In this case the assessed unacceptable chronic risk for earthworms has to be addressed. For the metabolites only acute earthworm studies were provided. However the metabolite NOA448112 has a DT_{90} > 100 days and the intended uses allow more than three applications. Thus in analogy to the requirements for active substances also the long-term risk to earthworms should be addressed for the metabolite NOA448112. The risk for earthworms posed by the exposure to the soil relevant metabolites was not addressed in a quantitative assessment. It is only stated that the PEC for the active substance presents a worst case and hence the assessment for the parent also covers the metabolites. As commented above	

Earthworms and other non-target soil macro- and mesofauna			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
		for the environmental fate section from our point of view the PEC_{soil} should be calculated for the metabolites and these values should be used for a TER calculation based on the available endpoints for the metabolites. No tests were provided for the soil metabolites. However, within the list of endpoints the metabolites NOA457464, NOA457465 and the unknown metabolite U8 are stated as relevant soil metabolites. The only statement is that in view of the LC_{50} for the metabolite NOA448112 it can be assumed that the toxicity of these metabolites will also not be higher as the toxicity of the parent. However, no real explanation is presented for this assumption. Is this assumption made based on a structural similarity? Please clarify this assumption.	
(2)	DAR Addendum 11 Vol. 3 CP, B.9.6.3, Risk assessment for earthworms	DE: Only toxicity data and a risk assessment for earthworms were presented. As stated for the risk assessment for non-target arthropods tests with *Folsomia candida* and *Hypoaspis aculeifer* are required to address the risk for soil dwelling organisms. Beside that it has to be taken into account that a test for other non-target soil organisms is triggered if the long-term TER for earthworms is < 5.	

Section 5 - Ecotoxicology

Soil nitrogen transformation			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 11 Vol. 3 CP, B.9.7.2, Risk assessment for soil micro-organisms	DE: We agree with the assessment presented by the RMS. According to chapter B.8.3 of Vol. 3 part B.8 the PEC_{soil} was calculated for an application in walk-in tunnels which is regarded as an open field application. Thus the calculated PEC_{soil} values present a worst case for an indoor application as they account for the exposure of natural soil for this specific form of an indoor use. No tests were provided for the soil metabolites. However, within the list of endpoints the metabolites NOA457464, NOA457465 and the unknown metabolite U8 are stated as relevant soil metabolites. It is argued that according to the available aquatic studies with metabolites it can be assumed that the toxicity of the metabolites is lower as for the parent. On the other side the exposure towards these metabolites can be expected to be lower as for the parent and hence the risk for the metabolites can be regarded to be covered. As additional argument it is stated that it is very unusual that the toxicity of a metabolite is more than ten times higher as the toxicity of the parent. We agree with this statement but than we would suggest the provision of a risk assessment based on the worst case assumption of a ten time higher toxicity and the calculated PEC_{soil} for the respective metabolites. Such an assessment would clearly demonstrate the risk posed by the metabolites and underline the conclusion presented by the RMS.	

Terrestrial non-target higher plants			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	DAR Addendum 11 Vol. 3 CP, B.9.8.2, Risk assessment for terrestrial non-target plants	DE: We agree with the RMS but only on the basis of the restriction to the indoor soil drip application.	

Section 1 – Physical/Chemical Properties; Details of Uses and Further Information; Methods of analysis (B.1 – B.5)

1. Physical/Chemical Properties; Details of Uses and Further Information; Methods of Analysis (B.1-B.5)

Identity (B.1, Annex C)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.1.1, identity of the formulation	UNAF: on page 4: abamectin typical purity is 92%. Information of the B1a, B1b, B1a 8,9 Z isomer content should be added and information on the 8% impurities is missing	

Physical and chemical properties of the active substance (B.2.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(2)	Vol. 3, B.2.2, physical and chemical properties of the plant protection product	UNAF: on page 7, into the table, "storage stability after 14 days at 54°C (IIIA 2.7.1)": in addition to the active substance content, the initial purity profile and the purity profile after storage are missing when these profiles are necessary to conclude on the stability of the representative product.	For establishing the active substance content and the impurity profile specific methods are needed. The used methods should be reported in the dossier.

Further information (B.3)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(3)	Vol. 3, B.3, Data on application and efficacy	UNAF: on page 4, the proposed application rate (dose – number of treatments) should be justified	When abamectin is used as insecticide and acaricide, the maximum application rate is 21,6g/ha and the maximum number of treatments is 5 (tomato), i.e. 108g/ha/year. In the present submission dossier, as nematicide the quantity of active substance is much higher (max quantity 600g/ha for a 100g/ha dose with 6 applications, tomato). An explanation to justify this application rate is requested.

2. Mammalian toxicology (B.6)

Toxicokinetics (B.6.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(4)	Vol. 3, B.6.3.1, Inhalation	UNAF: page 10 (animal assignment and treatment), The 4-hours exposure period and the 14-day observation period are questionable compared to the operator exposure in working conditions all the more so since several applications are allowed all along the plant growth (typically, BBCH 12 to 89).	

3. Residues (B.7)

Storage Stability (B.7.0)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(5)	Vol. 3, B.7.6.2 supervised residues trials in tomato	UNAF: page 16, considering the potential impact of Abamectin on insects, a LOQ of 2ppb should be challenged. In table 7.6.2-1, the results are reported versus the LOQ. The results versus the LOD should be added. In addition, LOD and LOQ in pollen and nectar should be evaluated and tests of the residues evaluation in pollen and nectar should be considered.	Abamectin is highly toxic for insects (among others for bees) and bees' exposure leads to sublethal effects (cfr B.9.4.1.2). For substances showing such toxic properties, residues concentrations as low as < 1 ppb can lead to effects that are sublethal at the level of individuals but lethal at the level of the colony (see for instance, among a lot of peer-reviewed articles: DeGrandi-Hoffman G *et al.* 2013: The Effects of Pesticides on Queen Rearing and Virus Titers in Honey Bees (*Apis mellifera L.*), Insects 2013(4), 71-89 Perry CJ *et al.* 2015: Rapid behavioral maturation accelerates failure of stressed honey bee colonies, PNAS 112(11): 3427-3432 Whitehorn PR *et al.* 2012: Neonicotinoid pesticide reduces bumblebee colony growth and queen production, Science 336: 351–352.).

4. Environmental fate and behaviour (B.8)

Route and rate of degradation in soil (B.8.1)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(6)	Vol. 3, B.8.3 PEC soil	UNAF: page 4, the maximum field DT50 of the as is 1.8 days. In the case of abamectin the DT50 field is not the worst case. Moreover the relevance of DT50 field values for glasshouse uses is questionable. A PECsoil calculation using lab values should be at least reported and the use of field values should be justified.	The reported DT50 field is strongly different from the lab DT50. How can this difference be explained? Photolysis is usually limited to the top 2 mm of the soil (see for instance EFSA PPR 2010: Guidance for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil, p. 14). Thus photolysis cannot be the unique explanation of the difference. Further explanations on this topic are needed.

5. Ecotoxicology (B.9)

Aquatic organisms (B.9.2)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(7)	Vol. 3, B.9.2.1.3 Acute toxicity of the formulated product	UNAF: page 8, the low recoveries for the highest tested concentrations are considered to be the result of sampling mistake. As a consequence, the test should not be considered as valid and should be redone.	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(8)	Vol. 9, B.9 4 .1.2: Acute toxicity of the formulated product	For establishing the oral and contact DL50 five doses were used. This is not sufficient for defining the toxicity curve, all the more so since abamectin curve seems not to be the usual sigmoid curve.	For the characteristics of abamectin curve, see the conclusion on the peer review on abamectin (2008) p. 31: *However the oral acute endpoint was not taken into account in the risk assessment since it was considered not reliable since the mortality rate at a dose of 0.001 µg a.s./bee was greater than the mortality at the next higher dose of 0.005 µg a.s./bee.* However the quoted figures are plausible since the relation between dose and toxicity may be really different from a sigmoid, see for instance Suchail, S., Guez, D., and Belzunces, L.P., 2000: Characteristics of Imidacloprid toxicity in two *Apis mellifera* subspecies, Environmental Toxicology and Chemistry: 19(7): 1901–1905.

Section 5 - Ecotoxicology (B.9)

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(9)	Vol. 9, B.9 4 and B.9.5.: "The proposed soil drip use indoors will result in negligible exposure…	UNAF: Notifier's statement is not acceptable. The intended crops (pepper, tomato, eggplant, cucurbits) are entomophilous. In fact bumble bees or honeybees are introduced in the glasshouses when the crop is flowering. The risk for these pollinators should be considered.	

Bees and non-target arthropods (B.9.4 and B.9.5)			
No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(10)	Vol. 9, B.9 4 and B.9.5.	UNAF: Bees consume water, mainly for brood breeding. Active substance concentration in the drip water is 0,5-1 g/hL i.e. 5-10 mg/L (see vol1 p. 7). This concentration level is clearly higher than the DL50 measured in the oral and contact toxicity tests. The risk associated with water consumption is thus high and should be considered.	Glasshouses don't remain continuously closed and bees are attracted to drip water - bees don't like open water and prefer drinking from moist soils or from dropping water. In oral and contact toxicity test, bees' exposure to 6 ng results in 72% and 100% mortality respectively. 6 ng in 10 or 20 microL (see EPPO 170) mean 0,6mg/L or 0,3 mg/L respectively. DL50 concentrations are thus lower than the ones used in drip water.

PEER REVIEW REPORT ON **ABAMECTIN** APRIL 2016

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0. General

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
0(1)	Vol. 1, 3.1, Proposed decision	DE: The proposed decision that the extension of the conditions of approval for the active substance abamectin can be approved under Regulation (EC) No 1107/2009 is currently not supported, as no sufficient assessment of the soil metabolites with regard to the risks to consumers is presented. At least a case evaluation should be presented covering residue and toxicity aspects. For a further explanation, please refer to comment #1 on metabolism, distribution and expression of residues in plants in the residue section.	Syngenta (08/15): Please refer to response against comment #1 on metabolism, distribution and expression of residues in plants in the residue section. NL(Sept 2015): Refer to comment #1 on metabolism, distribution and expression of residues in plants in the residue section	See open point in 3(3)
0(2)	Volume 1, 1.5.1 and Volume 3, CP B.8, A12115I	DE: In Volume 1 (DAR Addendum 01 Volume 1) it is stated (chapter 1.5.1) that the representative product is intended to be applied indoor as soil drip. In Volume 3 CP B.8 A12115I directly at the beginning it is stated that the addendum concerns the extension of the approval for the use of abamectin as nematicide in glasshouses only. It is further stated that the applicant narrowed the specific use down to an indoor drip irrigation on soil in walk-in tunnels. From our point of view the intended use for the extension of the approval should be clarified as the application in walk-in tunnels is something different as an application in	Syngenta (08/15): The applicant applied for an indoor drip irrigation walk-in tunnel use. NL(Sept 2015): Agree with applicant.	Open point RMS to update Vol 1, 1.5.1 and Vol. 3, CP B.9, A121151 to consistently indicate that the representative uses applied for is for application to certain crops via drip irrigation in the protected cropping system of walk-in tunnels that remain in place till the crop has been harvested. See reporting table comments 0(2) and 5(2)

General				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		glasshouses.		
0(3)	Vol. 3, B.3, efficacy data package	EFSA: The efficacy data have not been evaluated	Syngenta (08/15): The Applicant notes that efficacy data is not a requirement for an active substance extension dossier and that efficacy is formulation dependant. Tervigo DAR, Volume 1, point 2.3.1 states: "*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*" and therefore, Syngenta considers that the provided information was adequate for the intend of the document. Nevertheless, further information can be provided on request. NL(Sept 2015): Additional information added to Appendix 1 in order to justify the dosage and efficacy. This information will be incorporated in in the updated addendum in due time.	Open point: A full evaluation of the supporting efficacy data should be provided. See also 1(6)

1. Physical/Chemical Properties; Data on application and efficacy; Further Information; Methods of Analysis

Identity				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(1)	Vol. 4, C.1.3.2, limits	FR: page 4, the limits should be 2.25% w/w instead of 2.26% and 2.08% w/w, instead of 2.09%. Please RMS, correct.	NL(Sept 2015): Unrounded values were used. The values as stated are correct and do not need to be amended (example: 1.67% / 0.85 = 1.9647, using the FAO allowed tolerance results in 2,259%, rounding up to 2.26%).	Addressed.
1(2)	Vol. 3, B.1. The representative formulation	No comments. All presented information is sufficient for identification of the representative formulation	NL(Sept 2015): Thank you.	Addressed.
1(3)	Vol. 3, B.1.1, identity of the formulation	UNAF: on page 4: abamectin typical purity is 92%. Information of the B1a, B1b, B1a 8,9 Z isomer content should be added and information on the 8% impurities is missing	Syngenta (08/15): Data/information on impurities is CONFIDENTIAL information - data provided in Volume 4. NL(Sept 2015): The content of the individual components of abamectin is not required. The substance is defined within the ISO name and the information in the substance dossier.	Addresssed:

Physical and chemical properties of the active substance				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(4)	Vol. 3, B.2.1	FR: No new study. No comment.	NL(Sept 2015): Thank you.	Addressed.
1(5)	Vol. 3, B.2.2, physical and chemical properties of the plant protection product	UNAF: on page 7, into the table, "storage stability after 14 days at 54°C (IIIA 2.7.1)": in addition to the active substance content, the initial purity profile and the purity profile after storage are missing when these profiles are necessary to conclude on the stability of the representative product. Further explanation: For establishing the active substance content and the impurity profile specific methods are needed. The used methods should be reported in the dossier.	Syngenta (08/15): Analysis of the impurity profile of the active ingredient in the formulation before and after storage is not a requirement under regulation 1107/2009. Analysis of relevant impurities before and after storage may be required if these can increase during storage. However, this is irrelevant for abamectin as no relevant impurities are identified. NL(Sept 2015): Agree with the applicants' answer.	Addressed: This is not a requirement.

Physical and chemical properties of the active substance				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(6)	Vol. 3, B.3, Data on application and efficacy	UNAF: on page 4, the proposed application rate (dose – number of treatments) should be justified. Further explanation: When abamectin is used as insecticide and acaricide, the maximum application rate is 21,6g/ha and the maximum number of treatments is 5 (tomato), i.e. 108g/ha/year. In the present submission dossier, as nematicide the quantity of active substance is much higher (max quantity 600g/ha for a 100g/ha dose with 6 applications, tomato). An explanation to justify this application rate is requested.	Syngenta (08/15): Please refer to Appendix 1 NL(Sept 2015): Additional information added to Appendix 1 in order to justify the dosage and efficacy. This information will be incorporated in in the updated addendum in due time.	See open point in comment 0(3)

Physical and chemical properties of the plant protection product				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(7)	Vol. 3, B.2.2	FR: page 4, point 2.5.3. It should be specified that the product is surface active. Please RMS, add.	NL(Sept 2015): Agree to add this information.	Addressed: The formulation is surface active.

Physical and chemical properties of the plant protection product				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(8)	Vol. 3, B.2.2	FR: We consider that, to ease the review, it is useful to recall, before physico-chemical table, the maximum and minimum use concentrations, relevant impurities, claimed packaging and content of H304 Asp Cat. 1 classified co-formulants.	NL(Sept 2015): Agree to add the information related to in-use concentrations. The viscosity of the product is well outside the range for consideration of classification as an aspiration hazard. Packaging is further information related to the ppp and does not need to be presented in B2.2.	Addressed.
1(9)	Vol. 3, B.2.2	FR: It is not indicated, when required, whether the tests are performed at the minimal or the maximal concentration. Please RMS, specify.	NL(Sept 2015): See 1(8).	Addressed.
1(10)	Vol. 3, B.2. IIIA 2.5.3 ; page 5	PL: According to provisions of Commission Regulation (EU) No 284/2013, the surface tension shall be determined at the highest concentration level being proposed for the representative formulation. It would be useful if RMS confirms that this test supports the requirement for that property.	NL(Sept 2015): The new data requirements do not apply. The data presented satisfy the requirements of 545/2011/EC.	Addressed.

Physical and chemical properties of the plant protection product				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(11)	Vol. 3, B.2. IIIA 2.8.2 page 10	PL: For suspensibility and persistent foaming tests, if several concentrations are recommended, the highest and lowest concentrations within the scope of the method should be used. It would be useful if ZRMS confirms that the both tests support the minimum and maximum in-use concentrations being proposed for the evaluated product.	NL(Sept 2015): See 1(8). RMS agrees to add this information.	Addressed: The data are sufficient.

Methods of analysis				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(12)	Vol. 3, B.5	FR: No new study. No comment.	NL(Sept 2015): Thank you.	Addressed.
1(13)	Vol. 3, B.5.1.1 page 5 Representative formulation study 2	PL: It would be beneficial for the evaluation if the more detailed description of the parameters evaluated in the method validation will be presented in the report. Additionally, the RMS statement is needed whether the end-points from the validation method fulfills the acceptance criteria presented in guidance SANCO/3030/99 rev.4.	NL(Sept 2015): Agreed the data presented is too consice. Validation complies with the requirements, but this will be reported in more detail in a revised version of volume 3.	Open point: RMS to report validation results of the method of analysis for the PPP in more detail.

Methods of analysis				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		For completeness, the linearity in the validation should be reported in terms of the working range of concentrations used for the determination of the active substance in the representative formulation. For accuracy in the validation, it would be useful if RMS clarifies the type of samples used for recovery assessment. The recovery should be determined by replicate analysis of fortified samples (Samples should ideally be laboratory-prepared co-formulant mixes to which a known quantity of analyte is added). For precision, the acceptability of the % RSD may be assessed using the modified Horwitz equation (the proposed acceptable value of Horwitz x 0.67 should be included in the report as an acceptance criterion).		

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
1(14)	LOEP. Chapter 2.1. Identity	FR: page 4, please RMS, explain why minimum purity of the active substance is an open point.	NL(Sept 2015): There was no new data related to the LoEP, therefore the original LoEP included in the EFSA Scientific Report (2008) 147 was used. Considering the specification was addressed (SANCO/138/08 – final 20 November 2012), the LoEP will be amended to included a minimum purity of 850 g/kg.	EFSA notes that the specification was confirmed in the revised review report, despite the disagreement expressed during the commenting on the confirmatory data assessment.
1(15)	LOEP. Chapter 2.2. Methods of Analysis	FR: page 9, MRLs are set for animal products by Reg. (EU) No 508/2011. Please RMS, correct.	NL(Sept 2015): Agreed. Will be corrected.	Addressed: This is not the subject of this submission.
1(16)	Vol. 4; C.1.3.3 page 7	PL: It would be useful if the available toxicological data for each formulant being a part of the formulation will be presented in the report. Such an information on toxicological data can be a basis for resultant classification of the evaluated formulation.	Syngenta (08/15): This is CONFIDENTIAL information, provided in Doc J sent to the RMS with the main submission. NL(Sept 2015): Will be included in a revision of volume 4.	Open point RMS to present the available toxicological data on co-formulants in volume 4.

2. Effects on human and animal health

Further toxicological studies				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(1)	Vol. 3 Literature review	EFSA: a summary of the literature search conducted by the applicant is briefly summarised in B.6.15. Could the RMS clarify how relevance was assessed? Could the RMS clarify the search terms for abamectin metabolites? The assessment of the literature search appears to be incomplete since reliability assessment was not conducted or at least it was not included in the assessment report. Please note that EFSA could not find the applicant's document on the literature search in the dossier available to EFSA.	Syngenta (08/15): A literature review was provided as it would have been mandatory for new active substances or renewal, abamectin does not fall into any of the two categories. The approach taken was based on extensive experience in conducting such reviews of the open literature and ensured that all literature of relevance and potential concern would have been identified. The review of the published literature for the nematicide use of abamectin did not reveal any studies considered to affect the assessment on human health, animal health or the environment. This data has been adequately addressed and consequently there is no data gap. An open literature review will be submitted in the AIR4 for abamectin (to be submitted in October 2016) as part of new requirement for active substance dossier submission. Reliability assessment was considered not required as no publications were considered relevant. NL(Sept 2015): - The relevance criteria were not clearly	Data requirement: Applicant to provide a revised literature review on abamectin and metabolites. This has to be conducted and reported (with sufficient details on the relevance/eligibility criteria and search strategies/concepts) in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No '1107/2009 (EFSA Journal 2011;9(2):2092). See also 2(10), 3(11), 4(10) and 5(25). Data requirement For the approval of pesticide active substances under Regulation (EC) No 1107/2009 the applicant needs to address whether abamectin fulfil the approval criteria considering the potential for endocrine disruption and classification and labelling of abamectin.

Further toxicological studies				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			defined other than that studies were dismissed that did not relate to each section. - Six metabolites were searched for: ○ 4'oxoaveremctin B1a (NOA426289) , ○ avermectin A1a, 5-O-dimethyl (NOA 427011), ○ Avermectin A1a, 5-O-dimethyl-28-oxo (NOA 448111) ○ Avermectin A1a, 5-O-dimethyl-28-hydroxy (NOA 448112) ○ Abamectin B1b (NOA 421704) ○ Abamectin B1a (NOA 422601) The same search terms as for the parent compounds were applied. - Two potentially relevant papers were identified. However, on further inspection of the information both were concluded to be not relevant (see also comment 2(10)). Therefore, no reliability assessment is required. - The literature search was submitted to the RMS in December 2013.	

Product exposure and risk assessment, including dermal absorption				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(2)	Vol. 3CP, B.6.1.3 Inhalation	FR: Please precise if the test article corresponds to the undiluted product or to the 50% (v/v) solution of product as indicated at the beginning of the chapter "generation of the test atmosphere". In case of a 50% (v/v) solution of Abamectin SC (A12115I), it would change the LC50 and would impact the classification of the preparation.	Syngenta (08/15): The dilution in water is simply to enable generation of a suitable test atmosphere. All concentrations quoted are for the neat formulation. The MLC was >1.02mg formulation/L air. NL(Sept 2015): As indicated the concentrations reflect the actual achieved concentration of the neat formulation.	Addressed. RMS to consider to add further details in a revised addendum.
2(3)	Vol. 3CP, B.6.1.6 Skin sensitisation	FR: Please precise how the induction and challenge concentrations have been established.	Syngenta (08/15): Induction & challenge concentrations were chosen based on the results of an initial irritation screen using 6 animals exposed to a range of concentrations between 3 and 100%. The results of this are detailed in the study report. Selection of concentrations for the main study was based on the following criteria: Epidermal Induction (25%): Concentration that produced some irritation but no other adverse effects. Epidermal Challenge (3% & 1%): Concentration that was the highest tested non-irritant concentration. NL(Sept 2015):	Addressed. RMS to consider to add further details in a revised addendum.

Product exposure and risk assessment, including dermal absorption				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			As indicated in the addendum the concentration were selected based on an preliminary irritation screen. The lowest concentration resulting in irritation (grade 1) during the induction phase was 25%. For the challenge phase no skin reaction was observed at 3% in the irritation screen.	
2(4)	Vol. 3, CP B.6.4, Toxicological data co-formulants	DE: No information on the toxicological properties of the co-formulants is given. Please add.	Syngenta (08/15): This is CONFIDENTIAL information, provided in Doc J sent to the RMS with the main submission. NL(Sept 2015): the information can be included in a revised Volume 4.	See open point under comment 1(16)
2(5)	Vol. 3, CP B.6.4.1.1, Operator exposure	DE: A work rat of 4 ha for drip irrigation in greenhouses might be a more realistic worst-case than 1 ha. However, this has no impact on the outcome of the risk assessment.	Syngenta (08/15): Syngenta agrees with the comment of the DE reviewer NL(Sept 2015): This can be amended in a revised addendum although it does not impact the outcome of the risk assessment.	Open point: RMS to amend the operator exposure assessment from 1ha to 4ha treatment.
2(6)	Vol. 3, CP B.6.4.3, Worker exposure	DE: Worker exposure might be relevant during harvesting of fruits that grow close to the soil such as melons since application can take place shortly before harvest. In that case, gloves are necessary for the worker.	Syngenta (08/15): Syngenta agrees with the comment of the DE reviewer NL(Sept 2015): Agreed, the worker exposure can be amended in a revised addendum.	Open point: RMS to amend the worker exposure calculation.

Product exposure and risk assessment, including dermal absorption				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(7)	LoEP	DE: For completeness the dermal absorption value for Tervigo should be given in the LoEP as well.	NL(Sept 2015): Agreed this can be done in a revised LoEP.	Open point: RMS to revise the LoEP to include the dermal absorption values of Tervigo.
2(8)	Vol. 3, B.6.3.1, Inhalation	UNAF: page 10 (animal assignment and treatment), The 4-hours exposure period and the 14-day observation period are questionable compared to the operator exposure in working conditions all the more so since several applications are allowed all along the plant growth (typically, BBCH 12 to 89).	Syngenta (08/15): This appears to refer to section B.6.1.3, which is a summary of the regulatory acute inhalation study. This is the only inhalation study required for this submission, and is intended to assess the acute toxicity of abamectin via this route. This study is not used for the operator risk assessment, which is conducted using the most sensitive, relevant endpoint derived from a repeat dose study. NL(Sept 2015): the study was conducted in compliance with OECD guideline 403. As also indicated by the notifier such a study is not intended to reflect the exposure conditions of operators and is not used for that purpose.	Addressed.
2(9)	Vol. 3, Operator exposure	EFSA: Agreed with non-dietary exposure estimates during mixing/loading before drip irrigation in greenhouses according to the German BBA model. Could the RMS provide non-dietary exposure estimates during mixing/loading before	Syngenta (08/15): Syngenta considers that provision of German model is according to the requirements for this modification of the active substance. Nevertheless, to be helpful to EFSA and RMS, please find here below a summary of the	Open point: RMS to include non-dietary exposure estimates during mixing/loading before drip irrigation in greenhouses according to the UK POEM model in a revised DAR.

Product exposure and risk assessment, including dermal absorption				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		drip irrigation in greenhouses according to the UK POEM model?	outcome with the UK POEM model during mixing/loading exposure for drip irrigation of A12115I to 4ha results in a total exposure of 0.00119 mg/kg/day, equivalent to 48% of the AOEL without use of PPE (German model). Using the UK POEM, the mixing/loading exposure for drip irrigation of A12115I to 4ha results in a total exposure of 0.00028 mg/kg/day, equivalent to 11% of the AOEL with the use of gloves. Therefore it can be concluded that the use of A12115I is acceptable. For further detailed information and modelling, please refer to Appendix 2. NL(Sept 2015): No specific exposure is required since at the time of submission no harmonized exposure model was adopted. An exposure calculation with the German BBA model was provided with shows a safe use. This should be sufficient for approval of the modification of the active substance.	

Other comments, incl comments on volume 4 (impurities, batches)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(10)	Vol. 3, CP B.6.6, Literature search	DE: It is appreciated that an up-to-date literature search was conducted. According to the evaluation, two articles were considered potentially relevant. Please state where in the addendum these articles are evaluated!	Syngenta (08/15): Only 2 publications (in the area of toxicology) were considered to be potentially relevant – these references were provided. Upon further detailed assessment (see section 2 (10) neither of these publications was considered to be relevant. An evaluation of these articles was not provided in the addendum. They are provided here now: **Castana et al (2012) Abamectin affects the bioenergetics of liver mitochondria: A potential mechanism of hepatotoxicity.** This paper reports *in vitro* effects which may correlate with previously reported effects of abamectin on liver toxicity *in vivo*. These reported effects are at dose levels higher than those used to set the regulatory endpoints, so are of no significant regulatory impact. **Bartram et al (2013) Clinical safety of rapid sequential administration of moxidectin injection and oral derquantel-abamectin as a quarantine treatment for introduced sheep.** This short communication reports the safety to sheep of a combined treatment including abamectin. The safety of abamectin alone has been previously demonstrated. The	See point 2(1)

Other comments, incl comments on volume 4 (impurities, batches)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			report has no regulatory impact. Neither of these publications is considered to add anything to the understanding of the toxicological profile of abamectin. NL(Sept 2015): As indicated in the addendum two potentially relevant references were identified. However, upon closer inspection of the studies they were concluded to be not relevant. The first study concerns a mechanistic study to identify the mechanism of hepatotoxicity of abamectin. As it concerns an *in vitro* study the information is not useful for risk assessment purposes. The liver was already identified as a critical target during the original Annex I review of abamectin. Therefore, the study does not provide any new information. The second study was a study in which the clinical safety of moxidectin injection followed by oral derquantel-abamectin administration was evaluated. This study does not provide any useful information for the assessment of abamectin on itself. Since both studies are not considered to be relevant no full evaluation in the addendum is required.	

Other comments, incl comments on volume 4 (impurities, batches)				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
2(11)	Vol. 3, Table of Contents	DE: Please correct the numbering in the Table of Contents.	NL(Sept 2015): Minor comment which does not impact the risk assessment. It will be changed in the revised addendum.	Addressed. RMS to consider to amend in a revised DAR.
2(12)	General comment	PL: Front page: It is not clear whether the data relate to the active substance abamectin as such or to the abamectin in plant protection product A12115I which is Syngenta trade code number of Tervigo (Addendum, Volume 1).	Syngenta (08/15): In Addendum, Volume 1, Point 2.1.1 states the identity of the product: "*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.*" NL(Sept 2015): As Volume 1 explains that no new data on abamectin was evaluated. If needed this section can also be included in Volume 3CP, B.6.	Open point: RMS to include the section explaining that no new data on abamectin was submitted in a revised DAR (B.6). See also 2(13).
2(13)	B.6	PL: We propose to clarify that in Addendum only the information on acute toxicity of formulation A12115I are included. Other data can be found in original DAR for active substance abamectin	NL(Sept 2015): See point 2(12)	See 2(12).

3. Residue data

Storage stability of residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(1)	Vol. 3, CP B.7.6.7, Storage stability	DE: The level of detail in the storage data hardly allows for a profound assessment of the analyses (refers to all data). E.g., for the spike level of 0.05 mg/kg, the recovered 0.04 mg/kg are reported as either 80 % recovery or 67 % (runner bean; Table B.7.6.7-4).	Syngenta (08/15): The recovered residues in the storage stability report are calculated on unrounded values. Mean recovered uncorrected residues for avermectin B1a, avermectin B1b and avermectin B1a 8,9-Z-isomer of all stored samples were in the range 80-121% compared to actual spiking levels determined at the day 0 storage interval. Mean recovered residues corrected for procedural recovery for avermectin B1a, avermectin B1b and avermectin B1a 8,9-Z-isomer of stored samples were in the range 84-114% compared to actual spiking levels corrected for procedural recovery determined at the day 0 storage interval. Residues of avermectin B1a, avermectin B1b and avermectin B1a 8,9-Z-isomer have therefore been demonstrated to be stable in orange peel (representative of acidic crops) for at least 12 months and in tomato (representative of high water content crops), runner bean (beans, green with pod, representative of high protein crops), sunflower seed (representative of high oil content crop), and potato (representative of high starch content crops) when stored at ≤ -18° C for at least 2 years.	Open point RMS to amend in a revised DAR Tables on storage stability in section B.7.6., considering the unrounded values reported in the study reports.

Storage stability of residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			NL(Sept 2015): Agrees that the values for uncorrected recovery show little variation. Result to be re-assessed using the results from report T022438-04-REG, tables 3 to 7. The conclusion will not change.	
3(2)	Vol. 3, B.7.6.2 supervised residues trials in tomato	UNAF: page 16, considering the potential impact of Abamectin on insects, a LOQ of 2 ppb should be challenged. In table 7.6.2-1, the results are reported versus the LOQ. The results versus the LOD should be added. In addition, LOD and LOQ in pollen and nectar should be evaluated and tests of the residues evaluation in pollen and nectar should be considered. Further explanation: Abamectin is highly toxic for insects (among others for bees) and bees' exposure leads to sublethal effects (cfr B.9.4.1.2). For substances showing such toxic properties, residues concentrations as low as < 1 ppb can lead to effects that are sublethal at the level of individuals but lethal at the level of the colony (see for instance, among a lot of peer-reviewed articles: DeGrandi-Hoffman G et al. 2013: The Effects of Pesticides on Queen Rearing and Virus	Syngenta (08/15): The supervised residue trials are designed for assessing consumer safety and LOQ is used in setting the MRL. The studies are not designed to generate exposure data from pollen and nectar. Currently there is no requirement for providing analytical methods for pollen and nectar. NL(Sept 2015): There is no need whatsoever to challenge the LOQ of 0.002 mg/kg and since this concerns storage stability studies, there is no need to investigate residues in pollen and nectar.	Addressed The LOQ of 0.002 mg/kg achieved by the method used to analyse the samples from the supervised residue trials is a sufficient low appropriate level for MRL setting.

Storage stability of residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		Titers in Honey Bees (Apis mellifera L.), Insects 2013(4), 71-89 Perry CJ et al. 2015: Rapid behavioral maturation accelerates failure of stressed honey bee colonies, PNAS 112(11): 3427-3432 Whitehorn PR et al. 2012: Neonicotinoid pesticide reduces bumblebee colony growth and queen production, Science 336: 351–352.).		

Metabolism, distribution and expression of residues in plants				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(3)	Vol. 3, CP B.7.1, Metabolism, distribution and expression of residues in plants and Vol. 3, CP B.7.16, p. 44, Summary and evaluation of residue behaviour	DE: The metabolism studies available were all carried out as foliar spray. The intended uses as soil application (drip/drench) are therefore not covered by the data. Although the metabolite spectra in plant and soil metabolism studies are identical (except minor soil hydroxy-metabolites NOA 457464 and NOA 457465), large parts of the soil radioactivity are not covered by the residue analytical method, and the soil-plant transfer after drench application cannot be	Syngenta (08/15): We acknowledge that the metabolism studies submitted were carried out as a foliar spray. Seed treatment (not previously submitted) and soil applied (confined crop rotation, DAR section B.7.9) studies provide a good model for the soil-plant transfer of residues following a soil drip/drench application. A summary of available seed treatment metabolism and confined rotational crop studies are provided in the attached Appendix 3. This concludes	Open point RMS to assess in a revised DAR the additional metabolism study submitted by the applicant (seed treatment), considering also the confined rotational crop studies already available in section B.7.9 of the DAR, in order to conclude whether the metabolic profile observed following soil application can be considered similar to the metabolic profile observed following foliar

Metabolism, distribution and expression of residues in plants				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		quantitatively assessed. Further uncertainty is caused by the low identification rate in soil metabolism studies. No toxicological assessment of metabolites is noted. A case should be presented (minimum requirement) covering residue and toxicity aspects.	that there is no significant translocation of abamectin and structurally related compounds from soil systems to aerial parts of plants. Residue trials conducted at the proposed cGAP are consistent with this conclusion (residues of avermectin B_{1a}, avermectin B_{1b} and 8,9-Z avermectin B_{1a} were <0.002 mg/kg in green beans, cucurbits and solanaceae). A toxicological assessment of metabolites is therefore not required. NL(Sept 2015): The additional metabolism study with treated seeds will add sufficient information to address the metabolism of abamectine after soil application. To be evaliueted in revised DAR	applications. Toxicological profile of the identified metabolites should be described as well. See comments in 0(1), 3(4)
3(4)	Addendum Vol. 3, B.7, Metabolism in plants	EFSA: Metabolism in plants has been investigated following foliar applications only, while the intended uses as nematicide refers to soil drip applications. Plant metabolism study using soil applications is requested.	Syngenta (08/15): Please refer to response 3(3). NL(Sept 2015): See comment 3(3)	See open point 3(3)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
3(5)	Vol. 3 CA-B7, General	FR: No comment, we agree with the assessment	NL(Sept 2015): Thank you, noted.	Addressed
3(6)	General comment	PL On the first page a code number A12115l is given. This is Syngenta trade code number of plant protection product Tervigo (Addendum, Volume 1), whereas the information provided relates to the active substance abamectin. Please verify.	Syngenta (08/15): Please refer to comment 2 (12) NL(Sept 2015): The DAR concerns the extension of the active substance abamectin, but since this is marketed as a formulation and since residue trials are conducted with a formulation, B.7 is used both for active substance and product evaluation. The DAR always needs to contain (at least) one representative formulation.	See comment 2(12)
3(7)	B.7.5	PL: Invalid number of the table "Intended Good Agricultural Practices (GAP) for the abamectin as a nematocide in Europe"- the table should be numbered as Table 7.5.1	NL(Sept 2015): So noted, to be amended in revised DAR	Open point RMS to reference in a revised DAR, Table on "Intended Good Agricultural Practices (GAP) for the abamectin as a nematicide in Europe" in page 9 as 7.5.1 (instead of 7.4.1)
3(8)	B.7.6.2	PL: In the description of study design two residue trials on tomato are mentioned, whereas conclusions refer to four trials.	NL(Sept 2015): RMS can agree on the confusion. However, the trial was designed as a two-trial set-up. In each trial, different plots were used: 1) control; 2) 1x drench + 4x drip;	Addressed In each of the two locations, two different experimental conditions were investigated: 1 - drench application,

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			3) 6x drip. Since set-up 2 and 3 can be considered as independent trials, the initial two trials are in fact four independent supervised residue trials.	2 - drip application, Resulting in a total of 4 residue data.
3(9)	B.7.6.3	PL: In the description of study design two residue trials on pepper are mentioned, whereas conclusions refer to four trials.	NL(Sept 2015): See 3(8)	See comment 3(8)
3(10)	B.7.6.4	PL: In the description of study design two residue trials on cucumber are mentioned, whereas conclusions refer to four trials.	NL(Sept 2015): See 3(8)	See comment 3(8)
3(11)	Addendum Vol. 3, B.7 References relied on,	EFSA: Regulation (EC) No 1107/2009 requires a search of the scientific peer-reviewed open literature to be included in all applications made under the regulation. This information is missing in section B.7 residues and should be provided.	Syngenta (08/15): Please refer to comment 2 (1) NL(Sept 2015): A literature search was submitted to the RMS in December 2013. Although no reference is made to the EFSA guidance on literature reviews, a systemic review approach was followed. RMS will include the relevant information in an updated addendum to the DAR. The same approach will be taken as already done in Volume 3CP B-6 A12115I of April 2015. In the literature search two studies were identified as potentially relevant for this	Open point RMS to include in a revised DAR, information on the literature search provided by the applicant. See also data requirement 2(1)

Other comments				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			section. In the updated addendum, RMS will review these studies and if relevant indeed, incorporate these in the addendum.	

4. Environmental fate and behaviour

Route and rate of degradation in soil				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(1)	DAR Addendum 13, LoEP, DT50, lab	DE: For PECgw new normalised DT50 values were used. These values should also be presented in the part 'Rate of degradation in soil'. The title 'extension of approval' could be used to make the difference to the 'original approval'.	NL(Sept 2015): No new studies were conducted. The endpoints of the existing rate studies have been normalised for moisture. The extension only allows for a product assessment, not active substance assessment. Therefore in principle the section route and rate is not relevant. In fact this normalisation shouldn't have been carried out in the scope of this extension. As stated in the addendum RMS accepted this in this particular case. RMS agrees that the normalisation procedure could have been presented in a separate section but this would be merely a layout issue.	See open point at reporting table 4(6).

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(2)		EFSA: See comment in the PECsw section where it is identified that PECsw for the soil metabolites reaching levels that the	Syngenta (08/15): PEC_{SW} for abamectin was calculated in line with EFSA Guidance for protected uses and concluded that entry of abamectin to surface water via	Data requirement Consequent whatever is

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		EU peer review concluded trigger assessment, i.e. NOA448111, NOA448112, NOA457464 and NOA457465 need to be calculated. If these estimates (that are currently missing) were to indicate there might be residues in surface water at the point of drinking water extraction, then Regulation (EC) No 1107/2009 requires in its approval criteria that 'it shall have no immediate or delayed harmful effects on human health, including that of vulnerable groups, or animal health, ….through drinking water (taking into account substances resulting from water treatment). So information on the effect of water treatment processes on the nature of residues when surface water is abstracted for drinking water might need to be considered. If residues at the point of drinking water extraction could not be excluded, in the first instance a consideration of the processes of ozonation and chlorination would appear appropriate.	drainage was negligible. Syngenta noted that EFSA indicated that "the approach chosen by the notifier is conservative". As such, the formation of abamectin water metabolites in surface water, are therefore considered negligible. For soil metabolites, given the similar soil properties of the metabolites to parent (specifically sorption), combined with the low formation fraction means that drainage of soil metabolites is also considered negligible. Since there is no indication that abamectin metabolites will enter into surface water, an assessment of the impact on water treatment plants is not considered necessary. NL(Sept 2015): See RMS reaction at the PECsw/sed section concerning the need for PECsw calculations for the soil metabolites. The mentioned impact on water treatment is a new data point for substances and hence outside the scope of this extension (product assessment).	provided to address the data requirement at reporting table comment 4(8), applicant to demonstarte that NOA448111, NOA448112, NOA457464 and NOA457465 in surface water at any point of abstraction for drinking water will be negligible. Should this not be demonstrated applicant to provide information on the effect of water treatment processes on the nature of residues when surface water is abstracted for drinking water. In the first instance a consideration of the water treatment processes of ozonation and chlorination on the nature of residues should be provided. Note this is not 'a new data point' but an approval criterion specified in Regulation (EC) No

Fate and behaviour in water and sediment and effect of water treatment procedures on the nature of residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
				1107/2009, that needs to be addressed.

PEC in soil				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(3)	DAR Addendum 10 Vol. 3 CP, B.8.3, PECsoil for metabolites	DE: In our opinion PECsoil should be calculated for all relevant soil metabolites. In the LoEP from April 2015 in the part 'Definition of the Residue' it is stated that all soil metabolites are triggered for soil exposure assessment. Within the list of endpoints the unknown metabolite U8 is also listed as relevant soil metabolite but was not included in the part 'Definition of the Residue'. Please clarify if a PECsoil calculation is required for the metabolite U8.	Syngenta (08/15): No specific PEC_{soil} was provided for U8 as the maximum formation was <8% of applied radioactivity. Since there was no definitive chemical identification, the risk assessment for the soil compartment is considered to be covered by the risk assessment for the parent. NL(Sept 2015): A PECsoil calculation is not required for U8 since it does not exceed the trigger of 10%. See also the original inclusion inclusion and addendum confirmatory data.	Addressed.

PEC in soil				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(4)	Vol. 3, B.8.3 PEC soil	UNAF: page 4, the maximum field DT50 of the as is 1.8 days. In the case of abamectin the DT50 field is not the worst case. Moreover the relevance of DT50 field values for glasshouse uses is questionable. A PECsoil calculation using lab values should be at least reported and the use of field values should be justified. Further explanation: The reported DT50 field is strongly different from the lab DT50. How can this difference be explained? Photolysis is usually limited to the top 2 mm of the soil (see for instance EFSA PPR 2010: Guidance for evaluating laboratory and field dissipation studies to obtain DegT50 values of plant protection products in soil, p. 14). Thus photolysis cannot be the unique explanation of the difference. Further explanations on this topic are needed.	Syngenta (08/15): The risk assessment for PEC_{soil} used the EFSA Annex I endpoint for soil of 1.8 days as stated in EFSA journal. **(Abamectin, EFSA Journal (2008) 147, 1-106).** Additionally, as stated in the Tervigo DAR 2015, Volume 1, Point 2.8.6, PECgroundwater *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.* Syngenta wants to highlight the fact that a dossier for Abamectin AIR4 is scheduled for submission in October 2016. NL(Sept 2015): it is not uncommon to see such a difference between lab and field DT50. The lab and field DT50 values were already evaluated during the original inclusion and are no part of the current product evaluation. The use of higher tier field DT50 instead of lab DT50 is according to guidance. Whether the field DT50 is relevant for the current application could be an item of discussion. However, the guidance on clustering and ranking of emisions from protected crops clearly states: *„Open-field methodology is to be used for walk-in tunnels*".There is no indication that field DT50 values should not be used. Also there is no indication that photolysis could not occur in walk-in tunnels (that do not prevent UV radiation).	Addressed. Note under the polythene or other material of a walk in tunnel, the quality and energy of light that might drive photolysis will not be equivalent to that of natural sunlight. Therefore the last sentence of the RMS comment in column 3 is considered by EFSA to be misleading. Photolysis may occur in the tunnel but its rate may be lower than in the open field.

<table>
<tr><th colspan="5">PEC in soil</th></tr>
<tr><td>No.</td><td>Column 1
Reference to DAR (vol., point, page)</td><td>Column 2
Comments from Member States or applicant</td><td>Column 3
Evaluation by (RMS) rapporteur and
- if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant</td><td>Column 4
Data requirement or Open point (if data point not addressed or fulfilled)</td></tr>
<tr><td>4(5)</td><td>Addendum Vol. 3, B.8.3 PECsoil, page 5</td><td>EFSA: PEC in soil have not been calculated for the major soil metabolites. It is also noted the effects database regarding soil organisms is incomplete for the soil metabolites. Therefore the statement that PEC in soil for metabolites are not required because the risk assessment for the metabolites is covered by that for the active substance does not seem appropriate.</td><td>Syngenta (08/15): PEC_{soil} were provided in the original dossier by the Notifier. Please refer to the original dossier.

NL(Sept 2015):
RMS agrees that the PECsoil values in the original dossier do not necessarily cover for the now proposed use. Therefore, RMS performed indicative calculations for the 4 metabolites using the agreed endpoints and the worst-case application scheme (assuming two consecutive crop cycles with a minimum interval between the cycles) of ten applications with an interval of 10 days. The parent dose rate was corrected for max observed % and relative molar weight for each metabolite. This results in the following PECsoil values:
<table>
<tr><th>metabolite</th><th>Dose rate metabolites (g a.s./ha)</th><th>DT50 (days)</th><th>PECsoil (mg/kg)</th></tr>
<tr><td>NOA448111</td><td>10</td><td>50.6</td><td>0.078</td></tr>
<tr><td>NOA448112</td><td>16</td><td>75.4</td><td>0.146</td></tr>
<tr><td>NOA457464</td><td>10</td><td>99.0</td><td>0.099</td></tr>
<tr><td>NOA457465</td><td>10</td><td>173.0</td><td>0.112</td></tr>
</table>
For all metabolites except NOA448112 this results in PECvalues lower than the PEC for the parent substance (0.136 mg/kg). For NOA448112 the available acute endpoint is about 10 times higher (i.e. less critical) than the parent LC50.
For the other metabolites, for which no threshold values are available, a worst-case assumption is that they might be ten times more toxic than the parent. However it was accepted during the review of the confirmatory data that the most critical first tier active substance endpoint was used.</td><td>Open point
RMS to provide their metabolite PEC soil calculations as set out in column 3 of the reporting table at comment 4(5) and add these PEC to the list of endpoints.</td></tr>
</table>

PEC in surface water and ground water				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(6)	Addendum Vol. 3, B.8.6.1 PECgroundwater, pages 11-15 and 16-20	EFSA: The normalisations carried out for incubation soil moisture content are wrong / do not comply with FOCUS guidance. The incubation gravimetric soil moisture contents are available for each soil (are clearly described in the original DAR). Therefore FOCUS default MWHC values for each soil texture should not have been used as the basis for the calculations of the incubation soil moisture, rather the known moisture contents of the incubations should have been used for the moisture correction factors. If the correction factors are correctly calculated, the geometric means appropriate for use in FOCUS modelling are: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d NOA457465 112.3 d. Consequently updated PECgw may need to be calculated. The above DT50 are all longer than those used in the available modelling. Note in any surface water modelling that would be provided in the future for these soils metabolites, EFSA considers the soil DT50 indicated in this comment would need to be used. Further explanation: see commenting table EFSA	Syngenta (08/15): Syngenta acknowledge the EFSA comments concerning the normalisation for PEC_{GW}. The impact of the different input parameters is considered to be of minor consequence when compared to the modelled soil loading of 5000 g/ha. Given the worst case application rate of abamectin, the modelling is still considered relevant to demonstrate negligible leaching of abamectin and metabolites – see comment 4(3). NL(Sept 2015): RMS agrees with the EFSA comment regarding the normalisation but also agrees with the applicant that no impact on the outcome of the groundwater assessment is to be expected.	Open point RMS to update the list of endpoints laboratory studies rate of aerobic degradation to include the appropriate FOCUS reference condition and guidance normalised geomean lab soil DT50 of: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d and NOA457465 112.3 d. Data requirement Applicant to provide new PECgw using the soill DT5: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d NOA457465 112.3 d.

PEC in surface water and ground water				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(7)	B.8.6.2	PL: It is likely that PECsw values calculated for other D scenarios (not only D6) could be also useful for risk assessment. Although it is not possible to calculate the PECsw values for fruiting vegetables, but maybe the substitute crops could be used instead of fruiting vegetables. However, if it is assumed that PECsw for other D scenarios would be lower than PECsw for D6, and the value for D6 scenario represents the worst case, the report should contain some information/ justification about that.	Syngenta (08/15): D6 was modelled since it is the only scenario available for fruiting vegetables, however given the sorption parameters of abamectin. PEC_{SW} for D6 is considered indicative for other D scenarios - see comment 4(3). NL(Sept 2015): At this moment there is no EU agreed surrogate crop to perform additional calculations with other scenarios. This could be addressed at Member State level.	Addressed
4(8)	Addendum Vol. 3, B.8.6.2 PECsurface water, pages 11-15 and 16-20	EFSA: PECsurface water have not been calculated for the soil metabolites that the peer review considered reached levels that triggered consideration. Namely NOA448111, NOA448112, NOA457464 and NOA457465. These metabolites were only present at very low levels in the sediment water systems. Therefore it is considered unlikely that microcosm / mesocosm study effect endpoints might be used to cover the risk for these compounds. Anyway endpoints from microcosm / mesocosms are low indicating toxicity from whatever compounds were present in these effects studies. Effects data where a metabolite	Syngenta (08/15): PEC_{SW} for abamectin was calculated in line with EFSA Guidance for protected uses and concluded that entry of abamectin to surface water via drainage was negligible. Furthermore there is no indication that abamectin metabolites will enter into surface water - see comment 4(3). NL(Sept 2015): During the original inclusion a STEP 1-2 assessment was performed for the soil metabolites in the addendum (November 207, revised February 2008) for reasons of completeness, although the exposure of these metabolites was expected to be low.	Data requirement Applicant to provide PECsw at step 3 and possibly step 4 for the soil metabolites NOA448111, NOA448112, NOA457464 and NOA457465 and present a consequent aquatic risk assesment. Note the soil DT50 to be used in the calculations are: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d NOA457465 112.3 d.

PEC in surface water and ground water				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		was dosed only appears available for one of these metabolites (NOA448112, daphnia EC50 1.6µg/L) but this endpoint indicates, that at least NOA448112 is quite hazardous. Therefore to complete a risk assessment PECsw at step 3 and possibly step 4 for NOA448111, NOA448112, NOA457464 and NOA457465 would need to be provided, noting that they all have higher geomean soil DT50 and lower adsorption constants than the values used for the active substance abamectin in the available PECsw calculations for the nematicide uses. Therefore the available simulations for abamectin, do not 'cover' the exposure that may occur from these metabolites.	These outcomes were not included in the list of endpoints. Please note that the mentioned EC50 for Daphnia of NOA 448112 is a factor 10 less toxic than the Daphnia endpoint for the parent (comparable to the ratio observed for the soil organism endpoint). The fact that for other metabolites effects data are missing is no different than the situation at the original inclusion. RMS would like to emphasize that the current use extension is a product assessment and not a substance assessment. This issue was already addressed in the addendum on confirmatory data (see pp 133) by showing the much lower surface water exposure of the metabolites compared to the parent. If a STEP 3 assessment using the available drainage scenarios would be performed for the current use, it is expected that based on the comparable sorption and degradation endpoints of the metabolites in combination with a lower "dose rate" compared to the parent the PEC of the soil metabolites in surface water will also be negligible (as is already shown for groundwater).	

Definition of the residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(9)	DAR addendum 13_List of endpoints_2015-04-14, Definition of residue	DE: In the provided list of endpoints within the paragraph `Route of degradation in soil´ the unknown metabolite U8 is listed as relevant soil metabolite, occurring with > 5 % of AR on > 2 consecutive time points. However, later on within the paragraph `Definition of residue´ this metabolite is not stated any more. Please clarify why no assessment is triggered for this metabolite.	Syngenta (08/15): Confirmatory data concerning U8 addressed the Annex 1 inclusion directive specific provision regarding the risk to groundwater with respect to the metabolite U8. Additional data was provided concerning the unidentified soil metabolite U8 found in Phaff (2003) study. In three soils tested, U8 was found in two of them (18 Acre and Marsillargues soils) at levels below 8%. Other characterised metabolites have all been shown to be of similar structure to the parent and of low risk to the environment. A study data review was conducted and no structural information was forthcoming. A detailed review of the 2D-TLC for this unknown metabolite indicates one spot on some 2D-TLC and on others it appears as two spots. Therefore the percentage U8 reported is a worst case and is likely to be less in reality. Despite exhaustive attempts made during the study U8 remains uncharacterised. It is considered that U8 will be of similar risk to the other metabolites. As a result, no additional assessment of the risk from U8 metabolite was considered necessary. This is consistent with the EFSA Annex I conclusion for abamectin.	Open point To aid transparency, as the updated addendum for the confirmatory data submission that resulted in the Commission concluding in their review report that the issue regarding U8 and groundwater exposure was addressed is not publically available, RMS is requested to add their evaluation of the information previously provided regarding this (i.e. updated addendum for the confirmatory data submission (section B.8.6.2 of addendum dated April 2012)) in an updated addendum to the addendum of April 2015.

Definition of the residues				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			NL(Sept 2015): U8 is only included in the definition of the residue for groundwater since it only exceeds the triggers for groundwater (see also the confirmatory data addendum). Furthermore this is a substance issue and not within the scope of the current application for extension.	

Other comments incl. available monitoring data				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
4(10)	Addendum Vol. 3, B.8.10 References relied on, page 31	EFSA: Regulation (EC) No 1107/2009 requires a search of the scientific peer-reviewed open literature to be included in all applications made under the regulation. What is provided should follow the EFSA guidance on literature reviews, so follow a systematic review approach. There is no evidence from what is presented in the addendum to volume 3 B.8 that the applicant completed this task in relation to information on fate and behaviour in the environment.	Syngenta (08/15): Please refer to comment 2 (1) NL(Sept 2015): A literature search was submitted to the RMS in December 2013. Although no reference is made to the EFSA guidance on literature reviews, a systemic review approach was followed. RMS will include the relevant information in an updated addendum to the DAR. The same approach will be taken as	Open point RMS to include in a revised DAR, information on the literature search provided by the applicant. See also data requirement 2(1)

Other comments incl. available monitoring data				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			already done in Volume 3CP B-6 A12115I of April 2015. In the literature search two studies were identified as potentially relevant for this section. In the updated addendum, RMS will review these studies and if relevant indeed, incorporate these in the addendum.	

5. Ecotoxicology

Birds and other terrestrial vertebrates				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(1)	DAR Addendum 11 Vol. 3 CP, B.9.1.5, Risk assessment for birds	DE: We agree with the RMS but only on the basis of the restriction to the indoor application as soil drip as presented in Vol. 1, chapter 1.5.1.	NL(Sept 2015): Noted.	Addressed.
5(2)	Addendum Vol. 3, B.9.1.5 Risk assessment for birds	EFSA: according to the GAP, the application is performed indoor. However, no consideration is provided about later stage. Can the RMS confirm that the treated plants remain in indoor conditions after being treated (no transplanting to open field or removal of non-permanent structures)? Please note that this comment is relevant for other areas of the risk assessment where negligibility of exposure was claimed (i.e. mammals).	Syngenta (08/15): Syngenta uses presented in this Tervigo submission are grown, cultivated and harvested indoor, under structures that are semi-permanent considered to last a maximum of 5 years. NL(Sept 2015): As mentioned also by the notifier the crops are considered to be grown, cultivated and harvested indoor and no removal of non-permanent structures is assumed. Perhaps this issue could be addressed even better by applying a restriction sentence.	Addressed.

Aquatic organisms				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(3)	Vol. 3, IIIA, 10.2.2.1/01	AT: It is agreed that the endpoint should be recalculated, but we question whether it is	Syngenta (08/15): Studies with the formulated product are not designed to	Addressed. **Note**: the comment from Austria is

Aquatic organisms				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		completely correct to calculate the Probit analysis only with two concentrations (5.91µg a.s./L according to our calculations). However, the result may not change considerably.	maintain the test concentrations. Therefore poor maintenance of test concentrations is not an error. These static design studies are used to assess the risk from the formulation for • classification and labelling for shipping and transportation • assess the effect from the formulation. Zero time analysis is required to demonstrate correct dosing at study start. Analysis at later time points is using one component (in this case the active ingredient) to illustrate what happens under test conditions. The decline of abamectin in test concentrations is expected due to the properties of the technical material. Therefore the conduct and reporting of these studies is entirely correct and fit for purpose. The studies with the formulated product are not designed to be a surrogate to assess the toxicity of the technical material. Syngenta believe it's inappropriate to recalculate the endpoints from the formulation aquatic studies. NL(Sept 2015): The comment is not really clear, because the	referred to the acute FISH toxicity test (Liedtke, 2011), while the response from the RMS seems to be related to the acute DAPHNIA toxicity test (Höger, 1997). EFSA in principle agrees with the comment from Austria. However, in this case, the space between tested concentrations is rather small (2.5 µg a.s./L from 0 to 100% effect). EFSA also tried to recalculate the endpoint The calculated values were always reasonable close to that reported by the RMS, irrespectively of the dose-response model used. Overall, the result is considered acceptable.

Aquatic organisms				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			EC50 is calculated on basis of three concentrations and not two concentrations. Based on three concentrations the EC50 is 0.0759 µg as/L.	
5(4)	Vol. 3, IIIA, 10.2.2.2/01	AT: Reference and year of execution should probably be in line. It would be helpful to have the results presented within a table.	NL(Sept 2015): Reference and year of execution have been brought in line. In the given table the results are presented.	Open point For the acute study on daphnia (Vol. 3, IIIA, 10.2.2.2/01), reference and year of execution should be aligned. In addition, the table presented under the evaluation by the RMS should be revised (e.g. under the column "immobility %, one value reports "10 µg")
5(5)	DAR Addendum 11 Vol. 3 CP, B.9.2.5, Risk assessment for aquatic organisms	DE: We agree with the RMS but only on the basis of the restriction to the indoor application as soil drip as presented in Vol. 1, chapter 1.5.1.	NL(Sept 2015): Noted.	Addressed.
5(6)	Vol. 3.B.9, B.9.2.4 Summary of aquatic toxicity data	PL: There is a mistake in the first sentence: instead of "*avian toxicity data*" should be "*aquatic toxicity data*".	NL(Sept 2015): Noted. Addendum has been adjusted.	Addressed. RMS to correct in an amended DAR, this action is needed according to SANCO/10190/2013-rev.1
5(7)	Vol.3 B.9, B.9.2.5 Risk assessment for aquatic organisms	PL: From the sentence in first paragraph: "The higher tier RAC from the mesocosm study is 0.049 µg/L with a safety factor of 3 is 0.016 µg/L" is difficult to distinguish which the value is a RAC, is this equal 0.049 µg/L or 0.016 µg/L? This sentence should be rewrite to make it clear.	NL(Sept 2015): Noted. Addendum has been adjusted.	Open point RMS to better clarify which value is the mesocosm endpoint and which is the higher tier RAC for the aquatic risk assessment.

Aquatic organisms				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(8)	Vol. 3, B.9.2.1.3 Acute toxicity of the formulated product	UNAF: page 8, the low recoveries for the highest tested concentrations are considered to be the result of sampling mistake. As a consequence, the test should not be considered as valid and should be redone.	Syngenta (08/15): please refer to comment 5(3) NL(Sept 2015): There was only a sampling mistake in the highest test concentration (1.25 µg a.s./L), but this concentration is not important for the calculation of the EC50 value, because already 100% immobility was reached in the two lower test concentrations (0.125 and 0.39 µg a.s./L). Hence, the test can be considered as valid and the endpoint can be used for risk assessment.	Addressed.
5(9)	Addendum Vol. 3, B.9.2.5 Risk assessment for aquatic organisms	EFSA: RMS claimed that the risk for the metabolites which are formed in water is covered by the risk assessment of the parent. However, the risk for soil metabolites isn't. There are 4 soil metabolites (namely NOA448111, NOA448112, NOA457464, and NOA457465) which are more persistent and more mobile than the parent. Furthermore, aquatic toxicity data are available for only one of them (NOA448112), which showed to be rather toxic to daphnids (EC50=1.6 µg/L). A full risk assessment for these metabolites	Syngenta (08/15): PEC_{SW} for abamectin was calculated in line with EFSA Guidance for protected uses and concluded that entry of abamectin to surface water via drainage was negligible. Furthermore there is no indication that abamectin metabolites will enter into surface water - see comment 4(3). NL(Sept 2015): RMS agrees that the PECsoil values in the original dossier do not necessarily cover for the now proposed use. Under comment 4(5) indicative calculations for	Data requirement The risk assessment for the active substance does not necessarily "cover" the risk assessment for soil metabolites (NOA448111, NOA448112, NOA457464, and NOA457465). Following data requirement under point 4(8) in the RT in the e-fate section, the notifier is requested to provide a full risk assessment for these metabolites, including ecotoxicological data/information. Note to the RMS:

Aquatic organisms				
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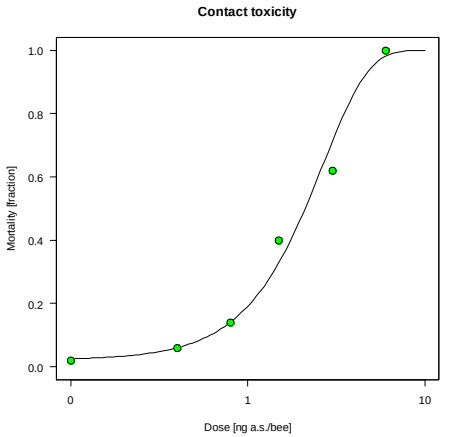
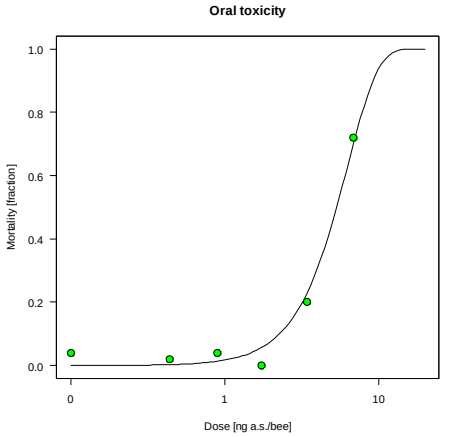
		should be carried out. See also the relevant comment in the e-fate section.	PECsoil for the soil metabolites were performed. For all metabolites except NOA448112 this results in PECvalues lower than the PEC for the parent substance (0.136 mg/kg). For NOA448112, however, the available acute endpoint is about 10 times higher (i.e. less critical) than the parent LC50. For the other metabolites, for which no threshold values are available, a worst-case assumption is that they might be ten times more toxic than the parent. However it was accepted during the review of the confirmatory data that the most critical first tier active substance endpoint was used.	PECsoil for metabolites does not necessarily represent a "proxy" for PECsw, considering the persistency and the mobility of the metabolites. Furthermore, in case no ecotoxicity data are available, the screening risk assessment should be in line with similar previous evaluations i.e. assuming that the metabolites are ten times more toxic than the parent.

Bees and non-target arthropods				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(10)	DAR Addendum 11 Vol. 3 CP, B.9.5.2, Risk assessment for other non-target arthropods	DE: We agree with the opinion of the RMS that it is not clear if the risk for P. cupreus is acceptable. We also agree that it is not sufficient to test only one species and beside	Syngenta (08/15): No data with the abamectin formulation A12115I are available; however data on *Folsomia* and *Hypoaspis* are available with an abamectin 18 SC	Data requirement Applicant to submit information to address the risk to non-target arthropods, especially to provide

Bees and non-target arthropods				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		that one which is known to be really insensitive. Thus we also think that test on Folsomia candida and Hypoaspis aculeifer are required.	formulation. Further data has been submitted in the product dossier submission to the different Member States. NL(Sept 2015): No new data will be taken into account at this stage. As further data has been submitted in the product dossier to the different Member States it is proposed to take these data into account at Member State level.	information on the toxicity of abamectin to Folsomia candida and Hypoaspis aculeifer. See also point 5(14); 5(17)
5(11)	Vol. 9, B.9 4 .1.2: Acute toxicity of the formulated product	UNAF: For establishing the oral and contact DL50 five doses were used. This is not sufficient for defining the toxicity curve, all the more so since abamectin curve seems not to be the usual sigmoid curve. Further explanation: For the characteristics of abamectin curve, see the conclusion on the peer review on abamectin (2008) p. 31: However the oral acute endpoint was not taken into account in the risk assessment since it was considered not reliable since the mortality rate at a dose of 0.001 µg a.s./bee was greater than the mortality at the next higher dose of 0.005 µg a.s./bee. However the quoted figures are plausible	Syngenta (08/15): Please see OECD Guidelines 213 and 214 for information on the recommended number of test doses. The test with the formulation is considered valid. Syngenta note that the data presented by Suchail et al have not been reproducible by others and the offered dose rather than actual consumed dose was reported. NL(Sept 2015): Agreed with the reaction of the applicant. The study is considered valid.	Addressed. The data provided respect the number of tested doses (5) as required in the OECD 213 and 214 guideline. Furthermore, the available study clearly shows that the spacing of the doses was able to caracterise the entire dose-response curve. Finally, both contact and oral exposure resulted in a clear monotonic effect trend, which is well described by sigmoidal curves.

Bees and non-target arthropods				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		since the relation between dose and toxicity may be really different from a sigmoid, see for instance Suchail, S., Guez, D., and Belzunces, L.P., 2000: Characteristics of Imidacloprid toxicity in two Apis mellifera subspecies, Environmental Toxicology and Chemistry: 19(7): 1901–1905.		 

Bees and non-target arthropods				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(12)	Vol. 9, B.9 4 and B.9.5.: "The proposed soil drip use indoors will result in negligible exposure…	UNAF: Applicant's statement is not acceptable. The intended crops (pepper, tomato, eggplant, cucurbits) are entomophilous. In fact bumble bees or honeybees are introduced in the glasshouses when the crop is flowering. The risk for these pollinators should be considered.	Syngenta (08/15): Syngenta acknowledge that the intended crops are entomophilous, however note that honeybees are rarely used indoors for pollination. Bumble bees, on the other hand, are used for pollination services indoors. Given the physico-chemical characteristics of abamectin, exposure of bumble bees is considered negligible. NL(Sept 2015): Agreed with the opinion of the applicant.	Open point EFSA to include a sentence in the conclusion, highlighting that risk for pollinators intentionally introduced in the closed system is not covered by the present assessment.
5(13)	Vol. 9, B.9 4 and B.9.5.	UNAF: Bees consume water, mainly for brood breeding. Active substance concentration in the drip water is 0,5-1 g/hL i.e. 5-10 mg/L (see vol1 p. 7). This concentration level is clearly higher than the DL50 measured in the oral and contact toxicity tests. The risk associated with water consumption is thus high and should be considered. Further explanation: Glasshouses don't remain continuously closed and bees are attracted to drip water - bees don't like open water and prefer drinking from moist soils or from dropping water. In oral and contact toxicity test, bees' exposure to 6 ng results in 72% and 100% mortality respectively.	Syngenta (08/15): Syngenta acknowledge that bees consume water, however as stated above, honeybees are rarely used indoors for pollination. Bumble bee exposure is also considered negligible as they do not actively consume water. Furthermore, physical screening is typically undertaken to keep out unwanted insect pests. While exposure to individual honeybees may occur, exposure to honeybee populations is considered negligible. NL(Sept 2015):	Addressed.

Bees and non-target arthropods				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Notifier/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		6 ng in 10 or 20 microL (see EPPO 170) mean 0,6mg/L or 0,3 mg/L respectively. DL50 concentrations are thus lower than the ones used in drip water.	Agreed with the applicant that mostly bumble bees are used for pollination. To exclude any risk the following restriction sentence can be placed on the label: *Dangerous for bees. Do not allow bees and other pollinators into the greenhouse (for example, close off all openings with screens).*	
5(14)	Addendum Vol. 3, B.9.5.2 Risk assessment for NTA	EFSA: we agree with the RMS that tests on other soil species, such as *Folsomia candida* and *Hypoaspis aculifer*, should be carried out for a more transparent risk assessment.	Syngenta (08/15): Please refer to comment 5(10). NL(Sept 2015): Please refer to comment 5(10).	See data requirement 5(10).

Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(15)	Vol., B 9.6.2	AT: Significant, dose dependent effects on the mean biomass change were observed, but not discussed further in the risk assessment. Are these effects not considered to be of relevance?	Syngenta (08/15): The effects are presented in the study summary and also presented in the overall summary of the available toxicity data. These effects are deemed relevant and are reflected in the study NOEC. NL(Sept 2015):	Addressed.

Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
			Agreed with the reaction of the applicant. Furthermore it is an acute test and the endpoint is based on mortality.	
5(16)	DAR Addendum 11 Vol. 3 CP, B.9.6.3, Risk assessment for earthworms	DE: We agree with the RMS but only on the basis of the restriction to the indoor application as presented in Vol. 1, chapter 1.5.1 and in the case that the exposure of natural soil can be excluded. However if the application takes place as soil drip irrigation in walk-in tunnels as specified by the applicant it has to be expected that the tunnels are constructed on natural soil and hence an exposure of earthworms and other non-target soil organisms cannot be excluded. According to Vol. 3, Part B.8 PECsoil calculation the application on soil in walk-in tunnels has to be regarded as an open field application. In this case the assessed unacceptable chronic risk for earthworms has to be addressed. For the metabolites only acute earthworm studies were provided. However the metabolite NOA448112 has a DT90 > 100 days and the intended uses allow more than three applications. Thus in analogy to the requirements for active substances also the long-term risk to earthworms should be addressed for the metabolite NOA448112. The risk for earthworms posed by the	Syngenta (08/15): The toxicity of the soil metabolites to soil organisms was assessed during the Annex I approval and the EFSA conclusion was that "*it can be assumed that toxicity of these metabolites will also not be higher than that of the parent.*" With respect to the unknown metabolite U8 please see comment 4(4). NL(Sept 2015): It is agreed that the chronic risk for earthworms has to be addressed when the soil can be considered as a natural soil. That is also stated in the Addendum. Because not in all Member States the soil in glasshouses is considered as a natural soil with a natural soil community, this issue is considered as a Member State specific issue. With regard to the soil metabolites; under comment 4(5) indicative calculations for PECsoil for the soil metabolites were performed. For all metabolites except NOA448112 this	Data requirement: Applicant to provide data to address the risk for soil metabolites of abamectin. The chronic risk for the soil metabolite NOA448112 should be addressed as well. As present data are not enough to demonstrate a low chronic risk for the active substance abamectin, further information to address this risk should be provided. Open point RMS to include a full risk assessment to earthworms for all soil metabolites. In line with previous evaluations, where toxicity data for metabolites are missing, a toxicity 10 times higher than the parent is assumed for a screening assessment. Since for metabolite NOA448112 a chronic risk assessment is triggered, this should be included as well. Please note that for the evaluation at the EU level, it is not possible to exclude that the application will be performed on

Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		exposure to the soil relevant metabolites was not addressed in a quantitative assessment. It is only stated that the PEC for the active substance presents a worst case and hence the assessment for the parent also covers the metabolites. As commented above for the environmental fate section from our point of view the PECsoil should be calculated for the metabolites and these values should be used for a TER calculation based on the available endpoints for the metabolites. No tests were provided for the soil metabolites. However, within the list of endpoints the metabolites NOA457464, NOA457465 and the unknown metabolite U8 are stated as relevant soil metabolites. The only statement is that in view of the LC50 for the metabolite NOA448112 it can be assumed that the toxicity of these metabolites will also not be higher as the toxicity of the parent. However, no real explanation is presented for this assumption. Is this assumption made based on a structural similarity? Please clarify this assumption.	results in PECvalues lower than the PEC for the parent substance (0.136 mg/kg). The PECsoil for NOA448112 was just a little bit higher than the PECs for the parent (0.146 mg/kg). The qualitiative risk assessment is the same as the one used for Annex I approval and at that time it was accepted by all Member States.	natural soil. As a consequence, the risk to soil organisms should be addressed as an open field application. See also points 4(5); 5(18); 5(19); 5(20).
5(17)	DAR Addendum 11 Vol. 3 CP, B.9.6.3, Risk assessment for earthworms	DE: Only toxicity data and a risk assessment for earthworms were presented. As stated for the risk assessment for non-target arthropods tests with Folsomia candida and Hypoaspis aculeifer are required to address the risk for	Syngenta (08/15): please refer to comment 5(17) NL(Sept 2015):	Data requirement Applicant to submit further information to address the risk to other non-target soil organisms.

Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		soil dwelling organisms. Beside that it has to be taken into account that a test for other non-target soil organisms is triggered if the long-term TER for earthworms is < 5.	Agreed that these tests are necessary. Please, refer to coomment 5(10).	See also data requirement 5(10).
5(18)	Vol.3. B.9. B.9.6.3 Risk assessment for earthworms	PL: The toxicity data for metabolites NOA 427011 and NOA448112 are available, therefore for completeness of the evaluation, the PECsoil for these metabolites could be calculated and the risk assessment might be based on the corresponding values for metabolites.	Syngenta (08/15): please refer to comment 4(6) NL(Sept 2015): Please, refer to comment 5(16).	See open point 4(5) and 5(16)
5(19)	Addendum Vol. 3, B.9.6.3 Risk assessment for earthworms	EFSA: the maximum initial PECs for abamectin does not necessarily represent a worst-case for metabolites, as these are more persistent and may reach higher concentrations after 4-6 applications. See also the respective comment in the e-fate section.	Syngenta (08/15): The risk assessment approach taken was based on the relatively low formation fraction for the soil metabolites combined with using the maximum initial PECS of abamectin. This was considered appropriate in setting a reasonable worst case. NL(Sept 2015): Please, refer to comment 5(16).	See open point 4(5) and 5(16)
5(20)	Addendum Vol. 3, B.9.6.3 Risk assessment for earthworms	EFSA: no toxicity data are available for 3 soil metabolites. In the Addendum, the toxicity of these metabolites was assumed to be equal to that of the parent. However, there are no data underpinning this assumption. Normally, when no data are	Syngenta (08/15): please refer to comment 5 (16) NL(Sept 2015): please refer to comment 5(16).	See data requirement and open point 5(16)

Earthworms and other non-target soil macro- and mesofauna				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		available for metabolites, the risk assessment is carried out assuming that these are 10 times more toxic than the parent.		

Soil nitrogen transformation				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(21)	DAR Addendum 11 Vol. 3 CP, B.9.7.2, Risk assessment for soil micro-organisms	DE: We agree with the assessment presented by the RMS. According to chapter B.8.3 of Vol. 3 part B.8 the PECsoil was calculated for an application in walk-in tunnels which is regarded as an open field application. Thus the calculated PECsoil values present a worst case for an indoor application as they account for the exposure of natural soil for this specific form of an indoor use. No tests were provided for the soil metabolites. However, within the list of endpoints the metabolites NOA457464, NOA457465 and the unknown metabolite U8 are stated as relevant soil metabolites. It is argued that according to the available aquatic studies with metabolites it can be assumed that the toxicity of the metabolites is lower as	Syngenta (08/15): please refer to comment 5 (16) NL(Sept 2015): Please, refer to comment 5(16).	Data requirement: Applicant to provide data to address the risk to soil microorganisms for soil metabolites of abamectin. See also point 4(5); 5(22); 5(23)

Soil nitrogen transformation				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		for the parent. On the other side the exposure towards these metabolites can be expected to be lower as for the parent and hence the risk for the metabolites can be regarded to be covered. As additional argument it is stated that it is very unusual that the toxicity of a metabolite is more than ten times higher as the toxicity of the parent. We agree with this statement but than we would suggest the provision of a risk assessment based on the worst case assumption of a ten time higher toxicity and the calculated PECsoil for the respective metabolites. Such an assessment would clearly demonstrate the risk posed by the metabolites and underline the conclusion presented by the RMS.		
5(22)	Addendum Vol. 3, B.9.7.2 Risk assessment for soil micro-organisms	EFSA: the maximum initial PECs for abamectin does not necessarily represent a worst-case for metabolites, as these are more persistent and may reach higher concentrations after 4-6 applications. See also the respective comment in the e-fate section.	Syngenta (08/15): please refer to comment 5 (16) NL(Sept 2015): Please refer to comment 5(16).	See open point 5(21)
5(23)	Vol.3. B.9. B.9.7.2 Risk assessment for soil micro-organisms	PL: Since the toxicity data for metabolites NOA 427011 and NOA448112 are available, therefore for completeness of the evaluation, the PECsoil for these metabolites could be calculated and the risk assessment might be	Syngenta (08/15): please refer to comment 4(6) NL(Sept 2015):	See open point 5(21)

Soil nitrogen transformation				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		based on the corresponding values for metabolites.	please refer to comment 5(16).	

Terrestrial non-target higher plants				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(24)	DAR Addendum 11 Vol. 3 CP, B.9.8.2, Risk assessment for terrestrial non-target plants	DE: We agree with the RMS but only on the basis of the restriction to the indoor soil drip application.	Syngenta (08/15): Please refer to comment 0(2) NL(Sept 2015): Noted.	Addressed.

Other comments incl. available monitoring data				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
5(25)	Addendum Vol. 3, B.9	EFSA: Regulation (EC) No 1107/2009 requires a search of the scientific peer-reviewed open literature to be included in all applications made under the regulation. What is provided should follow the EFSA guidance on literature reviews, so follow a	Syngenta (08/15): Please refer to comment 2 (1) NL(Sept 2015): A literature search was submitted to the RMS	Open point RMS to report in a revised addendum the summary and the evaluation of the available literature search. Relevant studies retrieved during the literature seach should be summarised and

Other comments incl. available monitoring data				
No.	Column 1 Reference to DAR (vol., point, page)	Column 2 Comments from Member States or applicant	Column 3 Evaluation by (RMS) rapporteur and - if available - (Co-RMS) Co-rapporteur / response from the Applicant/applicant	Column 4 Data requirement or Open point (if data point not addressed or fulfilled)
		systematic review approach. There is no evidence from what is presented in the addendum to volume 3 B.9 that the applicant completed this task in relation to information on ecotoxicology.	in December 2013. Although no reference is made to the EFSA guidance on literature reviews, a systemic review approach was followed. RMS will include the relevant information in an updated addendum to the DAR. The same approach will be taken as already done in Volume 3CP B-6 A12115I of April 2015. In the literature search two studies were identified as potentially relevant for this section. In the updated addendum, RMS will review these studies and if relevant indeed, incorporate these in the addendum.	evaluated in the revised DAR as well. See also data requirement 2(1)

Appendix 1. ARGUMENTATION FOR DOSE JUSTIFICATION OF A12115I

Proposed intended use of A12115I in tomato is maximum 6 applications with 5 l/ha of formulated product per application. This would bring 100 g of abamectin per application, with maximum 6 application (600 g a.i/ha per crop cycle).
For Pepper, aubergine, green beans and cucurbits the maximum number of applications is 4, with 5l/ha of formulated product per application. See also document D1..

Dose justification
Trials were carried out by Syngenta organisations, contractor companies and official research institutes, all of which follow the EPPO guidelines and are officially recognized by the competent authorities to carry out field registration trials in accordance with the principles of Good Experimental Practice (GEP).

All efficacy trials were done under protected conditions. Data were presented from the Mediterranean EPPO zone, since in this area the trial success rate is high due to the pressure of root-knot nematodes and the natural infestation of trial sites. No data from other EPPO zones were available.
A12115I was tested from 1 to 5 L/ha (20 -100 g abamectin/ha) in tomato, eggplant, pepper, melon, watermelon, cucumber, zucchini and green beans for the control of root-knot nematodes (Meloidogyne spp). In all the trials the product was applied as a soil drip (soilbound application) with 4 applications and 10-14 days application intervals, starting with first application just after transplanting. Efficacy was tested under protected indoor conditions, according to the intended use.

Crops	EPPO Zone	# trials	% control of A12115I					
			1 l/ha		2-2,5 l/ha		5 l/ha	
			Mean	S.D	Mean	S.D	Mean	S.D
Solanaceae (tomato, eggplant, pepper)	Mediterranean	7	**38.4**	**26.78**	**51.9**	**29.27**	**59.98**	**26.7**
Cucurbitaceae (melon, watermelon, cucumber, zucchini)	Mediterranean	11	**37.78**	**24.09**	**55**	**20.95**	**61.56**	**18.75**

According to the presented results, the dose of 5 L/ha of A12115I provided the optimum overall control and should be considered as effective against the root-knot nematodes, for which activity of A12115I is claimed. 5 l/ha of A12115I per application showed the highest efficacy on average. The dose of 5 l/ha is selected on the basis of its efficacy performance, product safety parameters and environmental limitations. As root-knot nematodes are causing the damage throughout the season and hatching occurs in 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 applicant asks for six applications because tomato is a crop where farmers make long growing cycles (much more often than in other fruiting vegetable crops).

With the more restrictive legislation environment, many nematicide solutions are at the moment withdrawn from the market and there is a clear need for the new solutions.

100 g/ha of abamectin is much higher rate than foliar use rate of abamectin. However we should emphasize that in foliar use abamectin is used on completely different pest spectrum (mites, leafminers, thrips and some Lepidoptera species). Nematodes from Meloidogyne genus are organisms from soil pest complex and as such require the product application in/onto the soil where product has to come in the contact with the pest. The patterns for expression of product control potential in the soil environment is very different than on plant tissue, especially taking into account the fact that abamectin applied as a foliar solution has strong translaminar activity and acts in a great manner by ingestion, while in the soil abamectin doesn't have significant root uptake, so it's activity is based on contact activity which means it has to be spread all over the root zone to come into the contact with the organisms like nematodes which are very numerous and spread in the upper soil layer.
The proposed rate of 5 L/ha should be considered the minimum effective dose to deliver control of root-knot nematodes (Meloidogyne spp) in indoor growing tomato, eggplant, pepper, melon, watermelon, cucumber, zucchini and green bean as a soil drip application.

Efficacy tests

Efficacy data for root-knot nematodes (Meloidogyne spp) are presented from 41 efficacy trials assessed. These trials were carried out between 2009 and 2011 in Spain, Italy and Greece. In all the trials the product was applied as a soil drip with 4 applications with 10-14 days application interval, starting with first application just after transplanting. Efficacy was tested under protected indoor conditions, according to the intended use and compared to a reference product based on oxamyl.
The table below shows a summary of root galling control on tomato, eggplant, pepper, melon, watermelon, cucumber, zucchini, green bean.

Crop	EPPO Zone	# trials	% control			
			A12115I at 5 l/ha with 4 applications		Reference product based on oxamyl with 4 applications	
			Mean	S.D	Mean	S.D
tomato	Mediterranean	10	**48.55**	**29.64**	**37.861**	**25.88**
eggplant	Mediterranean	6	**67.54**	**18.33**	**47.05**	**28.53**
pepper	Mediterranean	2	**56.90**	**5.51**	**39.17**	**27.10**
melon	Mediterranean	10	**60.89**	**21.91**	**50.27**	**18.02**
watermelon	Mediterranean	2	**58.5**	**23.33**	**42**	**12.73**
cucumber	Mediterranean	5	**52.98**	**20.19**	**39.95**	**23.68**
zucchini	Mediterranean	5	**46.69**	**23.51**	**31.52**	**25.53**
Green bean	Mediterranean	1	**70.29**	**na**	**52.66**	**na**

Data demonstrated that A12115I at the proposed rate of 5 l/ha was superior to the efficacy of the reference product based on oxamyl against root-knot nematodes (Meloidogyne spp).

Regarding the **number of applications** it is important to say that abamectin is the product with limited soil dissipation time and to achive the protection through the extended period of time it is needed to make several consecutive applications. Root knot nematodes can be found in the soil in different life stages: eggs or juveniles (J2). J2 stage is infective stage of the pest and cannot survive for a long time without the host, while egg stage can stay incative in the soil for a longer period and hatch when conditions become favourable.

Abamectin does not have real ovicide properties and therefore it is required the prolonged period of a.i. presence in the soil to ensure that infective stages coming from later hatching could be controled. Prolonged period of a.i. presence in the root zone is possible to maintain with multiple applications applied as consecutive with certain interval between the application.

Results from the efficacy trials have shown that **application interval** should not exceed 14 days. Number of application depends on the needed period of protection of root zone which depends on longevity of the growing cycle. For short growing cycle (3-4 months) 4 applications can achieve satisfactory contol level. However tomato is the crop frequently grown in long cycle growing period (6 or more months). In this condition, it is needed an extended period of protection against nematodes which can be achieved with increased number of application - maximum 6. Therefore the proposed intended use for tomato includes possibility of maximum 6 applications per growing season.

Appendix 2. UK POEM model during mixing/loading exposure for drip irrigation of A12115I

Exposure data

Product information

Product : A12115I

Purpose: nematocide

Active substance (a.s.): abamectin

Product type: SC

Package size: various container sizes

Table 6.4-1 describes the critical use patterns that has been defined following of the individual GAPs for each crop.

Table 6.4-1 Summary of critical use (i.e. worst case)

Application equipment	Representative Crop	Max Application rate (kg product/ha)	Max Application rate (kg a.s./ha)	Minimum Spray dilution (L/ha)	Number applications
Greenhouse, soil drip	Pepper, aubergine, tomato, cucurbits, green beans.	**5 (L/ha)**	**0.1**	**10,000-20,000**	**4-6**

B6.4.1Operator exposure

Table B.6.4.1-1: Toxicological endpoints of abamectin required for evaluation of operator, worker, bystander and residential risk

Endpoint	EU agreed endpoint (Commission Implementing Regulation (EU) No. 540/2011 of 25 May 2011)	Dermal Absorption for A121151I
AOEL (mg/kg bw/day)	0.0025	
Dermal absorption of concentrate	1% (18 g/L EC)	10%
Dermal absorption of in-use dilution	1% (18 g/L EC)	10%

Estimations of potential operator exposure for the formulation A12115I are made for the intended critical uses described in table 6.4-1 and the following predictive models:

- Uniform Principles for Safeguarding the Health of Applicators of Plant Protection Products (Uniform Principles for Operator Protection);, Mitteilungen aus der Biologischen Bundesanstalt, Heft 277, Berlin 1992 ("German model")

B.6.4.1.1 Estimation of operator exposure without personal protective equipment

The input parameters that were applied in the models for the operator exposure estimation are described in Table B.6. 4.1.1-1.

Table B.6. 4.1.1-1 Input parameter in the German model

Application method	Input parameter
Tractor mounted application, high crops	Treated area: 4 ha/day Max. dose rate: 0.1 kg abamectin/ha Operator body weight: 70 kg (German model) Operatory body weight: 60 kg (UK POEM)

The formulation is a suspension concentrate (SC) packaged in various container sizes. The estimation of potential operator exposure has been undertaken for abamectin using the critical uses (Table B.6.14.1) and both the German and UK POEM models.

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 supplying the diluted material. In some circumstances the concentrate is likely be metered directly into the irrigation water directly from the container. Below is an exposure assessment where a measure of concentrate is poured directly into a large tank of water connected to the drip system for 1 hectare of crop. The estimations were compared to EU agreed AOEL for abamectin. The operator exposure estimates assuming that no protective clothing is worn are summarized in Table B.6.4.1.1-2. The detailed calculator spreadsheets are included in Appendix A.

Table B.6.4.1.1-2 Exposure prediction and risk assessment without PPE

Application method	Model	Total systemic exposure (mg/kg bw/day)[1]	% of AOEL
Tractor mounted application, high crops	German model	0.00119	57.5
Tractor mounted application, high crops	UK POEM	0.00405	162.1

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

Conclusion

The German model estimate shows that for the intended use of the formulation A12115I the predicted systemic exposure for the unprotected operator is 57.5% of the AOEL in the German model and 162.1% of the AOEL using gloves. Therefore, it is concluded according to the model calculations, that the risk for the operator mixing A12115I for use in soil drip systems on protected vegetables is acceptable without the use of personal protective equipment.

B.6.4.1.2 Estimation of operator exposure with personal protective equipment

The UK POEM assessment for mixing/loading A12115I to treat 4 ha/day exceeds the AOEL without PPE. Subsequently a further assessment using the UK POEM with PPE (gloves for mixing/loading) has also been conducted.

Table B.6.4.1.1-2 Exposure prediction and risk assessment with gloves

Application method	Model	Total systemic exposure (mg/kg bw/day)[1]	% of AOEL
Tractor mounted application, high crops	UK POEM	0.00028	11.1

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

Conclusion

The UK POEM model estimate shows that for the intended use of the formulation A12115I the predicted systemic exposure for the operator using gloves is 11.1% of the AOEL.

Therefore, it is concluded according to the model calculations, that the risk for the operator mixing A12115I for use in soil drip systems on protected vegetables is acceptable.

Appendix A: Detailed exposure models

German BBA Model, high crop tractor mounted

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer				
Product	**A12115I**		Active substance		
Formulation type	WG		a.s. concentration	**20**	g/kg
Dermal absorption from product	**10** %		Dermal absorption from spray	**10**	%
RPE during mix/loading	None		RPE during application	None	
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	**5**	kg product/ha	Work rate/day	**4**	ha
AOEL	**0.0025**	mg/kg bw/day	Percent AOEL	**47.5**	% AOEL

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	2	mg/kg a.s.
Hand contamination/day	0.8	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	0.8	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.008	mg/kg a.s.
Inhalation exposure/day	0.0032	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0032	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.8	mg/day	0	mg/day
Percent absorbed	10	%	10	%
Absorbed dose (dermal route)	0.08	mg/day	0	mg/day
Inhalation exposure to a.s.	0.0032	mg/day	0	mg/day
Total systemic exposure	0.0832	mg/day	0	mg/day

PREDICTED EXPOSURE

Total systemic exposure	0.0832	mg/day
Operator body weight	70	kg
Operator exposure	0.001188571	mg/kg bw/day
AOEL	0.0025	mg/kg bw/day
Percent AOEL	47.54285714	% AOEL

UK POEM, high crop tractor mounted without PPE

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha				
Product	**A12115I**		Active substance	**Abamectin**	
Formulation type	WG or SG		a.s. concentration	**20**	mg/g
Dermal absorption from product	**10**	%	Dermal absorption from spray	**0**	%
PPE during mix/loading	None		PPE during application	None	
Dose	**5**	kg product/ha	Work rate/day	**4**	ha
Application volume	**10000**	l/ha	Duration of spraying	**6**	h
AOEL	**0.0025**	mg/kg bw/day	% AOEL	**162.1**	

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	5.72	mg/kg a.s.
Hand contamination/day	2.288	mg/day
Protective clothing	None	
Transmission to skin	100	%
Dermal exposure to a.s.	2.288	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0358	mg/kg a.s.
Inhalation exposure/day	0.01432	mg/day
RPE	None	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.01432	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	2.288	mg/day	0	mg/day
Percent absorbed	10	%	0	%
Absorbed dose (dermal route)	0.2288	mg/day	0	mg/day
Inhalation exposure to a.s.	0.01432	mg/day	0	mg/day
Absorbed dose	0.24312	mg/day	0	mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.24312	mg/day
Operator body weight	60	kg
Operator exposure	0.004052	mg/kg bw/day

% AOEL	162.08

UK POEM, high crop tractor mounted with gloves mixing/loading

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM)

Application method	Tractor-mounted/trailed broadcast air-assisted sprayer: 500 l/ha				
Product	**A12115I**		Active substance	**Abamectin**	
Formulation type	WG or SG		a.s. concentration	**20**	mg/g
Dermal absorption from product	**10**	%	Dermal absorption from spray	**0**	%
PPE during mix/loading	Gloves		PPE during application	None	
Dose	**5**	kg product/ha	Work rate/day	**4**	ha
Application volume	**10000**	l/ha	Duration of spraying	**6**	h
AOEL	**0.0025**	mg/kg bw/day	% AOEL	**11.07**	

DERMAL EXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s.	5.72	mg/kg a.s.
Hand contamination/day	2.288	mg/day
Protective clothing	Gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.02288	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0358	mg/kg a.s.
Inhalation exposure/day	0.01432	mg/day
RPE	None	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.01432	mg/day

ABSORBED DOSE

	Mix/load		Application	
Dermal exposure to a.s.	0.02288	mg/day	0	mg/day
Percent absorbed	10	%	0	%
Absorbed dose (dermal route)	0.002288	mg/day	0	mg/day
Inhalation exposure to a.s.	0.01432	mg/day	0	mg/day
Absorbed dose	0.016608	mg/day	0	mg/day

PREDICTED EXPOSURE

Total absorbed dose	0.016608	mg/day
Operator body weight	60	kg
Operator exposure	0.0002768	mg/kg bw/day

% AOEL	11.072

Appendix 3. Plant metabolism

Syngenta acknowledges that the metabolism studies submitted were all carried out as a foliar spray. However, seed treatment and soil applied (confined crop rotation) studies provide a good model for the outcome of employing a soil drip/drench application.

Seed Treatment

Abamectin is used as a seed treatment as a nematicide to control nematodes attacking the seed and the soil surrounding the seed and initial roots systems. By direct application to seed, abamectin is placed in close proximity to the developing root zone of the target crop and, as such, ensures the highest potential exposure and probability of uptake. The metabolism of ^{14}C-labelled NOA422601 (avermectin B_{1a}) applied as a seed treatment has been studied in tomatoes[i], lettuce[ii], soya[iii], beets[iv], corn[v], cotton[vi] and carrots[vii]. In the cited metabolism studies application rates of ^{14}C-labelled avermectin B_{1a} varied from nominally 0.9 to 0.016 mg ai/seed. Extrapolations to g ai/ha based on typical[viii] seeding rates ranged from 26 – 209 g ai/ha (it is important to note when examining the extrapolated rates in terms of g ai/ha that in the case of direct seed treatment, exposure to abamectin may be significantly higher than in a drip application where abamectin is applied in near proximity to the target plant). Total radioactive residues (TRR) ranged from 0.0007 to 0.008 mg/kg in the aerial agricultural commodities of tomatoes, lettuce, soya, beets, corn and cotton. Extraction of select commodities and chromatographic analysis of the extracts determined that no abamectin or structurally related residues were detectable.

Crop Metabolism

In addition, results from foliar applied crop metabolism studies in citrus[ix] and cotton[x] provide direct evidence that there was no significant translocation of abamectin and related metabolites within plants. Citrus fruit, lemons, oranges and grapefruit, on bearing trees were treated topically with 4 and 40 µg (oranges) of ^{14}C-avermectin B_{1a} and the fruit harvested 1, 2, 4, 8 and 12 weeks after application. Harvested fruit were rinsed and peel and pulp separated and extracted. Determination of the radioactivity distribution in the rinsate and extracts demonstrated that very little activity translocates from the fruit surface to the pulp (pulp less core) (≤0.008 mg/kg) and none to the pulp core.

Cotton plants were treated with ^{14}C-avermectin B_{1a} at 2 x 20 g ai/ha with plants and roots harvested at maturity and, 3 x 22.4 and 224 g ai/ha with plants and roots harvested 21 days after the last application. Separate extraction of roots, stems, leaves, bract/calyx, lint and seed showed the majority of the activity remained in the foliar part of the plant (leaves and bract/calyx) exposed to the applications with significantly less activity translocating to parts of the plant (roots and seed) not exposed to application.

Confined Rotational Crop Metabolism

Results from confined rotational crop metabolism studies[xi] in three soils provide further evidence that there is no significant uptake of abamectin and related metabolites from soil into plants. Bare soil plots were treated with ^{14}C-avermectin B_{1a} at rates of 3 x 29.1 g ai/ha with 50 day spray intervals and 12 x 33.6 g ai/ha with 7 day spray intervals. Sorghum, lettuce and turnips were planted back in the soil 14, 123 and 365 days after the last application. In a separate study, sorghum, lettuce and carrots were planted back 31, 120 and 365 and 29, 123 and 365 days after the last application, respectively. Total radioactive residues in mature plants from all plant back intervals were <0.006 mg/kg in all mature crop commodities. The highest TRR observed was 0.011 mg/kg in one sample of sorghum forage. Extraction of immature lettuce (TRR 0.007 mg/kg) released only 4.4% of the TRR indicating the residues were most likely a result of natural incorporation.

Soil Adsorption/Desorption

The mobility of abamectin based on K_{OC} as classified according to Guth[xii] and McCall[xiii] is immobile. Experimental results for abamectin characterize abamectin as a substance that binds strongly to a broad range of soils with a medium K_{OC} value of 6343 mL/g.

Classification as immobile does not preclude a substance from being available for absorption into plant root systems, as evidenced by low levels of uptake of abamectin and related metabolites within plants following application to seeds or soil. However, the high K_{OC} coupled with the low water solubility and high molecular weight of abamectin suggest any equilibrium between soil and an aqueous plant vascular system would lie in favour of soil binding.

Conclusion

Seed treatment studies, cited as a model for soil drench application, on tomatoes, lettuce, soya, beets, corn and cotton demonstrate that there is no significant translocation of abamectin and structurally related compounds from the root system to aerial parts of plants. This conclusion is supported by low radioactive residues in rotational crops planted in treated soils. Supporting evidence is provided by crop metabolism studies conducted on citrus and cotton which also demonstrates that there is no significant translocation of avermectin within crops. In addition, soil mobility studies indicating abamectin is highly immobile and its intrinsic properties, high molecular weight and low water solubility, suggest any migration of abamectin from soil to plant vascular systems will be minimal. The results from the residue trials conducted with soil drip applications

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[i] May-Hertl, U (2004): "[23-^{14}C]-Avermectin A1a, 5-O-demethyl: Nature of the Residue Greenhouse Grown Tomatoes", Syngenta Crop Protection, Greensboro, North Carolina, United States, Unpublished Report No. 2190-02, SmartDoc Regulatory Ref. MK936/1182.

[ii] Ray, W (2007): "[23-^{14}C]-Avermectin A1a, 5-O-demethyl: Nature of the Residue Greenhouse Grown Leaf Lettuce", Syngenta Crop Protection, Greensboro, North Carolina, United States. Unpublished Report No. T007080-05, SmartDoc Regulatory Ref. MK936/1760.

[iii] May-Hertl, U and Ray, W (2007): "[23-^{14}C]-Avermectin A1a, 5-O-demethyl: Nature of the Residue Greenhouse Grown Soybeans", Syngenta Crop Protection, Greensboro, North Carolina, United States. Unpublished Report No. T019689-04, SmartDoc Regulatory Ref. MK936/1823.

[iv] May-Hertl, U and Ray, W (2007): "[23-^{14}C]-Avermectin A1a, 5-O-demethyl: Nature of the Residue Greenhouse Grown Sugar Beets", Syngenta Crop Protection, Greensboro, North Carolina, United States. Unpublished Report No. T007081-05, SmartDoc Regulatory Ref. MK936/1824.

[v] May-Hertl, U and Ray, W (2007): "[23-^{14}C]-Avermectin A1a, 5-O-demethyl: Nature of the Residue Greenhouse Grown Corn", Syngenta Crop Protection, Greensboro, North Carolina, United States. Unpublished Report No. T019688-04, SmartDoc Regulatory Ref. MK936/1748.

[vi] May-Hertl, U (2005): "[23-^{14}C]-Avermectin A1a, 5-O-demethyl: Nature of the Residue in Cotton After Seed Treatment", Syngenta Crop Protection, Greensboro, North Carolina, United States. Unpublished Report No. T003034-03, SmartDoc Regulatory Ref. MK936/1438.

[vii] The aerial portion of the crop was not analyzed and, as such, the study was not included in this assessment.

[viii] Seeding rates vary significantly based on geographical location and local agricultural practices. The provided examples are based on established practices in a significant production region for the cited crop.

1. Seeding rate for production tomatoes in California, USA (http://anrcatalog.ucdavis.edu/pdf/7228.pdf)
2. Seeding rate for leaf lettuce in California, USA (http://ucanr.org/freepubs/docs/7216.pdf)
3. Seeding rate for soybeans in Midwest USA (http://www.planthealth.info/crops_population.htm)
4. Seeding rate for sugar beets in California, USA (http://sugarbeet.ucdavis.edu/sbchap.html)
5. Seeding rate for production corn in Iowa, USA (http://www.extension.iastate.edu/Publications/PM1885.pdf)

Seeding rate for cotton in Arkansas, USA (http://arkansasagnews.uark.edu/562-9.pdf)

[ix] Grosso, LS and Dybas, RA (1984): "Degradation of Avermectin B1a" Merck Sharp & Dohme Research Laboratories, Merck and Co., Inc, Three Bridges, New Jersey, United States, Unpublished Report No. 50658-EUP-R. Attachment 3: Maynard, MS (1984) "Metabolism of Avermectin B1a in Citrus Fruits", SmartDoc Regulatory Ref. MK936/0016.

[x] Wislocki, P (1986): "Fate of Avermectin B1a on Cotton Plants", Merck Sharp & Dohme Research Laboratories, Merck and Co., Inc, Three Bridges, New Jersey, United States, Unpublished Report No MSD-PLM2A, SmartDoc Regulatory Ref. MK936/0004.

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[xi] Moye, AH, Malagodi, MR and Leibee, GL (1987): "Avermectin B_{1a} – Rotational Crop Study", Department of Food Science and Human Nutrition, Pesticide Research Laboratory, University of Florida, Gainsville, Florida, United States, Unpublished Report No. ENC#1, SmartDoc Regulatory Ref. MK936/0322.
[xii] Guth, JA, Adsorption/Desorption, International Symposium – Canterbury, 1 – 3 July 1985
[xiii] McCall;, PJ, Lawskowski, DA, Swann, RL and Dishburger, HJ (1981): "Measurement of sorption coefficients of organic chemicals and there use, in environmental fate analysis", in Test Protocols for Environmental Fate and Movement of Toxicants, Proceedings of AOAC Synposium, AOAC, Wasington DC

PEER REVIEW REPORT ON **ABAMECTIN** APRIL 2016

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0. General

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Open point 0.1 RMS to update Vol 1, 1.5.1 and Vol. 3, CP B.9, A121151 to consistently indicate that the representative uses applied for is for application to certain crops via drip irrigation in the protected cropping system of walk-in tunnels that remain in place till the crop has been harvested. See reporting table comments 0(2) and 5(2) See reporting table 0(2)	NL (February 2016): requested information has been added to Vol 1, 1.5.1 and Vol.3, CP B.9. Also changed in Vol 3, B3 With the addition that: *These representative uses are in protected cropping systems of walk-in tunnels The product may only be used in walk-in tunnels which remain in place for at least 5 years.* Also in the GAP table of uses (Vol 1 1.5.1, Loep, Vol 3 B3), the use was changed to (G) greenhouse (initially indicated as (I), Indoor).			Addressed: The information considering the representative use has been added to Vol. 1, 1.5.1 and Vol. 3, CP B.9 and also in Vol. 3, B3
Open point 0.2 A full evaluation of the supporting efficacy data should be provided. See	NL (February 2016): This is information is provided in the document: Abamectin addendum DAR Volume 3 B10 A12115I			Addressed: The evaluation was presented in the addendum to DAR Volume 3 B10 (February 2015)

section 0 – General

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
also 1(6) See reporting table 0(3)	February 2015.			

1. Identity, Physical and chemical properties, Details of uses and further information, Methods of analysis

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Open point 1.1 RMS to report validation results of the method of analysis for the PPP in more detail. See reporting table 1(13)	NL (February 2016): The linearity, accuracy and precision are now addressed in more detail.			Addressed: The linearity, accuracy and precision were addressed in more detail in the revised Vol. 3 (February 2016)
Open point 1.2 RMS to present the available toxicological data on co-formulants in volume 4. See reporting table 1(16)	NL (February 2016): the available information has been added to the revised addendum (Volume 4).			Addressed: The available toxicological data on co-formulants has been presented in the revised Vol. 4.

2. Mammalian toxicology

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Data requirement 2.1 Applicant to provide a revised literature review on abamectin and metabolites. This has to be conducted and reported (with sufficient details on the relevance/eligibility criteria and search strategies/concepts) in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No '1107/2009 (EFSA Journal 2011;9(2):2092). See also 2(10), 3(11), 4(10) and 5(25). See reporting table 2(1)	NL (February 2016): The literature review was provided in appendix 1 of the additional information. Some extra information on the conduct of the search has been added to the revised addendum to the DAR in section B.6.6	Written procedure on additional information: comments received from DE		According to the RMS two potential relevant publications do not provide any new information. As highlighted by one Member State during the written procedure on additional information there is one additional publication that would challenge the previous conclusions on the non-relevance of the observed effects of abamectin in neonatal rats for humans. On the basis of these comments received EFSA considered that further assessment on the findings described by Lam, J. et al, 2015 should be done leading to a data gap. Lam, J. et al. 2015: The ontogeny of P-glycoprotein in the developing human blood-brain barrier: implication for opioid toxicity in neonates. Pediatric Research, vol. 78, number 4, October 2015

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Data requirement 2.2 For the approval of pesticide active substances under Regulation (EC) No 1107/2009 the applicant needs to address whether abamectin fulfil the approval criteria considering the potential for endocrine disruption and classification and labelling of abamectin. See reporting table 2(1)	NL (February 2016): An evaluation on the potential endocrine disruption properties is included in Volume 1 of the revised addendum in section 2.6.8. Abamectin does not fulfil the interim criteria for endocrine disruption. There is no indication of endocrine disruption in the *in vivo* studies. In addition, abamectin was tested in the US EPA Endocrine Disruption Screening Program which concluded that there was no convincing evidence of potential interaction with the estrogen, androgen or thyroid pathways. It is therefore concluded that abamectin is not an endocrine disruptor.	Written procedure on additional information: comments received from DE		EFSA would agree that there are no clear indications of a potential endocrine disruption of abamectin. However, it is noted that mechanistic studies available to US EPA were not submitted for an independent assessment during the EU peer review process leading to a data gap. US-EPA (2015) EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals, June 29 2015.
Open point 2.1 RMS to amend the operator exposure	NL (February 2016): the operator exposure assessment has been amended in the revised			Fulfilled.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
assessment from 1ha to 4ha treatment. See reporting table 2(5)	addendum. The conclusion of the risk assessment based on the German model does not change. A safe use was found for the unprotected worker (55% of the AOEL).			
Open point 2.2 RMS to amend the worker exposure calculation. See reporting table 2(6)	NL (February 2016): a worker exposure calculations using EUROPOEM II and the German re-entry model has been included in the revised addendum.			Fulfilled.
Open point 2.3 RMS to revise the LoEP to include the dermal absorption values of Tervigo. See reporting table 2(7)	NL (February 2016): The dermal absorption has been included in the revised RAR. The results from the exposure assessment has been included as well.			Fulfilled.
Open point 2.4 RMS to include non-	NL (February 2016): An exposure assessment according to the UK POEM			Fulfilled.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
dietary exposure estimates during mixing/loading before drip irrigation in greenhouses according to the UK POEM model in a revised DAR. See reporting table 2(9)	model has been carried out and included in the revised addendum.			
Open point 2.5 RMS to include the section explaining that no new data on abamectin was submitted in a revised DAR (B.6). See also 2(13). See reporting table 2(12)	NL (February 2016): This has been added to the revised addendum.			Fulfilled.

3. Residues

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Open point 3.1 RMS to amend in a revised DAR Tables on storage stability in section B.7.6., considering the unrounded values reported in the study reports. See reporting table 3(1)	NL (February 2016): The Dar was amended to take into consideration the unrounded values from the storage stability study, the overall conclusion does not change			Open point The reported values do not allow to fully understand the recoveries observed at the different time points (e.g. Table B.7.6.7-2, Tomato, spiking level 0.05, after 3 months at -18°, individual levels in the stored sample of 0.05, 0.05 and 0.05 mg/kg result in a recovery of 91%). As initially requested, unrounded residue levels observed after storage should be provided.
Open point 3.2 RMS to assess in a revised DAR the additional metabolism study submitted by the applicant (seed treatment), considering also the confined rotational crop studies already available in section B.7.9 of the DAR, in order to conclude	NL (February 2016): Applicant did not submit the actual study reports for metabolism after seed treatment in tomatoes, lettuce, soya, beets, corn, cotton and carrots. RMS can only use the statement as a base. Considering the argumentation by the applicant and the reference			Data gap The study reports related to the metabolism studies conducted using seed treatment are requested. A short summary only on the metabolism studies conducted with abamectin using seed treatments has been provided. Information related to these studies cannot be considered as long as the study reports

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
whether the metabolic profile observed following soil application can be considered similar to the metabolic profile observed following foliar applications. Toxicological profile of the identified metabolites should be described as well. See comments in 0(1), 3(4) See reporting table 3(3)	to the metabolism studies in seed, it appears that there is no significant translocation of abamectin residues from the roots to other plant parts.			have not been submitted. Based on the rotational crop studies submitted and assessed in the framework of the peer review, and considering the experiments conducted with 12 weekly applications at 39 g/ha (total 408 g/ha), no significant translocation of abamectin has been observed at any plant back interval (14/31, 120 and 365 days), the TRRs in all plant parts at maturity being in the range of <0.0004 to 0.007 mg eq/kg.
Open point 3.3 RMS to reference in a revised DAR, Table on "Intended Good Agricultural Practices (GAP) for the abamectin as a nematicide in Europe" in page 9 as 7.5.1 (instead of 7.4.1)	NL (February 2016): The heading of the table was changed to 7.5.1			Addressed Table reference has been changed.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
See reporting table 3(7)				
Open point 3.4 RMS to include in a revised DAR, information on the literature search provided by the applicant. See also data requirement 2(1) See reporting table 3(11)	NL (February 2016): The information from the literature search were included in the revised Dar. No studies from public literature were considered relevant.			Addressed Information on literature search has been included in the revised DAR of February 2016

4. Environmental fate and behaviour

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Data requirement 4.1 Consequent whatever is provided to address the data requirement at reporting table comment 4(8), applicant to demonstrate that NOA448111, NOA448112, NOA457464 and NOA457465 in surface water at any point of abstraction for drinking water will be negligible. Should this not be demonstrated applicant to provide information on the effect of water treatment processes on the nature of residues when surface water is abstracted for drinking water. In the first instance a consideration of the water treatment processes of ozonation	NL (February 2016): The applicant provided a statement to address this data requirement. This statement is included into the revised addendum (bottom of PECsw calculations).	Written procedure on additional information: comments received from DE		Data gap Satisfactory information was not available to demonstrate that NOA448111, NOA448112, NOA457464 and NOA457465 in surface water at any point of abstraction for drinking water will be negligible nor on the effect of water treatment processes on the nature of residues when surface water is abstracted for the production of drinking water. In the first instance a consideration of the water treatment processes of ozonation and chlorination on the nature of residues should be provided. Should any consideration indicate novel compounds might be expected to be formed from water treatment, the risk to human or animal health through the consumption of drinking water containing them should be addressed.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
and chlorination on the nature of residues should be provided. Note this is not 'a new data point' but an approval criterion specified in Regulation (EC) No 1107/2009, that needs to be addressed. See reporting table 4(2)				Note the argumentation provided by the applicant was not accepted as the available PECsw (from GAP with lower dose rates than being requested for the new use as a nematicide) are not well below the appropriate threshold of toxicological concern, as the units quoted in the case presented are incorrect. The TTC that covers genotoxicity is 0.0025µg/kg bw per day, which assuming a body weight of 60kg and a water consumption of 2 L gives a concentration of 0.075 µg/L and not 0.075mg/L. The sum of the available PECsw of the metabolites is in the range of the TTC. Hence the reason for retaining a data gap
Open point 4.1 RMS to provide their metabolite PEC soil calculations as set out in column 3 of the reporting table at	NL (February 2016): These calculations have been added to the addendum and to the LoEP.			Addressed The addendum and list of endpoints dated February 2016 were appropriately updated by the RMS.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
comment 4(5) and add these PEC to the list of endpoints. See reporting table 4(5)				
Open point 4.2 RMS to update the list of endpoints laboratory studies rate of aerobic degradation to include the appropriate FOCUS reference condition and guidance normalised geomean lab soil DT50 of: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d and NOA457465 112.3 d. See reporting table 4(6)	NL (February 2016): These values and details on the normalisation have been added to the List of Endpoints.			Addressed The list of endpoints dated February 2016 was appropriately updated by the RMS.
Data requirement 4.2 Applicant to provide new PECgw using the soill	NL (February 2016): The applicant provided a statement to address this data requirement. This	Written procedure on additional information: comments received from DE		Addressed The argumentation provided by the applicant was evaluated by the RMS on

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
DT5: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d NOA457465 112.3 d. See reporting table 4(6)	statement is included into the revised addendum.			pages 21-22 of addendum Vol. 3 B.8 dated February 2016. The conclusion of the RMS is agreed. The potential for groundwater exposure from the uses as a nematicide by abamectin and its metabolites above the parametric drinking water limit 0.1 µg/L can be concluded as low.
Data requirement 4.3 Applicant to provide PECsw at step 3 and possibly step 4 for the soil metabolites NOA448111, NOA448112, NOA457464 and NOA457465 and present a consequent aquatic risk assesment. Note the soil DT50 to be used in the calculations are: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d NOA457465 112.3 d.	NL (February 2016): The applicant provided a statement to address this data requirement. This statement is included into the revised addendum. Furthermore, as this issue was already addressed in the confirmatory data addendum, the relevant section of this confirmatory data addendum has been copied into the current addendum for extension of use (as for groundwater).	Written procedure on additional information: comments received from DE		Data gap PECsw at step 3 for the soil metabolites NOA448111, NOA448112, NOA457464 and NOA457465 and a consequent aquatic risk assessment for the pattern of use (GAP) being requested for nematode control was not available. The argumentation provided by the applicant was evaluated by the RMS on pages 33-44 of addendum Vol. 3 B.8 dated February 2016. EFSA has not accepted the applicant's case that the sorption and degradation endpoints are comparable to

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
See reporting table 4(8)				the parent. For example the geomean DT50 of NOA 457465 is 112 days compared to only 20.8 days for the parent and NOA 457464 has a KFoc of 1738 mL/g compared to 5638 mL/g for the parent. The RMS also presented drainage and runoff PEC for the metabolites for a number of crops that are not the subject of the extension of use and were not representative uses assessed in the EFSA conclusion. The GAP for these crops used in this modelling has not been indicated by the RMS in their addendum to the extension of use application. For the GAP assessed in the EFSA conclusion where dose rates were lower than those currently being requested only Step 2 PEC for the metabolites are available. The EFSA conclusion identified a data gap for risk assessments to aquatic organisms for the soil metabolites that may reach surface water. In the (not

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
				publically available) confirmatory data addendum new PECsw results up to Step 3 were presented for a range of other uses not considered in the EFSA conclusion. However the maximum GAP assessed was only 5 x 21.6 g/ha, which is lower than that of the nematicide uses and a transparent evaluation of how the PECsw for metabolites at Step 3 for these less critical uses were calculated remains unavailable (member states are referred to the EFSA comments on the confirmatory data addendum). In any case the available (not transparently evaluated) Step 3 calculations have not covered the GAP of 6 x 100 g/ha being requested for the extension of use as a nematicide.
Open point 4.3 To aid transparency, as the updated addendum	NL (February 2016): The body text of confirmatory data addendum B.8 section B.8.6.2 (final version April 2012, CIRCABC) is copied			Addressed The addendum was appropriately updated by the RMS.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
for the confirmatory data submission that resulted in the Commission concluding in their review report that the issue regarding U8 and groundwater exposure was addressed is not publically available, RMS is requested to add their evaluation of the information previously provided regarding this (i.e. updated addendum for the confirmatory data submission (section B.8.6.2 of addendum dated April 2012)) in an updated addendum to the addendum of April 2015. See reporting table 4(9)	into the addendum. Note RMS did not include the link to the pdf of (part of) the Pfaff study in which U8 was detected into the addendum. It is copied here, should the peer review need to see it. This study was part of the original Annex I submission and has as such been evaluated in the Abamectin DAR.  'faff.pdf (723 KB			
Open point 4.4 RMS to include in a revised DAR, information	NL (February 2016): The literature review was provided in appendix 1 of the additional information			Addressed The RMS appropriate evaluation of the literature search has been included in

section 4 – Environmental fate and behaviour

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting/EFSA request for RMS' action	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
on the literature search provided by the applicant. See also data requirement 2(1) See reporting table 4(10)	submitted by the applicant. The applicant literature survey is included into the revised addendum section B.8.10.			the updated addendum.

5. Ecotoxicology

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Open point 5.1 For the acute study on daphnia (Vol. 3, IIIA, 10.2.2.2/01), reference and year of execution should be aligned. In addition, the table presented under the evaluation by the RMS should be revised (e.g. under the column "immobility %, one value reports "10 µg") See reporting table 5(4)	NL (February 2016): This has been adjusted in the addendum.			Open point fulfilled. The DAR addendum was modified accordingly.
Open point 5.2 RMS to better clarify which value is the mesocosm endpoint and which is the higher tier RAC for the aquatic risk assessment See reporting table 5(7)	NL (February 2016): This has been adjusted in the addendum.			Open point fulfilled. The DAR addendum was modified accordingly.

section 5 - Ecotoxicology

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Data requirement 5.1 The risk assessment for the active substance does not necessarily "cover" the risk assessment for soil metabolites (NOA448111, NOA448112, NOA457464, and NOA457465). Following data requirement under point 4(8) in the RT in the e-fate section, the notifier is requested to provide a full risk assessment for these metabolites, including ecotoxicological data/information. Note to the RMS: PECsoil for metabolites does not necessarily represent a "proxy" for PECsw, considering the persistency and the mobility of the metabolites.	NL (February 2016): The notifier has submitted a risk assessment for the soil metabolites for aquatic organisms and soil organisms. This information has been included in the addendum.	Written procedure on additional information: comments received from DE		**Data gap** Step2 PECsw are available for soil metabolites, only considering spray uses. Based on these PECs a low risk cannot be concluded for soil metabolites. Furthermore, please note that the claim that "PECsw values of the soil metabolites are two orders of magnitude lower than respective abamectin" is only true for open field applications, where multiple route of exposure are likely to be relevant. For applications in protected crops, where only drainage is relevant, such difference cannot be verified.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
Furthermore, in case no ecotoxicity data are available, the screening risk assessment should be in line with similar previous evaluations i.e. assuming that the metabolites are ten times more toxic than the parent. See reporting table 5(9)				
Data requirement 5.2 Applicant to submit information to address the risk to non-target arthropods, especially to provide information on the toxicity of abamectin to Folsomia candida and Hypoaspis aculeifer. See also point 5(14); 5(17) See reporting table 5(10)	NL (February 2016): the applicant has submitted studies regarding the toxicity of abamectin to Folsomia candida and Hypoaspis aculeifer. The summaries and evaluation of the studies are included in the addendum as well as the risk assessment based on the endpoints of the studies.	Written procedure on additional information: comments received from DE		**Data gap** The risk assessment for *Folsomia candida* and *Hypoaspis aculeifer* presented by the RMS is agreed upon. As a high risk cannot be excluded for collembolans, a data gap for further refining the risk is identified.
Open point 5.3				Open point fulfilled.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
EFSA to include a sentence in the conclusion, highlighting that risk for pollinators intentionally introduced in the closed system is not covered by the present assessment. See reporting table 5(12)				This is included in the EFSA conclusion. However, it should be noted that the application is on soil (drip irrigation). The physico-chemical characteristics of abamectin suggests that the active will be rather strongly bound to soil, and even if taken up by the roots, it is unlikely that it would be translocated to the upper parts of the plants.
Data requirement 5.3 Applicant to provide data to address the risk for soil metabolites of abamectin. The chronic risk for the soil metabolite NOA448112 should be addressed as well. As present data are not enough to demonstrate a low chronic risk for the active substance abamectin, further information to address this risk should be provided.	NL (February 2016): The applicant has submitted information to address the risk of the soil metabolites for aquatic and soil organisms. The information and subsequent risk assessment is included in the addendum. The notifier submitted a statement with regard to the risk of the active substance to soil organisms. The statement and reaction of the RMS is included in the addendum.	Written procedure on additional information: comments received from DE		**Data gap** A high chronic risk to earthworms was identified for abamectin on the basis of Tier I data. The only metabolite for which other experimental data available is metabolite NOA448112. The available data only cover the acute risk. However, the extrapolation of the acute-to-chronic ratio based on the active substance is considered sufficient in this case. No experimental data at all are available for the other metabolites. As the screening

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
See reporting table 5(16)				assessment (considering the metabolites as 10 times more toxic than the parent) is not enough to demonstrate a low risk, a data gap is identified.
Open point 5.4 RMS to include a full risk assessment to earthworms for all soil metabolites. In line with previous evaluations, where toxicity data for metabolites are missing, a toxicity 10 times higher than the parent is assumed for a screening assessment. Since for metabolite NOA448112 a chronic risk assessment is triggered, this should be included as well. Please note that for the evaluation at the EU level, it is not possible to exclude that the application will be performed on natural soil. As a consequence,	NL (February 2016): The RMS has included a full risk assessment to earthworms in the addendum, taking into account a 10 times higher toxicity for the metabolites than for the parent, when no toxicity data are available. See the addendum for the risk assessment. Also the chronic risk assessment for metabolite NOA448112 is included in the addendum.			Open point fulfilled. A risk assessment to earthworms for all soil metabolites was included in the addendum. EFSA acknowledges that the request for a chronic assessment was only mentioned for the metabolite NOA448112. However, this specific reference was added only because the acute risk assessment was already provided. In fact, all soil metabolites have DT90 > 100 days, so a chronic risk assessment is triggered for all of them.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
the risk to soil organisms should be addressed as an open field application. See also points 4(5); 5(18); 5(19); 5(20). See reporting table 5(16)				
Data requirement 5.4 Applicant to submit further information to address the risk to other non-target soil organisms. See also data requirement 5(10). See reporting table 5(17)	NL (February 2016): the applicant has submitted studies regarding the toxicity of abamectin to Folsomia candida and Hypoaspis aculeifer. The summaries and evaluation of the studies are included in the addendum as well as the risk assessment based on the endpoints of the studies.	Written procedure on additional information: comments received from DE		**Data gap** (same as for DR 5.2) The risk assessment for *Folsomia candida* and *Hypoaspis aculeifer* presented by the RMS is agreed upon. As a high risk cannot be excluded for collembolans, a data gap for further refining the risk is identified.
Data requirement 5.5 Applicant to provide data to address the risk to soil microorganisms for soil	NL (February 2016): the notifier has submitted a statement. This statement and the reaction of the RMS has been included in	Written procedure on additional information: comments received from DE		**Data gap** EFSA disagrees with the conclusion of the RMS. In fact, considering the worst case assumption of a 10-times

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
metabolites of abamectin. See also point 4(5); 5(22); 5(23) See reporting table 5(21)	the addendum.			higher toxicity compared to the parent and the PEC_{soil} values calculated for the metabolites, a high risk cannot be excluded.
Open point 5.5 RMS to report in a revised addendum the summary and the evaluation of the available literature search. Relevant studies retrieved during the literature seach should be summarised and evaluated in the revised DAR as well. See also data requirement 2(1) See reporting table 5(25)	NL (February 2016): The notifier did not submit a list of all captured studies. Also the selected ecotoxicological studies which were selected (two studies) were not submitted and also no summary and evaluation of the selected studies is available. Furthermore the notifier did not provide the criteria considered for relevancy of the studies. Hence, based on the available data, it is not possible to check the selection process as performed by the notifier and also it is not possible to use the results of the two			**Data gap** The applicant did not submit a list of all studies retrieved. Furthermore, the relevance criteria were not reported.

Column A Conclusions from the Reporting Table	Column B Rapporteur Member State comments (reference to addenda where necessary)	Column C Recommendations of the Pesticides Peer Review Meeting	Column D Rapporteur Member State homework (reference to addenda where necessary)	Column E EFSA conclusion
	selected studies in the risk assessment. The work done by the notifier regarding this issue is considered insufficient.			

PEER REVIEW REPORT ON **ABAMECTIN** APRIL 2016

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Report of Pesticides Peer Review written procedure on additional information

ABAMECTIN

Rapporteur Member State: NL

Comments on the assessment report are listed in the relevant reporting table. Comments submitted during the written procedure on the points for clarification are listed in Appendix 1.

Documents submitted for written procedure:

Date	Supplier	File Name
15.02.2016	RMS	Abamectin evaluation table section 1 February 2016
15.02.2016	RMS	Abamectin evaluation table section 2 February 2016
15.02.2016	RMS	Abamectin evaluation table section 3 February 2016
15.02.2016	RMS	Abamectin evaluation table section 4 February 2016
15.02.2016	RMS	Abamectin evaluation table section 5 February 2016
15.02.2016	RMS	Abamectin reporting table-2015-09-11
15.02.2016	RMS	Abamectin_revised DAR-all volumes

Appendix 1: Discussion table written procedure: ABAMECTIN

Appendix 1: Discussion Table Written Procedure, Abamectin

2. Mammalian toxicology

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	Data requirement 2.1 Applicant to provide a revised literature review on abamectin and metabolites. This has to be conducted and reported (with sufficient details on the relevance/eligibility criteria and search strategies/concepts) in accordance with the Guidance of EFSA on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No '1107/2009 (EFSA Journal 2011;9(2):2092). See also 2(10), 3(11), 4(10) and 5(25). See reporting table 2(1)	DE: A literature review was submitted. However, it is proposed to include into the literature review an additional study by Lam et al. (2015). This study is considered to be of high relevance in the discussion of observed effects of abamectin in neonatal rats and the conclusions for humans. Up to now it was discussed that effects in neonatal rats were caused by limited expression of p-glycoproteins. It was concluded that there would be a hypersusceptibility of neonatal rats which would be in contrast to man. However, this discussion is questionable if the new results on ontogeny of p-glycoprotein in developing humans are considered. In the publication of Lam et al. (2015) it was reported that P-glycoprotein expression in the human brain is about 50 % lower compared to adults, and reaches adult levels at 3-6 months of age. Reference: Lam, J. et al.: The ontogeny of P-glycoprotein in the developing human blood-brain barrier: implication for opioid toxicity in neonates. Pediatric Research, vol. 78, number 4, October 2015	**Data gap** Further assessment on the relevance of neonatal findings in rats for human health taking into account the publication by Lam, J. et al. 2015.

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
2	Data requirement 2.2 For the approval of pesticide active substances under Regulation (EC) No 1107/2009 the applicant needs to address whether abamectin fulfil the approval criteria considering the potential for endocrine disruption and classification and labelling of abamectin. See reporting table 2(1)	DE: Adressed	EFSA would agree that there are no clear indications of a potential endocrine disruption of abamectin. However, it is noted that mechanistic studies available to US EPA were not submitted for an independent assessment during the EU peer review process leading to a data gap.

4. Environmental fate and behaviour

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	Data requirement 4.1 Consequent whatever is provided to address the data requirement at reporting table comment 4(8), applicant to demonstrate that NOA448111, NOA448112, NOA457464 and NOA457465 in surface	DE: No comment.	Data gap Satisfactory information was not available to demonstrate that NOA448111, NOA448112, NOA457464 and NOA457465 in surface water at any point of abstraction for drinking water will be negligible nor on the effect of water treatment processes on the nature of residues when surface water is abstracted for the production of drinking water. In the first instance a

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	water at any point of abstraction for drinking water will be negligible. Should this not be demonstrated applicant to provide information on the effect of water treatment processes on the nature of residues when surface water is abstracted for drinking water. In the first instance a consideration of the water treatment processes of ozonation and chlorination on the nature of residues should be provided. Note this is not 'a new data point' but an approval criterion specified in Regulation (EC) No 1107/2009 that needs to be addressed. See reporting table 4(2)		consideration of the water treatment processes of ozonation and chlorination on the nature of residues should be provided. Should any consideration indicate novel compounds might be expected to be formed from water treatment, the risk to human or animal health through the consumption of drinking water containing them should be addressed. Note the argumentation provided by the applicant was not accepted as the available PECsw (from GAP with lower dose rates than being requested for the new use as a nematicide) are not well below the appropriate threshold of toxicological concern, as the units quoted in the case presented are incorrect. The TTC that covers genotoxicity is 0.0025µg/kgbw/day, which assuming a body weight of 60kg and a water consumption of 2 L gives a concentration of 0.075 µg/L and not 0.075mg/L. The sum of the available PECsw (for less critical GAPs) of the metabolites is in the range of the TTC. Hence the reason for retaining a data gap

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
2	Data requirement 4.2 Applicant to provide new PECgw using the soill DT5: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d NOA457465 112.3 d. See reporting table 4(6)	DE: No comment.	Addressed The argumentation provided by the applicant was evaluated by the RMS on pages 21-22 of addendum Vol. 3 B.8 dated February 2016. The conclusion of the RMS is agreed. The potential for groundwater exposure from the uses as a nematicide by abamectin and its metabolites above the parametric drinking water limit 0.1µg/L can be concluded as low.
3	Data requirement 4.3 Applicant to provide PECsw at step 3 and possibly step 4 for the soil metabolites NOA448111, NOA448112, NOA457464 and NOA457465 and present a consequent aquatic risk assesment. Note the soil DT50 to be used in the calculations are: abamectin 20.8 d, NOA448111 42.6 d, NOA448122 33.6 d, NOA457464 65.8 d NOA457465 112.3 d. See reporting table 4(8)	DE: No comment.	Data gap PECsw at step 3 for the soil metabolites NOA448111, NOA448112, NOA457464 and NOA457465 and a consequent aquatic risk assessment for the pattern of use (GAP) being requested for nematode control was not available. The argumentation provided by the applicant was evaluated by the RMS on pages 33-44 of addendum Vol. 3 B.8 dated February 2016. EFSA has not accepted the applicant's case that the sorption and degradation endpoints are comparable to the parent. For example the geomean DT50 of NOA 457465 is 112 days compared to only 20.8 days for the parent and NOA 457464 has a KFoc of 1738 mL/g compared to 5638 mL/g for the parent. The RMS also presented drainage and runoff PEC for the

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
			metabolites for a number of crops that are not the subject of the extension of use and were not representative uses assessed in the EFSA conclusion. The GAP for these crops used in this modelling has not been indicated by the RMS in their addendum to the extension of use application. For the GAP assessed in the EFSA conclusion where dose rates were lower than those currently being requested only Step 2 PEC for the metabolites are available. The EFSA conclusion identified a data gap for risk assessments to aquatic organisms for the soil metabolites that may reach surface water. In the (not publically available) confirmatory data addendum new PECsw results up to Step 3 were presented for a range of other uses not considered in the EFSA conclusion. However the maximum GAP assessed was only 5 x 21.6 g/ha, which is lower than that of the nematicide uses and a transparent evaluation of how the PECsw for metabolites at Step 3 for these less critical uses were calculated remains unavailable (member states are referred to the EFSA comments on the confirmatory data addendum). In any case the available (not transparently evaluated) Step 3 calculations have not covered the GAP of 6 x 100 g/ha being requested for the extension of use as a nematicide.

5. Ecotoxicology

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
1	Data requirement 5.1 The risk assessment for the active substance does not necessarily "cover" the risk assessment for soil metabolites (NOA448111, NOA448112, NOA457464, and NOA457465). Following data requirement under point 4(8) in the RT in the e-fate section, the notifier is requested to provide a full risk assessment for these metabolites, including ecotoxicological data/information. See reporting table 5(9)	DE: Please refer to comment 3 regarding data requirement 5.3.	**Data gap** Step2 PECsw are available for soil metabolites, only considering spray uses. Based on these PECs a low risk cannot be concluded for soil metabolites. Furthermore, please note that the claim that "PECsw values of the soil metabolites are two orders of magnitude lower than respective abamectin" is only true for open field applications, where multiple route of exposure are likely to be relevant. For applications in protected crops, where only drainage is relevant, such difference cannot be verified. Note: this comment is related to the aquatic risk assessment, while DE seems to refer to soil risk assessment.
2	Data requirement 5.2 Applicant to submit information to address the risk to non-target arthropods, especially to provide information on the toxicity of abamectin to Folsomia candida and	DE: A study on *Folsomia candida* and *Hypoaspis aculeifer* was provided. Based on the presented summaries the new provided studies seem to be acceptable. However one point of the Folsomia study needs clarification. It is stated that the toxic reference had only 30 % effect (not significantly different from control). This seems to be a rather low effect for the toxic reference. No explanation is given for this result. We agree to the risk assessment presented for Hypoaspis. For Folsomia the EC10 and a correction factor of 2 was considered based on the technical report "Outcome of the pesticides peer review meeting on general	**Data gap** Studies with *Folsomia candida* and *Hypoaspis aculeifer* were presented. Regarding the toxic reference, please note that this is usually selected for exerting an effect on reproduction, rather than mortality. In this case, the inhibition of reproduction was 99% compared to the control, while a minimum of 50% is

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	Hypoaspis aculeifer. See also point 5(14); 5(17) See reporting table 5(10)	recurring issues in ecotoxicology", published 22 December 2015. We agree to the risk assessment presented for Folsomia and Hypoaspis. As concluded by the RMS a long-term risk for collembolans cannot be excluded and has to be further addressed.	recommended in the OECD 232. As a high risk cannot be excluded for collembolans, a data gap for further refining the risk is identified.
3	Data requirement 5.3 Applicant to provide data to address the risk for soil metabolites of abamectin. The chronic risk for the soil metabolite NOA448112 should be addressed as well. As present data are not enough to demonstrate a low chronic risk for the active substance abamectin, further information to address this risk should be provided. See reporting table 5(16)	DE: We agree with the RMS that even if there is some uncertainty regarding the risk assessment for the metabolites based on the toxicity to earthworms overall it can be assumed that the risk for earthworms is acceptable. However Collembolans are clearly more sensitive regarding the active substance and hence it cannot be excluded that the same is the case for the relevant soil metabolites. Thus we agree that the risk for Collembolans caused by the exposure to the relevant soil metabolites has also to be addressed.	**Data gap** A high chronic risk to earthworms was identified for abamectin on the basis of Tier I data. The only metabolite for which other experimental data available is metabolite NOA448112. The available data only cover the acute risk. However, the extrapolation of the acute-to-chronic ratio based on the active substance is considered sufficient in this case. No experimental data at all are available for the other metabolites. As the screening assessment (considering the metabolites as 10 times more toxic than the parent) is not enough to demonstrate a low risk, a data gap is identified.
4	Data requirement 5.4 Applicant to submit further information to address the risk to other non-target soil organisms. See also data requirement 5(10).	DE: Please refer to comment 2 regarding data requirement 5.2.	**Data gap** (same as for DR 5.2) The risk assessment for *Folsomia candida* and *Hypoaspis aculeifer* presented by the RMS is agreed upon. As a high risk cannot be excluded for collembolans, a data gap for further refining the risk is identified.

No.	Subject	Discussion Written Procedure	Conclusions Written Procedure
	See reporting table 5(17)		
5	Data requirement 5.5 Applicant to provide data to address the risk to soil microorganisms for soil metabolites of abamectin. See also point 4(5); 5(22); 5(23) See reporting table 5(21)	DE: Overall we agree with the RMS that an acceptable risk can be concluded for soil microorganisms following the exposure to the relevant soil metabolites. For the metabolites NOA 448111, NOA 457464 and NOA 457465 no toxicity data are available, however considering the worst case assumption of a 10-times higher toxicity compared to the parent and the PEC_{soil} values calculated for these metabolites the risk is acceptable.	**Data gap** EFSA disagrees with the conclusion of the RMS. In fact, considering the worst case assumption of a 10-times higher toxicity compared to the parent and the PEC_{soil} values calculated for the metabolites, a high risk cannot be excluded. Highest tested concentration for abamectin = 0.347 mg/kg -> 10 times more toxic = 0.0347 mg/kg. NOA448111 PECsoil=0.078 mg/kg NOA457464 PECsoil=0.099 mg/kg NOA457465 PECsoil=0.112 mg/kg All metabolites PECsoil are higher than the maximum tested concentration of the parent/10.

PEER REVIEW REPORT ON **ABAMECTIN** APRIL 2016

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Member States' comments on the draft EFSA Conclusion on abamectin (amendment of approval conditions) (RMS: NL)

(19.04.2016) 1/13

Pesticides Peer Review Written Procedure: April 2016

Background			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
1	Summary and Background	NL: The Netherlands received the application from Syngenta on 29 August 2013.	Thank you. Conclusion has been updated accordingly

Identity, physical/chemical/technical properties and methods of analysis			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
1		AT: No comments.	Noted
2		NL: No comments.	Noted

Mammalian toxicity			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
1		AT: No comments.	Noted
2		NL: No comments.	Noted

Residues			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
1		AT: No comments.	Noted
2		NL: No comments.	Noted

Environmental fate and behaviour			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
1	Conclusion text (summary and section 4)	NL: it seems the conclusion text is merely a repetition of the original EFSA conclusion on abamectin. This is fine when it concerns substance properties (as these were not re-evaluated for the extension of the approval) but the exposure assessment part does not seem to cover the extension of use. For instance, the 0.1% emission approach which was followed for the original inclusion is mentioned, but nowhere in the section the approach taken for the current use extension is mentioned. The data gap concerning the metabolites PEC values in water and sediment is only set for the extension of use, because a data gap cannot be set in hindsight for the already approved uses. It seems EFSA ignores the existence of the peer reviewed confirmatory data addendum (2011). Of course the original conclusion did not contain this information (since it concerns *confirmatory* data), but it could at least be mentioned that these issues were considered to be adequately addressed. RMS NL suggests a better division of earlier approved uses (91/414) and now assessed uses for extension	The conclusion follows the style developed by EFSA for its conclusions and contains the usual level of detail. It is assumed that the comments in the first paragraph relate primarily to the surface water exposure assessment for the active substance though this is not explicitly indicated in the comment. In this respect the text 'The necessary surface water and sediment exposure assessments (Predicted environmental concentrations (PEC) calculations) for the active substance abamectin, were appropriately carried out using the FOCUS (FOCUS, 2001) step 1, step 2 and step 3 approaches.' encompasses what was done for both the extension of use and the initial representative uses. Contrary to the comment on the data gap in the second paragraph, the data gap is not identified just for the extension of use but all the uses assessed. In this respect the text 'For the metabolites 8a-oxo-avermectin B1a (NOA 448111), 8a-hydroxy-avermectin B1a (NOA

Environmental fate and behaviour			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
		(1107/2009). (this was done more clearly in section 7 data gaps) NL notes that the groundwater assessment of the original approval was made on the basis of FOCUS-PEARL 2.2.2. EFSA only mentions the PEARL 4.4.4 and PELMO 5.5.3 which were only used for the extension of use.	448112), 4,8a-dihydroxy-avermectin B1a (NOA 457464) and 8a-oxo-4-hydroxy-avermectin B1a (NOA 457465) appropriate PEC in surface water and sediment are only available for spray field uses up to FOCUS step 2. Appropriate step 3 calculations are needed for the aquatic risk characterisation for these metabolites for all the representative uses and were not made available. In addition for [8,9-Z]- avermectin B1a (NOA 427011) and 4"-oxo-avermectin B1a (NOA 426289) reliable PEC are not available for the spray uses. The provision of all these PECs are identified as data gap.' indicates data gaps for all the uses including those originally considered. As is clear from the background documents to the conclusion (eg. reporting and evaluation tables) EFSA did not ignore the existence of the confirmatory data addendum of 2011, however this addendum was not peer reviewed by EFSA as the Commission did not mandate EFSA to peer review this document. Only commenting on this addendum followed by discussions in the standing committee took place. There was not an EFSA peer review. This

Environmental fate and behaviour			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
			EFSA conclusion is completely in line with the EFSA comments made on the confirmatory data addendum of 2011 prior to the Member State discussions in the standing committee. These EFSA comments made it clear that we considered that the available surface water and sediment exposure and associated aquatic risk assessment for metabolites were inadequate / not appropriate. Contrary to the RMS, EFSA does not consider that the exposure and risk assessments for metabolites for aquatic organisms have been adequately addressed with transparent credible risk assessments. We have updated the conclusion text to indicate that the RMS disagrees with the data gaps identified. EFSA has updated the text regarding the groundwater modelling so that it accurately reflects the available modelling information. Thank you for highlighting this inaccuracy in the draft conclusion.
2	Conclusion text section 6	NL: how can there be a data gap for ecotoxicology for the groundwater metabolites? An ecotoxicological assessment	Agreed, the table column entries have been updated to indicate 'Assessment not triggered

Environmental fate and behaviour			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
		is not required, since the levels do not exceed 0.1 µg/L. See toxicological relevance and pesticidal activity where it also states "no information available, not required". Maybe EFSA refers to the potential route that groundwater may become surface water, however then it is still not relevant for the current table that is intended to address the risk to groundwater using the groundwater parametric limit. The data gap for metabolite toxicity is already set at the relevant section and should not be repeated here.	predicted concentrations < 0.001 µg/L'.
3	Conclusion text section 7	NL: do not agree with the following data gap: • Predicted environmental concentrations in surface water at FOCUS step 3, for the soil metabolites NOA 448111, NOA 448112, NOA 457464 and NOA 457465 that may enter surface water via drainage and consequent aquatic risk assessments for the pattern of use being requested for nematode control and also foliar spray uses (that might warrant FOCUS step 4 assessment) were not available (relevant for all representative uses evaluated; submission date proposed by the applicant unknown; see Section 4). The data gap for STEP 3 calculations for the foliar use	As already indicated at comment 1, it is clear from the background documents to the conclusion (eg. reporting and evaluation tables) EFSA did not ignore the existence of the confirmatory data addendum of 2011, however this addendum was not peer reviewed by EFSA as the Commission did not mandate EFSA to peer review this 2011 addendum. As indicated at comment 1 we have updated the conclusion text to indicate that the RMS disagrees with the data gaps identified.

Environmental fate and behaviour			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
		was already addressed in the peer reviewed confirmatory data addendum (2011) and the relevant section of this addendum was copied into the extension addendum (on request of EFSA). This data gap that was already solved cannot be brought back to life.	
4	Conclusion text section 9	NL: EFSA seems to open new data gaps for the already approved uses: consumer risk assessment not finalised since no PEC values available and hence no impact on water treatment could be assessed. However this data requirement (1107/2009) was not existing during the original review. Maybe EFSA wants to mention this for future assessments (ie substance renewal), however when stated like this, it has no ground for the currently approved uses. Moreover, as stated before STEP 3 values for metabolites are available in the peer reviewed confirmatory data addendum for the already approved uses (and copied into the addendum for approval extension).	As is clear from the wording of the data gap in section 7, the data gap only relates to the uses evaluated as a nematicide. This is consequent to the regulatory procedure. The wording in section 9.1 is factually accurate and does not contradict the identified data gap. As already noted EFSA does not agree that the available STEP 3 values for metabolites available in the confirmatory data addendum can be considered to have been previously peer reviewed.
5	List of Endpoints 2.5	NL: EFSA added the STEP 1-2 sw/sed calculations for soil metabolites pertaining to the original inclusion. However they did not add the STEP 3 calculations for these uses	As already noted EFSA does not agree that the available STEP 3 values for metabolites available in the confirmatory data addendum

Environmental fate and behaviour			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
		that are in the peer reviewed confirmatory data addendum (and copied into the addendum for use extension). If EFSA would like to repair the existing LoEP for the existing uses it seems to RMS that <u>all</u> assessments should be included. NL notes that in error the PELMO 5.5.3 model was not mentioned at the groundwater assessment for the extension of use whilst it was used in the assessment. This might be added.	have been peer reviewed and consequently they are not considered to be agreed peer reviewed endpoints that can be included in our conclusion. The Step 1 and 2 PEC were peer reviewed. The relevant text from the EFSA conclusion from 2008 section 4.2.1 is 'FOCUS surface water modelling was evaluated up to step 3 for abamectin and step 2 for the metabolites 8a-hydroxy-avermectin B1a, 8a-oxo-avermectin B1a, 4,8a-dihydroxy-avermectin B1a and 8a-oxo-4-hydroxy-avermectin B1a in an addendum. The peer review agreed these PEC surface water and sediment as presented in the addendum were appropriate for use in risk assessment.' The fact that these Step 2 PEC were omitted from the list of endpoints of the conclusion of 2008 was an error that has been corrected in this conclusion. EFSA updated the list of endpoints to indicate that groundwater simulations were completed with PELMO 5.5.3 as well as PEARL 4.4.4 as proposed by the RMS

Environmental fate and behaviour			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
6		AT: not considered	Noted

Ecotoxicology			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
1	Conclusion text, section 5	NL: A data gap for the risk assessment of the soil metabolites of abamectin to aquatic organisms has been identified. However, the RMS has performed an aquatic risk assessment for these metabolites showing that the risk from these metabolites to aquatic organisms is acceptable. The following is mentioned in the risk assessment: *RMS has copied the relevant part of the confirmatory data addendum (final version April 2012) in the Fate and Behaviour part of the Addendum (see Addendum Volume 3 - Annex B (A12115I), B.8, February 2016).* *From the calculations (see B.8) it appears that the*	Noted. Please see the relevant response given in the evaluation table: Step2 PECsw are available for soil metabolites, only considering spray uses. Based on these PECs a low risk cannot be concluded for soil metabolites. Furthermore, please note that the claim that "PECsw values of the soil metabolites are two orders of magnitude lower than respective abamectin" is only true for open field applications, where multiple route of exposure are likely to be relevant. For applications in protected crops, where only drainage is

Ecotoxicology			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
		PECsw values of the soil metabolites are two orders of magnitude lower than respective abamectin PECsw. Although the currently proposed GAP differs from the proposed uses at the original approval, a similar difference in exposure level between parent and metabolites can be expected. Hence, even when it is assumed that the toxicity of the metabolites is ten times higher than the parent, the risk from the soil metabolites to aquatic organisms is acceptable. Hence, the RMS is of the opinion that this data gap has been solved already.	relevant, such difference cannot be verified.
2	Conclusion text, section 5	NL: RMS is of the opinion that the proposed soil drip use indoors will result in negligible exposure to bees. Hence, the risk to bees is considered to be acceptable without mitigation measures.	Noted.
3	Conclusion text, section 7	NL: In section 7 a refined risk assessment for insectivorous birds and a refinement to address the long-term risk to mammals are required. The RMS does not understand why these requirements for the uses of abamectin as a nematicide are necessary. In section 5 it is concluded in the third paragraph that no relevant dietary exposure is anticipated for birds and wild mammals and a low risk is	The data gaps the RMS is referring to were set for field uses of abamectin, not for the uses as nematicide. EFSA never considered these assessments to be addressed by the confirmatory data and the data gaps are therefore still considered open.

Ecotoxicology			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
		concluded. Hence, this seems contradictory to each other.	
4	Conclusion text, section 7	NL: The RMS is of the opinion that the risk from the soil metabolites to earthworms is acceptable, as stated in the DAR. The data requirement with respect to the risk from the soil metabolites to *Folsomia candida* is agreed, also because Folsomia seems to be considerably more sensitive for abamectin than earthworms. In the opinion of the RMS the data requirement for the soil metabolites could be limited to *Folsomia candida* in this case (and consequently the requirement for earthworms could be deleted).	Noted. The conclusion in the DAR was based on the fact that the acute TER for the metabolites using the screening assumption of 10 times more toxic than the parent is not "far below" the trigger. This element alone is not considered a strong evidence for concluding a low risk.
5	Conclusion, section 8	NL: The proposed risk mitigation measures for aquatic organisms, bees and non-target arthropods are not in line with the risk assessment regarding the use of abamectin as a nematicide in protected crops. According to the risk assessment for these uses no risk mitigation measures are necessary.	As clearly mentioned in the conclusions, all of these mitigation measures apply to previously evaluated uses, not to the use of abamectin as a nematicide in protected crops.
6	Conclusion, section 9.1	NL: RMS is of the opinion that the risk assessment for aquatic organisms is finalised (see DAR).	Noted. See above.

Ecotoxicology			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
7	Conclusion, section 9.3	NL: RMS is of the opinion that the risks to wild non-target terrestrial vertebrates and the risks to aquatic organsims are solved and acceptable for the use of abamectin as a nematicide.	Noted. See also above. The secondary poisoning risk assessment for earthworm-eating birds and mammals was not considered in the DAR. This route of exposure is considered relevant and the assessment resulted in the identification of a high risk for wild mammals. The risk assessment for water metabolites was not addressed.
8		AT: not considered	Noted.

Other			
No.	**Reference** (e.g. conclusion text, list of endpoints, evaluation table etc)	**Member State comment**	**EFSA response to comment**
1		NL: No comments.	Noted