European Commission

Addendum

VOLUME 3 – Annex B (A12115l)

Abamectin

B.7 Residues

Rapporteur Member State: The Netherlands

April 2015

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

Version history page

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B.7 Introduction

Abamectin was included in Annex I of Directive 91/414/EEC as per May 1st 2009, by means of Directive 2008/107/EC, as an acaricide in the cultivation of citrus fruits, lettuce and tomatoes.

The notifier requested to extend the approval of abamectin to the use as a nematicide in fruiting vegetables and green beans.

To this extend, the dossier was updated with regard to supervised residue trials and storage stability of abamectin only, since the dossier evaluated for Annex I inclusion for residues covers the extension of the approval.

B.7.1 Metabolism, distribution and expression of residues in plants

No new additional metabolism studies were submitted for the extension of approval. In EFSA Journal 2010; 8(7): 1683 Modification of the existing MRLs for abamectin in apricots and peaches (including nectarines) the following assessment for metabolism in plants was presented:

The metabolism of abamectin in primary crops was investigated using ^{14}C- or 3H-avermectin B_{1a} in the framework of the peer review under Directive 91/414/EEC (the Netherlands, 2005). The following crop categories were studied:

- *Fruits and fruiting vegetables: direct application to citrus fruits (oranges, lemons and grapefruits) (4 µg/fruit or 40 µg/fruit; samples collected several times up to 12 wks from the application); indoor spray application on tomatoes (5 x 0.026 kg a.s./ha with 7-day intervals or 3 x 0.28 kg a.s./ha with 14-day intervals; BBCH stage 63-71; samples collected up to 28 days after the last application); outdoor spray application on tomatoes (5 x 0.026 kg a.s./ha or 5 x 0.25 kg a.s./ha; 7-day intervals; BBCH stage 65-72/73; samples collected up to 28 days after the last application);*
- *Leafy vegetables: foliar application on celery (immature: 4 x; mature: 10 x; 3 dose groups: 0.011 kg a.s./ha or 0.11 kg a.s./ha or 0.017 kg a.s./ha, 7-day intervals; samples collected up to 22 and 43 days after the last application);*
- *Pulses and oilseeds: direct application to cotton leaves (100 µg/leaf; samples collected up to 8 days post-treatment); foliar spray application on cotton (2 x 0.020 kg a.s./ha; 7-day interval; PHI: ± 60 days; 3 x 0.022 kg a.s./ha or 0.22 kg a.s./ha; PHI: 21 days).*

Furthermore, an in-vitro study was conducted with a methanol solution of ^{14}C-avermectin B_{1a} in a thin film onto a glass surface exposed to artificial light and analysed after 19, 30, 60 and 137 hours to classify and quantify the compound degradation products.

The metabolism of avermectin B1a in celery, cotton, tomato and citrus was complex, qualitatively similar and occurred predominantly by photo-oxidation on the plant surface and by oxidation.

Photolysis represented the major and most rapid degradation pathway under certain conditions (i.e.sun light exposure). In the in-vitro study, avermectin B_{1a} rapidly degraded to a large pool of compounds more polar than the parent compound that after 30 hours of artificial light exposure represented over the 90 % of the TRR while avermectin B_{1a} was about the 7% of the TRR. In the tomato metabolism studies, the surface residues declined much faster under field conditions than in greenhouse, accounting at 28 days after the last application for 19-22 % and 77-86 % of the total radioactivity, respectively. No difference was observed between the normal and exaggerated application rates used in the various studies.

Avermectin B_{1a} was found in almost all plant parts and in many cases as the major identified compound, ranging from 4 to 23 % of the TRR eight days after the last application. Several metabolites were formed at longer PHI and few of them were also identified. A large fraction of extracted residues, which varied from 30 to 82 % of the TRR, was polar and moderately polar in nature and was considered less toxic than the parent compound. At longer PHI, also a non-polar fraction of metabolites containing the avermectin structure was observed. The levels of individual metabolites were primarily below 10 % of the TRR and they were also considered of non toxicological significance. One metabolite was identified as the 8,9-Z isomer (also named δ-8,9 isomer) of avermectin B_{1a}. Its concentration did not exceed the 8 % of the TRR but its toxicity was tested and shown to be comparable to that of avermectin B1a (see section 2). In celery, also traces of 8α-hydroxy avermectin B_{1a} were found.

The metabolism studies on citrus fruits after direct application showed that only little migration of avermectin B_{1a} or its metabolites from the site of treatment to the edible (pulp) portion of the fruits was noted. The residues remained mostly at the surface of the peel (rinse: 6.4-41%; peel: 55-84 %; pulp: 4.3-9.3 % of TRR at 12 weeks after the last application).

The metabolic pathway of avermectin B_{1a} proceeds through:

- *re-arrangement to form 8,9-Z-isomer of avermectin B_{1a};*
- *hydroxylation in the C-8a-position to form 8a-hydroxy-avermectin B_{1a};*
- *oxidation in the C-8a-position to form 8a-oxo-avermectin B_{1a};*
- *demethylation to form 3"-O-desmethyl-avermectin B_{1a};*
- *photolytic cleavage to form the acetic acid derivative ((2S,4S,6S,8R,9S)-8-sec-butyl-4-hydroxy-9-methyl-1,7-dioxa-spiro[5.5]undec-10-en-2-yl)-acetic acid.*

The metabolism of avermectin B_{1b}, which may account for up to 20 % of the residues, was not investigated in these studies. However, because the content of avermectin B_{1a} in abamectin is ≥ 80% and given the small difference in structure, the peer review considered the deficiency not a safety concern (EFSA, 2008).

The available metabolism studies cover the intended use as an nematicide in fruiting vegetables and green beans.

B.7.2 Metabolism, distribution and expression of residues in livestock

No new additional metabolism studies were submitted for the extension of approval. Since peppers, tomatoes, eggplants, cucurbits with edible peel, cucurbits with inedible peel and green beans are not potentioal feedstuff for livestock, the nature and magnitude of abametcin residues in livestock does not need to be assessed.

B.7.3 Definition of the residue

The residue definition for risk assessment was defined as the combination of avermectin B1a, avermectin B1a δ-8,9 isomer and avermectin B1b, expressed as avermectin B1a. Since the analytical method is able to determine all three analytes separately in a single run, the same residue definition was applied for monitoring with no need to establish conversion factors for each commodity.

With regard to the proposed uses of abamectin on fruiting vegetables and green beans, no further metabolism studies are required.

B.7.4 Use pattern

Table 7.4.1 Intended Good Agricultural Practices (GAP) for the abamectin as a nematicide in Europe

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
Pepper	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	
Aubergine	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	
Tomato	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	6	10	0.5 - 1.0	10000 - 20000	100	0	
Cucurbits - edible peel (Cucumber, zucchini, etc)	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	
Cucurbits - inedible peel (Melon, Watermelon, Squash)	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	
Green beans	C EU, S EU	A12115I	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	0.5 - 1.0	10000 - 20000	100	0	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*eg.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) eg. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

B.7.5 Identification of critical GAP

Table 7.4.1 Intended Good Agricultural Practices (GAP) for the abamectin as a nematicide in Europe

Crop and/ or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	g as/hL min max	water L/ha min max	g as/ha min max		
Pepper	C EU, S EU	A12115l	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	1.0	10000	100	0	
Aubergine	C EU, S EU	A12115l	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	1.0	10000	100	0	
Tomato	C EU, S EU	A12115l	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	6	10	1.0	10000	100	0	
Cucurbits - edible peel (Cucumber, zucchini, etc)	C EU, S EU	A12115l	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	1.0	10000	100	0	
Cucurbits - inedible peel (Melon, Watermelon, Squash)	C EU, S EU	A12115l	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	1.0	10000	100	0	
Green beans	C EU, S EU	A12115l	I	*Meloidogyne* sp.	SC	20	Soil drip	BBCH 12-89	4	10	1.0	10000	100	0	

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*eg.* fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) eg. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) eg. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(f) All abbreviations used must be explained
(g) Method, eg. high volume spraying, low volume spraying, spreading, dusting, drench
(h) Kind, eg. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions

B.7.6 Residues resulting from supervised trials

B.7.6.1 Methods of analysis applied in the supervised trials

Abamectin residues in tomato, pepper, cucumber, melons and beans were determined using method REM 198.02. The method is validated during the peer review for the determination of avermectin B1a, avermectin B1b and delta-8,9-isomer of avermectin B1a in crops with high water content, high acid content and high oil content (EFA, 2008).
Concurrent recoveries were run together with the analysis of the samples with method REM 198.02. Details of recovery data are shown in table 7.6.1-1. All values were within acceptable ranges, except for Avermectin B1a delta-8,9-Z isomer in melons at 0.2 mg/kg. Since results at LOQ are acceptable, the method is accepted for analysis in melons.

Table 7.6.1-1: Recovery data for the determination of Avermectin B1a, Avermectin B1b and Avermectin B1a delta-8,9-Z isomer in tomato, peppers, cucumbers, melons and green beans with method REM 198.02

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortification level (mg/kg)	Recovery (%)		
						individual	mean	RSD
T001014-09-REG	tomato	fruit	Avermectin B1a (NOA422601)	n.r. n.r.	0.002 0.02	92 84	- -	- -
			overall				88	
			Avermectin B1b (NOA421704)	n.r. n.r.	0.002 0.02	96 88	- -	- -
			overall				92	
			Avermectin B1a 8,9-Z isomer (NOA427011)	n.r. n.r.	0.002 0.02	89 78	- -	- -
			overall				84	
T001977-09-REG	pepper	fruit	Avermectin B1a (NOA422601)	n.r. n.r.	0.002 0.02	81 86	- -	- -
			overall				84	
			Avermectin B1b (NOA421704)	n.r. n.r.	0.002 0.02	86 89	- -	- -
			overall				88	
			Avermectin B1a 8,9-Z isomer (NOA427011)	n.r. n.r.	0.002 0.02	79 85	- -	- -
			overall				82	
T001016-09-REG	cucumber	fruit	Avermectin B1a	n.r. n.r.	0.002 0.02	84 78		- -

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi-cation level (mg/kg)	Recovery (%)		
						individual	mean	RSD
			(NOA422601)	n.r.	0.2	71		
			overall				78	8.4
			Avermectin B1b (NOA421704)	n.r.	0.002	81	-	-
				n.r.	0.02	82	-	-
				n.r.	0.2	79		
			overall				81	1.9
			Avermectin B1a 8,9-Z isomer (NOA427011)	n.r.	0.002	80	-	-
				n.r.	0.02	73	-	-
				n.r.	0.2	69		
			overall				74	7.5
TK0055923-REG	melon	pulp	Avermectin B1a (NOA422601)	n.r.	0.002	87	-	-
				n.r.	0.02	79	-	-
				n.r.	0.2	71	-	-
			overall				79	10.1
			Avermectin B1b (NOA421704)	n.r.	0.002	96	-	-
				n.r.	0.02	93	-	-
				n.r.	0.2	81	-	-
			overall				90	8.8
			Avermectin B1a 8,9-Z isomer (NOA427011)	n.r.	0.002	100	-	-
				n.r.	0.02	74	-	-
				n.r.	0.2	63	-	-
			overall				79	24.1
		peel	Avermectin B1a (NOA422601)	n.r.	0.002	89	-	-
				n.r.	0.02	81	-	-
				n.r.	0.2	72	-	-
			overall				81	10.5
			Avermectin B1b (NOA421704)	n.r.	0.002	92	-	-
				n.r.	0.02	88	-	-
				n.r.	0.2	87	-	-
			overall				89	3.0
			Avermectin B1a 8,9-Z isomer (NOA427011)	n.r.	0.002	94	-	-
				n.r.	0.02	71	-	-
				n.r.	0.2	64	-	-
			overall				76	20.6
TK0055927-REG	Beans (fresh with pods)	Whole pods	Avermectin B1a (NOA422601)	n.r.	0.002	104	-	-
				n.r.	0.02	87	-	-
			overall				96	-
			Avermectin B1b (NOA421704)	n.r.	0.002	108	-	-
				n.r.	0.02	109	-	-
			overall				109	-
			Avermectin	n.r.	0.002	95	-	-

Study No. Trial No.	Crop	Portion analysed	a.s./ metabolite	n	Fortifi-cation level (mg/kg)	Recovery (%)		
						individual	mean	RSD
			B1a 8,9-Z isomer (NOA427011)	n.r.	0.02	94	-	-
			overall				95	-
		Plants without pods	Avermectin B1a (NOA422601)	n.r.	0.002	92, 94	93	-
				n.r.	0.02	68	-	-
			overall				85	17.1
			Avermectin B1b (NOA421704)	n.r.	0.002	75	-	-
				n.r.	0.02	95	-	-
			overall				85	-
			Avermectin B1a 8,9-Z isomer (NOA427011)	n.r.	0.002	74	-	-
				n.r.	0.02	67	-	-
			overall				71	-

B.7.6.2 Supervised residues trials in tomato

STUDY 1

Characteristics

reference	:	Schulz, H. 2010a KIIIA 8.3.1./01	GLP statement	:	yes (certified laboratory);
Type of study	:	Supervised residue trial (Greenhouse Europe)	Guideline	:	EEC 7029/VI/95 rev. 5, appendix B (1997)
Year of execution	:	2009	Dose	:	5x 40 g as/ha / 6x 100 g as/ha
test substance	:	A12115I SC 20 formulation Batch no: SMU8KL001/ SMU9AL001	LOQ	:	Avermectin B1a (NOA422601): 0.002 mg/kg Avermectin B1b (NOA421704): 0.002 mg/kg Avermectin B1a 8,9-Z isomer (NOA427011): 0.002 mg/kg
Species	:	Tomato (*Solanum lycopersicum*)	storage	:	≤ 100 d at -18°C
			Acceptability	:	Y

Study design

Two residue trials on protected tomato were conducted in Germany and the United Kingdom in 2009. Abamectin was applied as A12115I, a suspension concentrate (SC) formulation containing 20 g abamectin per litre. In each trial, three plots were used;

- no 1: control;
- no 2: one drench application at 40 g ai/ha was made to tomato plants at growth stage BBCH 13 – 14 prior to transplanting. After transplanting four drip applications separated by 14 days interval were made at 40 g ai/ha respectively, at growth stages BBCH 51 – 61, BBCH 63 – 69, BBCH 71 and BBCH 73.
- no 3: 14 days after transplanting tomato plants six drip applications separated by 9 – 11 days interval were made at 100 g ai/ha respectively at growth stages BBCH 51 – 61, BBCH 62 – 69, BBCH 64 – 71, BBCH 71 – 72, BBCH 73 and BBCH 75 – 81.

Samples were collected at BBCH 73-84.
Samples sizes were in accordance with guidelines, except for the sample taken at PHI 20 days in 09-DE-063. Climatic data were recorded and showed no anomalies.

Residues were analysed with method REM 198.02, limit of quantification for all analytes was 0.002 mg/kg. A homogenized sub-sample was extracted by maceration with methanol.
After centrifugation, the extract was cleaned up on a C8-coated solid phase extraction (SPE) tube. The remaining residue solution is injected into an HPLC-system with a two-column switch and a MS/MS-detection for the common determination of the three analytes.

Results

No residues of avermectin B1a, avermectin B1b or avermectin B1a 8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg) in any of the untreated or treated samples. See table 7.6.2-1.

Conclusion

Four supervised residue trials in protected tomato with abamectin applied as a drip irrigation are available. In two trials, the application rate was too low with 40 g as/ha. No residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg).

Use of abamectin as a nematicide through drip irrigation does not result in detectable residues. Abamectin is currently approved and authorised as an acaricide through foliar spray applications. From existing reviews (e.g. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005 and Conclusion on the peer review of Abamectin), it can be concluded that the foliar treatment is worst case compared to the drip irrigation treatment and that the foliar treatment drives the MRL.

Even though aubergines have a different intended use than tomatoes (four applications vs. six), results from trials in tomato can be extrapolated to aubergine since the trials resulted in no detectable residues.

Table 7.6.2-1: Summary of residue trials in protected tomatoes treated with abamectine in Europe

Report-No. Location incl. Postal code and date	Commodity/ Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Application rate per treatment			Dates of treatments or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)			PHI (days) (d)	Remarks (e)
			g as/ha	Water l/ha	g a.s./hl				Avermectin B1a 8,9-Z-isomer	Avermectin B1a	Avermectin B1b		
Tomatoes													
T001014-09-REG Trial no: 09-DE-063 26160 Bad Zwischenahn Rostrup Germany 2009	Harzfeuer	1) 30-JUL-09 2) 20-AUG-09 3) October 09	40.0 40.0 40.0 40.0 40.1	2128 15819 15819 15819 15819		Drench: 30-JUL-09 Drip: 13-AUG-09 27-AUG-09 10-SEP-09 24-SEP-09	 BBCH 13 BBCH 51 BBCH 69 BBCH 71 BBCH 73	Fruit	< 0.002	< 0.002	< 0.002	28	
			99.9 100.0 100.2 99.9 100.0 99.6	15819 15819 15819 15819 15819 15819		Drip: 13-AUG-09 24-AUG-09 02-SEP-09 11-SEP-09 22-SEP-09 02-OCT-09	 BBCH 51 BBCH 69 BBCH 71 BBCH 71 BBCH 73 BBCH 81	Fruit	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 3 7 14 20	
T001014-09-REG Trial no: 09-UK-064 Wellesbourne, Warwick, CV35 9EF United Kingdom 2009	Shirley	1) 20-MAY-09 2) 08-JUL-09 3) September 09	40.1 40.4 40.0 40.3 40.0	1786 14445 14286 14411 14303		Drench: 24-JUN-09 Drip: 08-JUL-09 22-JUL-09 05-AUG-09 19-AUG-09	 BBCH 14 BBCH 61 BBCH 63 BBCH 71 BBCH 73	Fruit	< 0.002	< 0.002	< 0.002	20	
			100.7 100.1 100.1 100.8 100.1 100.8	14385 14298 14298 14398 14311 14410		Drip: 08-JUL-09 17- JUL -09 28- JUL -09 07-AUG-09 17-AUG-09 27-AUG-09	 BBCH 61 BBCH 62 BBCH 64 BBCH 72 BBCH 73 BBCH 75	Fruit	< 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002	0 3 7 14	

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; indoor/outdoor, Reference to analytical method and information which metabolites are included
Note: All entries to be filled in as appropriate

B.7.6.3 Supervised residues trials in pepper

STUDY 1

Characteristics

reference	:	Schulz, H. 2010b KIIIA 8.3.2./01	GLP statement	:	yes (certified laboratory);
Type of study	:	Supervised residue trial (Greenhouse Europe)	Guideline	:	EEC 7029/VI/95 rev. 5, appendix B (1997)
Year of execution	:	2009	Dose	:	5x 40 g as/ha / 6x 100 g as/ha
test substance	:	A12115I SC 20 formulation Batch no: SMU8KL001	LOQ	:	Avermectin B1a (NOA422601): 0.002 mg/kg Avermectin B1b (NOA421704): 0.002 mg/kg Avermectin B1a 8,9-Z isomer (NOA427011): 0.002 mg/kg
Species	:	Pepper (*Capsicum annuumm*)	storage Acceptability	: :	≤ 131 d at -18°C Y

Study design

Two residue trials on protected pepper were conducted in Germany and the United Kingdom in 2009. Abamectin was applied as A12115I, a suspension concentrate (SC) formulation containing 20 g abamectin per litre.

In each trial, three plots were used;

- no 1: control;
- no 2: one drench application at 40 g ai/ha was made to pepper plants at growth stage BBCH 14 prior to transplanting. After transplanting, four drip applications separated by 14 days interval were made at 40 g ai/ha respectively, at growth stages BBCH 24-51, BBCH 52-65, BBCH 62-67 and BBCH 71.
- no 3: 14 days after transplanting pepper plants six drip applications separated by 9 – 11 days interval were made at 100 g ai/ha respectively at growth stages BBCH 24-51, BBCH 51-53, BBCH 61-64, BBCH 63-67, BBCH 71 and BBCH 73.

Samples were collected at BBCH 73-83.

Samples sizes were in accordance with guidelines. Climatic data were recorded and showed no anomalies.

Residues were analysed with method REM 198.02, limit of quantification for all analytes was 0.002 mg/kg. A homogenized sub-sample was extracted by maceration with methanol.

After centrifugation, the extract was cleaned up on a C8-coated solid phase extraction (SPE) tube. The remaining residue solution is injected into an HPLC-system with a two-column switch and a MS/MS-detection for the common determination of the three analytes.

Results

No residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg) in any of the untreated or treated samples. See table 7.6.3-1.

Conclusion

Four supervised residue trials in protected peppers with abamectin applied as a drip irrigation are available. In two trials, the application rate was too low with 40 g as/ha. In the two remaining trials, six instead of four applications were made, this is considered acceptable, since no residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg).

Use of abamectin as a nematicide through drip irrigation does not result in detectable residues. Abamectin is currently approved and authorised as an acaricide through foliar spray applications. From existing reviews (e.g. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005), it can be concluded that the foliar treatment is worst case compared to the drip irrigation treatment and that the foliar treatment drives the MRL.

Table 7.6.3-1: Summary of residue trials in protected peppers treated with abamectine in Europe

Report-No. Location incl. Postal code and date	Commodity/ Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Application rate per treatment			Dates of treatments or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)			PHI (days) (d)	Remarks (e)
			g as/ha	Water l/ha	g a.s./hl				Avermectin B1a 8,9-Z-isomer	Avermectin B1a	Avermectin B1b		
peppers													
T001977-09-REG Trial no: 09-DE-071 26160 Bad Zwischenahn Rostrup Germany 2009	Yellowonder	1) 08-JUL-09 2) 20-AUG-09 3) October 09	40.0 40.0 39.9 40.0 40.1	2128 15819 15819 15819 15819		Drench: 30-JUL-09 Drip: 13-AUG-09 27-AUG-09 10-SEP-09 24-SEP-09	 BBCH 14 BBCH 51 BBCH 65 BBCH 67 BBCH 71	Fruit	< 0.002	< 0.002	< 0.002	28	
			100.0 99.9 100.1 99.9 100.1 100.1	15819 15819 15819 15819 15819 15819		Drip: 13-AUG-09 24-AUG-09 02-SEP-09 11-SEP-09 22-SEP-09 02-OCT-09	 BBCH 51 BBCH 53 BBCH 65 BBCH 67 BBCH 71 BBCH 73	Fruit	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 3 7 14 20	
T001977-09-REG Trial no: 09-UK-072 Wellesbourne, Warwick, CV35 9EF United Kingdom 2009	Sweet Banana	1) 20-MAY-09 2) 03-AUG-09 3) September 09	40.1 40.4 40.0 40.3 40.0	1786 14411 14304 14375 14464 16599		Drench: 24-JUN-09 Drip: 08-JUL-09 22-JUL-09 05-AUG-09 19-AUG-09	 BBCH 14 BBCH 24 BBCH 52 BBCH 62 BBCH 71	Fruit	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 3 7 14 NCH	NCH = 03 sept
			100.7 100.1 100.1 100.8 100.1 100.8	16599 16599 16599 16599 16599 16599		Drip: 08-JUL-09 17- JUL -09 28- JUL -09 07-AUG-09 17-AUG-09 27-AUG-09	 BBCH 24 BBCH 51 BBCH 61 BBCH 63 BBCH 71 BBCH 73	Fruit	<u>< 0.002</u> < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002	0 14 NCH	

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; indoor/outdoor, Reference to analytical method and information which metabolites are included
Note: All entries to be filled in as appropriate

B.7.6.4 Supervised residues trials in cucumber

STUDY 1

Characteristics

reference	:	Schulz, H. 2010c KIIIA 8.3.3/01	GLP statement	:	yes (certified laboratory);
Type of study	:	Supervised residue trial (Greenhouse Europe)	Guideline	:	EEC 7029/VI/95 rev. 5, appendix B (1997)
Year of execution	:	2009	Dose	:	5x 40 g as/ha / 6x 100 g as/ha
test substance	:	A12115I SC 20 formulation Batch no: SMU8KL001	LOQ	:	Avermectin B1a (NOA422601): 0.002 mg/kg Avermectin B1b (NOA421704): 0.002 mg/kg Avermectin B1a 8,9-Z isomer (NOA427011): 0.002 mg/kg
Species	:	Cucumber	storage Acceptability	: :	≤ 131 d at -18°C Y

Study design

Two residue trials on protected cucumber were conducted in Germany and the United Kingdom in 2009. Abamectin was applied as A12115I, a suspension concentrate (SC) formulation containing 20 g abamectin per litre.

In each trial, three plots were used;

- no 1: control;
- no 2: one drench application at 22.9 g ai/ha was made to cucumber plants at growth stage BBCH 11-14 prior to transplanting. After transplanting, three or four drip applications separated by 14 days interval were made at 40 g ai/ha respectively, at growth stages BBCH 51-61, BBCH 69-72, BBCH 72-79 and BBCH 89.
- no 3: 14 days after transplanting cucumber plants five or six drip applications separated by 9 – 11 day intervals were made at 100 g ai/ha respectively at growth stages BBCH 24-51, BBCH 51-61, BBCH 68-69, BBCH 71-75, BBCH 87 and BBCH 89.

Samples were collected at BBCH 79-89.

Samples sizes were in accordance with guidelines. Climatic data were recorded and showed no anomalies.

Residues were analysed with method REM 198.02, limit of quantification for all analytes was 0.002 mg/kg. A homogenized sub-sample was extracted by maceration with methanol.

After centrifugation, the extract was cleaned up on a C8-coated solid phase extraction (SPE) tube. The remaining residue solution is injected into an HPLC-system with a two-column switch and a MS/MS-detection for the common determination of the three analytes.

Results

No residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg) in any of the untreated or treated samples. See table 7.6.4-1.

Conclusion

Four supervised residue trials in protected cucumbers with abamectin applied as a drip irrigation are available. In two trials, the application rate was too low with 40 g as/ha. In the two remaining trials, six or five instead of four applications were made, this is considered acceptable since trials result in no detectable residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg).

Use of abamectin as a nematicide through drip irrigation does not result in detectable resideus. Abamectin is currently approved and authorised as an acaricide through foliar spray applications. From existing reviews (e.g. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005), it can be concluded that the foliar treatment is worst case compared to the drip irrigation treatment and that the foliar treatment drives the MRL.

Results from the trials in cucumbers can be extrapolated to all cucurbits with edible peel.

Table 7.6.4-1: Summary of residue trials in protected cucumbers treated with abamectine in Europe

Report-No. Location incl. Postal code and date	Commodity/ Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Application rate per treatment			Dates of treatments or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)			PHI (days) (d)	Remarks (e)
			g as/ha	Water l/ha	g a.s./hl				Avermectin B1a 8,9-Z-isomer	Avermectin B1a	Avermectin B1b		
cucumbers													
T001016-09-REG Trial no: 09-DE-067 26160 Bad Zwischenahn Rostrup Germany 2009	Majestrona	1) 30-JUL-09 2) 15-AUG-09 3) September 09	22.9 39.9 40.0 40.1 40.0	2128 15744 15744 15744 15744		Drench: 30-JUL-09 Drip: 13-AUG-09 27-AUG-09 10-SEP-09 24-SEP-09	 BBCH 11 BBCH 51 BBCH 72 BBCH 79 BBCH 89	Fruit	< 0.002	< 0.002	< 0.002	28	NCH = 24 sept
			100.0 100.0 100.0 99.9 100.1 99.7	15744 15744 15744 15744 15744 15744		Drip: 13-AUG-09 24-AUG-09 02-SEP-09 11-SEP-09 22-SEP-09 02-OCT-09	 BBCH 51 BBCH 69 BBCH 75 BBCH 79 BBCH 87 BBCH 89	Fruit	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 3 7 14 NCH	
T001016-09-REG Trial no: 09-UK-068 Wellesbourne, Warwick, CV35 9EF United Kingdom 2009	F1 Carmen	1) 20-MAY-09 2) from 08-JUL-09 3) August 09	22.8 40.5 40.0 40.5	1786 14464 14304 14464		Drench: 24-JUN-09 Drip: 08-JUL-09 22-JUL-09 05-AUG-09	 BBCH 14 BBCH 52 BBCH 69 BBCH 72	Fruit	< 0.002	< 0.002	< 0.002	NCH	NCH = 03 sept
			101.0 100.2 100.8 100.4 100.5	14435 14323 14422 14348 14360		Drip: 08-JUL-09 17- JUL -09 28- JUL -09 07-AUG-09 17-AUG-09	 BBCH 61 BBCH 68 BBCH 71 BBCH 75 BBCH 87	Fruit	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 3 7 14 NCH	

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; indoor/outdoor, Reference to analytical method and information which metabolites are included
Note: All entries to be filled in as appropriate

B.7.6.5 Supervised residues trials in melon

STUDY 1

Characteristics

reference	:	Schulz, H. 2012a KIIIA 8.3.5/01	GLP statement	:	yes (certified laboratory);
Type of study	:	Supervised residue trial (Greenhouse Europe)	Guideline	:	EEC 7029/VI/95 rev. 5, appendix B (1997)
Year of execution	:	2011	Dose	:	5x 40 g as/ha / 6x 100 g as/ha
test substance	:	A12115I SC 20 formulation Batch no: SMU8KL001	LOQ	:	Avermectin B1a (NOA422601): 0.002 mg/kg Avermectin B1b (NOA421704): 0.002 mg/kg Avermectin B1a 8,9-Z isomer (NOA427011): 0.002 mg/kg
Species	:	Melon (*Cucumis Melo*)	storage Acceptability	: :	≤ 174 d at -18°C Y

Study design

Three residue trials on protected melon were conducted in Southern France and Spain in 2011. Abamectin was applied as A12115I, a suspension concentrate (SC) formulation containing 20 g abamectin per litre.

In each trial, two plots were used;

- no 1: control;
- no 2: 12-14 days after transplanting melon plants four drip applications, separated by 10-11 day intervals, were made each at 100 g ai/ha for abamectin..

Samples of treated melon (whole fruit) were collected immediately after last application (0 DALA) at BBCH 72 - 85, as well as 1 DALA (BBCH 72 - 89), 3 DALA (BBCH 72 - 89) and 7 DALA (BBCH 72 - 89). Untreated samples of melon (whole fruit) were taken at 0 DALA (BBCH 72 - 85).

Samples sizes were in accordance with guidelines. Climatic data were recorded and showed no anomalies.

Residues were analysed with method REM 198.02, limit of quantification for all analytes was 0.002 mg/kg. A homogenized sub-sample was extracted by maceration with methanol.

After centrifugation, the extract was cleaned up on a C8-coated solid phase extraction (SPE) tube. The remaining residue solution is injected into an HPLC-system with a two-column switch and a MS/MS-detection for the common determination of the three analytes.

Results

No residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg) in any of the untreated or treated samples. See table 7.6.5-1.

Conclusion

Three supervised residue trials in protected melons with abamectin applied as a drip irrigation are available. Trials were performed in accordance with the critical GAP. No detectable residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg).
Use of abamectin as a nematicide through drip irrigation does not result in detectable residues. Abamectin is currently approved and authorised as an acaricide through foliar spray applications. From existing reviews (e.g. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005), it can be concluded that the foliar treatment is worst case compared to the drip irrigation treatment and that the foliar treatment drives the MRL.
Results from the trials in melons can be extrapolated to all cucurbits with inedible peel.

Table 7.6.5-1: Summary of residue trials in protected melons treated with abamectine in Europe

Report-No. Location incl. Postal code and date	Commodity/ Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Application rate per treatment			Dates of treatments or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)			PHI (days) (d)	Remarks (e)
			g as/ha	Water l/ha	g a.s./hl				Avermectin B1a 8,9-Z-isomer	Avermectin B1a	Avermectin B1b		
melons													
TK0055923-REG Trial no: 11/01911660-01 47400 Tonneins, Lot-et –Garonne France (South) 2011	Indola	1) 26-JUL-11 2) 15-AUG to 10 SEP-11 3) 15-SEP- 11	100 100 100 100	10000 10000 10000 10000		09-AUG-11 19-AUG-11 29-AUG-11 08-SEP-11	BBCH 22 BBCH 61 BBCH 71 BBCH 72	Peel Pulp 	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 1 3 7 0 1 3 7	NCH = 24 sept
TK0055923-REG Trial no: 11/01911660-02 29001, Malaga Spain 2011	Galia	1) 08-AUG-11 2) 01-SEP to 11-SEP-11 3) 28-SEP-11	100 100 100 100	16667 16619 16888 16642		22-AUG-11 01-SEP-11 11-SEP-11 21-SEP-11	BBCH 14 BBCH 61 BBCH 69 BBCH 82	Peel Pulp 	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 <u>< 0.002</u> < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 <u>< 0.002</u> < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 <u>< 0.002</u> < 0.002 < 0.002 < 0.002	0 1 3 7 0 1 3 7	
		1) 16-JUN-11 2) 07-JUL to 18-JUL-11 3) 05-AUG-11	100 100 100 100	20000 17083 17167 17067		28-JUN-11 09-JUL-11 19-JUL-11 29-JUL-11	BBCH 14 BBCH 62 BBCH 75 BBCH 85	Peel Pulp 	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 <u>< 0.002</u> < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 <u>< 0.002</u> < 0.002 < 0.002 < 0.002	<u>< 0.002</u> < 0.002 < 0.002 < 0.002 <u>< 0.002</u> < 0.002 < 0.002 < 0.002	0 1 3 7 0 1 3 7	NCH = 03 sept

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; indoor/outdoor, Reference to analytical method and information which metabolites are included
Note: All entries to be filled in as appropriate

B.7.6.6 Supervised residues trials in beans with pods (fresh)

STUDY 1

Characteristics

reference	:	Schulz, H. 2012b KIIIA 8.3.5/01	GLP statement	:	yes (certified laboratory);
Type of study	:	Supervised residue trial (Greenhouse Europe)	Guideline	:	EEC 7029/VI/95 rev. 5, appendix B (1997)
Year of execution	:	2011	Dose	:	5x 40 g as/ha / 6x 100 g as/ha
test substance	:	A12115I SC 20 formulation Batch no: SMU8KL001	LOQ	:	Avermectin B1a (NOA422601): 0.002 mg/kg Avermectin B1b (NOA421704): 0.002 mg/kg Avermectin B1a 8,9-Z isomer (NOA427011): 0.002 mg/kg
Species	:	Beans	storage Acceptability	: :	≤ 158 d at -18°C Y

Study design

Two residue trials on protected fresh beans with pods were conducted in Spain in 2011. Abamectin was applied as A12115I, a suspension concentrate (SC) formulation containing 20 g abamectin per litre.

In each trial, two plots were used;

- no 1: control;
- To plot 2, 13-14 days after transplanting bean plants four drip applications, separated by 10-12 day intervals were made each at 100 g ai/ha for abamectin.

Samples of whole pods (beans with pods) and plant without pods were collected immediately after last application (0 DALA) at BBCH 75, as well as 1 DALA (BBCH 75), 3 DALA (BBCH 75-77) and 7 DALA (BBCH 75-78). Untreated samples of whole pods (beans with pods) and plant without pods were taken at 0 DALA (BBCH 75).

Samples sizes were in accordance with guidelines. Climatic data were recorded and showed no anomalies.

Residues were analysed with method REM 198.02, limit of quantification for all analytes was 0.002 mg/kg. A homogenized sub-sample was extracted by maceration with methanol.

After centrifugation, the extract was cleaned up on a C8-coated solid phase extraction (SPE) tube. The remaining residue solution is injected into an HPLC-system with a two-column switch and a MS/MS-detection for the common determination of the three analytes.

Results

No residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg) in any of the untreated or treated pods samples. See table 7.6.6-1.

Conclusion

Two supervised residue trials in protected beans (fresh with pods) with abamectin applied as a drip irrigation are available. Trials were performed in accordance with the critical GAP. No detectable residues of avermectin B1a, avermectin B1b or avermectin B1a delta-8,9-Z isomer were found at or above the limit of quantification (0.002 mg/kg).
Use of abamectin as a nematicide through drip irrigation does not result in detectable residues. Abamectin is currently approved and authorised as an acaricide through foliar spray applications. From existing reviews (e.g. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005), it can be concluded that the foliar treatment is worst case compared to the drip irrigation treatment and that the foliar treatment drives the MRL.

Table 7.6.6-1: Summary of residue trials in protected beans treated with abamectine in Europe

Report-No. Location incl. Postal code and date	Commodity/ Variety (a)	Date of 1) Sowing or planting 2) Flowering 3) Harvest (b)	Application rate per treatment			Dates of treatments or no. of treatments and last date (c)	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)			PHI (days) (d)	Remarks (e)
			g as/ha	Water l/ha	g a.s./hl				Avermectin B1a 8,9-Z-isomer	Avermectin B1a	Avermectin B1b		
beans													
TK0055927-REG Trial no: 11/01911641-02 29001, Malaga Spain 2011	Festival	1) 28-JUL-11 2) 21-AUG to 30-AUG-11 3) 10-SEP-11	100 100 100 100	18567 19300 18813 19527		11-AUG-11 21-AUG-11 31-AUG-11 10-SEP-11	BBCH 12 BBCH 61 BBCH 65 BBCH 75	Whole pods Plants without pods	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 1 3 7 0 1 3 7	NCH = 03 sept
TK0055927-REG Trial no: 11/01911641-03 29001, Malaga Spain 2011	Festival	1) 16-JUN-11 2) 17-JUL to 28-JUL-11 3) 31-JUL- 11	100 100 100 100	19717 18333 18917 17567		29-JUN-11 09-JUL-11 19-JUL-11 31-JUL-11	BBCH 22 BBCH 61 BBCH 71 BBCH 72	Whole pods Plants without pods	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 0.009 < 0.002 < 0.002 < 0.002	< 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002 < 0.002	0 1 3 7 0 1 3 7	Result at PHI 0d of 0.009 mean value of duplicate analysis (individual values 0.009 mg/kg and 0.009 mg/kg)

Remarks: (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; indoor/outdoor, Reference to analytical method and information which metabolites are included
Note: All entries to be filled in as appropriate

B.7.6.7 Storage stability (IIA 6.1)

STUDY 1

Characteristics

Reference	:	Kwiatkowski A., Hill S., 2007; KIIIA 8.1.1 /01	GLP statement	:	Y
Type of study	:	Storage stability	Guidelines	:	European Commission Guideline 7032/VI/95 rev. 5
Year of execution	:	2005-2007			
Storage duration	:	12-18 months	Matrix	:	High acid (orange peel), high oil (sunflower seed), high protein (runner bean), high starch (potato), high water (tomato)
Test substance	:	avermectin B1a, avermectin B1b and avermectin B1a 8,9-Z-isomer	Acceptability	:	Acceptable

Study design

Untreated control samples of tomato, runner bean (beans, green with pods), sunflower seed, potato and orange peel were homogenized and aliquots of 10 g of each sample (n=42 except for orange peel: n=30) were dispensed into centrifuge tubes. The weighed samples were fortified with 25 µL of mixed standard of avermectin B1a, avermectin B1b and avermectin B1a delta-8,9-Z-isomer in methanol at 0.05 mg/kg for each analyte. The solvent was allowed to evaporate and the sample containers sealed and stored frozen at -18°C for up to 2 years, except orange peel (up to 1 year). The remaining bulk control sample was also stored at -18°C to provide control and procedural recovery samples for analysis at each interval. Six replicate samples of the crop matrices were analysed at zero time and triplicate samples were removed after 3, 6, 12, 18 and 24 months of storage at -18°C. The samples were analysed using method REM 198.02 (LC-MS/MS analysis, LOQ 0.002 mg/kg for each analyte).

Results

The results are summarized in the tables below. The report did not present individual procedural recovery data for each time point, but presented for each matrix the mean recovery per time point and the individual data for all time points together, including the overall mean and RSD. Procedural recoveries for all analytes were acceptable for each matrix. Residues of abamectin (avermectin B1a, avermectin B1b and avermectin B1a delta-8,9-Z-isomer) were stable during storage at ≤-18°C in tomato, runner bean, sunflower seed and potato for up to 24 months and in orange peel for up to 12 months. Mean uncorrected residues and uncorrected recoveries are reported in the tables below.

Table B.7.6.7-1 Summary of concurrent recoveries of abamectin from tomato.

Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)*[A]	*Recoveries (%)*[B]	*Mean ± rel std dev*[C]
avermectin B1a					
Tomato	0.05	0	2		
	0.05	3	2		

Table B.7.6.7-1 Summary of concurrent recoveries of abamectin from tomato.					
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)[A]*	*Recoveries (%)[B]*	*Mean ± rel std dev[C]*
	0.05	6	2	80-112	90 ± 9
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1b					
Tomato	0.05	0	2	96-123	91 ± 12
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1a 8,9-Z-isomer					
Tomato	0.05	0	2	83-93	87 ± 4
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		

(A) The number of procedural recoveries for each time point was not specified in the report, but based on the total number of procedural recoveries and the number of sampling times, it is likely that two procedural recovery samples were analyzed at each time point.
(B) Overall range for entire study (see text above table).
(C) The report presented mean and RSD (SD was not reported) of results for entire study (see text above tables).

Table B.7.6.7-2 Stability of abamectin residues in tomato following storage at ≤-18°C.				
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Mean recovered residues (mg/kg)*	*Uncorrected % recovery*
avermectin B1a				
Tomato	0.05	0	0.05	100
	0.05	3	0.05	100
	0.05	6	0.04	93
	0.05	12	0.04	80
	0.05	18	0.04	87
	0.05	24	0.05	100
avermectin B1b				
Tomato	0.05	0	0.05	100
	0.05	3	0.05	100

Table B.7.6.7-2 Stability of abamectin residues in tomato following storage at ≤-18°C.				
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Mean recovered residues (mg/kg)*	*Uncorrected % recovery*
	0.05	6	0.04	80
	0.05	12	0.04	80
	0.05	18	0.04	80
	0.05	24	0.04	80
avermectin B1a 8,9-Z-isomer				
Tomato	0.05	0	0.04	80
	0.05	3	0.04	80
	0.05	6	0.04	87
	0.05	12	0.04	80
	0.05	18	0.04	80
	0.05	24	0.05	100

Table B.7.6.7-3 Summary of concurrent recoveries of abamectin from runner bean.					
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)*[A]	*Recoveries (%)*[B]	*Mean ± rel std dev*[C]
avermectin B1a					
Runner bean	0.05	0	2	73-83	77 ± 4
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1b					
Runner bean	0.05	0	2	74-90	80 ± 6
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1a 8,9-Z-isomer					
Runner bean	0.05	0	2	66-90	75 ± 9
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		

Table B.7.6.7-3 Summary of concurrent recoveries of abamectin from runner bean.					
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)[A]*	*Recoveries (%)[B]*	*Mean ± rel std dev[C]*
	0.05	24	2		

(A) The number of procedural recoveries for each time point was not specified in the report, but based on the total number of procedural recoveries and the number of sampling times, it is likely that two procedural recovery samples were analyzed at each time point.
(B) Overall range for entire study (see text above table).
(C) The report presented mean and RSD (SD was not reported) of results for entire study (see text above tables).

Table B.7.6.7-4 Stability of abamectin residues in runner bean following storage at ≤-18°C.				
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Recovered residues (mg/kg)*	*Uncorrected % recovery*
avermectin B1a				
runner bean	0.05	0	0.04	80
	0.05	3	0.04	73
	0.05	6	0.04	80
	0.05	12	0.03	60
	0.05	18	0.03	67
	0.05	24	0.04	80
avermectin B1b				
runner bean	0.05	0	0.04	80
	0.05	3	0.04	80
	0.05	6	0.04	80
	0.05	12	0.04	80
	0.05	18	0.03	60
	0.05	24	0.04	80
avermectin B1a 8,9-Z-isomer				
runner bean	0.05	0	0.04	67
	0.05	3	0.03	60
	0.05	6	0.03	67
	0.05	12	0.03	60
	0.05	18	0.03	60
	0.05	24	0.04	73

Table B.7.6.7-5 Summary of concurrent recoveries of abamectin from sunflower seed.					
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)[A]*	*Recoveries (%)[B]*	*Mean ± rel std dev[C]*
avermectin B1a					

Table B.7.6.7-5 Summary of concurrent recoveries of abamectin from sunflower seed.					
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)[A]*	*Recoveries (%)[B]*	*Mean ± rel std dev[C]*
Sunflower seed	0.05	0	2	75-98	84 ± 9
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1b					
Sunflower seed	0.05	0	2	73-91	83 ± 7
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1a 8,9-Z-isomer					
Sunflower seed	0.05	0	2	73-95	83 ± 9
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		

(A) The number of procedural recoveries for each time point was not specified in the report, but based on the total number of procedural recoveries and the number of sampling times, it is likely that two procedural recovery samples were analyzed at each time point.
(B) Overall range for entire study (see text above table).
(C) The report presented mean and RSD (SD was not reported) of results for entire study (see text above tables).

Table B.7.6.7-6 Stability of abamectin residues in sunflower seed following storage at ≤-18°C.				
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Recovered residues (mg/kg)*	*Uncorrected % recovery*
avermectin B1a				
sunflower seed	0.05	0	0.04	73
	0.05	3	0.04	87
	0.05	6	0.04	80
	0.05	12	0.04	80

Table B.7.6.7-6	**Stability of abamectin residues in sunflower seed following storage at ≤-18°C.**			
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Recovered residues (mg/kg)*	*Uncorrected % recovery*
	0.05	18	0.04	87
	0.05	24	0.04	87
avermectin B1b				
sunflower seed	0.05	0	0.04	80
	0.05	3	0.04	80
	0.05	6	0.04	80
	0.05	12	0.04	80
	0.05	18	0.04	80
	0.05	24	0.04	80
avermectin B1a 8,9-Z-isomer				
sunflower seed	0.05	0	0.04	80
	0.05	3	0.05	93
	0.05	6	0.05	100
	0.05	12	0.04	80
	0.05	18	0.04	80
	0.05	24	0.05	93

Table B.7.6.7-7	**Summary of concurrent recoveries of abamectin from potato.**				
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)[(A)]*	*Recoveries (%)[(B)]*	*Mean ± rel std dev[(C)]*
avermectin B1a					
Potato	0.05	0	2	79-91	84 ± 4
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1b					
Potato	0.05	0	2	77-94	86 ± 6
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		
avermectin B1a 8,9-Z-isomer					

Table B.7.6.7-7 Summary of concurrent recoveries of abamectin from potato.					
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)[A]*	*Recoveries (%)[B]*	*Mean ± rel std dev[C]*
Potato	0.05	0	2	68-85	79 ± 6
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
	0.05	18	2		
	0.05	24	2		

(A) The number of procedural recoveries for each time point was not specified in the report, but based on the total number of procedural recoveries and the number of sampling times, it is likely that two procedural recovery samples were analyzed at each time point.
(B) Overall range for entire study (see text above table).
(C) The report presented mean and RSD (SD was not reported) of results for entire study (see text above tables).

Table B.7.6.7-8 Stability of abamectin residues in potato following storage at ≤-18°C.				
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Recovered residues (mg/kg)*	*Uncorrected % recovery*
avermectin B1a				
potato	0.05	0	0.04	80
	0.05	3	0.04	80
	0.05	6	0.04	80
	0.05	12	0.04	80
	0.05	18	0.04	80
	0.05	24	0.04	80
avermectin B1b				
potato	0.05	0	0.04	80
	0.05	3	0.04	80
	0.05	6	0.04	80
	0.05	12	0.04	80
	0.05	18	0.04	80
	0.05	24	0.04	80
avermectin B1a 8,9-Z-isomer				
potato	0.05	0	0.04	80
	0.05	3	0.03	60
	0.05	6	0.04	87
	0.05	12	0.04	80
	0.05	18	0.04	73
	0.05	24	0.04	80

Table B.7.6.7-9 Summary of concurrent recoveries of abamectin from orange peel.					
Matrix	*Spike level (mg/kg)*	*Storage Interval (months)*	*Sample size (n)[(A)]*	*Recoveries (%)[(B)]*	*Mean ± rel std dev[(C)]*
avermectin B1a					
orange peel	0.05	0	2	76-95	84 ± 8
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
avermectin B1b					
orange peel	0.05	0	2	76-95	85 ± 7
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		
avermectin B1a 8,9-Z-isomer					
orange peel	0.05	0	2	74-91	81 ± 6
	0.05	3	2		
	0.05	6	2		
	0.05	12	2		

(A) The number of procedural recoveries for each time point was not specified in the report, but based on the total number of procedural recoveries and the number of sampling times, it is likely that two procedural recovery samples were analyzed at each time point.
(B) Overall range for entire study (see text above table).
(C) The report presented mean and RSD (SD was not reported) of results for entire study (see text above tables).

Table B.7.6.7-10 Stability of abamectin residues in orange peel following storage at ≤-18°C.				
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Recovered residues (mg/kg)*	*Unorrected % recovery*
avermectin B1a				
orange peel	0.05	0	0.04	80
	0.05	3	0.04	80
	0.05	6	0.04	80
	0.05	12	0.04	80
avermectin B1b				
orange peel	0.05	0	0.04	80
	0.05	3	0.04	80
	0.05	6	0.04	80
	0.05	12	0.04	80
avermectin B1a 8,9-Z-isomer				
orange peel	0.05	0	0.04	80

Table B.7.6.7-10	**Stability of abamectin residues in orange peel following storage at ≤-18°C.**			
Commodity	*Spike level (mg/kg)*	*Storage interval (days)*	*Recovered residues (mg/kg)*	*Unorrected % recovery*
	0.05	3	0.03	60
	0.05	6	0.04	80
	0.05	12	0.04	80

Conclusion

Residues of abamectin (avermectin B1a, avermectin B1b and avermectin B1a delta-8,9-Z-isomer) were stable during storage at ≤-18°C in tomato, runner bean, sunflower seed and potato for up to 24 months and in orange peel for up to 12 months.

B.7.7 Effects of industrial processing and/or household preparation

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

B.7.8 Livestock feeding studies

No new additional metabolism studies were submitted for the extension of approval. Since peppers, tomatoes, eggplants, cucurbits with edible peel, cucurbits with inedible peel and green beans are not potential feedstuff for livestock, the nature and magnitude of abametcin residues in livestock does not need to be assessed.

B.7.9 Residues in succeeding or rotational crops

No new rotational crop studies have been submitted. In EFSA Scientific Report (2008) 147, 1-106, Conclusion on the peer review of abamectin, the following conclusion for residues in rotational crops was presented:

A confined study demonstrated that under practical use conditions TRR in rotational crops are in the range of 0.001 mg/kg. In addition more than 90% of these TRR are not solvent extractable, suggesting that they mostly result from incorporation into natural endogenous plant constituents.

B.7.10 Proposed pre-harvest intervals for envisaged uses, or withholding periods, in the case of post-harvest uses

A withholding period is not proposed for the crops in the intended use, since they are all crops with continuous harvest and the product is applied as a drip irrigation.

B.7.11 Community MRLs

MRLs for abamectin have been set in Regulation (EC) 396/2005. The Art 12 review is ongoing, the Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005 has recently been published (EFSA Journal 2014;12(9):3823 [84 pp.].).

B.7.12 Proposed EU-MRLs and justification for the acceptability of those MRLs (IIA 6.7.2; IIIA 8.7.2)

Abamectin is already approved and authorised as an acaricide. The currently established MRLs are based on this use, where abamectin is applied as a foliar treatment.

Comparison between residues arising from the foliar treatment as an acaricide and the drip irrigation treatment as an nematicide shows that the foliar treatments results in higher residue levels than the drip irrigation treatment. MRLs are driven by the foliar treatment. In the Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2014;12(9):3823 [84 pp.].), existing EU MRLs, Existing CXL and proposed MRLs are reported.

For the crops in the intended use the MRLs from the Reasoned Opinion are given below:

Code number	Commodity	Exisiting EU MRL (mg/kg)	Exisiting CXL MRL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition: sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a, expressed as avermectin B1a					
231010	Tomato	0.02	0.02	0.09	Further consideration needed (a)
231020	Pepper	0.05	0.02	0.07	Further consideration needed (a)
231030	Aubergine (egg plants)	0.02	-	0.09	Further consideration needed (b)
232010	Cucumbers	0.02	0.01	0.04	Further consideration needed (a)
232020	Gherkins	0.02	-	0.04	Further consideration needed (b)
232030	Courgettes	0.02	0.01*	0.04	Further consideration needed (a)
233010	Melons	0.01*	0.01*	0.01	Further consideration needed (a)
233020	Pumpkins	0.01*	-	0.01	Further consideration needed (b)
233030	Watermelons	0.01*	0.01*	0.01	Further consideration needed (a)
260010	Beans (fresh with pods)	0.01*	-	0.03	Further consideration needed (b)

(a): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; existing CXL is covered by the tentative MRL (combination E-III in Appendix D).

(b): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified; no CXL is available (combination E-I in Appendix D).

Since the residues from supervised residue trials in the crops concerned, where abamectin was applied as a nematicide, were all below LOQ of 0.002 mg/kg for all three analytes (except for one

bean sample, i.e. whole plant without pods), it can be concluded that the currently established and proposed MRLs cover the use a a nematicide in these crops.

B.7.13 Proposed import tolerances and justification for the acceptability of those residues

Import tolerances are currently not proposed for abamectin.

B.7.14 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs

CAC MRLs have been considered by EFSA in their Reasoned Opinion concerning the Review of exisiting MRLs but were not considered by RMS for the amendment of the approval of abamectin.

B.7.15 Estimates of potential and actual dietary exposure through diet and other means

In the Reasoned opinion on the review of the existing maximum residue levels (MRLs) for abamectin according to Article 12 of Regulation (EC) No 396/2005 (EFSA Journal 2014;12(9):3823 [84 pp.].), a consumer risk assessment was performed using all existing EU MRLs.

For this assessment, the current EU-MRLs for the crops in the intended use, the ADI of 0.0025 mg/kg bw/d (EFSA, 2008) and the ARfD of 0.005 mg/kg bw (EFSA, 2008), were used as input parameters.

The maximum TMDI for abamectin for the crops in the intended use and the existing EU-MRLs is 4.8% for WHO Cluster Diet B and the maximum IESTI is 63% for peppers.
No refinement of the risk assessment was performed, no risk for the European consumer is identified.

Prepare workbook for refined calculations

Undo refined calculations

Abamectin

Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):	0,006	proposed LOQ:	0,006
Toxicological end points			
ADI (mg/kg bw/day):	**0,0025**	ARfD (mg/kg bw):	**0,005**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL).
The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment

TMDI (range) in % of ADI minimum - maximum: 0 – 5

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
4,8	WHO Cluster diet B	2,5	Tomatoes	1,0	Peppers	0,3	Watermelons	
2,3	DK child	1,3	Cucumbers	0,4	Peppers	0,4	Tomatoes	
2,0	DE child	0,8	Tomatoes	0,6	Peppers	0,5	Cucumbers	
1,8	WHO cluster diet D	0,8	Tomatoes	0,2	Peppers	0,2	Watermelons	
1,7	WHO regional European diet	0,9	Tomatoes	0,3	Peppers	0,1	Melons	
1,7	SE general population 90th percentile	0,6	Tomatoes	0,4	Peppers	0,3	Cucumbers	
1,6	IT kids/toddler	1,1	Tomatoes	0,1	Courgettes	0,1	Peppers	
1,5	IT adult	0,9	Tomatoes	0,1	Courgettes	0,1	Peppers	
1,5	FR toddler	0,6	Tomatoes	0,4	Beans (with pods)	0,4	Courgettes	
1,5	IE adult	0,3	Melons	0,3	Tomatoes	0,3	Peppers	
1,3	ES child	0,8	Tomatoes	0,2	Peppers	0,1	Beans (with pods)	
1,2	ES adult	0,6	Tomatoes	0,3	Peppers	0,1	Beans (with pods)	
1,2	PT General population	0,7	Tomatoes	0,4	Peppers	0,0	Melons	
1,1	NL child	0,5	Tomatoes	0,2	Cucumbers	0,2	Beans (with pods)	
1,1	FR infant	0,5	Courgettes	0,3	Beans (with pods)	0,1	Tomatoes	
1,0	WHO cluster diet E	0,4	Tomatoes	0,2	Peppers	0,1	Beans (with pods)	
1,0	PL general population	0,7	Tomatoes	0,2	Peppers	0,1	Cucumbers	
0,9	WHO Cluster diet F	0,5	Tomatoes	0,1	Peppers	0,1	Cucumbers	
0,9	LT adult	0,5	Tomatoes	0,3	Cucumbers	0,0	Peppers	
0,9	UK vegetarian	0,5	Tomatoes	0,2	Peppers	0,1	Cucumbers	
0,8	DK adult	0,3	Tomatoes	0,2	Cucumbers	0,2	Peppers	
0,8	FR all population	0,3	Tomatoes	0,1	Courgettes	0,1	Cucumbers	
0,7	NL general	0,3	Tomatoes	0,1	Peppers	0,1	Beans (with pods)	
0,7	UK Toddler	0,5	Tomatoes	0,1	Cucumbers	0,0	Peppers	
0,7	FI adult	0,3	Tomatoes	0,2	Cucumbers	0,1	Peppers	
0,5	UK Adult	0,3	Tomatoes	0,1	Peppers	0,0	Cucumbers	
0,3	UK Infant	0,3	Tomatoes	0,0	Beans (with pods)	0,0	Courgettes	

Conclusion:

The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI.
A long-term intake of residues of Abamectin is unlikely to present a public health concern.

Acute risk assessment /children						Acute risk assessment / adults / general population					
The acute risk assessment is based on the ARfD.											
For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.											
In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used. In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.											
Threshold MRL is the calculated residue level which would leads to an exposure equivalent to 100 % of the ARfD.											
Unprocessed c											
No of commodities for which ARfD/ADI is exceeded (IESTI 1):		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		---	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		---
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
63,0	Peppers	0,05 / -	45,0	Peppers	0,05 / -	16,3	Peppers	0,05 / -	11,7	Peppers	0,05 / -
30,3	Melons	0,01 / -	30,3	Melons	0,01 / -	10,8	Courgettes	0,02 / -	10,6	Pumpkins	0,01 / -
24,5	Watermelons	0,01 / -	24,5	Watermelons	0,01 / -	10,6	Pumpkins	0,01 / -	10,0	Aubergines (egg plants)	0,02 / -
23,4	Cucumbers	0,02 / -	23,4	Cucumbers	0,02 / -	10,0	Aubergines (egg	0,02 / -	8,1	Courgettes	0,02 / -
23,3	Tomatoes	0,02 / -	16,9	Tomatoes	0,02 / -	8,1	Watermelons	0,01 / -	8,1	Watermelons	0,01 / -
No of critical MRLs (IESTI 1)			---			**No of critical MRLs (IESTI 2)**			---		
Processed co											
No of commodities for which ARfD/ADI is exceeded:		---				**No of commodities for which ARfD/ADI is exceeded:**		---			
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
7,0	Tomato juice	0,02 / -				0,8	Tomato (preserved-	0,02 / -			
*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.											
**) pTMRL: provisional temporary MRL											
***) pTMRL: provisional temporary MRL for unprocessed commodity											
Conclusion:											
For Abamectin IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.											
No exceedance of the ARfD/ADI was identified for any unprocessed commodity.											
For processed commodities, no exceedance of the ARfD/ADI was identified.											

B.7.16 Summary and evaluation of residue behaviour

Abamectin was included in Annex I of Directive 91/414/EEC as per May 1st 2009, by means of Directive 2008/107/EC, as an acaricide in the cultivation of citrus fruits, lettuce and tomatoes.
The notifier requested to extend the approval of abamectin to the use as a nematicide in fruiting vegetables and green beans.
To this extend, the dossier was updated with regard to supervised residue trials and storage stability of abamectin only, since the dossier evaluated for Annex I inclusion for residues covers the extension of the approval.

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

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

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

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

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

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

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

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

B.7.17.1 References relied on

OECD data point number / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
KIIIA1 8.1.1 / 01	Kwiatkowski A., Hill S.	2007	Abamectin - Storage Stability in Crops Stored Deep Frozen for up to Two Years - Final Report Syngenta Crop Protection AG, Basel, Switzerland Syngenta - Jealott's Hill International, Bracknell, Berkshire, United Kingdom, T022438-04-REG 05-S504 GLP, not published Syngenta File No MK936/1798	Y	SYN
KIIIA1 8.3.1 / 01	Schulz H.	2010a	Abamectin - Residue Study on Protected Tomatoes in Germany and the United Kingdom in 2009 Syngenta SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T001014-09-REG GLP, not published Syngenta File No A12115I_10028	Y	SYN
KIIIA1 8.3.2 / 01	Schulz H.	2010b	Abamectin - Residue Study on Protected Pepper in Germany and the United Kingdom in 2009 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T001977-09-REG GLP, not published Syngenta File No A12115I_10027	Y	SYN
KIIIA1 8.3.4 / 01	Schulz H	2010c	Abamectin - Residue Study on Protected Cucumber in Germany and the United Kingdom in 2009 Syngenta - Jealott's Hill, Bracknell, United Kingdom SGS INSTITUT FRESENIUS GmbH, Im Maisel 14, D-65232 Taunusstein, Germany, T001016-09-REG GLP, not published Syngenta File No A12115I_10026	Y	SYN

OECD data point number / reference number	Author(s)	Year	Title Source (where different from company) Company, Report No GLP or GEP status (where relevant), Published or not	Data Protection Claimed Y/N	Owner
KIIIA1 8.3.5 / 01	Schulz H.	2012a	Abamectin - Residue Study on Protected Melon in Southern France and Spain in 2011 Syngenta SGS Institut Fresenius GmbH, Taunusstein, Germany, TK0055923-REG GLP, not published Syngenta File No A12115l_10064	Y	SYN
KIIIA1 8.3.6 / 01	Schulz H.	2012b	Abamectin - Residue Study on Protected Beans with Pods (Fresh) in Spain in 2011 Syngenta SGS Institut Fresenius GmbH, Taunusstein, Germany, TK0055927-REG GLP, not published Syngenta File No A12115l_10063	Y	SYN