

REASONED OPINION OF EFSA

Modification of the existing MRL for famoxadone in herbal infusions (dried, flowers)¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-368)

Issued on 21 April 2009

SUMMARY

According to Article 6(2) of Regulation (EC) No 396/2005, Germany has made an application to modify the existing MRL for herbal infusions (dried, flowers). The applicant proposes to raise the existing MRL, which is currently set at the analytical limit of quantification of 0.05 mg/kg, to 2 mg/kg. The evaluation report drafted by Germany was forwarded to EFSA on 30 January 2009 according to Article 9 of the Regulation.

Based on the review report prepared by the Commission, the evaluation report of Germany, the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) France under Directive 91/414/EEC and the full report prepared by the ECCO-team at the Pesticides Directorate, York, EFSA derives the following conclusion regarding the application.

The metabolism of famoxadone was investigated for foliar applications close to harvest in grapes, potatoes and wheat. Three crop groups (fruit, root and cereal group) are covered by the available studies. Famoxadone was the main component in all investigated crops. Therefore, the parent compound famoxadone was proposed as a general residue definition for all crop groups for enforcement and risk assessment. An analytical method is available for enforcement of MRLs for famoxadone in herbal infusions.

The available set of residue trials on camomile does not completely fulfil the requirements of draft guidance document SANCO 7525/VI/95-rev. 8 concerning the number of representative trials. However, as the results of the acceptable trials are consistent, they were regarded as sufficient for an MRL proposal.

Confined rotational crop studies show a similar metabolism as in primary crops. On the basis of the results of these studies it is concluded that the currently set MRLs will not be exceeded in rotational crops intended for human consumption after application of famoxadone on camomile according to the critical GAP.

Residues in commodities of animal origin were not assessed in the framework of this application considering that the crop under evaluation is usually not fed to livestock.

¹ For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for famoxadone in herbal infusions (dried). *EFSA Scientific Report* (2009) 274, 1-23

Chronic intake calculations were performed using revision 2 of the EFSA PRIMo. The chronic intake calculations considered all existing MRLs for the active substance. No chronic intake concerns were identified for all available European diets. The potential chronic exposure was not higher than 77% of the ADI. Since no data for the acute intake of herbal infusions (dried, flowers) were reported by Member States, the acute intake calculation is based on a default assumptions (intake of 2 g camomile per day for a child of 10 kg). An estimation of the acute risk for the consumption of herbal teas (flowers) did not reveal potential consumer health risks (0.1 % of the ARfD).

EFSA recommendations resulting from the assessment are summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: famoxadone			
Herbal infusions (dried, flowers)	0.05*	2	The proposed MRL is sufficiently supported by data. No risk for consumers was identified.

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

Key words: Famoxadone, herbal infusions (dried, flowers), MRL application, Regulation (EC) No 396/2005, consumer risk assessment, strobilurins, fungicide

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that where a Member State considers that the modification of an MRL is necessary, that Member State may compile and evaluate an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

In particular, Germany, hereafter referred to as the Evaluating Member State (EMS)², compiled an application to modify the existing MRL of 0.05 mg/kg for the active substance famoxadone in herbal infusions (dried, flowers) to 2 mg/kg. This application was notified to the European Commission and EFSA and subsequently evaluated 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 30 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-368 and the following subject:

- *Famoxadone- Application to modify the existing MRL for famoxadone in herbal infusions (dried, flowers) from 0.05* mg/kg to 2 mg/kg*

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

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

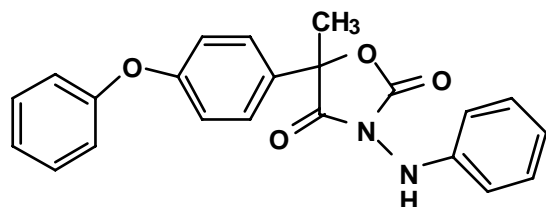
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the data of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 30 April 2009.

² Bundesamt für Verbraucherschutz und Lebensmittelsicherheit - Abteilung 2, Messeweg 11/12, 38104 Braunschweig, Germany

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Famoxadone is the ISO common name for 3-anilino-5-methyl-5-(4-phenoxyphenyl)-2,4-oxazolidinedione (IUPAC).



Famoxadone belongs to the class strobilurin type fungicides. It is a contact fungicide affecting the fungal mitochondrial electrontransport by blocking ubiquinol-cytochrome c oxidoreductase at complex III. It inhibits mycelial growth and spore survival and/or germination. It is effective against *Oomycetes* and *Ascomycetes*.

Famoxadone has been evaluated in the framework of Directive 91/414/EEC as a new active substance with France being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review were applications on grapes, tomatoes, wheat and barley. Outdoor applications close to harvest have been supported. Since EFSA was not yet involved in the peer review, no EFSA conclusion is available for this compound. The peer review for this active substance has been finalised and it has been decided to include famoxadone in Annex I of Directive 91/414/EEC (Commission Directive 2002/64/EC). Only uses as fungicide may be authorized. The inclusion in Annex I entered into force on 1 October 2002.

MRLs for famoxadone were set for the first time by Commission Directive 2004/95/EC and were amended by Directives 2008/17/EC. They were transferred to Annex II of Regulation (EC) No 396/2005 by Regulation (EC) No 149/2008 and were amended by Regulation (EC) No 839/2008. A list of the existing MRLs can be found in Appendix B of this document. Codex Alimentarius Commission has set MRLs for famoxadone for a variety of crops, but not for herbal infusions.

Germany now considers authorizing a use for famoxadone in camomile flowers. A modification of the existing MRL for herbal infusions (dried, flowers) from 0.05 mg/kg* to 2 mg/kg is requested. A detailed overview of the proposed GAP is available in Appendix A to this document. It concerns a maximum of 2 foliar applications at an application rate of 0.113 kg a.s./ha. The treatments are performed close to the harvest with a PHI of 14 days. Although not specified in the GAP summary, it is assumed that the application concerns outdoor uses.

In support of the MRL application an evaluation report has been submitted by Germany (no date). EFSA also relied on the DAR prepared by France under Directive 91/414/EEC (1998), the review report prepared by the Commission (2002) and the full report prepared by the ECCO-team at the Pesticides Directorate, York (2000).

ASSESSMENT

1. Methods of analysis

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

In the DAR (France, 1998) two single residue methods for enforcement of famoxadone in dry crops (cereal grain and straw) have been evaluated. The first method using C18 solid-phase extraction for clean-up and HPLC-UV and LC-MS for the determination of famoxadone was validated at an LOQ of 0.05 mg/kg for cereal grain and straw. The second method uses Florisil for clean-up and GC-NPD for the determination of famoxadone. The LOQ was 0.02 mg/kg for cereal grain and 0.05 mg/kg for cereal straw. According to the DAR, both methods were fully validated. Also validation in independent laboratories has been carried out.

In the meantime also multi-residue methods have been evaluated for the analysis of famoxadone. The EMS refers to the DFG-S19 method with determination by GC-MS and the QuEChERS-method with determination by LC-MS-MS as suitable methods for the determination of famoxadone residues in cereals and other dry crops. For both methods the LOQ is 0.01 mg/kg for these matrices.

Aside from the methods provided by the applicant in the framework of the peer review, laboratories responsible for the official control of MRLs have developed their own methods or have included the active substance in the established multi-residue methods. In the database developed by the Community Reference Laboratories for Residues of Pesticide (CRL, 2009), in total 385 validation datasets have been submitted regarding LC- and GC-methods routinely used for the determination of famoxadone residues in different matrices. An overview is provided in Table 1-1.

Chr	Matrix Type	Level min	Level max	Rec Median	Rec Mean	CV [%]	# of rec	% Rec (70-120%)	# of Labs
GC	Acidic	0,1	0,75	115	113	14,3	6	67	2
GC	Dry (cereals, dry pulses)	0,1	0,1	116	115	13,7	10	60	1
GC	Other	0,25	0,25		113		1	100	1
GC	Sugar containing	0,1	0,25	101	99	9	6	100	2
GC	Water containing	0,025	0,75	104	105	15,3	30	83	4
LC	Acidic	0,01	0,1	99	100	12	76	95	6
LC	Dry (cereals, dry pulses)	0,01	0,1	102	100	12,6	47	94	4
LC	Other	0,025	0,025		34		1	0	1
LC	Sugar containing	0,01	0,1	102	101	8,7	51	100	5
LC	Water containing	0,01	0,1	94	88	28,1	157	81	6

Although no specific methods for camomile are available, it is concluded that sufficiently validated methods are available to enforce famoxadone MRLs in camomile.

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

An analytical method for the enforcement of famoxadone residues in food of animal origin is not relevant for the current application as the crop under evaluation is usually not fed to animals and residues in animal commodities resulting from the proposed GAPs are therefore not expected.

2. Mammalian toxicology

The toxicological properties of famoxadone have been evaluated in the DAR prepared under Directive 91/414/EEC (France, 2002) and an ADI has been derived. The proposal of the RMS has been revised and an ARfD has been derived during the peer review (European Commission, 2002). The reference values derived are summarised 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
Famoxadone					
ADI	COM	2002	0.012	1 year dog study	100
ARfD	COM	2002	0.2	14 day oral mouse study	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 studies on primary crops have been evaluated in the DAR (France, 1998). Grapes, potatoes and wheat have been treated with foliar applications of famoxadone labelled in the phenoxyphenyl- and the phenylamine-ring, respectively. The application rates were higher than the intended application rate for camomile (3-4 times the seasonal application rate).

Metabolism was shown to be moderate in grapes (leaves and berries) and potatoes (foliage and tubers), but more extensive in wheat (straw). Residues in grain were too low to allow the identification of metabolites and not detectable in potato tubers. Famoxadone was the main component of radioactive residues in all plant samples accounting for 10% (wheat straw) to 90% (grape foliage and berries) of the TRR. The metabolism was shown to proceed along the following pathways: hydroxylation of famoxadone followed in some cases by formation of conjugates, opening of the oxazolidinedione ring and subsequent formation of 4-phenoxyacetophenon and cleavage of the N-N-bond. Whereas hydroxylation was the main route of metabolism in wheat, only hydrolysis products were found in grapes and potato samples.

The evaluated studies cover cereals, fruits and root crops. All metabolites identified in primary and rotational crops with the exception of a malonyl glucose conjugate of hydroxylated famoxadone were also found in the rat metabolism. As famoxadone was the only component found in concentrations above 10% of TRR in crop samples in the metabolism studies the following residue definitions for enforcement and risk assessment were proposed for all crop groups: famoxadone.

Analytical methods are available for enforcement of famoxadone in the crop under consideration for this application (see also section 1.1).

3.1.1.2. Magnitude of residues

A total of four supervised residue trials on wild camomile carried out in Northern Europe in 2004 are reported in the evaluation report of Germany (no date). All trials were carried out with the critical application rate. However, in one trial samples were taken at a significantly longer PHI (26 days instead of 14 days). Since the results of the three representative trials are consistent and the crop under consideration is of minor importance for the human diet (“very minor crop”), an MRL on the basis of the results of these trials is proposed. However, it is noted that according to draft guidance document SANCO 7525/VI/95–rev.8 (1 February 2008), at least four trials supporting the critical GAP and trials from different growing seasons should be available for the proposal of an MRL for a minor crop.

Extrapolation from residue trials on camomile to the whole group of herbal infusions (dried, flowers) is possible.

According to the DAR (France, 1998) storage stability of famoxadone residues has been demonstrated for a period of 18 Months at -20 °C in dry crops (cereal grain and straw). Information concerning the duration of storage of samples before analysis is included only for one of the relevant residue trials in the evaluation prepared by Germany (2008). The storage time was 18 months in this case and the trial is therefore supported by the stability study. No information on the storage time is available to EFSA for the other two trials.

Information if the analytical methods used in the residue trials were demonstrated to be valid is not available to EFSA.

The results of the residue trials, as well as the derived MRL proposals and values used in the risk assessment are summarised in Table 3-1. The MRL proposals were derived using the statistical methodologies agreed at European level. It is concluded that it is appropriate to raise for the MRL for herbal infusions (dried, flowers) from 0.05 * mg/kg to 2 mg/kg.

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

Commodity	Region ^(a)	Outdoor /Indoor	Individual trial results (mg/kg)		STM ^R (mg/kg) ^(b)	HR (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement	Risk assessment					
Residue definition for enforcement and risk assessment: famoxadone									
Wild Camomile	NEU	Outdoor	0.43; 0.49; 0.85 (1)	0.43; 0.49; 0.85 (1)	0.49	0.85	2	1	Rmax = 2.33 Rber = 1.70

(1) Results of a further trial (<0.01 mg/kg) were excluded from the data set as samples were taken at a significantly longer PHI than specified in the GAP as critical PHI.

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

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

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

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

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

3.1.1.3. Effect of industrial processing and/or household preparation

Studies on the effect of processing on the nature of residues are not available. The DAR relied on the results of hydrolysis studies carried out at 25 °C (France, 1998). These studies showed that famoxadone is hydrolysed relatively quickly with DT₅₀ values of 41 days, 2 days and 1.5 h at pH 5, 7 and 9 respectively. As hydrolysis is also a pathway of the metabolism in animals, most of the metabolites were found in the rat metabolism studies.

Camomile is dried at moderate temperatures. Therefore, the results of the metabolism on wheat straw can be regarded as representative for herbal infusions (dried, flowers).

Herbal infusions are consumed only in small amounts and no intake values for the acute or chronic risk assessment are available. Therefore, studies on the effect of processing on the levels of residues are not required.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Unlike the other flowers used for herbal infusions, camomile is an annual crop and therefore rotation with other crops is possible. Laboratory degradation studies in soil show DT₉₀ values for famoxadone up to 248 days (France, 1998). Field degradation studies are not available. Therefore, confined rotational crop studies are required.

3.1.2.2. Nature of residues

Confined rotational crop studies are reported in the DAR (France 1998). Famoxadone was applied to bare soil at a rate of 400 g a.i./ha which is approximately two times the critical seasonal application rate on camomile. Leafy, root and cereal crops (lettuce, sugar beets and wheat) were planted at plant back intervals of 30 and for cereals also after 120 days. Studies were performed using famoxadone radiolabelled in the phenoxyphenyl- and the phenylamine-ring respectively.

Levels of total radioactive residues found in the crops were low. Famoxadone was the main compound in most of the samples analysed for metabolites. Hydroxylation and conjugation products of famoxadone, which were also found in primary crops (wheat straw), were the only metabolites identified in rotational crops.

On the basis of the results of the rotational crop study famoxadone levels of maximum 0.02 mg/kg are expected in parts intended for human consumption of leafy, root and cereal crops grown in rotation with camomile after application of famoxadone with the critical application rate. These results apply for a plant-back interval of 30 days, which is rather unlikely. MRLs for famoxadone are currently set at 0.02 mg/kg or higher (Appendix B).

3.1.2.3. Magnitude of residues

No studies on the magnitude of residues of famoxadone are required, as no exceedence of the MRLs in parts intended for human consumption of rotational crops is expected after application of famoxadone on camomile according to the critical GAP.

3.2. Nature and magnitude of residues in livestock

Occurrence of famoxadone residues in food of animal origin was not further considered in the framework of this application. The crop under evaluation is usually not fed to animals and residues in animal commodities resulting from the reported GAPs are therefore not expected.

4. Consumer risk assessment

Chronic and acute intake calculations were carried out using revision 2 of the EFSA PRIMo. The input values for the crop under assessment for this application are summarized in Table 4-1. For all remaining commodities chronic exposure calculations have been conducted using the existing MRLs as input values (Appendix B).

The results of the intake calculations are reported in Appendix C to this document. Intake calculations for all European diets resulted in a chronic exposure not higher than 77% of the ADI. It should be noted that consumption data for the chronic intake of herbal infusions (dried, flowers) are only available for one diet (German child). In this diet, the contribution of herbal infusions to the total intake was insignificant (<0.2% of the ADI).

Consumption data for the acute intake of herbal infusions (dried, flowers) are not available. Assuming that a child with a body weight of 10 kg consumes 2 g of herbal infusions per day (equivalent to the weight of a tea-bag) the intake corresponds to 0.1% of the ARfD. In other terms, it means that the ARfD would be fully exhausted if a child of 10 kg weight consumes herbal infusions prepared from 1000 g dried flower within one day. It can therefore be concluded that the use of famoxadone on camomile and the setting of an MRL of 2 mg/kg would not lead to an acute consumer risk.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: famoxadone				
Herbal infusions (dried, flowers)	0.49	STMR	0.85	HR
Other crops	MRLs		Not relevant	

CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(2) of Regulation (EC) No 396/2005, Germany has made an application to modify the existing MRL for herbal infusions (dried, flowers). The applicant proposes to raise the existing MRL, which is currently set at the analytical limit of quantification of 0.05 mg/kg, to 2 mg/kg. The evaluation report drafted by Germany was forwarded to EFSA on 30 January 2009 according to Article 9 of the Regulation.

Based on the review report prepared by the Commission, the evaluation report of Germany, the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) France under Directive 91/414/EEC and the full report prepared by the ECCO-team at the Pesticides Directorate, York, EFSA derives the following conclusion regarding the application.

The metabolism of famoxadone was investigated for foliar applications close to harvest in grapes, potatoes and wheat. Three crop groups (fruit, root and cereal group) are covered by the available studies. Famoxadone was the main component in all investigated crops. Therefore, the parent compound famoxadone was proposed as a general residue definition for all crop groups for enforcement and risk assessment. An analytical method is available for enforcement of MRLs for famoxadone in herbal infusions.

The available set of residue trials on camomile does not completely fulfil the requirements of draft guidance document SANCO 7525/VI/95-rev. 8 concerning the number of representative trials. However, as the results of the acceptable trials are consistent, they were regarded as sufficient for an MRL proposal.

Confined rotational crop studies show a similar metabolism as in primary crops. On the basis of the results of these studies it is concluded that the currently set MRLs will not be exceeded in rotational crops intended for human consumption after application of famoxadone on camomile according to the critical GAP.

Residues in commodities of animal origin were not assessed in the framework of this application considering that the crop under evaluation is usually not fed to livestock.

Chronic intake calculations were performed using revision 2 of the EFSA PRIMo. The chronic intake calculations considered all existing MRLs for the active substance. No chronic intake concerns were identified for all available European diets. The potential chronic exposure was not higher than 77% of the ADI. Since no data for the acute intake of herbal infusions (dried, flowers) were reported by Member States, the acute intake calculation is based on a default assumptions (intake of 2 g camomile per day for a child of 10 kg). An estimation of the acute risk for the consumption of herbal teas (flowers) did not reveal potential consumer health risks (0.1 % of the ARfD).

EFSA recommendations resulting from the assessment are summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Enforcement residue definition: famoxadone			
Herbal infusions (dried, flowers)	0.05*	2	The proposed MRL is sufficiently supported by data. No risk for consumers was identified.

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

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report submitted by Germany (no date): ‘Health assessment report MRL-proposal for famoxadone on camomile flowers’ and ‘Famoxadone – proposal to change a harmonised MRL’.

REFERENCES

- France. Draft Assessment Report on famoxadone prepared under Directive 91/414/EEC (August, 1998).
- ECCO-team at the Pesticides Safety Directorate, York. Full report on famoxadone, 22 March 2000.
- European Commission, 2002. Review report for the active substance famoxadone; 6505/VI/99-final, 18 September 2002

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Federal Office for Consumer protection and Food Safety
 Division 2 – Plant Protection Product – Section 207
 D-38104 Braunschweig, Messeweg 11 – 12

Date: 2008-AUG-15

Country: Federal Republic of Germany

Pesticides(s) (common name(s)) : Famoxadone
 EEC, CIPAC and CCPR No(s). : EQUATION PRO
 Main uses e.g.. insecticide, fungicide : Fungicide
 Applicant: : Landesanstalt für Landwirtschaft, Gartenbau und Forsten, Dezernat 23, Bernburg (Sachsen-Anhalt)

Crop and/or situation	F, G or I	Pest or group of pests controlled (c)	Formulation rate per treatment		Application			Application rate per treatment			PHI (days)	Remarks:
			Type	Conc. of a.i.	method, kind	growth stage	number (range)	kg ai./hl	water l/ha	kg ai./ha		
(a)	(b)		(d-f)	(i)	(f-h)	(j)					(k)	(l)
Wild Camomile		Downy mildew, perenosporaceae	WG	225 g/kg	Spraying	At the beginning of infestation and/or when first symptoms appear	2; 2	0.028 – 0.038	300 - 400	0.113	14	

- Remarks:
- (a) In case of group of crops the Codex classification should be used
 - (b) Outdoor or field uses (F), glasshouse application (G) or indoor application (I)
 - (c) e.g. biting and sucking insects, soil born insects, foliar fungi
 - (d) Suspension concentration (= flowable concentrate) (SC)
 - (e) Use CIPAC/FAO codes were appropriate
 - (f) All abbreviations used must be explained
 - (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
 - (h) Kind, overall, broadcast, aerial spraying, row, individual plant, between the plants
 - (i) g/kg or g/l
 - (j) Growth stage at last treatment
 - (k) PHI = Pre-harvest interval
 - (l) Remarks may include: Extent of use/economic importance/restrictions (e.g. feeding, grazing)/minimal intervals between applications

APPENDIX B – LIST OF EXISTING EC MRLs

Pesticide residues and maximum residue levels (mg/kg)

(*) Indicates lower limit of analytical determination

Pesticides - Web Version - EU MRLs (File created on 20/03/2009 17:33)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,02*
110010	Grapefruit (Shaddocks, 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*
120000	(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*
130000	(iii) Pome fruit	0,02*
130010	Apples (Crab apple)	0,02*
130020	Pears (Oriental pear)	0,02*
130030	Quinces	0,02*
130040	Medlar	0,02*
130050	Loquat	0,02*
130990	Others	0,02*
140000	(iv) Stone fruit	0,02*
140010	Apricots	0,02*
140020	Cherries (sweet cherries, sour cherries)	0,02*
140030	Peaches (Nectarines and similar hybrids)	0,02*
140040	Plums (Damson, greengage, mirabelle)	0,02*
140990	Others	0,02*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2
151010	Table grapes	2
151020	Wine grapes	2

Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone
152000	(b) Strawberries	0,02*
153000	(c) Cane fruit	0,02*
153010	Blackberries	0,02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	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	Cranberries	0,02*
154030	Currants (red, black and white)	0,02*
154040	Gooseberries (Including hybrids with other ribes species)	0,02*
154050	Rose hips	0,02*
154060	Mulberries (arbutus berry)	0,02*
154070	Azarole (mediterranean medlar)	0,02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sawallowthorn), hawthorn, service berries, and other treeberries)	0,02*
154990	Others	0,02*
160000	(vi) Miscellaneous fruit	0,02*
161000	(a) Edible peel	0,02*
161010	Dates	0,02*
161020	Figs	0,02*
161030	Table olives	0,02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,02*
161050	Carambola (Bilimbi)	0,02*
161060	Persimmon	0,02*
161070	Jambolan (java plum) (Java apple (water apple), pommerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,02*
161990	Others	0,02*
162000	(b) Inedible peel, small	0,02*
162010	Kiwi	0,02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,02*
162030	Passion fruit	0,02*
162040	Prickly 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 mammey sapote)	0,02*
162990	Others	0,02*
163000	(c) Inedible peel, large	0,02*
163010	Avocados	0,02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,02*
163030	Mangoes	0,02*
163040	Papaya	0,02*
163050	Pomegranate	0,02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,02*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone	Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone
163070	Guava	0,02*	233000	(c) Cucurbits-inedible peel	
163080	Pineapples	0,02*	233010	Melons (Kiwano)	0,3
163090	Bread fruit (Jackfruit)	0,02*	233020	Pumpkins (Winter squash)	0,02*
163100	Durian	0,02*	233030	Watermelons	0,02*
163110	Soursop (guanabana)	0,02*	233990	Others	0,02*
163990	Others	0,02*	234000	(d) Sweet corn	0,02*
200000	2. VEGETABLES FRESH OR FROZEN		239000	(e) Other fruiting vegetables	0,02*
210000	(i) Root and tuber vegetables	0,02*	240000	(iv) Brassica vegetables	0,02
211000	(a) Potatoes	0,02*	241000	(a) Flowering brassica	0,02*
212000	(b) Tropical root and tuber vegetables	0,02*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,02*	241020	Cauliflower	0,02*
212020	Sweet potatoes	0,02*	241990	Others	0,02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,02*	242000	(b) Head brassica	0,02*
212040	Arrowroot	0,02*	242010	Brussels sprouts	0,02*
212990	Others	0,02*	242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,02*
213000	(c) Other root and tuber vegetables except sugar beet	0,02*	242990	Others	0,02*
213010	Beetroot	0,02*	243000	(c) Leafy brassica	0,02*
213020	Carrots	0,02*	243010	Chinese cabbage (Indian (Chinese) mustard, pak choy, Chinese flat cabbage (tai goo choy), peking cabbage (pe-tsai), cow cabbage)	0,02*
213030	Celeriac	0,02*	243020	Kale (Borecole (curly kale), collards)	0,02*
213040	Horseradish	0,02*	243990	Others	0,02*
213050	Jerusalem artichokes	0,02*	244000	(d) Kohlrabi	0,02*
213060	Parsnips	0,02*	250000	(v) Leaf vegetables & fresh herbs	0,02*
213070	Parsley root	0,02*	251000	(a) Lettuce and other salad plants including Brassicaceae	0,02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,02*	251010	Lamb's lettuce (Italian cornsalad)	0,02*
213090	Salsify (Scorzoneria, Spanish salsify (Spanish oysterplant))	0,02*	251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,02*
213100	Swedes	0,02*	251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leaf endive, sugar loaf)	0,02*
213110	Tumips	0,02*	251040	Cress	0,02*
213990	Others	0,02*	251050	Land cress	0,02*
220000	(ii) Bulb vegetables	0,02*	251060	Rocket, Rucola (Wild rocket)	0,02*
220010	Garlic	0,02*	251070	Red mustard	0,02*
220020	Onions (Silverskin onions)	0,02*	251080	Leaves and sprouts of Brassica spp (Mizuna)	0,02*
220030	Shallots	0,02*	251990	Others	0,02*
220040	Spring onions (Welsh onion and similar varieties)	0,02*	252000	(b) Spinach & similar (leaves)	0,02*
220990	Others	0,02*	252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,02*
230000	(iii) Fruiting vegetables		252020	Purslane (Winter purslane (miner' s lettuce), garden purslane, common purslane, sorrel, glasswort)	0,02*
231000	(a) Solanacea		252030	Beet leaves (chard) (Leaves of beetroot)	0,02*
231010	Tomatoes (Chery tomatoes,)	1	252990	Others	0,02*
231020	Peppers (Chilli peppers)	0,02*	253000	(c) Vine leaves (grape leaves)	0,02*
231030	Aubergines (egg plants) (Pepino)	1	254000	(d) Water cress	0,02*
231040	Okra, lady' s fingers	0,02*	255000	(e) Witloof	0,02*
231990	Others	0,02*	256000	(f) Herbs	0,02*
232000	(b) Cucurbits - edible peel	0,2	256010	Chervil	0,02*
232010	Cucumbers	0,2			
232020	Gherkins	0,2			
232030	Courgettes (Summer squash, marrow (patisson))	0,2			
232990	Others	0,2			

Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone	Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone
256020	Chives	0,02*	401030	Poppy seed	0,05*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,02*	401040	Sesame seed	0,05*
256040	Parsley	0,02*	401050	Sunflower seed	0,05*
256050	Sage (Winter savory, summer savory,)	0,02*	401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
256060	Rosemary	0,02*	401070	Soya bean	0,05*
256070	Thyme (marjoram, oregano)	0,02*	401080	Mustard seed	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,02*	401090	Cotton seed	0,05*
256090	Bay leaves (laurel)	0,02*	401100	Pumpkin seeds	0,05*
256100	Tarragon (Hyssop)	0,02*	401110	Safflower	0,05*
256990	Others	0,02*	401120	Borage	0,05*
260000	(vi) Legume vegetables (fresh)	0,02*	401130	Gold of pleasure	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,02*	401140	Hempseed	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,02*	401150	Castor bean	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,02*	401990	Others	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,02*	402000	(ii) Oilfruits	
260050	Lentils	0,02*	402010	Olives for oil production	0,02*
260990	Others	0,02*	402020	Palm nuts (palmoil kernels)	0,05*
270000	(vii) Stem vegetables (fresh)	0,02*	402030	Palmfruit	0,05*
270010	Asparagus	0,02*	402040	Kapok	0,05*
270020	Cardoons	0,02*	402990	Others	0,05*
270030	Celery	0,02*	500000	5. CEREALS	
270040	Fennel	0,02*	500010	Barley	0,02*
270050	Globe artichokes	0,02*	500020	Buckwheat	0,02*
270060	Leek	2	500030	Maize	0,02*
270070	Rhubarb	0,02*	500040	Millet (Foxtail millet, teff)	0,02*
270080	Bamboo shoots	0,02*	500050	Oats	0,2
270090	Palm hearts	0,02*	500060	Rice	0,02*
270990	Others	0,02*	500070	Rye	0,02*
280000	(viii) Fungi	0,02*	500080	Sorghum	0,02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,02*	500090	Wheat (Spelt Triticale)	0,02*
280020	Wild (Chanterelle, Truffle, Morel,)	0,02*	500990	Others	0,02*
280990	Others	0,02*	600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
290000	(ix) Sea weeds		610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*
300000	3. PULSES, DRY	0,02*	620000	(ii) Coffee beans	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,02*	630000	(iii) Herbal infusions (dried)	0,05*
300020	Lentils	0,02*	631000	(a) Flowers	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,02*	631010	Camomille flowers	0,05*
300040	Lupins	0,02*	631020	Hybiscus flowers	0,05*
300990	Others	0,02*	631030	Rose petals	0,05*
400000	4. OILSEEDS AND OILFRUITS		631040	Jasmine flowers	0,05*
401000	(i) Oilseeds	0,05*	631050	Lime (linden)	0,05*
401010	Linseed	0,05*	631990	Others	0,05*
401020	Peanuts	0,05*	632000	(b) Leaves	0,05*
			632010	Strawberry leaves	0,05*
			632020	Rooibos leaves	0,05*
			632030	Maté	0,05*
			632990	Others	0,05*
			633000	(c) Roots	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(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*
810990	Others	0,05*
820000	(ii) Fruits and berries	0,05*
820010	Allspice	0,05*
820020	Anise pepper (Japan 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	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Tumeric (Curcuma)	0,05*
840040	Horseradish	0,05*
840990	Others	0,05*
850000	(v) Buds	0,05*
850010	Cloves	0,05*
850020	Capers	0,05*
850990	Others	0,05*
860000	(vi) Flower stigma	0,05*
860010	Saffron	0,05*
860990	Others	0,05*
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone
900000	9. SUGAR PLANTS	0,02*
900010	Sugar beet (root)	0,02*
900020	Sugar cane	0,02*
900030	Chicory roots	0,02*
900990	Others	0,02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,05*
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Famoxadone
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) 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	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

Substance	Legislation	Entry in to force
Famoxadone	Reg. (EC) No 839/2008	01/09/2008 8

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Famoxadone			
Status of the active substance:		Code no.	
LOQ (mg/kg bw): 0.02		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day): 0.012		ARfD (mg/kg bw): 0.2	
Source of ADI: COM		Source of ARfD: COM	
Year of evaluation: 2002		Year of evaluation: 2002	

Explain choice of toxicological reference values.

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

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum						
		10 77						
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)		pTMRLs 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	
76.6	FR all population	66.7	Wine grapes	3.6	Tomatoes	1.8	Table grapes	1.4
74.6	WHO Cluster diet B	29.9	Wine grapes	25.7	Tomatoes	5.8	Table grapes	5.0
56.8	PT General population	41.5	Wine grapes	7.5	Tomatoes	4.6	Table grapes	2.7
43.6	DE child	21.2	Table grapes	8.0	Tomatoes	6.0	Milk and cream,	5.5
41.2	WHO cluster diet E	26.8	Wine grapes	4.4	Tomatoes	2.6	Table grapes	2.9
41.0	IE adult	20.8	Wine grapes	4.3	Table grapes	3.3	Tomatoes	4.6
38.2	NL child	12.7	Table grapes	12.2	Milk and cream,	5.2	Tomatoes	5.1
33.3	DK adult	23.2	Wine grapes	3.4	Tomatoes	2.2	Milk and cream,	1.2
32.6	FR toddler	16.5	Milk and cream,	6.4	Tomatoes	3.5	Table grapes	3.8
26.2	UK Adult	18.1	Wine grapes	3.6	Tomatoes	1.2	Milk and cream,	1.8
25.9	UK Toddler	8.6	Milk and cream,	4.9	Tomatoes	4.1	Table grapes	6.6
25.6	UK Infant	16.1	Milk and cream,	3.1	Tomatoes	1.7	Sugar beet (root)	4.4
25.6	WHO cluster diet D	8.4	Tomatoes	6.0	Wine grapes	3.2	Table grapes	2.9
24.4	WHO Cluster diet F	9.9	Wine grapes	5.7	Tomatoes	1.9	Table grapes	2.4
24.4	UK vegetarian	13.6	Wine grapes	5.2	Tomatoes	1.4	Milk and cream,	2.0
24.1	NL general	10.5	Wine grapes	3.8	Table grapes	3.6	Tomatoes	2.1
23.7	WHO regional European diet	9.2	Tomatoes	3.8	Wine grapes	2.6	Table grapes	2.4
22.2	DK child	5.3	Milk and cream,	4.4	Tomatoes	3.0	Table grapes	3.3
20.2	ES adult	6.9	Wine grapes	6.5	Tomatoes	2.1	Milk and cream,	1.7
19.7	ES child	8.2	Tomatoes	5.2	Milk and cream,	0.7	Wheat	2.6
17.9	FR infant	10.7	Milk and cream,	1.3	Table grapes	1.2	Tomatoes	2.7
17.5	IT kids/toddler	11.9	Tomatoes	1.8	Table grapes	1.1	Wheat	2.4
16.6	SE general population 90th percentile	6.4	Tomatoes	5.2	Milk and cream,	0.7	Potatoes	2.9
15.2	IT adult	9.7	Tomatoes	2.2	Table grapes	0.9	Aubergines (egg plants)	1.7
14.4	PL general population	7.4	Tomatoes	5.3	Table grapes	0.6	Potatoes	1.4
13.5	FI adult	5.1	Wine grapes	3.6	Tomatoes	2.4	Milk and cream,	1.0
10.4	LT adult	5.2	Tomatoes	1.7	Milk and cream,	0.7	Cucumbers	1.5

Conclusion:

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations
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The acute risk assessment is based on the ARfD.

For each commodity the calculation is based on the highest reported MS consumption per kg bw and the corresponding unit weight from the MS with the critical consumption. If no data on the unit weight was available from that MS an average European unit weight was used for the IESTI calculation.

In the IESTI 1 calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.

In the IESTI 2 calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variability factor of 3.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):		
	---			---			---			---		
	IESTI 1	*)	**)	IESTI 2	*)	**)	IESTI 1	*)	**)	IESTI 2	*)	**)
	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
	0.1	Camomile flowers	0.85 / -	0.1	Camomile flowers	0.85 / -						
	No of critical MRLs (IESTI 1)			---			No of critical MRLs (IESTI 2)			---		

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
		***)			***)	
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)
	32.9	Grape juice	2 / -	3.9	Wine	2 / -
	8.7	Tomato juice	1 / -	1.0	Tomato (preserved-	1 / -
	0.5	Apple juice	0.02 / -	0.4	Raisins	2 / -
	0.5	Orange juice	0.02 / -	0.1	Orange juice	0.02 / -
	0.5	Wine	2 / -	0.1	Apple juice	0.02 / -

*) The results of the IESTI calculations are reported for at least 5 commodities. If the ARfD is exceeded for more than 5 commodities, all IESTI values > 90% of ARfD are reported.

**) pTMRL: provisional temporary MRL

***) pTMRL: provisional temporary MRL for unprocessed commodity

Conclusion:

For Famoxadone IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.

No exceedance of the ARfD/ADI was identified for any unprocessed commodity.

For processed commodities, no exceedance of the ARfD/ADI was identified.

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DT ₅₀	period required for 50 percent hydrolysis
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
GAP	good agricultural practice
GC	gas chromatography
ha	hectare
HPLC	high performance liquid chromatography
HR	highest residue
LC	liquid chromatography
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	mass selective detector
NEU	Northern European Union
PHI	pre harvest interval
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
STMR	supervised trials median residue
TRR	total radioactive residue
UV	ultra-violet detection