

## **REASONED OPINION OF EFSA**

### **Setting of new MRLs for emamectin benzoate in various crops<sup>1</sup>**

**Prepared by the Pesticides Unit (PRAPeR)**

**(Question No EFSA-Q-2008-719)**

**Issued on 18 May 2009**

#### **SUMMARY**

The Netherlands received an application from Syngenta Crop Protection AG to set new MRLs for the active substance emamectin benzoate in pome fruit, peaches, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits (edible peel), cucurbits (inedible peel), cauliflower, broccoli, head cabbage, lettuce and other salad plants, scarole, herbs, fresh beans (with pods), fresh peas (with pods) and artichokes. The Netherlands as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 2 September 2009.

It should be noted that emamectin benzoate is a new active substance for which the peer review has not yet been finalized, therefore the conclusions reached in this reasoned opinion have to be taken as temporary and might need to be reconsidered in the light of the final conclusions of the peer review. In addition, before a risk management decision is taken, it should be clarified whether it is acceptable to set MRLs on the basis of intended GAPs notified by the manufacturer of the active substance without having clear evidence that the intended GAPs will be approved at the Member State level.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the Draft Assessment Report prepared by The Netherlands in the framework of Directive 91/414/EEC.

The toxicological reference values have been derived by the RMS Netherlands in the framework of the assessment of the active substance for Annex I inclusion and the proposed ADI is 0.0025 mg/kg bw/d and the ARfD is 0.05 mg/kg bw.

The nature of emamectin benzoate in primary plant commodities has been investigated in fruit and fruiting vegetables, leafy crops and cereals. The studies were sufficient to propose the risk assessment and the enforcement residue definition for the investigated crop groups as “emamectin benzoate B1a, expressed as emamectin, free base”. Adequate analytical methods are available for the enforcement of the proposed MRLs.

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<sup>1</sup> For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the setting of new MRLs for emamectin benzoate in various crops. *EFSA Scientific Report (2009) 290, 1-30*

The submitted supervised residue field trials support the intended GAPs and the respective MRL proposals could be derived.

The effect of processing on the nature of emamectin benzoate was investigated in hydrolysis study. Results demonstrate that emamectin B1a benzoate undergoes limited hydrolysis, which increases with pH and temperature. With regard to crops under consideration, it is not expected that significant residues (>0.1 mg/kg) of emamectin benzoate will occur in processed commodities.

The occurrence of emamectin benzoate residues in rotational crops was also investigated. The residues of emamectin benzoate in rotational crops are not of concern since no parent compound was identified and degradation products in rotational crops were characterized as natural products only (sugars, cellulose, starch, proteins).

The livestock dietary burden was calculated considering the expected residues in head cabbage and apple pomace. The calculated dietary burden does not exceed the trigger value of 0.1 mg/kg DM for any of the livestock species. Consequently it is concluded that no emamectin related residues are expected to occur in food of animal origin.

The consumer intake assessment was performed with revision 2 of EFSA PRIMo, using the STMR and HR values as obtained from the proposed use of emamectin benzoate on the crops under consideration. The total intake values ranged from 1 – 7 % of the ADI. The acute intake assessment did not identify any acute intake concerns either. The highest contribution to the ARfD was for lettuce amounting for up to 32% of the ARfD.

EFSA concludes that the intended uses of emamectin benzoate on the crops under consideration are acceptable with regard to consumer safety. Awaiting the peer review of emamectin benzoate to be finalized, MRL proposals should be considered as temporary.

### Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Emamectin B1a benzoate (expressed as emamectin, free base)			
Pome fruit	0.01*	0.02	The MRL proposals are supported by data and no risk for consumers was identified. Awaiting peer review of emamectin benzoate to be finalized, proposed MRLs should be set as temporary.
Peach, nectarine	0.01*	0.02	
Table and wine grapes	0.01*	0.05	
Strawberries	0.01*	0.05	
Tomatoes	0.01*	0.02	
Aubergines	0.01*	0.01*	
Pepper	0.01*	0.02	
Cucurbits (edible peel)	0.01*	0.01*	
Cucurbits (inedible peel)	0.01*	0.01*	
Cauliflower, broccoli	0.01*	0.01*	
Head cabbage	0.01*	0.01*	
Lettuce and other salad plants (except scarole )	0.01*	1.0	

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Scarole	0.01*	0.2	
Herbs	0.01*	1.0	
Fresh beans (with pods), fresh peas (with pods)	0.01*	0.01*	
Artichokes	0.01*	0.1	

(\*): Indicates that the MRL is set at the limit of analytical quantification.

**Key words:** Emamectin benzoate, pome fruit, peaches, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits (inedible peel), cucurbits (edible peel), cauliflower, broccoli, head cabbage, lettuce, beans, peas, globe artichokes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, emamectin, avermectin insecticides

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## BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

The Netherlands, hereafter referred to as the Evaluating Member State (EMS), received an application from Syngenta Crop Protection AG<sup>2</sup> to set new MRLs for the active substance emamectin benzoate in pome fruit, peaches, strawberries, grapes, tomatoes, aubergines, peppers, cucurbits (edible peel), cucurbits (inedible peel), cauliflower, broccoli, head cabbage, lettuce and other salad plants, scarole, herbs, fresh beans and peas with pods and artichokes. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application and the evaluation report to EFSA on 2 September 2008. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2008-719 and the following subject:

*Emamectin benzoate - Application to set new MRLs for emamectin B1a benzoate (expressed as emamectin, free base) in pome fruit at 0.02 mg/kg, in peaches at 0.02 mg/kg, in wine and table grapes at 0.05 mg/kg, in strawberries at 0.05 mg/kg, in tomatoes at 0.02 mg/kg, in aubergines (egg plants) at 0.01\* mg/kg, in peppers at 0.02 mg/kg, in cucurbits (inedible peel) at 0.01\* mg/kg, in cucurbits (edible peel) at 0.01\* mg/kg, in cauliflower at 0.01\* mg/kg, in broccoli at 0.01\* mg/kg, in head cabbage at 0.01\* mg/kg, in lettuce and other salad plants (except scarole) at 1.0 mg/kg, in scarole at 0.05 mg/kg, in herbs at 1.0 mg/kg, in beans (fresh, with pods) at 0.01\* mg/kg, in peas (fresh, with pods) at 0.01\* mg/kg and in globe artichokes at 0.1 mg/kg.*

In February 2009 the Evaluating Member State updated the Evaluation Report submitted to EFSA, correcting calculations for the consumer risk assessment and including additional data to complete the data set for two crops. EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

## TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been provided.

In this particular case the calculated deadline for providing the reasoned opinion was 2 March 2009.

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<sup>2</sup> Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4002 Basel, Switzerland

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

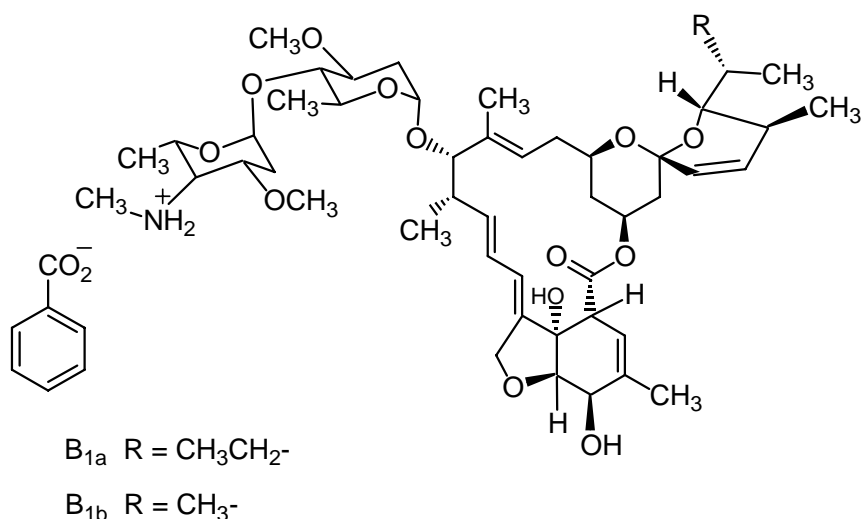
Emamectin benzoate is the ISO common name for a mixture containing

90% of emamectin B1a benzoate

(10E,14E,16E,22Z)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6'-[(S)-sec-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino- $\alpha$ -L-lyxo-hexopyranosyl)- $\alpha$ -L-arabino-hexopyranoside and

10% of emamectin B1b benzoate

(10E,14E,16E,22Z)- (1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-3,7,19-trioxatetracyclo[15.6.1.14,8.020,24]pentacosa-10,14,16,22-tetraene-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-3-O-methyl-4-O-(2,4,6-trideoxy-3-O-methyl-4-methylamino- $\alpha$ -L-lyxo-hexopyranosyl)- $\alpha$ -L-arabino-hexopyranoside



Emamectin benzoate is an insecticide with translaminar or local systemic properties which provides residual activity against foliar-feeding insects. It belongs to the group of avermectines. The active substance acts as a GABA (gamma-aminobutyric acid) and glutamate H receptor site agonist blocking neurochemical transmission leading to insect muscle contraction, paralysis and death. It paralyzes insects which stop feeding within hours of ingestion and die two to four days after treatment.

Emamectin benzoate is evaluated in the framework of Directive 91/414/EEC as a new active substance with the Netherlands being the designated Rapporteur Member State. The representative uses supported for the peer review are the foliar application on grapes (outdoor SEU and NEU), tomatoes (indoor and outdoor in NEU and SEU), peppers (outdoor SEU, indoor SEU and NEU), cucumbers (indoor NEU and SEU), melons (indoor NEU and SEU and outdoor SEU), and lettuce (indoor and outdoor in NEU and SEU). The peer review of this active substance by EFSA is currently in its early stage and a final decision concerning an inclusion in Annex I of the Directive is not expected within the next months.

Since emamectin benzoate is not explicitly mentioned in Annex II, III or IV of Regulation (EC) No 396/2005, the default MRL of 0.01 mg/kg applies for all commodities of plant and animal origin. The RMS Netherlands prepared an evaluation report to establish temporary MRLs for those uses for which authorisations are envisaged in EU MS. In addition to the uses supported in the DAR, the applicant requests the setting of MRLs for strawberries, aubergines and herbs (indoor and outdoor in NEU and SEU), cauliflower, broccoli, head cabbage (all outdoor SEU), scarole, fresh beans (with pods) and fresh peas (with pods) (all outdoor NEU and SEU), pome fruit (outdoor SEU and NEU), peaches and nectarines (outdoor SEU) and artichokes (outdoor SEU and NEU). The details of the intended GAPs are summarised in Appendix A. According to the RMS, the applications for these intended GAPs were already forwarded to the competent authorities in the Member States where the authorisation is requested.

For the evaluation of the applications EFSA relies on the evaluation report submitted by the RMS and the DAR prepared under Directive 91/414/EEC. Since the DAR has not yet been peer reviewed, the conclusions reached in this reasoned opinion have to be taken as temporary and might need to be reconsidered in the light of the final conclusions of the peer review.

## ASSESSMENT

### 1. Methods of analysis

#### 1.1. Methods for enforcement of residues in food of plant origin

Analytical methods for the determination of emamectin benzoate residues are reported in the DAR (The Netherlands, 2008). Since the multi-method DFG S-19 is not suitable for routine analysis of residues resulting from the use of emamectin benzoate, a single-method was developed as monitoring method. This method consists of extraction followed by dilution and determination of emamectin B1a benzoate by LC-LC-MS/MS. The validated matrices are:

- high water content crops (apple, lettuce, fresh sugar snaps with pods, tomatoes, sweet pepper, cucumber, melon peel, melon flesh)
- high acid content crops (grapes)
- dry crops with high fat/oil content (oil seed rape seeds),
- dry crops with high protein and starch content (winter wheat grain)
- special crops (wheat straw).

The method was validated for all crops for a LOQ of 0.001 mg/kg. The method was also validated by an ILV. Emamectin B1b benzoate and several other avermectin-like photodegradates which were identified in plant metabolism studies can be also determined with this method.

The results of emamectin B1a benzoate are recalculated to emamectins (free base) according to the residue definition, taking into account the ratio of emamectin B1a and emamectin B1b in emamectin (90:10) and the molecular weight (MW) of emamectin (884.7 g/mol) and emamectin benzoate (1008.3 g/mol):

$$\frac{10}{9} * \frac{MW(emamectin)}{MW(emamectinbenzoate)} = 0.97$$

The conversion factor of 0.97 is used to convert emamectin B1a benzoate to emamectin (free base).

#### 1.2. Methods for enforcement of residues in food of animal origin

The analytical methods for the determination of emamectin benzoate residues in food of animal origin are not of relevance with regard to the current application.

### 2. Mammalian toxicology

The RMS derived the toxicological reference values (Table 2-1) in the framework of the assessment of the active substance under Directive 91/414/EEC (The Netherlands, 2008). For this application, EFSA bases the risk assessment on the proposal of the RMS. If the toxicological reference values are changed during the peer review process, the conclusions on consumer safety regarding the MRL proposals have to be reconsidered.



Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Emamectin					
ADI	NL	2008	0.0025	Dog, 14 weeks Dog, 1 year, Rat, 2 years	100
ARfD	NL	2008	0.05	Rat, acute neurotoxicity	100

### 3. Residues

#### 3.1. Nature and magnitude of residues in plant

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

The nature of emamectin benzoate in plant commodities was investigated in the framework of the peer review and the studies are reported in the DAR (The Netherlands, 2008). Avermectins in emamectin benzoate differ by a methylene group at the C26 alkyl substituent:  $-\text{CH}_2\text{CH}_3$  for emamectin B1a benzoate and  $-\text{CH}_3$  for emamectin B1b benzoate. Metabolism studies were carried out with the emamectin B1a benzoate variant only, which is the major component of emamectin benzoate (90%), assuming that emamectin B1b benzoate variant will behave similarly.

Metabolism of emamectin B1a benzoate was investigated following spray application on fruit (pear trees), leafy crops (lettuce, head cabbage) and cereals (sweet corn).

In leafy crops the majority of the radioactivity was located in the wrapper leaves of lettuce plants (>85% TRR up to PHI 10 days) and cabbage plants (> 99% TRR up to PHI 2 days) with very little translocation to head leaves. In sweet corn plants the majority of the radioactivity (98% TRR) was located in parts of the crop directly exposed to the spray applications (leaf plus stalk and husk plus silk). The removal of a large proportion of residue by methanol rinsing procedure (>46% TRR in lettuce, >39% TRR in cabbage, >48.8% TRR in sweetcorn leaves/stalks/husks) indicated that much of the extractable residue was located on the crop surface. In foliar parts of plants (lettuce, cabbage, sweet corn leaves, stalks, husks) the major identified component of the extracted radioactivity was parent emamectin B1a benzoate (2.6% - 34.5% TRR), which decreased with PHI. Various primary and secondary avermectin-like degradation products were identified at levels up to 10% TRR at or after 3 days. The proposed degradation pathway for lettuce, cabbage and sweet corn forage (leaves, stalks, husks) involves photodegradation of emamectin B1a benzoate at the crop surface. Initial and secondary degradates then undergo further photolytic alteration to yield a very complex residue profile. These degradates are then further metabolised and finally incorporated into a range of natural plant components (glucose or protein based).

In sweet corn cobs and kernels no parent emamectin B1a benzoate and no primary degradation products were found.

In pear fruit the only compound identified in extracts was the parent (emamectin B1a benzoate), which ranged from 4 - 8% TRR in 14 and 28 day fruit. No primary degradation

products were found. Although the label was positioned at another part of the molecule compared to the other metabolism studies, avermectin-like compounds should have been detectable if present. The proposed degradation pathway for pear fruit involves degradation of emamectin B1a benzoate to low molecular weight products with subsequent incorporation into fruit sugars and other natural products. No explanation is available why the composition of residues on the pear fruit is different from the composition of residues on leafy plants (lettuce, cabbage, sweet corn forage) although both are exposed to the pesticide and to sunlight. Results suggest that photodegradation is not only induced by sunlight, but also by some additional factor present on the surface of leafy plant parts.

Finally in the DAR it was concluded that the metabolic profile for leafy vegetables (including foliar parts of corn) is different from the metabolic profile for sweet corn cobs and kernels and fruit and fruiting vegetables. For the latter two no parent compound was present. The RMS concluded that the residue definition for risk assessment and enforcement for all crop groups considered in the DAR should be set as “emamectin B1a benzoate (expressed as emamectin, free base)”. For leafy crops and fruit and fruiting vegetables under consideration EFSA concludes that metabolic pathway is sufficiently addressed and no additional metabolism studies are needed. With regard to fresh beans and peas with pods, no metabolism studies are available, but it can be assumed that metabolism in fresh beans and peas proceeds according to a similar pathway than in leafy crops.

EFSA currently agrees with the enforcement and risk assessment residue definitions as proposed by the RMS. If, during the peer review, residue definition will be changed, the current EFSA opinion on emamectin benzoate will be revised in the light of the new knowledge in accordance with Article 12(1) of Regulation (EC) No 396/2005.

#### 3.1.1.2. Magnitude of residues

In support of the intended GAPs the applicant submitted supervised residue field trials data reflecting the residue levels resulting in crops from the intended indoor and/or outdoor uses of emamectin benzoate in Southern and/or Northern European Member States. The MRL proposals for group tolerances (pome fruit, cucurbits (edible peel), cucurbits (inedible peel), herbs, lettuce and other salad plants, fresh legume vegetables with pods) were derived by extrapolating the residues data. Residues trials data are summarized in Table 3-1. Most of the residue trials have been designed as residue decline studies. All residue values were reported as emamectin B1a benzoate in the original report and were recalculated by EFSA to be in line with the residue definition by using the conversion factor of 0.97 (See section 1.1.) In Table 3-1 therefore all residue values are expressed as emamectin (free base).

The storage stability data of emamectin benzoate are reported in the DAR (The Netherlands, 2008). Residues of emamectin B1a benzoate were stable in frozen commodities with high water content for at least 18 months when stored at -20°C. Therefore it is concluded that the storage stability is sufficiently covered for the crops under consideration.

The analytical method used for the supervised field trials is identical with the proposed enforcement method for which sufficient validation data are available to demonstrate that it is fit for the purpose.

Table 3-1. Overview of the available residues trials data

Commodity	Region <sup>(a)</sup>	Outd/Ind.	Individual trial results (mg/kg)		STMR (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Emamectin B1a benzoate (expressed as emamectin, free base)									
Apples	NEU	O	< 0.00097; 0.00097; 0.0019; 0.0058; 2 x 0.0087	< 0.00097; 0.00097; 0.0019; 0.0058; 2 x 0.0087	0.004	0.009	0.02	1.0	Residue data sets from NEU and SEU are comparable. Trials were performed on apples but residues data can be extrapolated to the whole group of pome fruits. R <sub>ber</sub> (NEU)=0.017 mg/kg R <sub>max</sub> (NEU)=0.018 mg/kg R <sub>ber</sub> (SEU)=0.016 mg/kg R <sub>max</sub> (SEU)= 0.02 mg/kg
	SEU	O	0.0019; 0.0039; 2 x 0.0049; 2x 0.0078; 0.0145	0.0019; 0.0039; 2 x 0.0049; 2x 0.0078; 0.0145	0.005	0.015			
Peaches	SEU	O	0.0019; 0.0029; 0.0049; 0.0078; 2x 0.0087; 0.0097; 0.0136	0.0019; 0.0029; 0.0049; 0.0078; 2x 0.0087; 0.0097; 0.0136	0.008	0.014	0.02	1.0	R <sub>ber</sub> =0.019mg/kg R <sub>max</sub> =0.02 mg/kg
Table and wine grapes	SEU	O	<b>3 x &lt;0.00097; 0.0019; 0.0029; 0.0087; 0.0136; 0.021</b>	<b>3 x &lt;0.00097; 0.0019; 0.0029; 0.0087; 0.0136; 0.021</b>	<b>0.002</b>	<b>0.021</b>	<b>0.05</b>	<b>1.00</b>	The SEU use of emamectin benzoate results in higher residues therefore was used for deriving the MRL proposal and risk assessment values (indicated in bold) R <sub>ber</sub> (SEU)=0.025 mg/kg R <sub>max</sub> (SEU)= 0.03 mg/kg R <sub>ber</sub> (NEU)=0.007 mg/kg R <sub>max</sub> (NEU)=0.007 mg/kg
	NEU	O	3 x < 0.00097; 2 x 0.00097; 0.0029; 0.0039; 0.0049	3 x < 0.00097; 2 x 0.00097; 0.0029; 0.0039; 0.0049	0.001	0.005	0.01	1.00	

Commodity	Region <sup>(a)</sup>	Outd/ Ind.	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Strawberries	SEU	O	0.0019; 0.0029; 0.0049; 2 x 0.0058; 0.0078; 0.0097; 0.012	0.0019; 0.0029; 0.0049; 2 x 0.0058; 0.0078; 0.0097; 0.012	0.006	0.012	0.02	1.0	It should be noted that strawberries are considered as major crop and therefore at least 8 trials should be submitted for NEU outdoor use. However, the indoor use of emamectin benzoate results in higher residue levels therefore was used for deriving the MRL proposal and risk assessment values (indicated in bold).
	NEU	O	0.0049; 0.0058; 0.0068; 0.0165	0.0049; 0.0058; 0.0068; 0.0165	0.006	0.017	0.05	1.0	
	EU	I	<b>0.0029; 0.0049; 0.0068; 0.0078; 0.0097; 0.011; 0.028; 0.045</b>	<b>0.0029; 0.0049; 0.0068; 0.0078; 0.0097; 0.011; 0.028; 0.045</b>	<b>0.009</b>	<b>0.045</b>	<b>0.05</b>	<b>1.0</b>	

Commodity	Region <sup>(a)</sup>	Outd/ Ind.	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Tomatoes, aubergines	EU	I	<b>Cherry tomatoes: 0.0029; 2 x 0.0039; 0.0058; 0.0068; 3 x 0.0077</b>	<b>0.0029; 2 x 0.0039; 0.0058; 0.0068; 3 x 0.0077</b>	<b>0.006</b>	<b>0.008</b>	<b>0.02 tomatoes</b>	<b>1.0</b>	Trials were performed on tomatoes but residues data can be extrapolated to aubergines. The indoor use of emamectin benzoate results in higher residue levels. The indoor data on <u>cherry tomatoes</u> were used for deriving the MRL proposal and risk assessment values for tomatoes (indicated in bold), but the indoor data on <u>normal size tomatoes</u> were used for deriving the MRL proposal for aubergines  $R_{ber}(\text{indoor cherry t.})=0.015\text{mg/kg}$ $R_{max}(\text{indoor cherry t.})=0.012\text{mg/kg}$ $R_{ber}(\text{indoor tomatoes})= 0.007\text{mg/kg}$ $R_{max}(\text{indoor tomatoes})= 0.006\text{mg/kg}$ $R_{ber}(\text{SEU outdoor})=0.002\text{ mg/kg}$ $R_{max}(\text{SEU outdoor})=0.002\text{ mg/kg}$ $R_{ber}(\text{NEU outdoor})=0.003\text{ mg/kg}$ $R_{max}(\text{NEU outdoor})= 0.004\text{ mg/kg}$
			Normal size tomatoes: <0.00097; 2 x 0.00097; 2 x <0.00097; 2 x 0.00097; 2 x 0.0019; 0.0029; 2 x 0.0039	<0.00097; 2 x 0.00097; 2 x 0.0019; 0.0029; 2 x 0.0039	0.002	0.004	<b>0.01* aubergines</b>	1.0	
	SEU	O	Normal size tomatoes: 4 x <0.00097; 3 x 0.00097; 0.0019	4 x <0.00097; 3 x 0.00097; 0.0019	0.001	0.002	0.01	1.0	
	NEU	O	Normal size tomatoes: 3 x < 0.00097; 0.0019	3 x < 0.00097; 0.0019	0.001	0.002	0.01	1.0	

Commodity	Region <sup>(a)</sup>	Outd/ Ind.	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Peppers	EU	I	<b>2 x &lt;0.00097; 0.0019; 2 x 0.0029; 0.0039; 0.0068; 0.0126</b>	<b>2 x &lt;0.00097; 0.0019; 2 x 0.0029; 0.0039; 0.0068; 0.0126</b>	<b>0.003</b>	<b>0.013</b>	<b>0.02</b>	<b>1.0</b>	It should be noted that peppers are considered as major crop in SEU and therefore at least 8 trials should be submitted for SEU outdoor use. However, the indoor use of emamectin benzoate results in higher residue levels therefore was used for deriving the MRL proposal and risk assessment values (indicated in bold). $R_{ber(indoor)}=0.012$ mg/kg $R_{max(indoor)}=0.017$ mg/kg $R_{ber(outdoor)}=0.003$ mg/kg $R_{max(outdoor)}=0.004$ mg/kg
	SEU	O	2 x < 0.00097; 0.00097; 0.0019	2 x < 0.00097; 0.00097; 0.0019	0.001	0.002	0.01	1.0	
Cucumbers	EU	I	3 x < 0.00097; 3 x 0.00097; 2 x 0.0019	3 x < 0.00097; 3 x 0.00097; 2 x 0.0019	0.001	0.002	0.01*	1.0	Trials were performed on cucumbers but residues data can be extrapolated to the whole group of cucurbits with edible peel. $R_{ber}=0.003$ mg/kg $R_{max}=0.003$ mg/kg

Commodity	Region <sup>(a)</sup>	Outd/ Ind.	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Melons	EU	I	< <b>0.00097</b> ; 2 x <b>0.00097</b> ; 2 x <b>0.0019</b> ; <b>0.0029</b> ; <b>0.0039</b> ; <b>0.0049</b>	< <b>0.00097</b> ; 2 x <b>0.00097</b> ; 2 x <b>0.0019</b> ; <b>0.0029</b> ; <b>0.0039</b> ; <b>0.0049</b>	<b>0.002</b>	<b>0.005</b>	<b>0.01*</b>	<b>1.0</b>	Trials were performed on melons, but residues data can be extrapolated to the whole group of cucurbits with inedible peel. It should be noted that melons are considered as major crop in SEU and at least 8 trials on SEU outdoor use would be required. However, taking into account that residues in outdoor trials are ≤ LOQ and that the indoor use is more critical (indicated in bold), data are considered sufficient for deriving the MRL proposal and risk assessment values. R <sub>ber(indoor)</sub> =0.007 mg/kg R <sub>max(indoor)</sub> = 0.007 mg/kg R <sub>ber(outdoor)</sub> =0.002 mg/kg R <sub>max(outdoor)</sub> = 0.001 mg/kg
	SEU	O	<0.00097; 3 x 0.00097	<0.00097; 3 x 0.00097	0.001	0.001	0.01	1.0	

Commodity	Region <sup>(a)</sup>	Outd/ Ind.	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Cauliflower, broccoli	SEU	O	3 x <0.00097; 2 x 0.00097; 0.0019	3 x <0.00097; 2 x 0.00097; 0.0019	0.001	0.002	0.01*	1.0	Cauliflower is considered as minor crop in SEU. Residue trials data on cauliflower (4) and broccoli (2) were combined. Taking into account the low residue levels, trials data are considered acceptable and can be used for data extrapolation to broccoli and for deriving the MRL proposal and risk assessment values. R <sub>ber</sub> =0.002 mg/kg R <sub>max</sub> =0.003 mg/kg
Head cabbage	SEU	O	3 x < 0.00097; 0.0019	3 x < 0.00097; 0.0019	0.001	0.002	0.01*	1.0	Head cabbage is considered as minor crop in SEU therefore 4 trials are sufficient for deriving the MRL proposal and risk assessment values. R <sub>ber</sub> =0.003 mg/kg R <sub>max</sub> =0.004 mg/kg



Commodity	Region <sup>(a)</sup>	Outd/ Ind.	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Lettuce and other salad plants (excluding scarole). Herbs	EU	I	<b>0.148; 0.156; 0.189; 0.252; 0.291; 0.32; 0.388; 0.596</b>	<b>0.148; 0.156; 0.189; 0.252; 0.291; 0.32; 0.388; 0.596</b>	<b>0.272</b>	<b>0.60</b>	<b>1.0</b>	<b>1.0</b>	Trials were performed on lettuce but residues data can be extrapolated to the whole group of other salad plants (except scarole) and herbs. It should be noted that lettuce are considered as major crop and therefore at least 8 trials should be submitted for NEU outdoor use, especially since extrapolation is envisaged. However, the indoor use of emamectin benzoate results in higher residue levels therefore was used for deriving the MRL proposal and risk assessment values (indicated in bold). $R_{\text{ber}(\text{indoor})}=0.74 \text{ mg/kg}$ $R_{\text{max}(\text{indoor})}=0.77 \text{ mg/kg}$ $R_{\text{ber}(\text{SEU outdoor})}= 0.17 \text{ mg/kg}$ $R_{\text{max}(\text{SEU outdoor})}= 0.17 \text{ mg/kg}$ $R_{\text{ber}(\text{NEU outdoor})}= 0.03 \text{ mg/kg}$ $R_{\text{max}(\text{NEU outdoor})}=0.04 \text{ mg/kg}$
	SEU	O	0.0039; 0.0058; 0.0068; 0.029; 0.032; 0.0407; 0.097; 0.107	0.0039; 0.0058; 0.0068; 0.029; 0.032; 0.0407; 0.097; 0.107	0.03	0.11	0.2	1.0	
	NEU	O	0.0039; 0.0049; 0.0068; 0.0155	0.0039; 0.0049; 0.0068; 0.0155	0.006	0.016	0.05	1.0	

Commodity	Region <sup>(a)</sup>	Outd/ Ind.	Individual trial results (mg/kg)		STMR (mg/kg) <sup>(b)</sup>	HR (mg/kg) <sup>(c)</sup>	MRL proposal (mg/kg)	Median CF <sup>(d)</sup>	Comments
			Enforcement	Risk assessment					
Scarole	SEU	O	<b>0.0039; 0.0058; 0.0068; 0.029; 0.032; 0.0407; 0.097; 0.107</b>	<b>0.0039; 0.0058; 0.0068; 0.029; 0.032; 0.0407; 0.097; 0.107</b>	<b>0.03</b>	<b>0.11</b>	<b>0.2</b>	<b>1.0</b>	Trials were performed on lettuce but residues data can be extrapolated to scarole. The SEU outdoor use results in higher residues therefore is used for deriving the MRL proposal and risk assessment values (indicated in bold). $R_{\text{ber(SEU outdoor)}} = 0.17 \text{ mg/kg}$ $R_{\text{max(SEU outdoor)}} = 0.17 \text{ mg/kg}$ $R_{\text{ber(NEU outdoor)}} = 0.03 \text{ mg/kg}$ $R_{\text{max(NEU outdoor)}} = 0.04 \text{ mg/kg}$
	NEU	O	0.0039; 0.0049; 0.0068; 0.0155	0.0039; 0.0049; 0.0068; 0.0155	0.006	0.016	0.05	1.0	
Fresh beans (with pods) and peas (with pods)	EU	O	9 x 0.00097; 5 x 0.00097; 0.0019; 0.0087	9 x 0.00097; 5 x 0.00097; 0.0019; 0.0087	0.001	0.009	0.01*	1.0	Trials were performed in fresh beans (with pods) but residues data can be extrapolated to fresh peas (with pods) $R_{\text{ber}} = 0.002 \text{ mg/kg}$ $R_{\text{max}} = 0.006 \text{ mg/kg}$
Artichokes	EU	O	0.0136; 0.018; 2 x 0.025; 0.029; 0.031; 0.033; 0.036	0.0136; 0.018; 2 x 0.025; 0.029; 0.031; 0.033; 0.036	0.027	0.036	0.1	1.0	$R_{\text{ber}} = 0.065 \text{ mg/kg}$ $R_{\text{max}} = 0.05 \text{ mg/kg}$

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.

(b): Median value of the individual trial results according to the enforcement residue definition.

(c): Highest value of the individual trial results according to the enforcement residue definition.

(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.

(\*): Indicates that the MRL is set at the limit of analytical quantification.

### 3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of emamectin B1a benzoate was investigated in the degradation studies as reported in the DAR under conditions of pasteurisation, baking/brewing/boiling and sterilisation (The Netherlands, 2008). Results demonstrated that emamectin B1a benzoate undergoes limited hydrolysis (<10%), which increases with pH and temperature. No toxicologically significant degradation products were observed. It is assumed that emamectin B1b benzoate behaves in a comparable way.

The effect of processing on the magnitude of emamectin B1a benzoate was investigated in the framework of the peer review for melons by measuring the residue distribution between melon peel and flesh. Since residues in both melon peel and melon pulp were below the LOQ, no peeling factor could be derived. For other crops under consideration no processing studies on the magnitude of emamectin B1a benzoate residues have been submitted, but these, however, are not considered necessary since it is not expected that residues in the processed commodities will be above 0.1 mg/kg.

## 3.1.2. Rotational crops

### 3.1.2.1. Preliminary considerations

Most of the crops under consideration can be grown in rotation. The studies on the rate of degradation of emamectin B1a benzoate in soil are reported in the DAR (The Netherlands, 2008). The data from laboratory studies identify that DT<sub>90</sub> trigger value of 100 days for the active substance is exceeded, while the data from the field studies indicate that there is no potential for residues to be present in soil at the time rotational crops would be planted. Taking into account these uncertainties, rotational crop studies have been assessed and are reported in the DAR.

### 3.1.2.2. Nature of residues

Rotational crop studies were performed by applying [3, 7, 11, 13, 23 - <sup>14</sup>C] emamectin B1a benzoate on a bare soil at a total application rate of 0.1008 kg a.s./ha, which is approx.1.5N the highest application rate as envisaged in the intended GAPs for the crops under consideration. The soil was aged for 30, 120, 141 and 365 days and afterwards barley, carrots and lettuce were sown. In crop matrices from plants sown 30 DAT the total radioactive residues were <LOQ in lettuce and carrot samples and 0.009 mg/kg and 0.016 mg/kg in barley grain and straw respectively. In crop matrices from plants sown 141 DAT only in barley grain and straw samples residues amounted for up to 0.009 mg/kg and 0.03 mg/kg respectively. No residues above the limit of detection (0.001-0.003 mg/kg) were found in any crop matrix 365 DAT. No emamectin B1a benzoate and no avermectin-like degradates were detected in rotational crops. According to the DAR, the RMS concluded that metabolism in rotational crops can not be considered similar to metabolism in primary crops since no avermectin-like degradates were detected and degradation products were characterized as natural products only.

### 3.1.2.3. Magnitude of residues

Considering the metabolic pathway in rotational crops it is concluded that significant residue levels in rotational crops are not expected provided that emamectin benzoate is applied according to the proposed GAPs.

## 3.2. Nature and magnitude of residues in livestock

### 3.2.1. Dietary burden

From all the crops under consideration, only head cabbage and apple pomace can be fed to livestock. The dietary burden for different types of livestock was calculated using the EFSA livestock dietary burden calculator. For head cabbage the input values were the STMR and the HR. For apple pomace the default processing factor of 2.5 was applied to the STMR value. The summary of the input values is summarized in Table 3-2. The results of the calculations are reported in the Table 3-3.

Table 3-2. Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Apple pomace	0.0125	STMR-P	0.0125	STMR-P
Head cabbage	0.001	STMR	0.002	HR

Table 3-3. Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Dietary burden triggered?
Dairy ruminants	0.000198	0.000198	Apple pomace	No
Meat ruminants	0.000699	0.000699	Apple pomace	No
Poultry	0.000045	0.000023	Cabbage	No
Pigs	0.000086	0.000043	Cabbage	No

The calculated dietary burdens do not exceed the trigger value of 0.1 mg/kg DM for any of livestock species. Consequently it is concluded that no residues of emamectin B1a benzoate are expected to occur in food of animal origin.

## 4. Consumer risk assessment

The consumer risk assessment was performed with revision 2 of the EFSA PRIMo (Pesticide Residue Intake Model), using the STMR and HR values as obtained from the proposed use of emamectin benzoate on the crops under consideration. For other food commodities of plant and animal origin, no input values were used since currently no uses of emamectin benzoate are authorized. The input values are summarized in Table 4-1.

Table 4-1. Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Emamectin benzoate (expressed as emamectin, free base)				
Pome fruit	0.005	STMR	0.015	HR
Peaches	0.008	STMR	0.014	HR
Grapes	0.002	STMR	0.021	HR
Strawberries	0.009	STMR	0.045	HR
Tomatoes	0.006	STMR	0.008	HR
Aubergines	0.002	STMR	0.004	HR
Peppers	0.003	STMR	0.013	HR
Cucurbits (edible peel)	0.001	STMR	0.002	HR
Cucurbits (inedible peel)	0.002	STMR	0.005	HR
Cauliflower, broccoli, head cabbage	0.001	STMR	0.002	HR
Lettuce and other salad plants (excluding scarole)	0.27	STMR	0.6	HR
Herbs	0.27	STMR	0.6	HR
Scarole	0.03	STMR	0.11	HR
Fresh beans and peas (with pods)	0.001	STMR	0.009	HR
Artichokes	0.027	STMR	0.036	HR

The summary of intake calculations can be found in Appendix B. Consumer intake calculations did not reveal chronic intake concerns for any European diet. The total intake values ranged from 0.6 to 7 % of the ADI. The acute intake assessment did not identify any acute intake concerns either. The highest contribution to the ARfD was for lettuce amounting for up to 32% of the ARfD.

EFSA concludes that the intended uses of emamectin benzoate on the crops under consideration are acceptable with regard to consumer safety.

## CONCLUSIONS AND RECOMMENDATIONS

The Netherlands received an application from Syngenta Crop Protection AG to set new MRLs for the active substance emamectin benzoate in pome fruit, peaches, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits (edible peel), cucurbits (inedible peel), cauliflower, broccoli, head cabbage, lettuce and other salad plants, scarole, herbs, fresh beans (with pods), fresh peas (with pods) and artichokes. The Netherlands as the Evaluating Member State (EMS) drafted an Evaluation Report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 2 September 2009.

It should be noted that emamectin benzoate is a new active substance for which the peer review has not yet been finalized, therefore the conclusions reached in this reasoned opinion have to be taken as temporary and might need to be reconsidered in the light of the final conclusions of the peer review. In addition, before a risk management decision is taken, it should be clarified whether it is acceptable to set MRLs on the basis of intended GAPs notified by the manufacturer of the active substance without having clear evidence that the intended GAPs will be approved at the Member State level.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report and the Draft Assessment Report prepared by The Netherlands in the framework of Directive 91/414/EEC.

The toxicological reference values have been derived by the RMS Netherlands in the framework of the assessment of the active substance for Annex I inclusion and the proposed ADI is 0.0025 mg/kg bw/d and the ARfD is 0.05 mg/kg bw.

The nature of emamectin benzoate in primary plant commodities has been investigated in fruit and fruiting vegetables, leafy crops and cereals. The studies were sufficient to propose the risk assessment and the enforcement residue definition for the investigated crop groups as “emamectin benzoate B1a, expressed as emamectin, free base”. Adequate analytical methods are available for the enforcement of the proposed MRLs.

The submitted supervised residue field trials support the intended GAPs and the respective MRL proposals could be derived.

The effect of processing on the nature of emamectin benzoate was investigated in hydrolysis study. Results demonstrate that emamectin B1a benzoate undergoes limited hydrolysis, which increases with pH and temperature. With regard to crops under consideration, it is not expected that significant residues (>0.1 mg/kg) of emamectin benzoate will occur in processed commodities.

The occurrence of emamectin benzoate residues in rotational crops was also investigated. The residues of emamectin benzoate in rotational crops are not of concern since no parent compound was identified and degradation products in rotational crops were characterized as natural products only (sugars, cellulose, starch, proteins).

The livestock dietary burden was calculated considering the expected residues in head cabbage and apple pomace. The calculated dietary burden does not exceed the trigger value of 0.1 mg/kg DM for any of the livestock species. Consequently it is concluded that no emamectin related residues are expected to occur in food of animal origin.

The consumer intake assessment was performed with revision 2 of EFSA PRIMo, using the STMR and HR values as obtained from the proposed use of emamectin benzoate on the crops

under consideration. The total intake values ranged from 1 – 7 % of the ADI. The acute intake assessment did not identify any acute intake concerns either. The highest contribution to the ARfD was for lettuce amounting for up to 32% of the ARfD.

EFSA concludes that the intended uses of emamectin benzoate on the crops under consideration are acceptable with regard to consumer safety. Awaiting the peer review of emamectin benzoate to be finalized, MRL proposals should be considered as temporary.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Emamectin B1a benzoate (expressed as emamectin, free base)			
Pome fruit	0.01*	0.02	The MRL proposals are supported by data and no risk for consumers was identified. Awaiting peer review of emamectin benzoate to be finalized, proposed MRLs should be set as temporary.
Peach, nectarine	0.01*	0.02	
Table and wine grapes	0.01*	0.05	
Strawberries	0.01*	0.05	
Tomatoes	0.01*	0.02	
Aubergines	0.01*	0.01*	
Pepper	0.01*	0.02	
Cucurbits (edible peel)	0.01*	0.01*	
Cucurbits (inedible peel)	0.01*	0.01*	
Cauliflower, broccoli	0.01*	0.01*	
Head cabbage	0.01*	0.01*	
Lettuce and other salad plants (except scarole )	0.01*	1.0	
Scarole	0.01*	0.2	
Herbs	0.01*	1.0	
Fresh beans (with pods), fresh peas (with pods)	0.01*	0.01*	
Artichokes	0.01*	0.1	

(\*): Indicates that the MRL is set at the limit of analytical quantification.

#### DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the setting of new MRLs for emamectin benzoate in various vegetables under Regulation (EC) No 396/2005. Submitted to EFSA on 2 September 2008. Revision submitted to EFSA on 11 February, 2009. Prepared by the Ctgb, NL.

#### REFERENCES

The Netherlands, 2008. Draft Assessment Report on emamectin prepared by the Netherlands under Directive 91/414/EEC. February 2008.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

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 per treatment			PHI (days)	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)	kg as/hL; min-max	water L/ha; min-max	kg as/ha; min-max		
Pome fruit	EU	AFFIRM 095 SG	F	<i>Cydia pomonella</i> , <i>cydia molesta</i> , <i>Adoxophyes sp</i> , <i>Pandemis sp</i> , <i>Argyrotenia spp</i> , <i>Lithocolletis sp</i>	SG	9.5 g ai/kg	foliar spray	BBCH 75-90	3	7 days	0.0025-0.0038	1000-1500	0.0375	3	with or without oil
Peaches and nectarines	S-EU	AFFIRM 095 SG	F	<i>Cydia molesta</i> , <i>Anarsia lineatella</i>	SG	9.5 g ai/kg	foliar spray	BBCH 71-89	3	7 days	0.0038	1000	0.0375	7	with or without oil
Grapes	EU	AFFIRM 095 SG	F	<i>Lobesia botrana</i> <i>Eupoecilia ambiguella</i>	SG	9.5 g ai/kg	foliar spray	BBCH 53-89	4	14 days	0.0010-0.0075	200-1500	0.015	7	-
Strawberries	EU	AFFIRM 095 SG	F / G	<i>Plusia</i> , <i>Spodoptera</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-89	3	7 days	0.0025	800	0.020	1	
Tomatoes, cherry tomatoes	EU	AFFIRM 095 SG	F / G	<i>Heliothis armigera</i> <i>Spodoptera exigua</i> <i>Spodoptera littoralis</i> <i>Ostrinia nubilalis</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-89	3	7 days	0.0013-0.0025	800-1500	0.020	3	-
Aubergine	EU	AFFIRM 095 SG	F / G	<i>Heliothis armigera</i> <i>Spodoptera exigua</i> <i>Spodoptera littoralis</i> <i>Ostrinia nubilalis</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-89	3	7 days	0.0013-0.0025	800-1500	0.020	3	-
Pepper	EU	AFFIRM 095 SG	G	<i>Heliothis armigera</i> <i>Spodoptera exigua</i> <i>Spodoptera littoralis</i> <i>Ostrinia nubilalis</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-89	3	7 days	0.0013-0.0025	800-1500	0.020	3	-
	SEU	AFFIRM 095 SG	F												
Cucurbits edible peel	EU	AFFIRM 095 SG	G	<i>Heliothis armigera</i> <i>Spodoptera exigua</i> <i>Spodoptera littoralis</i> <i>Ostrinia nubilalis</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-89	3	7 days	0.0013-0.0025	800-1500	0.020	3	-
Cucurbits inedible peel	EU	AFFIRM 095 SG	G	<i>Heliothis armigera</i> <i>Spodoptera exigua</i> <i>Spodoptera littoralis</i> <i>Ostrinia nubilalis</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-89	3	7 days	0.0013-0.0025	800-1500	0.020	3	-
	SEU	AFFIRM 095 SG	F												



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 per treatment			PHI (days)	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)	kg as/hL; min-max	water L/ha; min-max	kg as/ha; min-max		
Cauliflower	SEU	AFFIRM 095 SG	F	<i>Plutella spp., Pieris sp.</i>	SG	9.5 g ai/kg	foliar spray	BBCH 41-49	3	7 days	0.0075	200	0.015	3	
Broccoli	SEU	AFFIRM 095 SG	F	<i>Plutella spp., Pieris sp.</i>	SG	9.5 g ai/kg	foliar spray	BBCH 41-49	3	7 days	0.0075	200	0.015	3	
Head cabbage	SEU	AFFIRM 095 SG	F	<i>Plutella spp., Pieris sp.</i>	SG	9.5 g ai/kg	foliar spray	BBCH 41-49	3	7 days	0.0075	200	0.015	3	
Lettuce and other salad plants, except scarole	EU	AFFIRM 095 SG	F / G	<i>Spodoptera exigua</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-49	3	7 days	0.0010-0.0030	500-1500	0.015	3	
Scarole	EU	AFFIRM 095 SG	F	<i>Spodoptera exigua</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-49	3	7 days	0.0010-0.0030	500-1500	0.015	3	
Herbs	EU	AFFIRM 095 SG	F / G	<i>Spodoptera exigua</i>	SG	9.5 g ai/kg	foliar spray	BBCH 11-49	3	7 days	0.0010-0.0030	500-1500	0.015	3	
Fresh beans with pods	EU	AFFIRM 095 SG	F	<i>Ostrinia</i>	SG	9.5 g ai/kg	foliar spray	BBCH 71-79	3	7 days	0.0040-0.0067	300-500	0.020	3	
Artichokes	EU	AFFIRM 095 SG	F	<i>Plutella, Depressaria, Spodoptera, Plusia</i>	SG	9.5 g ai/kg	foliar spray	BBCH 41-54	3	7 days	0.0030-0.0050	300-500	0.015	12 hrs	

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)

(c) E.g. biting and sucking insects, soil born insects, foliar fungi, weeds

(d) E.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF codes - GIFAP Technical monograph No2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated

(i) Concentration in g as/kg of g as/L

(j) Growth stage at last treatment (BBCH monograph, Growth stages of plants, 1997, Blackwell, ISBN 3-8263-3152-4)

(k) The minimum and maximum number of applications possible under practical conditions must be provided.

(l) PHI - minimum pre-harvest interval

(m) Remarks may include: extent of use / economic importance / restrictions

## APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Emamectin			
Status of the active substance:	#N/A	Code no.	#N/A
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0025	ARfD (mg/kg bw):	0.05
Source of ADI:	NL	Source of ARfD:	NL
Year of evaluation:	2008	Year of evaluation:	2008

### Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum 1 7						
		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)
6.9	IT adult	4.1	Lettuce	1.7	Other lettuce and other salad plants	0.3	Tomatoes	
6.5	ES adult	5.8	Lettuce	0.2	Tomatoes	0.2	Apples	
6.5	WHO Cluster diet B	3.9	Lettuce	0.7	Tomatoes	0.5	Herbs	
5.4	IT kids/toddler	3.1	Lettuce	1.2	Other lettuce and other salad plants	0.3	Tomatoes	
5.3	WHO regional European diet	4.1	Lettuce	0.4	Herbs	0.3	Tomatoes	
5.3	ES child	4.5	Lettuce	0.2	Tomatoes	0.2	Apples	
4.7	DE child	2.4	Apples	0.7	Lettuce	0.5	Herbs	
4.3	FR all population	2.1	Other lettuce and other salad plants	1.0	Lettuce	0.3	Table and wine grapes	
3.8	WHO Cluster diet F	3.2	Lettuce	0.2	Tomatoes	0.1	Apples	
3.2	NL child	1.3	Apples	1.1	Lettuce	0.2	Scarole (broad-leaf endive)	
2.7	WHO cluster diet E	1.0	Lettuce	0.5	Herbs	0.3	Other lettuce and other salad	
2.6	DK child	1.5	Lettuce	0.5	Apples	0.1	Pears	
2.5	IE adult	0.9	Lettuce	0.5	Herbs	0.2	Peaches	
2.1	NL general	1.3	Lettuce	0.2	Apples	0.1	Scarole (broad-leaf endive)	
2.1	UK vegetarian	1.5	Lettuce	0.1	Tomatoes	0.1	Apples	
1.7	UK Adult	1.3	Lettuce	0.1	Tomatoes	0.1	Table and wine grapes	
1.5	WHO cluster diet D	0.7	Herbs	0.2	Tomatoes	0.1	Apples	
1.3	LT adult	0.7	Lettuce	0.4	Apples	0.1	Tomatoes	
1.2	FR toddler	0.5	Apples	0.2	Strawberries	0.2	Tomatoes	
1.2	PT General population	0.2	Table and wine grapes	0.2	Tomatoes	0.2	Apples	
1.2	FI adult	0.8	Lettuce	0.1	Tomatoes	0.1	Apples	
1.1	PL general population	0.4	Apples	0.2	Tomatoes	0.1	Lettuce	
1.0	FR infant	0.5	Apples	0.2	Strawberries	0.1	Pears	
0.9	SE general population 90th percentile	0.2	Apples	0.2	Tomatoes	0.2	Herbs	
0.9	UK Toddler	0.3	Apples	0.2	Lettuce	0.1	Tomatoes	
0.7	DK adult	0.2	Apples	0.1	Table and wine grapes	0.1	Wine grapes	
0.6	UK Infant	0.3	Apples	0.1	Tomatoes	0.1	Strawberries	

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

Acute risk assessment / children - refined calculations	Acute risk assessment / adults / general population - refined calculations
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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 variability factor of 3.

Threshold MRL is the calculated residue level which would lead to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	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)
	32.3	Lettuce	0.6 / -	19.4	Lettuce	0.6 / -	13.2	Lettuce	0.6 / -	7.9	Lettuce	0.6 / -
	19.2	Scarole (broad-leaf)	0.11 / -	19.2	Scarole (broad-leaf)	0.11 / -	2.3	Lamb's lettuce	0.6 / -	2.3	Lamb's lettuce	0.6 / -
	6.9	Celery leaves	0.6 / -	6.9	Celery leaves	0.6 / -	2.0	Scarole (broad-leaf)	0.11 / -	2.0	Scarole (broad-leaf endive)	0.11 / -
3.7	Rocket, Rucola	0.6 / -	3.7	Rocket, Rucola	0.6 / -	1.4	Parsley	0.6 / -	1.4	Parsley	0.6 / -	
3.4	Lamb's lettuce	0.6 / -	3.4	Lamb's lettuce	0.6 / -	1.3	Table grapes	0.021 / -	1.3	Table grapes	0.021 / -	
No of critical MRLs (IESTI 1) ---			No of critical MRLs (IESTI 2) ---			No of critical MRLs (IESTI 1) ---			No of critical MRLs (IESTI 2) ---			

Processed commodities	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)
	3.3	Grape juice	0.05 / -	0.4	Wine	0.05 / -
	2.0	Apple juice	0.02 / -	0.3	Apple juice	0.02 / -
	0.7	Peach juice	0.02 / -	0.1	Peach preserved with	0.02 / -
0.7	Pear juice	0.02 / -	0.1	Tomato (preserved-	0.02 / -	
0.7	Tomato juice	0.02 / -	0.0	Quince jelly	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 Emamectin 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.

## GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CAS	Chemical Abstract Service
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CIPAC	Collaborative International Pesticide Analytical Council Limited
Ctgb	Board for the Authorisation of Plant Protection Products and Biocides
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DM	dry matter
DT <sub>90</sub>	period required for 90 percent dissipation
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
GAP	good agricultural practice
GC	gas chromatography
GS	growth stage
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre

LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOD	limit of detection
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
MW	molecular weight
NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
SG	water soluble granule
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue