

## REASONED OPINION OF EFSA

### Review of the existing MRLs for fenamiphos<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2008-540 and EFSA-Q-2009-00648)

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#### SUMMARY

Article 12(2) of Regulation (EC) No 396/2005 lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for fenamiphos as this active substance was included in Annex I to Directive 91/414/EEC before 02 September 2008. In order to collect the pesticide residues data supporting the existing MRLs for that active substance, EFSA asked The Netherlands, as the designated Rapporteur Member State, to complete the Pesticide Residues Overview File (PROFile). The completed PROFile was submitted to EFSA on 28 August 2008.

According to Article 6(1) of the Regulation, The Netherlands also received an application from the company Makhteshim Agan to maintain the existing MRL of 0.05 mg/kg for fenamiphos in melons for which EFSA identified potential intake concerns in the framework of a previous reasoned opinion. The subsequent evaluation report drafted by The Netherlands was forwarded to EFSA on 29 May 2009 according to Article 9 of the Regulation.

Based on the information provided in the evaluation report for melons, the PROFile and the EFSA conclusion on fenamiphos prepared in the framework of Directive 91/414/EEC, EFSA derives the following conclusions and recommendations.

Metabolism was investigated in four different crop groups using three different types of applications. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities could be defined as the sum of fenamiphos and its sulfone and sulfoxide, expressed as fenamiphos. A validated analytical method for enforcement of this residue definition with a LOQ of 0.02 mg/kg in all plant commodities is also available. Additionally, a sufficient number of supervised residues trials is available to support the GAPs reported by the RMS, except for bananas, carrots and head cabbage. Conclusions regarding these 3 crops were already derived in the framework of a previous reasoned opinion on MRLs of concern for fenamiphos. For the remaining crops, available trials allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs.

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As residues of fenamiphos are all below 0.1 mg/kg and contribution of these residues to chronic consumer exposure is generally low, investigating the effect of industrial and/or household processing was not considered necessary. Studies investigating the magnitude of residues in some processed products were submitted but were not sufficient to recommend robust processing factors for enforcement purposes. Derived processing factors were only considered as indicative for the risk assessment, in particular with regard to the peeling of melons.

Occurrence of fenamiphos residues in rotational crops was investigated during the peer review of fenamiphos and it was concluded that metabolic patterns in primary and succeeding crops are similar. Nevertheless, based on a confined rotational crop study and an additional field trial, it is concluded that residues in succeeding crops cannot be excluded and a plant-back interval of 8 months was recommended for the outdoor use of fenamiphos. For the indoor use in fruiting vegetables, an appropriate plant-back interval could not be proposed as no appropriate study was made available.

Occurrence of residues in food of animal origin was not considered in the framework of this review because the crops under consideration are not fed to livestock.

Both chronic and acute consumer exposure resulting from the MRLs proposed in the framework of this review were calculated, but exceedances of the ARfD were identified for melons and watermelons, representing 188 and 152% of the ARfD respectively. Excluding these two MRLs from the calculation, the highest chronic exposure represented 13.2% of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 52.4% of the ARfD (table grapes).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for fenamiphos. Additional calculations of the consumer exposure, including these CXLs, were therefore performed and exceedances of the ARfD were identified for the existing CXLs in melons and head cabbage, representing 303 and 105% of the ARfD, respectively. Excluding these two CXLs from the calculation, the highest chronic exposure represented 37.6% of the ADI (Dutch child) and the highest acute exposure amounted to 66.9% of the ARfD (bananas). An overview of the MRL recommendations resulting from these calculations is included in the table below. As all the proposed MRLs are fully supported by data, they are recommended for inclusion in Annex II to Regulation (EC) No 396/2005.

In conclusion, the above assessment revealed one data gap for a rotational crops study representative for fruiting vegetables in glasshouse. Critical areas of concern were identified with regard to the acute consumer exposure resulting from fenamiphos residues in melons and head cabbage.

### Overview of the recommended EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<u>Residue definition for enforcement</u> : sum of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, expressed as fenamiphos			
Table and wine grapes	0.02*	0.03	The proposed MRLs are sufficiently supported by data and no risk to consumers
Tomatoes	0.05	0.04	

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Peppers	0.1	0.04	is identified. MRL proposals are expected to cover the existing CXLs when available. Recommended for inclusion in Annex II.
Aubergines	0.05	0.04	
Cucumbers	0.05	0.02*	
Courgettes	0.05	0.02*	
Brussels sprouts	0.05	0.02*	
Apples	0.02*	0.02*	Recommendation based on CXLs but considering the European LOQ. No risk to the consumers was identified. Recommended for inclusion in Annex II.
Bananas	0.05	0.02*	
Peanuts	0.05*	0.02*	
Cotton seed	0.05*	0.02*	
Other products of plant origin	see App C	-	No recommendation possible as no safe use or CXL was reported/identified. Risk managers can decide whether a specific LOQ needs to be established or whether the default MRL of 0.01 mg/kg can apply.
Meat, fat, liver, kidneys and edible offals	0.01*	0.01*	Intake by livestock is not expected according to the GAPs evaluated at EU level, but existing MRLs can be maintained based on the CXLs. Recommended for inclusion in Annex II.
Milk	0.005*	0.005*	
Eggs	0.01*	0.01*	
Other products of animal origin	-	-	

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

**Key words: fenamiphos, MRL review, melon, Regulation (EC) No 396/2005, consumer risk assessment, phosphoramidate insecticides, organophosphate nematicides, fenamiphos sulfone, fenamiphos sulfoxide**

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## BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting as well as the review of pesticide MRLs at Community level. Article 12(2) of that regulation lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC before 02 September 2008.

According to Article 12(1) of the Regulation, EFSA shall base its reasoned opinion in particular on the relevant assessment report prepared under Directive 91/414/EEC. It should be noted, however, that in the framework of Directive 91/414/EEC only a few representative uses are evaluated while MRLs set out in Regulation (EC) No 396/2005 should accommodate for all uses authorised within the EC as well as uses authorised in third countries having a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

In order to have an overview on the pesticide residues data that have been considered for the setting of the MRLs under the former MRL legislation, EFSA developed the Pesticide Residue Overview File (PROFile). The PROFile is an electronic inventory of all pesticide residues data relevant to the risk assessment as well as the MRL setting for a given active substance. This includes data on:

- the nature and magnitude of residues in primary crops;
- the nature and magnitude of residues in processed commodities;
- the nature and magnitude of residues in rotational crops;
- the nature and magnitude of residues in livestock commodities and;
- the analytical methods for enforcement of the proposed MRLs.

As fenamiphos was included in Annex I to Directive 91/414/EEC on 01 August 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-540 was included in the EFSA Register of Question.

The Netherlands, the designated Rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, were asked to complete the PROFile for fenamiphos. The completed PROFile was submitted to EFSA on 28 August 2008 and subsequently checked for completeness. On 27 April 2009, after having clarified some issues with the RMS, the PROFile was considered complete for assessment.

In the meantime, The Netherlands also received an application from the company Makhteshim Agan<sup>2</sup> to modify the existing MRL for the fenamiphos in melons. 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, the evaluation report and the supporting dossier to EFSA on 29 May 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00648.

Based on the PROFile and the evaluation report submitted, EFSA prepared a draft reasoned opinion which was circulated to Member States (MS) for commenting on 22 June 2009. All

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<sup>2</sup> Makhteshim Agan, Irvita Plant Protection Branch, rue Troyon 2, 92316 Sevres Cedex, France

MS comments received by 13 July 2009 were considered by EFSA for finalization of the reasoned opinion.

### TERMS OF REFERENCE

According to Article 12(1) of Regulation (EC) No 396/2005, EFSA shall provide a reasoned opinion on:

- the inclusion of the active substance in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the active substance or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
- the setting of specific processing factors as referred to in Article 20(2) of the Regulation.

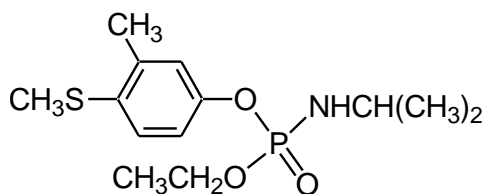
According to Article 12(2) of that Regulation, the reasoned opinion shall be provided within 12 months of the entry into force of this regulation. As the Regulation entered into force on 02 September 2008, the deadline for providing the reasoned opinion would be 01 September 2009. Considering however that the reasoned opinion is also addressing the MRL application for fenamiphos in melons, the calculated deadline in this particular case is 29 August 2009.

### ACKNOWLEDGEMENTS

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### THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fenamiphos is the ISO common name for ethyl 4-methylthio-m-tolyl isopropylphosphoramidate (IUPAC).



Fenamiphos belongs to the class of phosphoramidate insecticides and organophosphate nematicides. It is a systemic compound which is absorbed by the roots of the plant and translocated to the leaves. It is a cholinesterase inhibitor used for the control of nematodes, with a secondary effect against sucking insects.

Fenamiphos was evaluated in the framework of Directive 91/414/EEC in stage 2 with The Netherlands being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review process included a indoor treatment by drip irrigation in peppers at a rate of 10 kg a.s./ha with a PHI of 60 days and a outdoor treatment in tobacco at a rate of 6 kg a.s./ha when plants are transplanted. Both uses were supported for the Southern European region. Following the peer review a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was taken and published in Directive 2006/85/EC. The Annex I

inclusion entered into force on 01 August 2007 and is restricted to the use as nematicide in greenhouses with permanent structures. Member States are now required to review their national authorizations by 31 July 2011 in accordance with the uniform principles of Annex VI. Particular attention should be given to the protection of aquatic organisms, soil non-target organisms and groundwater in vulnerable situations.

EC MRLs for fenamiphos in products of plant and animal origin have been set for the first time in 2004 by means of Directive 2004/02/EC. These MRLs were based on the uses authorised within the EC at that time and are still valid since they were transferred to Annex II of Regulation (EC) No 396/2005 without any amendments. Additional MRLs for commodities that were not covered by the former European MRL legislation are established in Annex III B of the Regulation. These temporary MRLs were derived from the MRLs that have been set at national level before the Regulation entered into force. All existing EC MRLs for fenamiphos are summarized in Appendix C to this document. On 15 September 2008, EFSA provided a reasoned opinion on certain MRLs of concern for fenamiphos and on 12 June 2009 a regulation amending the existing MRLs for fenamiphos was voted by the Standing Committee on the Food Chain and Animal Health. This regulation is, however, still pending publication. CXLs for fenamiphos have been established by the Codex Alimentarius Commission and are reported in Appendix D to this reasoned opinion.

For the purpose of this MRL review, the critical uses of fenamiphos currently authorized within the EC have been reported by the RMS as well as uses authorised in third countries which might have a significant impact on international trade. A detailed overview of the critical GAPS is available in Appendix A to this document. For Northern and Southern Europe, only indoor applications in fruiting vegetables were reported (drip irrigation at 10 kg a.s./ha with a PHI of 60d). As Member States are still required to review their national approvals by 31 July 2011, modification of these GAPS might occur in the near future. Additionally, several outdoor soil treatments performed outside the EC were reported for grapes, bananas, carrots, Brussels sprouts and head cabbage. Within the EC, fenamiphos is also authorized for use on bananas in Spain (Canary Islands) and France (Martinique and Guadeloupe). These uses are, however, not compliant with the restrictions set out in the Annex I inclusion of fenamiphos and therefore not further considered in this review.

## ASSESSMENT

### 1. Methods of analysis

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

During the peer review under Directive 91/414/EC, an analytical method based on HPLC-MS/MS has been evaluated (EFSA, 2006). This method includes an oxidation of the extracted residues, converting all relevant residues to fenamiphos sulfone<sup>3</sup> and making the method suitable for the combined analysis of fenamiphos, fenamiphos sulfone and fenamiphos sulfoxide<sup>4</sup>. This method was sufficiently validated in commodities with high water content (tomato) and high acid content (oranges, kiwi) with an LOQ of 0.02 mg/kg, expressed as fenamiphos. Modifications of this method were evaluated and validated for determination of fenamiphos and its metabolites in commodities with high oil content and dry commodities,

<sup>3</sup> fenamiphos sulfone: *O*-ethyl-*O*-[4-(methylsulfonyl)-3-methylphenyl]-*N*-methylethyl phosphoramidate

<sup>4</sup> fenamiphos sulfoxide: *O*-ethyl-*O*-[4-(methylsulfinyl)-3-methylphenyl]-*N*-methylethyl phosphoramidate

also with an LOQ of 0.02 mg/kg. The described method, including its modifications, was also reported by the RMS in the PROFile.

Additionally, the 1999 JMPR reported the availability of several specific methods for determining fenamiphos, fenamiphos sulfone and fenamiphos sulfoxide in various plant commodities (WHO/FAO, 2000). These methods also include an oxidation step followed by quantification with GLC followed by FPD. LOQs ranged between 0.01 and 0.1 mg/kg, depending on the commodity being analysed. Multi-residue enforcement methods applied by the governments of Australia and The Netherlands were also reported, but it is not clear whether these methods include the sulfone and sulfoxide metabolites.

Hence it is concluded that residues of fenamiphos, fenamiphos sulfone and fenamiphos sulfoxide can be enforced in food of plant origin with an LOQ of 0.02 mg/kg.

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

During the peer review under Directive 91/414/EC, an analytical method for enforcement of residues in food of animal origin was not considered because the use of fenamiphos on crops likely to be fed to livestock was not supported (EFSA, 2006). Also in the framework of the PROFile, analytical methods for food of animal origin were not reported by the RMS.

The 1999 JMPR, however, reported a GLC method with detection by FPD which also included an oxidation of the extracted residues (WHO/FAO, 2000). Combined LOQs for fenamiphos, fenamiphos sulfone, fenamiphos sulfoxide and fenamiphos sulfoxide fenol of 0.005 and 0.01 mg/kg were reported for milk and animal tissues, respectively.

## 2. Mammalian toxicology

The toxicological assessment of fenamiphos was peer reviewed under Directive 91/414/EEC and toxicological reference values were published by EFSA (2006). These toxicological reference values are summarized in the table below.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Fenamiphos					
ADI	EFSA	2006	0.0008	1 yr cholinesterase dog study	100
ARfD	EFSA	2006	0.0025	acute oral neurotoxicity study in dogs	100



### 3. Residues

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

##### 3.1.1. Primary crops

###### 3.1.1.1. Nature of residues

Metabolism of fenamiphos was studied in fruits and fruiting vegetables (tomato and pineapples), root and tuber vegetables (carrots), pulses and oilseeds (beans and peanuts) and leafy vegetables (tobacco and cabbage) (EFSA, 2006). Several types of applications were investigated (local, foliar and soil) and metabolic pathways in all studies were found to be similar. Based on the available studies the residue definition of enforcement and risk assessment in all plant commodities was defined as the sum of fenamiphos, fenamiphos sulfoxide and fenamiphos sulphone, expressed as fenamiphos. Valid analytical methods for enforcement of the proposed residue definition are available (see also section 1.1). These conclusions reached by EFSA were accordingly reflected in the PROFile provided by the RMS in the framework of this review and are also in line with the findings of the 1999 JMPR (WHO/FAO, 2000).

It is noted that the need for simplification of residue definitions has been discussed on several occasions and that residue definitions for enforcement purposes should as much as possible be restricted to the parent compound only (EFSA, 2009). In the case of fenamiphos, however, the individual levels of parent compound and metabolites vary with time and type of plant, hampering the selection of one marker molecule (EFSA, 2006). It is therefore proposed by EFSA to maintain the residue definition for products of plant origin as derived in the framework of the peer review.

###### 3.1.1.2. Magnitude of residues

EFSA already evaluated the uses of fenamiphos in bananas, carrots, melons and head cabbage in the framework of a previous reasoned opinion, where safe MRLs for these crops could not be recommended (EFSA, 2008). Regarding melons, new information has been provided by the RMS in the framework of a new MRL application (EFSA-Q-2009-00465). The use of fenamiphos in melons is therefore reconsidered in this review. For bananas, carrots and head cabbage, however, additional information has not been provided. These crops are therefore not further considered in the framework of this review. For the remaining crops under assessment (see also Appendix A), EFSA relied on the supervised residues field trials that were reported by the RMS in the PROFile.

The combined results for all available residues trials are summarized in Table 3-1. For all supported crops a sufficient number of trials complying with the GAP was reported by the RMS. It is noted that for tomatoes and grapes a data requirement of 8 trials normally applies while only 6 and 7 trials are available, respectively. Nevertheless, the lower number of trials is considered acceptable because residue levels were found to be consistent and close to the LOQ.

Storage stability of fenamiphos was demonstrated for a period of 24 months at -5 °C in commodities with high water and high acid content (EFSA, 2006). According to the RMS, all

the residues trial samples were stored in accordance with these conditions and degradation of residues during storage of the trial samples is therefore not expected.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation (see also Table 3-1). In order to better reflect the real residue levels, the MRL proposals were calculated without consideration of the MRL classes usually applied in legislation. It is also noted that for melons the value of 0.043 mg/kg would be identified as an outlier according to the Dixon Q test. However, it is internationally agreed that outliers should only be excluded from the MRL calculations if an explanation for the outlier can be provided with regard to the study set-up. As such argumentation was not provided, the value was included in the calculation of the MRL for melons.

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

Commodity	Region <sup>(a)</sup>	Outdoor /Indoor	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					
<u>Residue definition for enforcement and risk assessment</u> : sum of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, expressed as fenamiphos									
Table grapes Wine grapes	Import (Chili)	Outdoor	2 x <0.01; 3 x 0.01; 2 x 0.02	2 x <0.01; 3 x 0.01; 2 x 0.02	0.01	0.02	0.03	1.0	Combined dataset on table and wine grapes (7 trials) in compliance with the GAP (PROFile). R <sub>max</sub> = 0.03 R <sub>ber</sub> = 0.03
Tomatoes Aubergines	NEU/ SEU	Indoor	5 x <0.02; 0.0214	5 x <0.02; 0.0214	0.02	0.02	0.04	1.0	6 trials on tomatoes in compliance with the GAP (PROFile). Extrapolation to aubergines acceptable. R <sub>max</sub> = 0.02 R <sub>ber</sub> = 0.04
Peppers	NEU/ SEU	Indoor	8 x <0.02; 0.022	8 x <0.02; 0.022	0.02	0.02	0.04	1.0	9 trials in compliance with the GAP (PROFile). R <sub>max</sub> = 0.02 R <sub>ber</sub> = 0.04
Cucumbers Courgettes	NEU/ SEU	Indoor	10 x <0.02	10 x <0.02	0.02	0.02	0.02*	1.0	10 trials on cucumbers in compliance with the GAP (PROFile). Extrapolation to courgettes acceptable.
Melons Watermelons	NEU/ SEU	Indoor	8 x <0.02; 4 x 0.02; 0.043	8 x <0.02; 4 x 0.02; 0.043	0.02	0.043	0.05	1.0	Combined dataset on melons (11) and watermelons (2) in compliance with the GAP (Evaluation report MRL application). R <sub>max</sub> = 0.04 R <sub>ber</sub> = 0.04

Commodity	Region ( <sup>a</sup> )	Outdoor /Indoor	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					
Brussels sprouts	Import (US, AU)	Outdoor	6 x <0.01; 0.02	6 x <0.01; 0.02	0.01	0.02	0.02*	1.0	7 trials in compliance with the GAP (PROFile). R <sub>max</sub> = 0.02 R <sub>ber</sub> = 0.02

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

(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. The individual conversion factor for each trial is defined as the ratio of the trial result according to the risk assessment residue definition and the result according to the enforcement residue definition.

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

Some of the crops evaluated in the framework of this review might be subject to processes that involve heating, hereby requiring the submission of studies investigating the effect of these processes on the nature of residues in the final product. However, residue levels in primary crops were all found to be below or slightly above the LOQ and total chronic exposure of the consumer to fenamiphos residues represents less than 15 % of the ADI. Additionally, based on the metabolism in plants and the hydrolytic stability studies (EFSA, 2006), it can be seen that the degradation pathway for fenamiphos is mainly expected to be through oxidation. Therefore, other metabolites than the ones identified in the primary crop metabolism studies are not expected. The nature of residues in processed commodities is expected to show a similar pattern as in the primary crops and further studies are not required.

Processing studies investigating the magnitude of residues in raisins, grape juice and grape pomace were reported in the PROFile. The data are summarized in Table 3-2 but one processing study for each process is not considered sufficient for deriving reliable processing factors.

In the evaluation report prepared by the RMS in the framework of the MRL application for melons, reported residues trials measured fenamiphos residues both in the peeled and unpeeled fruits. However, residues exceeding the LOQ of 0.02 mg/kg were reported for one trial only. It is noted that attempts were made by the applicant and by the RMS to quantify residue levels below the LOQ but they are not considered reliable by EFSA because the LOQ is the lowest measurable level for which the analytical method was properly validated. Consequently only one trial is available for deriving an indicative peeling factor for melons (see Table 3-2). As for the residues trials this indicative factor can be extrapolated to watermelons as well but additional trials with incurred residues exceeding the LOQ would be required in order to derive a more robust processing factor. For risk assessment in other crops, there is currently no need to provide further processing studies.

**Table 3-2. Overview of the available processing studies**

Processed commodity	Number of studies	Median PF <sup>(a)</sup>	Median CF <sup>(b)</sup>	Comments
<u>Residue definition for enforcement and risk assessment:</u> sum of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, expressed as fenamiphos				
Table grapes, dired	1	1.69	1.0	Number of processing studies are not sufficient to propose robust processing factors for enforcement, but the processing factor proposed for melons and watermelons could be used for indicative risk assessment.
Wine grapes, juice	1	1.00	1.0	
Wine grapes, dry pomace	1	5.00	1.0	
Wine grapes, wet pomace	1	1.00	1.0	
Melons, peeled	1	0.72	1.0	
Watermelons, peeled	1	0.72	1.0	

(a): The median processing factor is obtained by calculating the median of the individual processing factors of each processing study.

(b): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors of each processing study.

### 3.1.2. Rotational crops

#### 3.1.2.1. Preliminary considerations

The use of fenamiphos in third countries is not considered relevant with regard to the rotational crops. In Europe, however, the indoor use of fenamiphos is supported in fruiting vegetables and rotation of fruiting vegetables with other crops cannot be excluded. Considering that the indoor use of fenamiphos in peppers was supported in the framework of Directive 91/414/EEC, data reported in the EFSA conclusion on fenamiphos (EFSA, 2006) are therefore also applicable to the GAPs supported in the framework of this review.

#### 3.1.2.2. Nature of residues

Although  $DT_{90}$  values for fenamiphos, fenamiphos sulfone, fenamiphos sulfoxide, fenamiphos sulfone phenol<sup>5</sup> and fenamiphos sulfoxide phenol<sup>6</sup> in soil were shown to be below the trigger value of 100 days, nature of residues in rotational crops was investigated (EFSA, 2006). The EFSA conclusion on fenamiphos reports confined rotational crop studies performed on representative crops for the root and tuber vegetables, pulses and oilseeds, leafy vegetables and cereals. The metabolic pattern in rotational crops was found to be mostly similar to the pattern identified in the primary plant metabolism studies. An important difference was the identification of two new metabolites (M09<sup>7</sup> and M18<sup>8</sup>), which were not identified before. Nevertheless, both metabolites were not considered to be of toxicological concern and therefore not included in the residue definition. The RMS reported the same finding in the PROFile.

#### 3.1.2.3. Magnitude of residues

In addition to the confined rotational crop study, a rotational crop residues trial was evaluated in the framework of the peer review (EFSA, 2006). This trial was performed on turnips, mustard, spinach, wheat and sorghum in outdoor conditions and residues of 0.44 mg/kg were identified in sorghum forage planted 120 DAT. A waiting period of 8 months for the outdoor use of fenamiphos on tobacco was therefore proposed by the RMS and by EFSA. Although soil degradation studies predict that soil residues of the active substance and relevant metabolites decline by more than 90% at 100 days after treatment, actual rotational crop field studies show significant residues, both, in soil and in plants. The discrepancy between soil residues in the field rotational crop study and the soil degradation study can neither be explained by different release rate of the formulations used nor by the different soil types. Hence it was concluded that the rotational crops studied are not representative for fruiting vegetables grown indoor and a data gap for a rotational crops study reflecting these conditions was identified.

The requested study has not been submitted and fruiting vegetables supported in the framework of this review might still be rotated with other fruiting vegetables for which the primary use of fenamiphos is not supported. The data gap, which was also confirmed by the RMS in the PROFile, is therefore maintained.

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<sup>5</sup> fenamiphos sulfone phenol: 3-methyl-4-[methylsulfonyl]phenol

<sup>6</sup> fenamiphos sulfoxide phenol: 3-methyl-4-[methylsulfinyl]phenol

<sup>7</sup> des-isopropylamino fenamiphos sulfoxide: ethyl 3-methyl-4-(methylsulfinyl)phosphoric acid phenyl ester

<sup>8</sup> M18: 5-hydroxy-2-(methylsulfonyl)benzenemethanol

### 3.2. Nature and magnitude of residues in livestock

Occurrence of residues in food of animal origin was not considered in the framework of this review because the crops under consideration are not fed to livestock. MRLs in products of animal origin are therefore not required.

## 4. Consumer risk assessment

In this review, only the GAPs reported by the RMS were considered but, previously, the use of fenamiphos has also been assessed by the 1999 JMPR (WHO/FAO, 2000). The CXLs, resulting from this JMPR assessment and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate the consideration of CXLs by risk managers, the consumer exposure was calculated both with and without inclusion of the existing CXLs (see Appendix D).

### 4.1. Consumer risk assessment without the CXLs

Chronic and acute intake calculations considering the MRLs proposed in the framework of this review were performed using revision 2 of the EFSA PRIMo. The input values for the proposed MRLs are summarized in Table 4-1. The STMR and HR values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities. As melons are commonly peeled before consumption, relevant processing factors reported in Table 3-2 were considered as well. The contributions of other commodities, for which no MRL was derived in the framework of this review, were not included in the calculation.

The detailed results of the chronic and acute intake calculations are reported in Appendix B.1 to this document. The highest chronic exposure was calculated for the WHO Cluster diet B, representing 15.3% of the ADI. With regard to the acute exposure, however, exceedances of the ARfD were identified for melons and watermelons, representing 188 and 152% of the ARfD, respectively. In its reasoned opinion on MRLs of concern for fenamiphos, EFSA concluded that acute exposure to fenamiphos residues in watermelons was acceptable based on a HR value of 0.02 mg/kg (EFSA, 2008). This conclusion is however no longer valid because the new residues trials data reported under section 3.1.2 indicate that a HR value of 0.043 mg/kg in melons and watermelons is more appropriate, resulting in the above reported exposures.

The applicant also proposes, based on the studies of Caldas *et al.* (2006) and Ambrus (2006), to use a lower variability factor of 2.6 instead of the default variability factor of 5 for melons and watermelons that is applied in the EFSA PRIMo. The factor proposed by the applicant, however, is based on findings for parathion-methyl in summer squash and does not necessarily apply to fenamiphos in melons. The available data demonstrate that the real variability factor for fenamiphos in melons is likely to be lower than 5 but specific variability data should be provided in order to determine a robust factor. This is of particular importance because acute exposures are still close to the ARfD, even when using the presumed variability factor of 2.6.

In a second calculation of the consumer exposure, excluding the proposed MRLs for melons and watermelons (see Appendix B.2), the highest chronic exposure was also calculated for the

WHO Cluster diet B, but this time only representing 13.2% of the ADI. The highest acute exposure is now calculated for table grapes, representing 52.4% of the ARfD.

Consequently, the use of fenamiphos on melons and watermelons is not acceptable with regard to consumer exposure and safe MRLs for these crops cannot be recommended. The remaining MRLs proposed in the framework of this review (see Table 3-1) are not considered to be of concern for the European consumer and can be recommended for MRL setting.

**Table 4-1. Input values for the consumer risk assessment without CXLs**

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<u>Residue definition for risk assessment</u> : sum of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, expressed as fenamiphos				
Table grapes	0.01	STMR	0.02	HR
Wine grapes	0.01	STMR	0.02	HR
Tomatoes	0.02	STMR	0.02	HR
Peppers	0.02	STMR	0.02	HR
Aubergines	0.02	STMR	0.02	HR
Cucumbers	0.02	STMR	0.02	HR
Courgettes	0.02	STMR	0.02	HR
Melons	0.014	STMR * PF	0.031	HR * PF
Watermelons	0.014	STMR * PF	0.031	HR * PF
Brussels sprouts	0.01	STMR	0.02	HR

#### 4.2. Consumer risk assessment including the CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer risk assessment of the CXLs have been collected (PSD, 2009), the outcome of this data collection being reported in Appendix D to this document.

The MRLs proposed in the framework of this review and for which no consumer intake concerns were identified, were then compared with the existing CXLs for fenamiphos. For each commodity, the highest value was selected and corresponding input values for risk assessment are summarized in Table 4-2. For products of animal origin, EFSA decided as a worst case assumption to use the CXL for risk assessment because appropriate values for risk assessment could not be derived from the evaluation reports of the JMPR.

Chronic and acute intake calculations considering the input values of Table 4-2 were performed using revision 2 of the EFSA PRIMo and results are reported in Appendix B.3. In this case, the highest chronic exposure was calculated for the Dutch Children, representing 38.2% of the ADI. All acute exposures were below the ARfD, except for melons and head cabbage, each representing 303 and 105% of the ARfD, respectively. Excluding the CXLs for melons and head cabbage from the calculations (see Appendix B.4), the chronic exposure



decreases to 37.6% of the ADI. The highest acute exposure is then calculated for bananas, representing 66.9% of the ARfD.

It is therefore concluded that the existing CXLs for fenamiphos, except for melons and head cabbage, are not of concern for the European consumer. These CXLs are therefore recommended for inclusion in European legislation. It is noted, however, that based on the residues trials data of the 1999 JMPR (WHO/FAO, 2000) the CXLs set at the LOQ of 0.05 mg/kg could be lowered to the European LOQ of 0.02 mg/kg without affecting international trade. Similarly, it can also be concluded that the data evaluated for Brussels sprouts by the 1999 JMPR support a CXL of 0.02 mg/kg rather than 0.05 mg/kg.

Table 4-2. Input values for the consumer risk assessment including CXLs

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
<u>Residue definition for risk assessment</u> : sum of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, expressed as fenamiphos				
Apples	0.01	STMR (PSD, 2009)	0.01	HR (PSD, 2009)
Table grapes	0.01	STMR	0.02	HR
Wine grapes	0.01	STMR	0.02	HR
Bananas	0.01	STMR (PSD, 2009)	0.02	HR (PSD, 2009)
Tomatoes	0.02	STMR	0.02	HR
Peppers	0.02	STMR	0.02	HR
Aubergines	0.02	STMR	0.02	HR
Cucumbers	0.02	STMR	0.02	HR
Courgettes	0.02	STMR	0.02	HR
Melons	0.02	STMR (PSD, 2009)	0.05	HR (PSD, 2009)
Brussels sprouts	0.01	STMR	0.02	HR
Head cabbage	0.01	STMR (PSD, 2009)	0.05	HR (PSD, 2009)
Peanuts	0.01	STMR (PSD, 2009)	0.01	HR (PSD, 2009)
Cotton seed	0.01	STMR (PSD, 2009)	0.01	HR (PSD, 2009)
Meat, fat, liver, kidneys and edible offals	0.01	CXL	0.01	CXL
Milk	0.005	CXL	0.005	CXL
Eggs	0.01	CXL	0.01	CXL

## CONCLUSIONS AND RECOMMENDATIONS

Metabolism was investigated in four different crop groups using three different types of applications. Metabolic patterns in the different studies were shown to be similar and the relevant residue for enforcement and risk assessment in all plant commodities could be defined as the sum of fenamiphos and its sulfone and sulfoxide, expressed as fenamiphos. A validated analytical method for enforcement of this residue definition with a LOQ of 0.02 mg/kg in all plant commodities is also available. Additionally, a sufficient number of supervised residues trials is available to support the GAPs reported by the RMS, except for bananas, carrots and head cabbage. Conclusions regarding these 3 crops were already derived in the framework of a previous reasoned opinion on MRLs of concern for fenamiphos. For the remaining crops, available trials allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRLs.

As residues of fenamiphos are all below 0.1 mg/kg and contribution of these residues to chronic consumer exposure is generally low, investigating the effect of industrial and/or household processing was not considered necessary. Studies investigating the magnitude of residues in some processed products were submitted but were not sufficient to recommend robust processing factors for enforcement purposes. Derived processing factors were only considered as indicative for the risk assessment, in particular with regard to the peeling of melons.

Occurrence of fenamiphos residues in rotational crops was investigated during the peer review of fenamiphos and it was concluded that metabolic patterns in primary and succeeding crops are similar. Nevertheless, based on a confined rotational crop study and an additional field trial, it is concluded that residues in succeeding crops cannot be excluded and a plant-back interval of 8 months was recommended for the outdoor use of fenamiphos. For the indoor use in fruiting vegetables, an appropriate plant-back interval could not be proposed as no appropriate study was made available.

Occurrence of residues in food of animal origin was not considered in the framework of this review because the crops under consideration are not fed to livestock.

Both chronic and acute consumer exposure resulting from the MRLs proposed in the framework of this review were calculated, but exceedances of the ARfD were identified for melons and watermelons, representing 188 and 152% of the ARfD respectively. Excluding these two MRLs from the calculation, the highest chronic exposure represented 13.2% of the ADI (WHO Cluster diet B) and the highest acute exposure amounted to 52.4% of the ARfD (table grapes).

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for fenamiphos. Additional calculations of the consumer exposure, including these CXLs, were therefore performed and exceedances of the ARfD were identified for the existing CXLs in melons and head cabbage, representing 303 and 105% of the ARfD, respectively. Excluding these two CXLs from the calculation, the highest chronic exposure represented 37.6% of the ADI (Dutch child) and the highest acute exposure amounted to 66.9% of the ARfD (bananas). An overview of the MRL recommendations resulting from these calculations is included in the table below. As all the proposed MRLs are fully supported by data, they are recommended for inclusion in Annex II to Regulation (EC) No 396/2005.

In conclusion, the above assessment revealed one data gap for a rotational crops study representative for fruiting vegetables in glasshouse. Critical areas of concern were identified with regard to the acute consumer exposure resulting from fenamiphos residues in melons and head cabbage.

### Overview of the recommended EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
<u>Residue definition for enforcement</u> : sum of fenamiphos, fenamiphos sulfoxide and fenamiphos sulfone, expressed as fenamiphos			
Table and wine grapes	0.02*	0.03	The proposed MRLs are sufficiently supported by data and no risk to consumers is identified. MRL proposals are expected to cover the existing CXLs when available. Recommended for inclusion in Annex II.
Tomatoes	0.05	0.04	
Peppers	0.1	0.04	
Aubergines	0.05	0.04	
Cucumbers	0.05	0.02*	
Courgettes	0.05	0.02*	
Brussels sprouts	0.05	0.02*	
Apples	0.02*	0.02*	Recommendation based on CXLs but considering the European LOQ. No risk to the consumers was identified. Recommended for inclusion in Annex II.
Bananas	0.05	0.02*	
Peanuts	0.05*	0.02*	
Cotton seed	0.05*	0.02*	
Other products of plant origin	see App C	-	No recommendation possible as no safe use or CXL was reported/identified. Risk managers can decide whether a specific LOQ needs to be established or whether the default MRL of 0.01 mg/kg can apply.
Meat, fat, liver, kidneys and edible offals	0.01*	0.01*	Intake by livestock is not expected according to the GAPs evaluated at EU level, but existing MRLs can be maintained based on the CXLs. Recommended for inclusion in Annex II.
Milk	0.005*	0.005*	
Eggs	0.01*	0.01*	
Other products of animal origin	-	-	

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

### DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on fenamiphos prepared by the Rapporteur Member State The Netherlands. Submitted to EFSA on 28 August 2008. Clarifications provided on 27 April 2009.
2. Evaluation report on the modification of the existing MRL for fenamiphos in melon prepared by the Rapporteur Member State The Netherlands under Regulation (EC) No 396/2005. Forwarded to EFSA on 29 May 2009.

## REFERENCES

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- Caldas E.D., Jardim A. N. O., Ambrus A., de Souza L. C. K., 2006. Variability of Organophosphorous Insecticide Residues in Large Size Crops Grown in Commercial Farms in Brazil. *Food Additives and Contaminants* 23(2): 148-158.
- EFSA (European Food Safety Authority), 2006. Conclusion of EFSA prepared by the Pesticides Unit (PRAPeR) on the peer review of the pesticide risk assessment of the active substance fenamiphos. *EFSA Scientific Report* (2006) 62, 1-81.
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- WHO/FAO, 2000. Pesticide residues in food – 1999. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues. FAO Plant Production and Protection Paper 153, 2000.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs) REPORTED BY THE RMS

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application						Application rate			PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Number	Interval (days)		Min. rate	Max. rate	Rate Unit			
							Conc.	Unit					Min.	Max.						
Tomatoes	<i>Lycopersicon esculentum</i>	NEU/SEU	Indoor	NL, IT	Nematods:Meloidogyne incognitaAphids: Myzus persicaeMacrosiphum euphorbiaeAphis gossypiiAphis fabaeAulacortum solaniAleurodidae:Bemis ia tabaciTrialeurodes vaporariorum	CS	240.0	g/L	Soil treatment - general (see also comment field)	0	61	1	2	10	14	5.00	10.08	kg a.i./ha	60	application by drip irrigation, from transplanting. Max 10.08 kg as/ha per season
Peppers	<i>Capsicum annuum, var grossum and var. longum</i>	NEU/SEU	Indoor	NL, IT	Nematods:Meloidogyne incognitaAphids: Myzus persicaeMacrosiphum euphorbiaeAphis gossypiiAphis fabaeAulacortum solaniAleurodidae:Bemis ia tabaciTrialeurodes vaporariorum	CS	240.0	g/L	Soil treatment - general (see also comment field)	0	61	1	2	10	14	5.00	10.08	kg a.i./ha	60	application by drip irrigation, from transplanting. Max 10.08 kg as/ha per season
Aubergines (egg plants)	<i>Solanum melongena</i>	NEU/SEU	Indoor	NL, IT	Nematods:Meloidogyne incognitaAphids: Myzus persicaeMacrosiphum euphorbiaeAphis gossypiiAphis fabaeAulacortum solaniAleurodidae:Bemis ia tabaciTrialeurodes vaporariorum	CS	240.0	g/L	Soil treatment - general (see also comment field)	0	61	1	2	10	14	5.00	10.08	kg a.i./ha	60	application by drip irrigation, from transplanting. Max 10.08 kg as/ha per season
Cucumbers	<i>Cucumis sativus</i>	NEU/SEU	Indoor	NL, IT	Nematods:Meloidogyne incognitaAphids: Myzus persicaeMacrosiphum euphorbiaeAphis gossypiiAphis fabaeAulacortum solaniAleurodidae:Bemis ia tabaciTrialeurodes vaporariorum	CS	240.0	g/L	Soil treatment - general (see also comment field)	0	15	1	2	10	14	5.00	10.08	kg a.i./ha	60	application by drip irrigation, from transplanting. Max 10.08 kg as/ha per season
Courgettes	<i>Cucurbita pepo var. melopepo</i>	NEU/SEU	Indoor	NL, IT	Nematods:Meloidogyne incognitaAphids: Myzus persicaeMacrosiphum euphorbiaeAphis gossypiiAphis fabaeAulacortum solaniAleurodidae:Bemis ia tabaciTrialeurodes vaporariorum	CS	240.0	g/L	Soil treatment - general (see also comment field)	0	15	1	2	10	14	5.00	10.08	kg a.i./ha	60	application by drip irrigation, from transplanting. Max 10.08 kg as/ha per season
Melons	<i>Cucumis melo</i>	NEU/SEU	Indoor	NL, IT	Nematods:Meloidogyne incognitaAphids: Myzus persicaeMacrosiphum euphorbiaeAphis gossypiiAphis fabaeAulacortum solaniAleurodidae:Bemis ia tabaciTrialeurodes vaporariorum	CS	240.0	g/L	Soil treatment - general (see also comment field)	0	50	1	2	10	14	5.00	10.08	kg a.i./ha	60	application by drip irrigation, from transplanting. Max 10.08 kg as/ha per season

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application						Application rate			PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit				Min.	Max.	Min.	Max.					
Watermelons	<i>Citrullus lanatus</i>	NEU/SEU	Indoor	NL, IT	Nematods:Meloidogyne incognita Aphids: Myzus persicae Macrosiphum euphorbiae Aphis gossypii Aphis fabae Aulacortum solani Aleurodidae: Bemisia tabaci Trialeurodes vaporariorum	CS	240.0	g/L	Soil treatment - general (see also comment field)	0	50	1	2	10	14	5.00	10.08	kg a.i./ha	60	application by drip irrigation, from transplanting. Max 10.08 kg as/ha per season

n.a.: not applicable

Critical GAPs for Import Tolerances (non-European indoor, outdoor or post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application						Application rate			PHI or waiting period (days)	Comments (max. 250 characters)
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit				Min.	Max.	Min.	Max.					
Table grapes	<i>Vitis evvitis</i>	non-EU	Outdoor	Chili		sc	240.0	g/L	Soil treatment - general (see also comment field)	n.a.	n.a.	1	3	30	40	1.35	4.10	kg a.i./ha	15	application by drip irrigation, in spring or after harvest. One application of 4.1 kg as/ha, 2 of max. 2.05 kg as/ha or 3 of max. 1.35 kg as/ha
Wine grapes	<i>Vitis evvitis</i>	non-EU	Outdoor	Chili		sc	240.0	g/L	Soil treatment - general (see also comment field)	n.a.	n.a.	1	3	30	40	1.35	4.10	kg a.i./ha	15	application by drip irrigation, in spring or after harvest. One application of 4.1 kg as/ha, 2 of max. 2.05 kg as/ha or 3 of max. 1.35 kg as/ha
Bananas	<i>Musa x paradisiaca</i>	non-EU	Outdoor	Southern American countries		sc	240.0	g/L	Soil treatment - general (see also comment field)	n.a.	n.a.	1	1			5.10	5.10	kg a.i./ha	0	application at beginning of rainy season
Carrots	<i>Daucus carota</i>	non-EU	Outdoor	USA, Australia		GR	4.8	g/kg	Soil treatment - granules overall	n.a.	n.a.	1	1	10	10		9.60	kg a.i./ha	n.a.	application by drip irrigation, at transplanting
Brussels sprouts	<i>Brassica oleracea</i> var. <i>gemmifera</i>	non-EU	Outdoor	USA, Australia					Soil treatment - general (see also comment field)	n.a.	n.a.	1	1	10	10		6.70	kg a.i./ha	n.a.	application by drip irrigation, at transplanting
Head cabbage	<i>Brassica oleracea</i> convar <i>capitata</i>	non-EU	Outdoor	Australia					Soil treatment - general (see also comment field)	n.a.	n.a.	1	1	10	10		9.60	kg a.i./ha	90	application before sowing

n.a.: not applicable

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

Appendix B.1 – PRIMo including all EC MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – PRIMo including safe EC MRL proposals resulting from the GAPs reported by the RMS

Appendix B.3 – PRIMo including safe EC MRL proposals and all CXLs

Appendix B.4 – PRIMo including safe EC MRL proposals and safe CXLs

APPENDIX B.1 – PRIMO INCLUDING ALL EC MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

<b>Fenamiphos</b>			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0008	ARfD (mg/kg bw):	0.0025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		1 15						
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)
15.3	WHO Cluster diet B	7.7	Tomatoes	2.2	Wine grapes	1.3	Watermelons	15.3
7.3	FR all population	5.0	Wine grapes	1.1	Tomatoes	0.4	Melons	7.3
6.8	DK child	4.1	Cucumbers	1.3	Tomatoes	0.6	Peppers	6.8
6.8	DE child	2.4	Tomatoes	1.6	Table grapes	1.5	Cucumbers	6.8
6.4	PT General population	3.1	Wine grapes	2.2	Tomatoes	0.5	Peppers	6.4
6.3	IE adult	1.6	Wine grapes	1.4	Melons	1.0	Tomatoes	6.3
5.5	WHO cluster diet D	2.5	Tomatoes	0.8	Watermelons	0.5	Cucumbers	5.5
4.9	WHO regional European diet	2.8	Tomatoes	0.5	Melons	0.4	Peppers	4.9
4.9	IT kids/toddler	3.6	Tomatoes	0.5	Courgettes	0.2	Aubergines (egg plants)	4.9
4.5	WHO cluster diet E	2.0	Wine grapes	1.3	Tomatoes	0.3	Peppers	4.5
4.5	IT adult	2.9	Tomatoes	0.5	Courgettes	0.3	Aubergines (egg plants)	4.5
4.1	DK adult	1.7	Wine grapes	1.0	Tomatoes	0.7	Cucumbers	4.1
4.0	SE general population 90th percentile	1.9	Tomatoes	0.8	Cucumbers	0.5	Peppers	4.0
3.7	ES adult	2.0	Tomatoes	0.5	Wine grapes	0.4	Peppers	3.7
3.6	ES child	2.5	Tomatoes	0.3	Watermelons	0.3	Peppers	3.6
3.6	NL child	1.6	Tomatoes	0.9	Table grapes	0.6	Cucumbers	3.6
3.5	UK vegetarian	1.6	Tomatoes	1.0	Wine grapes	0.3	Cucumbers	3.5
3.4	FR toddler	1.9	Tomatoes	1.2	Courgettes	0.3	Table grapes	3.4
3.4	WHO Cluster diet F	1.7	Tomatoes	0.7	Wine grapes	0.3	Cucumbers	3.4
3.1	PL general population	2.2	Tomatoes	0.4	Table grapes	0.2	Peppers	3.1
2.9	UK Adult	1.4	Wine grapes	1.1	Tomatoes	0.2	Cucumbers	2.9
2.9	NL general	1.1	Tomatoes	0.8	Wine grapes	0.3	Cucumbers	2.9
2.7	LT adult	1.6	Tomatoes	1.0	Cucumbers	0.1	Aubergines (egg plants)	2.7
2.4	UK Toddler	1.5	Tomatoes	0.3	Table grapes	0.3	Cucumbers	2.4
2.3	FI adult	1.1	Tomatoes	0.7	Cucumbers	0.4	Wine grapes	2.3
2.2	FR infant	1.7	Courgettes	0.4	Tomatoes	0.1	Table grapes	2.2
1.3	UK Infant	0.9	Tomatoes	0.2	Brussels sprouts	0.0	Melons	1.3

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRls were below the ADI.  
A long-term intake of residues of Fenamiphos 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 leads to an exposure equivalent to 100 % of the ARfD.

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1): 2			No of commodities for which ARfD/ADI is exceeded (IESTI 2): 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 *) **)		
			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)
	Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities		Highest % of ARfD/ADI	Commodities	
	188.1	Melons	0.031 / 0.01	188.1	Melons	0.031 / 0.01	50.3	Watermelons	0.031 / -	50.3	Watermelons	0.031 / -
	151.6	Watermelons	0.031 / 0.02	151.6	Watermelons	0.031 / 0.02	48.9	Melons	0.031 / -	48.9	Melons	0.031 / -
52.4	Table grapes	0.02 / -	52.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -	
50.4	Peppers	0.02 / -	46.8	Cucumbers	0.02 / -	21.6	Courgettes	0.02 / -	19.9	Aubergines (egg plants)	0.02 / -	
46.8	Cucumbers	0.02 / -	36.0	Peppers	0.02 / -	19.9	Aubergines (egg)	0.02 / -	19.0	Wine grapes	0.02 / -	
<b>No of critical MRLs (IESTI 1)</b>			<b>No of critical MRLs (IESTI 2)</b>			<b>No of critical MRLs (IESTI 1)</b>			<b>No of critical MRLs (IESTI 2)</b>			
2			2			2			2			

Processed commodities	No of commodities for which ARfD/ADI is exceeded: ---			No of commodities for which ARfD/ADI is exceeded: ---		
	***)			***)		
			pTMRL/ threshold MRL (mg/kg)			pTMRL/ threshold MRL (mg/kg)
	Highest % of ARfD/ADI	Processed commodities		Highest % of ARfD/ADI	Processed commodities	
	39.5	Grape juice	0.03 / -	4.6	Wine	0.03 / -
27.9	Tomato juice	0.04 / -	3.1	Tomato (preserved- fresh)	0.04 / -	
0.6	Wine	0.03 / -	0.5	Raisins	0.03 / -	
0.5	Grapes (raisins)	0.03 / -				

\*) 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 Fenamiphos IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available. The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 2 commodities.

APPENDIX B.2 – PRIMO INCLUDING SAFE EC MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

Fenamiphos			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0008	ARfD (mg/kg bw):	0.0025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		1      13							
		No of diets exceeding ADI:      ---							
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)		2nd contributor to MS diet (in % of ADI)		3rd contributor to MS diet (in % of ADI)		pTMRs at LOQ (in % of ADI)	
		Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities	Commodity / group of commodities
13.2	WHO Cluster diet B	7.7	Tomatoes	2.2	Wine grapes	1.2	Peppers	13.2	
6.9	FR all population	5.0	Wine grapes	1.1	Tomatoes	0.3	Courgettes	6.9	
6.4	DE child	2.4	Tomatoes	1.6	Table grapes	1.5	Cucumbers	6.4	
6.2	PT General population	3.1	Wine grapes	2.2	Tomatoes	0.5	Peppers	6.2	
6.2	DK child	4.1	Cucumbers	1.3	Tomatoes	0.6	Peppers	6.2	
4.9	IE adult	1.6	Wine grapes	1.0	Tomatoes	0.7	Aubergines (egg plants)	4.9	
4.6	IT kids/toddler	3.6	Tomatoes	0.5	Courgettes	0.2	Aubergines (egg plants)	4.6	
4.5	WHO cluster diet D	2.5	Tomatoes	0.5	Cucumbers	0.5	Wine grapes	4.5	
4.2	WHO cluster diet E	2.0	Wine grapes	1.3	Tomatoes	0.3	Peppers	4.2	
4.1	WHO regional European diet	2.8	Tomatoes	0.4	Peppers	0.3	Wine grapes	4.1	
4.0	IT adult	2.9	Tomatoes	0.5	Courgettes	0.3	Aubergines (egg plants)	4.0	
3.9	DK adult	1.7	Wine grapes	1.0	Tomatoes	0.7	Cucumbers	3.9	
3.8	SE general population 90th percentile	1.9	Tomatoes	0.8	Cucumbers	0.5	Peppers	3.8	
3.4	NL child	1.6	Tomatoes	0.9	Table grapes	0.6	Cucumbers	3.4	
3.4	FR toddler	1.9	Tomatoes	1.2	Courgettes	0.3	Table grapes	3.4	
3.4	UK vegetarian	1.6	Tomatoes	1.0	Wine grapes	0.3	Cucumbers	3.4	
3.2	ES adult	2.0	Tomatoes	0.5	Wine grapes	0.4	Peppers	3.2	
3.1	WHO Cluster diet F	1.7	Tomatoes	0.7	Wine grapes	0.3	Cucumbers	3.1	
3.1	PL general population	2.2	Tomatoes	0.4	Table grapes	0.2	Peppers	3.1	
3.1	ES child	2.5	Tomatoes	0.3	Peppers	0.2	Courgettes	3.1	
2.9	UK Adult	1.4	Wine grapes	1.1	Tomatoes	0.2	Cucumbers	2.9	
2.8	NL general	1.1	Tomatoes	0.8	Wine grapes	0.3	Cucumbers	2.8	
2.7	LT adult	1.6	Tomatoes	1.0	Cucumbers	0.1	Aubergines (egg plants)	2.7	
2.3	UK Toddler	1.5	Tomatoes	0.3	Table grapes	0.3	Cucumbers	2.3	
2.3	FI adult	1.1	Tomatoes	0.7	Cucumbers	0.4	Wine grapes	2.3	
2.2	FR infant	1.7	Courgettes	0.4	Tomatoes	0.1	Table grapes	2.2	
1.2	UK Infant	0.9	Tomatoes	0.2	Brussels sprouts	0.0	Table grapes	1.2	

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

<b>Acute risk assessment /children - refined calculations</b>	<b>Acute risk assessment / adults / general population - refined calculations</b>
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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 leads 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)
	52.4	Table grapes	0.02 / -	52.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -
	50.4	Peppers	0.02 / -	46.8	Cucumbers	0.02 / -	21.6	Courgettes	0.02 / -	19.9	Aubergines (egg plants)	0.02 / -
	46.8	Cucumbers	0.02 / -	36.0	Peppers	0.02 / -	19.9	Aubergines (egg)	0.02 / -	19.0	Wine grapes	0.02 / -
	46.5	Tomatoes	0.02 / -	33.7	Tomatoes	0.02 / -	19.0	Wine grapes	0.02 / -	16.2	Courgettes	0.02 / -
	37.2	Courgettes	0.02 / -	26.6	Courgettes	0.02 / -	15.7	Cucumbers	0.02 / -	15.7	Cucumbers	0.02 / -
	<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---		

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)
	39.5	Grape juice	0.03 / -	4.6	Wine	0.03 / -
	27.9	Tomato juice	0.04 / -	3.1	Tomato (preserved-fresh)	0.04 / -
	0.6	Wine	0.03 / -	0.5	Raisins	0.03 / -
	0.5	Grapes (raisins)	0.03 / -			

\*) 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 Fenamiphos 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.

APPENDIX B.3 – PRIMO INCLUDING SAFE EC MRL PROPOSALS AND ALL CXLS

<b>Fenamiphos</b>			
Status of the active substance:	<b>Included</b>	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
<b>Toxicological end points</b>			
ADI (mg/kg bw/day):	<b>0.0008</b>	ARfD (mg/kg bw):	<b>0.0025</b>
Source of ADI:	<b>EFSA</b>	Source of ARfD:	<b>EFSA</b>
Year of evaluation:	<b>2006</b>	Year of evaluation:	<b>2006</b>

**Chronic risk assessment - refined calculations**

		TMDI (range) in % of ADI minimum - maximum							
		6                      38							
		<b>No of diets exceeding ADI:</b>		---					
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor		2nd contributor to		3rd contributor to		pTMRs at LOQ (in % of ADI)	
		(in % of ADI)	Commodity / group of commodities	MS diet (in % of ADI)	Commodity / group of commodities	MS diet (in % of ADI)	Commodity / group of commodities		
38.2	NL child	18.3	Milk and cream,	7.9	Apples	2.1	Bananas	38.2	
37.7	FR toddler	24.8	Milk and cream,	3.3	Apples	1.9	Tomatoes	37.7	
35.7	DE child	15.1	Apples	8.9	Milk and cream,	2.4	Tomatoes	35.7	
31.7	UK Infant	24.2	Milk and cream,	2.0	Apples	1.8	Bananas	31.7	
25.5	DK child	7.9	Milk and cream,	4.1	Cucumbers	2.9	Apples	25.5	
24.5	FR infant	16.1	Milk and cream,	3.1	Apples	1.7	Courgettes	24.5	
23.3	WHO Cluster diet B	7.7	Tomatoes	2.2	Wine grapes	2.0	Milk and cream,	23.3	
20.8	UK Toddler	12.9	Milk and cream,	2.1	Apples	1.5	Tomatoes	20.8	
20.4	ES child	7.8	Milk and cream,	2.5	Tomatoes	1.8	Bovine	20.4	
17.1	SE general population 90th percentile	7.7	Milk and cream,	2.3	Bananas	1.9	Tomatoes	17.1	
15.4	WHO regional European diet	3.0	Milk and cream,	2.8	Tomatoes	1.8	Swine	15.4	
14.9	IE adult	2.0	Melons	1.7	Milk and cream,	1.6	Wine grapes	14.9	
12.7	WHO cluster diet E	2.0	Wine grapes	1.9	Milk and cream,	1.3	Tomatoes	12.7	
12.3	FR all population	5.0	Wine grapes	1.7	Milk and cream,	1.1	Tomatoes	12.3	
11.9	ES adult	3.1	Milk and cream,	2.0	Tomatoes	1.0	Swine	11.9	
11.9	WHO cluster diet D	3.2	Milk and cream,	2.5	Tomatoes	0.9	Bovine	11.9	
11.7	DK adult	3.4	Milk and cream,	1.7	Wine grapes	1.2	Swine	11.7	
11.7	WHO Cluster diet F	2.5	Milk and cream,	1.7	Tomatoes	1.6	Swine	11.7	
11.3	NL general	4.1	Milk and cream,	1.5	Apples	1.2	Swine	11.3	
10.6	LT adult	2.5	Milk and cream,	2.3	Apples	1.6	Tomatoes	10.6	
8.2	PT General population	3.1	Wine grapes	2.2	Tomatoes	1.3	Apples	8.2	
8.2	FI adult	3.5	Milk and cream,	1.1	Tomatoes	0.7	Cucumbers	8.2	
7.5	UK vegetarian	2.0	Milk and cream,	1.6	Tomatoes	1.0	Wine grapes	7.5	
6.9	UK Adult	1.9	Milk and cream,	1.4	Wine grapes	1.1	Tomatoes	6.9	
6.6	IT kids/toddler	3.6	Tomatoes	1.1	Apples	0.7	Bananas	6.6	
6.4	PL general population	2.6	Apples	2.2	Tomatoes	0.5	Head cabbage	6.4	
5.7	IT adult	2.9	Tomatoes	1.0	Apples	0.5	Courgettes	5.7	

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRs were below the ADI.  
A long-term intake of residues of Fenamiphos 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 leads 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):		
	2			1			---			---		
	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)
	303.4	Melons	0.05 / 0.01	303.4	Melons	0.05 / 0.01	78.9	Melons	0.05 / -	78.9	Melons	0.05 / -
	105.3	Head cabbage	0.05 / 0.04	63.2	Head cabbage	0.05 / -	63.5	Head cabbage	0.05 / -	38.1	Head cabbage	0.05 / -
66.9	Bananas	0.02 / -	52.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -	
52.4	Table grapes	0.02 / -	48.5	Bananas	0.02 / -	21.6	Courgettes	0.02 / -	19.9	Aubergines (egg plants)	0.02 / -	
50.4	Peppers	0.02 / -	46.8	Cucumbers	0.02 / -	19.9	Aubergines (egg)	0.02 / -	19.0	Wine grapes	0.02 / -	
<b>No of critical MRLs (IESTI 1)</b>			2			<b>No of critical MRLs (IESTI 2)</b>			1			

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)
40.8	Apple juice	0.02 / -	5.3	Apple juice	0.02 / -	
39.5	Grape juice	0.03 / -	4.6	Wine	0.03 / -	
27.9	Tomato juice	0.04 / -	3.1	Tomato (preserved-	0.04 / -	
0.6	Wine	0.03 / -	0.5	Raisins	0.03 / -	
0.5	Grapes (raisins)	0.03 / -				

\*) 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 Fenamiphos IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 2 commodities.

APPENDIX B.4 – PRIMO INCLUDING SAFE EC MRL PROPOSALS AND SAFE CXLS

Fenamiphos			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):	0.02	proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0008	ARfD (mg/kg bw):	0.0025
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2006	Year of evaluation:	2006

Chronic risk assessment - refined calculations								
		TMDI (range) in % of ADI minimum - maximum						
		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)
37.6	FR toddler	24.8	Milk and cream,	3.3	Apples	1.9	Tomatoes	37.6
37.6	NL child	18.3	Milk and cream,	7.9	Apples	2.1	Bananas	37.6
35.5	DE child	15.1	Apples	8.9	Milk and cream,	2.4	Tomatoes	35.5
31.5	UK Infant	24.2	Milk and cream,	2.0	Apples	1.8	Bananas	31.5
24.7	DK child	7.9	Milk and cream,	4.1	Cucumbers	2.9	Apples	24.7
24.4	FR infant	16.1	Milk and cream,	3.1	Apples	1.7	Courgettes	24.4
21.9	WHO Cluster diet B	7.7	Tomatoes	2.2	Wine grapes	2.0	Milk and cream,	21.9
20.5	UK Toddler	12.9	Milk and cream,	2.1	Apples	1.5	Tomatoes	20.5
20.0	ES child	7.8	Milk and cream,	2.5	Tomatoes	1.8	Bovine	20.0
16.2	SE general population 90th percentile	7.7	Milk and cream,	2.3	Bananas	1.9	Tomatoes	16.2
14.2	WHO regional European diet	3.0	Milk and cream,	2.8	Tomatoes	1.8	Swine	14.2
12.7	IE adult	1.7	Milk and cream,	1.6	Wine grapes	1.2	Swine	12.7
12.1	WHO cluster diet E	2.0	Wine grapes	1.9	Milk and cream,	1.3	Tomatoes	12.1
11.8	FR all population	5.0	Wine grapes	1.7	Milk and cream,	1.1	Tomatoes	11.8
11.4	DK adult	3.4	Milk and cream,	1.7	Wine grapes	1.2	Swine	11.4
11.4	ES adult	3.1	Milk and cream,	2.0	Tomatoes	1.0	Swine	11.4
11.3	WHO Cluster diet F	2.5	Milk and cream,	1.7	Tomatoes	1.6	Swine	11.3
11.2	WHO cluster diet D	3.2	Milk and cream,	2.5	Tomatoes	0.9	Bovine	11.2
10.9	NL general	4.1	Milk and cream,	1.5	Apples	1.2	Swine	10.9
10.1	LT adult	2.5	Milk and cream,	2.3	Apples	1.6	Tomatoes	10.1
8.1	FI adult	3.5	Milk and cream,	1.1	Tomatoes	0.7	Cucumbers	8.1
8.0	PT General population	3.1	Wine grapes	2.2	Tomatoes	1.3	Apples	8.0
7.1	UK vegetarian	2.0	Milk and cream,	1.6	Tomatoes	1.0	Wine grapes	7.1
6.7	UK Adult	1.9	Milk and cream,	1.4	Wine grapes	1.1	Tomatoes	6.7
6.4	IT kids/toddler	3.6	Tomatoes	1.1	Apples	0.7	Bananas	6.4
5.9	PL general population	2.6	Apples	2.2	Tomatoes	0.4	Table grapes	5.9
5.3	IT adult	2.9	Tomatoes	1.0	Apples	0.5	Courgettes	5.3

**Conclusion:**  
The estimated Theoretical Maximum Daily Intakes (TMDI), based on pTMRLs were below the ADI. A long-term intake of residues of Fenamiphos 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 leads 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)
	66.9	Bananas	0.02 / -	52.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -	25.4	Table grapes	0.02 / -
	52.4	Table grapes	0.02 / -	48.5	Bananas	0.02 / -	21.6	Courgettes	0.02 / -	19.9	Aubergines (egg plants)	0.02 / -
	50.4	Peppers	0.02 / -	46.8	Cucumbers	0.02 / -	19.9	Aubergines (egg)	0.02 / -	19.0	Wine grapes	0.02 / -
	46.8	Cucumbers	0.02 / -	36.0	Peppers	0.02 / -	19.0	Wine grapes	0.02 / -	16.2	Courgettes	0.02 / -
	46.5	Tomatoes	0.02 / -	33.7	Tomatoes	0.02 / -	15.7	Cucumbers	0.02 / -	15.7	Cucumbers	0.02 / -
	<b>No of critical MRLs (IESTI 1)</b>			---			<b>No of critical MRLs (IESTI 2)</b>			---		

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
	IESTI 1	*)	***)	IESTI 2	*)	***)
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	40.8	Apple juice	0.02 / -	5.3	Apple juice	0.02 / -
	39.5	Grape juice	0.03 / -	4.6	Wine	0.03 / -
	27.9	Tomato juice	0.04 / -	3.1	Tomato (preserved-	0.04 / -
	0.6	Wine	0.03 / -	0.5	Raisins	0.03 / -
	0.5	Grapes (raisins)	0.03 / -			

\*) 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 Fenamiphos 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.

APPENDIX C – EXISTING EC MRLS

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenamiphos (sum of fenamiphos and its sulphoxide and sulphone expressed as fenamiphos)
10000	1. FRUIT FRESH OR FROZEN; NUTS	
11000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddock), pomelos, sweeties, tangelo, ugli and other hybrids	0,02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,02*
110030	Lemons (Citron, lemon)	0,02*
110040	Limes	0,02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0,02*
110990	Others	0,02*
12000	(ii) Tree nuts (shelled or unshelled)	0,02*
120010	Almonds	0,02*
120020	Brazil nuts	0,02*
120030	Cashew nuts	0,02*
120040	Chestnuts	0,02*
120050	Coconuts	0,02*
120060	Hazelnuts (Filbert)	0,02*
120070	Macadamia	0,02*
120080	Pecans	0,02*
120090	Pine nuts	0,02*
120100	Pistachios	0,02*
120110	Walnuts	0,02*
120990	Others	0,02*
13000	(iii) Pome fruit	0,02*
130010	Apples (Crabapple)	0,02*
130020	Pears (Oriental pear)	0,02*
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
14000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*
140030	Peaches (Nectarines and similar	0,02*

	hybrids)	
140040	Plums (Damson, greengage, mirabelle)	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	0,02*
151000	(a) Table and wine grapes	0,02*
151010	Table grapes	0,02*
151020	Wine grapes	0,02*
152000	(b) Strawberries	0,02*
153000	(c) Care fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,02*
153030	Raspberries (Wineberries)	0,02*
153990	Others	0,02*
154000	(d) Other small fruit & berries	0,02*
154010	Blueberries (Bilberries, cowberries (red bilberries))	0,02*
154020	Caribberries	0,02*
154030	Cumans (red, black and white)	0,02*
154040	Gooseberries (including hybrids with other berries species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azalea (mediterranean medlar)	0,02*
154080	Elkberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawtooth), hawthorn, service berries, and other tree berries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumikumquats, negamikumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (javan plum), Java apple (water apple), pomelo, rose apple, Brazilian cherry (gumichama), Surinam cherry	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, arbutan	0,02*

	(airy litchi)	
162030	Passion fruit	0,02*
162040	Picky pear (cactus fruit)	0,02*
162050	Star apple	0,02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05
163030	Mangos	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Chirimoya (Custard apple, sugar apple (sweetsop), lilkam and other medium sized Annonaceae)	0,02*
163070	Guava	0,02*
163080	Pineapples	0,02*
163090	Breadfruit (Jackfruit)	0,02*
163100	Durian	0,02*
163110	Soursop (guanabana)	0,02*
163990	Others	0,02*
20000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*
212010	Cassava (Dioscorea, edibe (Japanese taro), tanna)	0,02*
212020	Sweet potatoes	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*
212040	Arrowroot	0,02*
212990	Others	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,02*
213020	Carrots	0,5
213030	Celery	0,02*
213040	Horseradish	0,02*
213050	Jerusalem artichokes	0,02*
213060	Parsnips	0,02*
213070	Parsley root	0,02*
213080	Radishes (Black radish, Japanese	0,02*

	radish, small radish and similar varieties)	
213090	Salsify (Scorzoneria, Spanish salsify (Spanish salsify plant))	0,02*
213100	Swedes	0,02*
213110	Tunips	0,02*
213990	Others	0,02*
220000	(ii) Bulb vegetables	0,02*
220010	Garlic	0,02*
220020	Onions (Silver skin onions)	0,02*
220030	Shallots	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*
220990	Others	0,02*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	0,05
231020	Peppers (Chili peppers)	0,1
231030	Aubergines (egg plants) (Pepino)	0,05
231040	Okra, lady's fingers	0,02*
231990	Others	0,02*
232000	(b) Cucurbitis - edible peel	
232010	Cucumbers	0,05
232020	Gherkins	0,02*
232030	Courgettes (Summer squash, marrow (patisson))	0,05
232990	Others	0,02*
233000	(c) Cucurbitis - inedible peel	
233010	Melons (Kiwano)	0,05
233020	Pumpkins (Winter squash)	0,02*
233030	Watermelons	0,05
233990	Others	0,02*
234000	(d) Sweetcom	0,02*
235000	(e) Other fruiting vegetables	0,02*
240000	(iv) Brassica vegetables	
241000	(a) Flowering brassica	0,02*
241010	Broccoli (Cahitese, Chinese broccoli, Broccoflower)	0,02*
241020	Cauliflower	0,02*
241990	Others	0,02*
242000	(b) Head brassica	
242010	Brussels sprouts	0,05
242020	Head cabbage (Pointed head cabbage, red cabbage, snow cabbage, white cabbage)	0,05
242990	Others	0,02*
243000	(c) Leafy brassica	0,02*
243010	Chinese cabbage (Indian (Chinese)	0,02*



	mustard, pak choi, Chinese flat cabbage (ai gao choi), peking cabbage (pe-sai), cow cabbage)	
24300	Kale (Broccoli (curly kale), collards)	0,02*
24390	Others	0,02*
24400	(d) Kohlrabi	0,02*
25000	(v) Leaf vegetables & fresh herbs	0,02*
25100	(a) Lettuce and other salad plants including Brassicaceae	0,02*
251010	Lamb's lettuce (Italian com salad)	0,02*
251020	Lettuce (Head lettuce, lol rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
251030	Scarlet (brood-leaf endive) (Wild chicory, red-headed chicory, radicchio, cut-leaf endive, sugar loaf)	0,02*
251040	Cress	0,02*
251050	Land cress	0,02*
251060	Rocket, Rucola (Wild rocket)	0,02*
251070	Red mustard	0,02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
25190	Others	0,02*
25200	(b) Spinach & similar (leaves)	0,02*
252010	Spinach (New Zealand spinach, tumipgeers (tumip tops))	0,02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sand glasswort)	0,02*
252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
25290	Others	0,02*
25300	(c) Vine leaves (grape leaves)	0,02*
25400	(d) Watercress	0,02*
25500	(e) Witloof	0,02*
25600	(f) Herbs	0,02*
256010	Chervil	0,02*
256020	Chives	0,02*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, borage, angelica, sweet cicely and other Apiacea)	0,02*
256040	Parsley	0,02*
256050	Sage (Winter savory, summer savory)	0,02*
256060	Rosemary	0,02*
256070	Thyme (majoram, oregano)	0,02*
256080	Basil (Balm leaves, mint, peppermint)	0,02*
256090	Bay leaves (dorel)	0,02*
256100	Tamagori (Fussop)	0,02*

25690	Others	0,02*
26000	(vi) Legume vegetables (fresh)	0,02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yard long beans)	0,02*
260020	Beans (without pods) (Broad beans, Figeolets, jack bean, lima bean, cowpea)	0,02*
260030	Peas (with pods) (Mangout (sugar peas))	0,02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*
260050	Lentils	0,02*
26090	Others	0,02*
27000	(vii) Stem vegetables (fresh)	0,02*
270010	Asparagus	0,02*
270020	Cardoons	0,02*
270030	Celery	0,02*
270040	Fennel	0,02*
270050	Globe artichokes	0,02*
270060	Leek	0,02*
270070	Rhubarb	0,02*
270080	Bambooshoots	0,02*
270090	Palm hearts	0,02*
27090	Others	0,02*
28000	(viii) Fungi	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shiitake)	0,02*
280020	Wild (Chanterelle, Truffle, Morel)	0,02*
28090	Others	0,02*
29000	(ix) Seaweeds	
30000	3. PULSES, DRY	0,02*
300010	Beans (Broad beans, navy beans, figeolets, jack beans, lima beans, field beans, cowpeas)	0,02*
300020	Lentils	0,02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*
300040	Lupins	0,02*
30090	Others	0,02*
40000	4. OIL SEEDS AND OIL FRUITS	
40100	(i) Oil seeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soyabean	0,05*
401080	Mustard seed	0,05*

401090	Cottonseed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hemp seed	0,05*
401150	Castor bean	0,05*
40190	Others	0,05*
40200	(ii) Oil nuts	
402010	Olive for oil production	0,02*
402020	Palm nuts (palm kernels)	0,05*
402030	Palm fruit	0,05*
402040	Kapok	0,05*
40290	Others	0,05*
50000	5. CEREALS	0,02*
500010	Barley	0,02*
500020	Buckwheat	0,02*
500030	Maize	0,02*
500040	Millet (Foxtail millet, teff)	0,02*
500050	Oats	0,02*
500060	Rice	0,02*
500070	Rye	0,02*
500080	Sorghum	0,02*
500090	Wheat (Spelt, Triticale)	0,02*
50090	Others	0,02*
60000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
61000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
62000	(ii) Coffee beans	0,05*
63000	(iii) Herbal infusions (dried)	0,05*
63100	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
63190	Others	0,05*
63200	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
63290	Others	0,05*
63300	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
63390	Others	0,05*
63900	(d) Other herbal infusions	0,05*
64000	(iv) Cocoa (fermented beans)	0,05*

65000	(v) Carb (sorghum bread)	0,05*
70000	7. HOPS (dried), including hoppellets and unconcentrated powder	0,05*
80000	8. SPICES	0,05*
81000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
810040	Coriander seed	0,05*
810050	Cumin seed	0,05*
810060	Dill seed	0,05*
810070	Fennel seed	0,05*
810080	Fenugreek	0,05*
810090	Nutmeg	0,05*
81090	Others	0,05*
82000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Liquorice pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamand	0,05*
82090	Others	0,05*
83000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
83090	Others	0,05*
84000	(iv) Roots and rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horse radish	0,05*
84090	Others	0,05*
85000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
85090	Others	0,05*
86000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
86090	Others	0,05*
87000	(vii) Ail	0,05*
870010	Mace	0,05*
87090	Others	0,05*
90000	9. SUGAR PLANTS	
900010	Sugar beet (root)	0,1
900020	Sugarcane	0,02*
900030	Chicory roots	0,02*
90090	Others	0,02*

100000	10. PRODUCTS OF ANIMAL ORIGIN - TERRESTRIAL ANIMALS	
101000	(i) Meat, preparations of meat, offal, blood, animal fats (fresh, chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals or other processed products such as sausages and food preparations based on these	0,01 *
101100	(a) Swine	0,01 *
101101	Meat	0,01 *
101102	Fat (tissue of lean meat)	0,01 *
101103	Liver	0,01 *
101104	Kidney	0,01 *
101105	Edible offal	0,01 *
101199	Others	0,01 *
101200	(b) Bovine	0,01 *
101201	Meat	0,01 *
101202	Fat	0,01 *
101203	Liver	0,01 *
101204	Kidney	0,01 *
101205	Edible offal	0,01 *
101299	Others	0,01 *
101300	(c) Sheep	0,01 *
101301	Meat	0,01 *
101302	Fat	0,01 *
101303	Liver	0,01 *
101304	Kidney	0,01 *
101305	Edible offal	0,01 *
101399	Others	0,01 *
101400	(d) Goat	0,01 *
101401	Meat	0,01 *
101402	Fat	0,01 *
101403	Liver	0,01 *
101404	Kidney	0,01 *
101405	Edible offal	0,01 *
101499	Others	0,01 *
101500	(e) Horses, asses, mules or hinnies	0,01 *
101501	Meat	0,01 *
101502	Fat	0,01 *
101503	Liver	0,01 *
101504	Kidney	0,01 *
101505	Edible offal	0,01 *
101599	Others	0,01 *
101600	(f) Poultry - chicken, geese, duck, turkey and Guinea fowl, ostrich, pigeon	0,01 *
101601	Meat	0,01 *
101602	Fat	0,01 *
101603	Liver	0,01 *
101604	Kidney	0,01 *
101605	Edible offal	0,01 *

101699	Others	0,01 *
101700	(g) Other farm animals (Rabbit, Kangaroo)	0,01 *
101701	Meat	0,01 *
101702	Fat	0,01 *
101703	Liver	0,01 *
101704	Kidney	0,01 *
101705	Edible offal	0,01 *
101799	Others	0,01 *
102000	(i) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,005 *
102001	Cattle	0,005 *
102002	Sheep	0,005 *
102003	Goat	0,005 *
102004	Horse	0,005 *
102099	Others	0,005 *
103000	(ii) Birds' eggs, fresh preserved or cooked. Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,01 *
103001	Chicken	0,01 *
103002	Duck	0,01 *
103003	Goose	0,01 *
103004	Quail	0,01 *
103099	Others	0,01 *
104000	(iv) Honey (Royal jelly, pollen)	
105000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
106000	(vi) Snails	
107000	(vii) Other terrestrial animal products	

(\*) Indicates lower limit of analytical determination

APPENDIX D – EXISTING CXLs AND RELEVANT DATA FOR RISK ASSESSMENT

Summary of CXLs for fenamiphos in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation				Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation			
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
130010	Apples	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.05 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.01	0.01	7	n.c.	0.01	0.01	n.a.	1	1999	No	All trials conducted in the USA according to appropriate GAP
163020	Bananas	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.05 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.02	0.025	7	n.c.	0.01	0.02	n.a.	1	1999	No	The majority of trials were conducted outside of the EU according to appropriate GAP. Since residues in the whole fruit and pulp were all below the LOQ it was not possible to derive a MPF.
233010	Melons	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.05	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.02	0.02	5	n.c.	0.02	0.05	n.a.	1	1999	No	The majority of trials were conducted outside of the EU according to appropriate GAP. Since residues in the whole fruit and pulp were all below the LOQ it was not possible to derive a MPF.
242010	Brussels sprouts	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.05	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.01	0.01	0	n.c.	0.01	0.01	n.a.	1	1999	No	All trials conducted in the USA according to appropriate GAP.
242020	Head cabbage	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.05	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.01	0.05	5	n.c.	0.01	0.05	n.a.	1	1999	No	All trials conducted in the USA and Australia according to appropriate GAP.
401020	Peanuts	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.05 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	0.01	1	n.c.	0.01	0.01	n.a.	1	1999	No	Trials conducted in the USA and RSA according to appropriate GAP. JMPR states STMR as 0 as no detectable residues were found.
401090	Cotton seed	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.05 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0.01	0.01	1	n.c.	0.01	0.01	n.a.	1	1999	No	All trials conducted outside the EU according to appropriate GAP.

(\*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

n.k.: not known

Summary of CXLs for fenamiphos in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Cattle were fed at 2 mg/kg feed (15N) and residues in tissues and milk were <LOD (0.01 mg/kg and 0.001 mg/kg respectively). Therefore the CXLs have been set at the relevant LOQs.
1011030	Swine liver	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1011040	Swine kidney	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1011050	Swine edible offal	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1012010	Bovine meat	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Cattle were fed at 2 mg/kg feed (15N) and residues in tissues and milk were <LOD (0.01 mg/kg and 0.001 mg/kg respectively). Therefore the CXLs have been set at the relevant LOQs.
1012030	Bovine liver	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1012040	Bovine kidney	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1012050	Bovine edible offal	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1013010	Sheep meat	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Cattle were fed at 2 mg/kg feed (15N) and residues in tissues and milk were <LOD (0.01 mg/kg and 0.001 mg/kg respectively). Therefore the CXLs have been set at the relevant LOQs.
1013030	Sheep liver	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1013040	Sheep kidney	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1013050	Sheep edible offal	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1014010	Goat meat	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Cattle were fed at 2 mg/kg feed (15N) and residues in tissues and milk were <LOD (0.01 mg/kg and 0.001 mg/kg respectively). Therefore the CXLs have been set at the relevant LOQs.
1014030	Goat liver	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1014040	Goat kidney	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1014050	Goat edible offal	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	

Summary of CXLs for fenamiphos in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1015010	Horses, asses, mules or hinnies meat	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Cattle were fed at 2 mg/kg feed (15N) and residues in tissues and milk were <LOD (0.01 mg/kg and 0.001 mg/kg respectively). Therefore the CXLs have been set at the relevant LOQs.
1015030	Horses, asses, mules or hinnies liver	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1015040	Horses, asses, mules or hinnies kidney	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1015050	Horses, asses, mules or hinnies edible offal	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1016010	Poultry meat	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Hens were fed at 2 mg/kg feed (~1000N) and residues in tissues and milk were <LOQ. Therefore the CXLs have been set at the relevant LOQs.
1016030	Poultry liver	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1016040	Poultry kidney	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1016050	Poultry edible offal	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1017010	Other farm animals meat	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Cattle were fed at 2 mg/kg feed (15N) and residues in tissues and milk were <LOD (0.01 mg/kg and 0.001 mg/kg respectively). Therefore the CXLs have been set at the relevant LOQs.
1017030	Other farm animals liver	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1017040	Other farm animals kidney	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1017050	Other farm animals edible offal	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1020010	Cattle milk	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.005 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Cattle were fed at 2 mg/kg feed (15N) and residues in tissues and milk were <LOD (0.01 mg/kg and 0.001 mg/kg respectively). Therefore the CXLs have been set at the relevant LOQs.
1020020	Sheep milk	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.005 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1020030	Goat milk	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.005 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1020040	Horse milk	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	no	0.005 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	
1030000	Birds' eggs	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	n.a.	0.01 *	Sum of fenamiphos and its sulfoxide and sulfone, expressed as fenamiphos	0	n.c.	1999	no	Hens were fed at 2 mg/kg feed (~1000N) and residues in tissues and milk were <LOQ. Therefore the CXLs have been set at the relevant LOQs.

(\*) Indicates the lower limit of analytical quantification.

n.a.: not applicable

n.c.: not considered

## 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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CS	capsule suspension
CXL	codex maximum residue limit
d	day
DAT	days after treatment
DM	dry matter
DT <sub>90</sub>	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EU	European Union
FPD	flame-photometric detection
GAP	good agricultural practice
GLC	gas-liquid chromatography
GR	granule
ha	hectare
hL	hectolitre
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States

NEU	Northern European Union
PF	processing factor
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
PROFile	Pesticide Residues Overview File
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
SC	suspension concentrate
SEU	Southern European Union
STMR	supervised trials median residue
TRR	total radioactive residue