

REASONED OPINION OF EFSA

Modification of the existing MRL for fenbutatin oxide in tomatoes¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00208)

Issued on 16 April 2009

SUMMARY

Belgium received an application from BASF Agro BV to modify the existing MRL for fenbutatin oxide in tomatoes. The authorized GAP in Belgium is no longer compliant with the existing MRL for fenbutatin oxide in tomatoes since new trials are available. Therefore Belgium considers raising the current MRL of 1 mg/kg to 2 mg/kg. Belgium as the Evaluating Member State (EMS) drafted an evaluation report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA conclusions for this MRL application are based on the evaluation report prepared by the EMS and the Draft Assessment Report prepared by Belgium in the framework of Directive 91/414/EEC.

It should be noted that fenbutatin oxide was included in stage three of the peer review under Directive 91/414/EEC and voluntarily withdrawn by the notifier during the peer review. Therefore the active substance is currently not included in Annex I to that directive but a resubmission is expected. Awaiting the resubmission process to be finalized for this active substance, the conclusions made in this reasoned opinion should be considered as provisional.

The nature of fenbutatin oxide was investigated in a metabolism study on apples covering fruits and fruiting vegetables. It was concluded that metabolism of fenbutatin oxide in fruits and fruiting vegetables is sufficiently addressed and a residue definition for enforcement and risk assessment for this crop category was proposed as fenbutatin oxide (parent only).

Submitted supervised residues field trials indicate that the current MRL of 1 mg/kg for tomatoes does not accommodate the already authorized GAP in Belgium and a higher MRL of 2 mg/kg would be necessary. Adequate analytical methods are available for the enforcement of the proposed MRL of fenbutatin oxide in tomatoes.

The occurrence of fenbutatin oxide or its metabolites in rotational crops was also investigated. Even though the need for additional rotational crop studies was identified in the DAR and no conclusion on the nature of fenbutatin oxide residues in rotational crops was taken, EFSA

¹ For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for fenbutatin oxide in tomatoes. *EFSA Scientific Report* (2009) 268, 1-24

concludes that the parent fenbutatin oxide can be provisionally considered as the main compound of concern in rotational crops. Considering that the proposed application rates with regard to the current MRL application are significantly lower and that a part of the applied substance is intercepted by the treated crop, it is also concluded that fenbutatin oxide residues are not expected in rotational or succeeding crops provided that the active substance is applied according to the proposed GAP.

The effect of processing on the magnitude of fenbutatin oxide was investigated in the DAR and processing factors for tomatoes were derived. With regard to the current application EFSA is not proposing processing factors for enforcement because the nature of fenbutatin oxide residues in processed commodities is not sufficiently elucidated. Moreover, the contribution of tomatoes to a total dietary intake is not exceeding 1.3% of the ADI.

Residues in commodities of animal origin were not assessed in the framework of this application considering that tomatoes are not fed to livestock.

Chronic intake calculations were performed with revision 2 of the EFSA PRIMo, using the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 and the STMR value derived for the intended use of fenbutatin oxide on tomatoes. For refined intake calculations EFSA used the STMR values as obtained for pome fruit and citrus fruit in the DAR. No chronic consumer intake concerns were identified. The highest contribution of tomatoes to the dietary intake was 1.3 % of the ADI for the WHO Cluster diet B. No acute intake calculations were performed since no ARfD value for fenbutatin oxide is established.

EFSA concludes that the authorized use of fenbutatin oxide on tomatoes is acceptable with regard to consumer safety awaiting the resubmission process of fenbutatin oxide to be finalized.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Tomatoes	1	2 (provisional)	No risk for consumers was identified. However, the proposed MRL should be set as provisional awaiting the resubmission process of fenbutatin oxide to be finalized.

Key words: Fenbutatin oxide, tomatoes, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, organostannic acaricide

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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 any party having a legitimate commercial interest may submit to the Member State an application to modify the MRL in accordance with the provisions of Article 7 of that regulation.

Belgium, hereafter referred to as the Evaluating Member State (EMS), received an application from BASF Agro BV² to modify the existing MRL for fenbutatin oxide in tomatoes. 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 14 January 2009. The application was included in the EFSA Register of Questions with the reference number EFSA-Q-2009-00208 and the following subject:

Fenbutatin Oxide - Application to modify the existing MRL for fenbutatin oxide in tomatoes from 1 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.

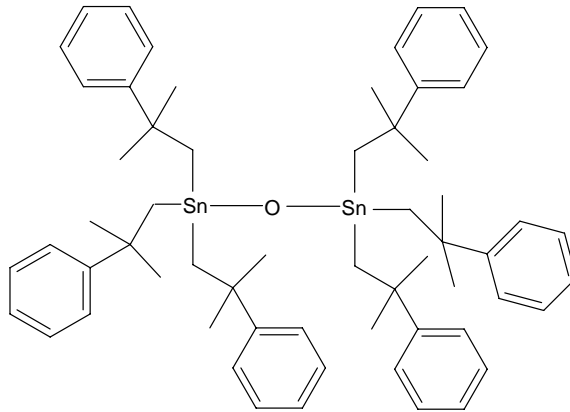
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

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THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Fenbutatin oxide is the ISO common name for bis[tris(2-methyl-2-phenylpropyl)-tin]oxide (IUPAC) and has the following chemical structure:



Fenbutatin oxide is non-systemic organostannic acaricide with contact and stomach action. Fenbutatin oxide is used to control all motile stages of a wide range of phytophagous mites on pome fruit, stone fruit, citrus fruit, soft fruit, vines, bananas, cucurbits, ornamentals, and glasshouse crops. It works by inhibition of a variety of biochemical processes.

Fenbutatin oxide was included in stage three of the peer review under Directive 91/414/EEC, but was voluntarily withdrawn by the notifier during the peer review process. Consequently, the European Commission on 5 December 2008 adopted the Decision (EC) No 2008/943/EC on the non-inclusion of fenbutatin oxide in Annex I to Directive 91/414/EEC. Currently a period of grace applies for fenbutatin oxide and a resubmission of the dossier is expected in May 2009.

The current MRLs for fenbutatin oxide were set under the former EC MRL legislation and after the entry into force of Regulation (EC) No 396/2005 these MRLs were transferred to Annexes II and IIIB to that regulation (Appendix B). The EC MRL for tomatoes is 1 mg/kg. The CXL for fenbutatin oxide in tomatoes is based on the EU proposal and is set at 1 mg/kg as well.

The authorized GAP in Belgium is no longer compliant with the existing MRL for fenbutatin oxide in tomatoes since new trials on cherry tomatoes are available. The GAP for which the MRL proposal is submitted to EFSA refers to an indoor foliar application of fenbutatin oxide on tomatoes at an application rate 2 x 0.375 kg a.s./ha. The minimum waiting period is 3 days.

For the assessment of the MRL application, Belgium as the Evaluating Member State, submitted evaluation report to EFSA. During the drafting of this reasoned opinion, EFSA also consulted the available Draft Assessment Report on fenbutatin oxide which was submitted to EFSA for the peer review process before the substance was voluntarily withdrawn by the notifier. **Since a resubmission of the dossier is now expected, the conclusions made in this reasoned opinion should be considered as provisional awaiting the resubmission process to be finalized.**

ASSESSMENT

1. Methods of analysis

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

In the Draft Assessment Report prepared by the RMS Belgium several GC-MS methods have been reported for the determination of fenbutatin oxide in matrices with high water (tomatoes, apple) and high acid (citrus) content (Belgium, 2006). The validated LOQ for commodities with high water content was reported to be 0.05 mg/kg.

From the available data it can be concluded that adequate analytical methods are available for the enforcement of the proposed MRL for fenbutatin oxide in tomatoes.

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

Tomatoes are not used as a livestock feeding stuff. Therefore analytical methods for determination of fenbutatin oxide residues in food of animal origin are not of relevance.

2. Mammalian toxicology

The toxicological reference values for fenbutatin oxide have been reported in the DAR (Belgium, 2006) and are summarized in Table 2-1.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
Fenbutatin oxide					
ADI	DAR	2006	0.05	2 yr rat	100
ARfD	DAR	2006	n.n.	n.n.	n.n.

n.n. - not necessary

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

The nature of fenbutatin oxide residues in plant commodities was investigated in the framework of the peer review and a metabolism study on apples covering fruits and fruiting vegetables was reported in the DAR (Belgium, 2006). The metabolism study was performed with ¹¹⁹Sn radiolabelled fenbutatin oxide. Leaves and fruits were treated 1-3 times at 30 day intervals with about 40 µg of radiolabelled fenbutatin oxide. Even though the total radioactive residues in apple fruit, peel, pulp and leaves were not characterised, it was concluded that the study is valid to sufficiently cover the metabolism of fenbutatin oxide in fruits and fruiting

vegetables. Fenbutatin oxide remained on the surface of the apple fruit and leaves and was recovered as the major compound of the total radioactivity applied on the apple fruit. The main degradation pathway of fenbutatin oxide consists of di-hydroxylation of the parent molecule forming metabolite di-hydroxy-fenbutatin oxide, which is present in smaller amounts than parent compound.

In the DAR it was concluded that a general residue definition for enforcement and risk assessment in fruits and fruiting vegetables can be proposed as parent fenbutatin oxide only. Regarding the current application, it is concluded that metabolism of fenbutatin oxide in tomatoes is sufficiently addressed and no additional studies are required.

3.1.1.2. Magnitude of residues

For the MRL proposal the applicant submitted eight supervised residues field trials on tomatoes, including two trials on cherry tomatoes. The number of trials is sufficient to propose a new MRL in tomatoes. Residues trials data are summarized in Table 3-1. In all trials the residues of fenbutatin oxide were in the range of 0.09 – 1.01 mg/kg. From the residues trials data it is concluded that a higher MRL of 2 mg/kg would be necessary to accommodate the authorized GAP on tomatoes.

The storage stability of fenbutatin oxide residues in treated crops is reported in the DAR (Belgium, 2006). Available studies demonstrate the storage stability of fenbutatin oxide under frozen storage conditions for at least 24 months in tomato and orange matrices. No formation of toxicologically significant metabolites was observed during storage. The supervised residues field trial samples were stored frozen (-20C°) prior to analyses for a time period not exceeding 4 months, which means that analytical results can be considered valid regarding storage stability.

According to the evaluation of the EMS, the analytical method applied for analysing supervised field trial samples is sufficiently validated and fit for purpose.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STM (mg/kg) (b)	HR (mg/kg) (c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement	Risk assessment					
Fenbutatin oxide									
Tomatoes	EU	Indoor	0.09; 0.16; 0.18; 0.19; 0.23; 0.25; 0.99; 1.01	0.09; 0.16; 0.18; 0.19; 0.23; 0.25; 0.99; 1.01	0.21	1.01	2.00	1.00	R _{ber} =1.61 mg/kg R _{max} = 1.60 mg/kg

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

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

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

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

3.1.1.3. Effect of industrial processing and/or household preparation

The need for studies on the effect of processing on the nature of fenbutatin oxide was reported in the DAR (Belgium, 2006).

The effect of processing on the magnitude of fenbutatin oxide in tomatoes was investigated in one balance and two follow-up studies (Belgium, 2006). Tomatoes were processed into juice, wet and dry pomace, paste, peeled tomatoes and canned tomatoes and several processing factors were obtained which are summarized in Table 3-2. The available studies demonstrate that fenbutatin oxide residues in processed products where the peel fraction is not present (juice, peeled tomatoes) are lower than in the products that still contain fractions of the peel (wet pomace, dry pomace).

Table 3-2. Overview of the available processing studies

Processed commodity	Number of studies	Median PF ^(a)	Median CF ^(b)	Comments
Wet pomace	3	1.86	1.00	
Dry pomace	3	7.05	1.00	
Juice	3	0.25	1.00	
Paste	3	0.92	1.00	
Peeled tomatoes	3	0.19	1.00	
Canned tomatoes	3	0.29	1.00	

(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.

EFSA did not consider the processing factors in the consumer intake calculations since the consumption data for processed tomatoes are not available. With regard to the current application EFSA is not proposing the processing factors for enforcement because the nature of fenbutatin oxide residues in processed commodities is not sufficiently elucidated and the contribution of tomatoes to a total dietary intake is not exceeding 1.3 % of the ADI.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Tomatoes can be grown in rotation with other crops. The DT_{90lab} value for fenbutatin oxide significantly exceeds 100 days, since the highest value reported in the DAR is 1322 days (Belgium, 2006). Consequently, the rotational crop studies are necessary.

3.1.2.2. Nature of residues

One metabolism study of fenbutatin oxide in rotational crops is reported in the DAR (Belgium, 2006). Studies indicate that the parent fenbutatin oxide amounts for up to 80-96 % of the TRR. Some unextractable radioactive residues were present at levels up to 16% of the TRR in crops planted 365 DAT but they were not characterized. In the DAR it was concluded that fenbutatin oxide residues should be regarded as relevant and therefore additional

rotational crop study is required to characterize the chemical nature of the residues which may occur in succeeding crops. No conclusion on metabolic pathway of fenbutatin oxide in rotational crops has therefore been taken.

However, assessing the available study, EFSA concludes that parent fenbutatin oxide can be provisionally considered as the main substance of concern in rotational crops.

3.1.2.3. Magnitude of residues

Under the peer review one rotational crop study was investigated (Belgium, 2006). A bare soil was treated with radiolabelled fenbutatin oxide at an application rate of 8.84 kg a.s./ha. The soil was aged for 30, 120 and 365 days and afterwards lettuce, wheat and turnips were planted. In turnip root the total radioactive residues ranged between 0.048 mg/kg and 0.088 mg/kg (turnips sown 30, 120 and 365 DAT). In wheat straw (wheat sown 30 DAT) the total residues accounted for 0.056 mg/kg. Considering that the proposed application rate in the framework of this application is significantly lower - 0.75 kg a.s./ha - and that a part of the applied substance is intercepted by the treated crop, it is concluded that fenbutatin oxide residues are not expected in rotational or succeeding crops at levels exceeding the LOQ.

3.2. Nature and magnitude of residues in livestock

Since tomatoes are not fed to livestock, studies on nature and magnitude of residues in livestock are not of relevance regarding the current MRL application.

4. Consumer risk assessment

Chronic intake calculations were performed with revision 2 of the EFSA PRIMo using the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 and the STMR value derived for the intended use of fenbutatin oxide on tomatoes. For refined intake calculations EFSA used the STMR values as obtained for pome fruit and citrus fruit in the DAR. Input values are summarized in Table 4-1. No acute intake calculations were performed since no ARfD value for fenbutatin oxide is established.

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
Tomatoes	0.21	STMR	The acute risk assessment was not performed since no ARfD value has been established.	
Pome fruit	0.64	STMR (Belgium, 2006)		
Citrus fruit	1.33	STMR (Belgium, 2006)		

The summary of the intake calculations can be found in Appendix C. No chronic consumer intake concerns were identified for any of European diets. The highest contribution of tomatoes to the dietary intake was 1.3 % of the ADI for the WHO Cluster diet B. EFSA concludes that the authorized use of fenbutatin oxide on tomatoes is acceptable with regard to consumer safety awaiting the resubmission process of fenbutatin oxide to be finalized.

CONCLUSIONS AND RECOMMENDATIONS

Belgium received an application from BASF Agro BV to modify the existing MRL for fenbutatin oxide in tomatoes. The authorized GAP in Belgium is no longer compliant with the existing MRL for fenbutatin oxide in tomatoes since new trials are available. Therefore Belgium considers raising the current MRL of 1 mg/kg to 2 mg/kg. Belgium as the Evaluating Member State (EMS) drafted an evaluation report according to Article 9 of Regulation (EC) No 396/2005 which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA conclusions for this MRL application are based on the evaluation report prepared by the EMS and the Draft Assessment Report prepared by Belgium in the framework of Directive 91/414/EEC.

It should be noted that fenbutatin oxide was included in stage three of the peer review under Directive 91/414/EEC and voluntarily withdrawn by the notifier during the peer review. Therefore the active substance is currently not included in Annex I to that directive but a resubmission is expected. Awaiting the resubmission process to be finalized for this active substance, the conclusions made in this reasoned opinion should be considered as provisional.

The nature of fenbutatin oxide was investigated in a metabolism study on apples covering fruits and fruiting vegetables. It was concluded that metabolism of fenbutatin oxide in fruits and fruiting vegetables is sufficiently addressed and a residue definition for enforcement and risk assessment for this crop category was proposed as fenbutatin oxide (parent only).

Submitted supervised residues field trials indicate that the current MRL of 1 mg/kg for tomatoes does not accommodate the already authorized GAP in Belgium and a higher MRL of 2 mg/kg would be necessary. Adequate analytical methods are available for the enforcement of the proposed MRL of fenbutatin oxide in tomatoes.

The occurrence of fenbutatin oxide or its metabolites in rotational crops was also investigated. Even though the need for additional rotational crop studies was identified in the DAR and no conclusion on the nature of fenbutatin oxide residues in rotational crops was taken, EFSA concludes that the parent fenbutatin oxide can be provisionally considered as the main compound of concern in rotational crops. Considering that the proposed application rates with regard to the current MRL application are significantly lower and that a part of the applied substance is intercepted by the treated crop, it is also concluded that fenbutatin oxide residues are not expected in rotational or succeeding crops provided that the active substance is applied according to the proposed GAP.

The effect of processing on the magnitude of fenbutatin oxide was investigated in the DAR and processing factors for tomatoes were derived. With regard to the current application EFSA is not proposing processing factors for enforcement because the nature of fenbutatin oxide residues in processed commodities is not sufficiently elucidated. Moreover, the contribution of tomatoes to a total dietary intake is not exceeding 1.3% of the ADI.

Residues in commodities of animal origin were not assessed in the framework of this application considering that tomatoes are not fed to livestock.

Chronic intake calculations were performed with revision 2 of the EFSA PRIMo, using the existing MRLs as established in Annexes II and IIIB of Regulation (EC) No 396/2005 and the STMR value derived for the intended use of fenbutatin oxide on tomatoes. For refined intake calculations EFSA used the STMR values as obtained for pome fruit and citrus fruit in

the DAR. No chronic consumer intake concerns were identified. The highest contribution of tomatoes to the dietary intake was 1.3 % of the ADI for the WHO Cluster diet B. No acute intake calculations were performed since no ARfD value for fenbutatin oxide is established.

EFSA concludes that the authorized use of fenbutatin oxide on tomatoes is acceptable with regard to consumer safety awaiting the resubmission process of fenbutatin oxide to be finalized.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Tomatoes	1	2 (provisional)	No risk for consumers was identified. However, the proposed MRL should be set as provisional awaiting the resubmission process of fenbutatin oxide to be finalized.

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for fenbutatin oxide in tomatoes prepared under Regulation (EC) No 396/2005 by the Evaluating Member State Belgium. Forwarded to EFSA on 14 January, 2009.
2. Dossier on fenbutatin oxide prepared under the Regulation (EC) No 396/2005 by Exponent International Ltd. on behalf of BASF Agro BV. Forwarded to EFSA on 14 January, 2009.

REFERENCES

Belgium, 2006. Draft Assessment Report on fenbutatin oxide prepared under Directive 91/414/EEC by the Rapporteur Member State Belgium. December, 2006.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and/or situation (a)	Member State or Country	Product Name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks: (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	No (min max) (k)	interval between applications (min)	kg as/hL (min max)	water L/ha (min max)	kg as/ha (min max)		
Tomato (<i>Lycopersicon esculentum</i>)	North and South Europe	Torque	G	Mites <i>Tetranychus urticae</i>	WP	500 g/kg	spray		2	14 days	0.025	1,500	0.375	3	

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

APPENDIX B – EXISTING EC MRLs

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	5
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	5
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	5
110030	Lemons (Citron, lemon)	5
110040	Limes	5
110050	Mandarins (Clementine, tangerine and other hybrids)	5
110990	Others	5
120000	(ii) Tree nuts (shelled or unshelled)	0,05*
120010	Almonds	0,05*
120020	Brazil nuts	0,05*
120030	Cashew nuts	0,05*
120040	Chestnuts	0,05*
120050	Coconuts	0,05*
120060	Hazelnuts (Filbert)	0,05*
120070	Macadamia	0,05*
120080	Pecans	0,05*
120090	Pine nuts	0,05*
120100	Pistachios	0,05*
120110	Walnuts	0,05*
120990	Others	0,05*
130000	(iii) Pome fruit	2
130010	Apples (Crab apple)	2
130020	Pears (Oriental pear)	2
130030	Quinces	2
130040	Medlar	2
130050	Loquat	2
130990	Others	2
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	2
151010	Table grapes	2
151020	Wine grapes	2
152000	(b) Strawberries	1
153000	(c) Cane fruit	
153010	Blackberries	5
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,05*
153030	Raspberries (Wineberries)	5
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Currants (red, black and white)	0,05*
154040	Gooseberries (Including hybrids with other ribes species)	0,05*
154050	Rose hips	0,05*
154060	Mulberries (arbutus berry)	0,05*
154070	Azarole (mediteranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea shallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
160000	(vi) Miscellaneous fruit	
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	3
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
	Annonaceae)	
163070	Guava	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	1
231010	Tomatoes (Cherry tomatoes,)	1
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	1
231040	Okra, lady's fingers	1
231990	Others	1
232000	(b) Cucurbits - edible peel	
232010	Cucumbers	0,5
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,5
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicacea	0,05*
251010	Lamb's lettuce (Italian cornsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel,)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	0,05*
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
401040	Sesame seed	0,05*
401050	Sunflower seed	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*
401070	Soya bean	0,05*
401080	Mustard seed	0,05*
401090	Cotton seed	0,05*
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
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	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
	these	
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*
1016030	Liver	0,05*
1016040	Kidney	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Fenbutatin oxide (F)
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	

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Fenbutatin oxide			
Status of the active substance:	not included	Code no.	#N/A
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.05	ARfD (mg/kg bw):	n.n.
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:	2006	Year of evaluation:	2006

For chronic risk assessment (refinement) STMR values were used as an input values: for tomatoes -0.21 mg/kg; for pome fruit - 0.64 mg/kg; for citrus fruit-1.33 mg/kg

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		6		49					
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	pTMRs at LOQ (in % of ADI)	
49.08	DE child	15.3	Apples	10.1	Oranges	9.3	Bananas		
40.5	NL child	10.2	Bananas	8.3	Oranges	8.0	Apples		
26.6	FR toddler	7.8	Bananas	5.3	Oranges	4.0	Milk and cream,		
25.6	IE adult	5.0	Wine grapes	4.7	Bananas	2.8	Oranges		
23.7	UK Toddler	6.5	Bananas	5.3	Oranges	2.3	Sugar beet (root)		
23.5	WHO Cluster diet B	7.2	Wine grapes	2.3	Oranges	1.9	Bananas		
22.4	FR all population	16.0	Wine grapes	1.5	Bananas	0.8	Oranges		
21.7	UK Infant	8.8	Bananas	3.9	Milk and cream,	3.5	Oranges		
20.8	SE general population 90th percentile	10.8	Bananas	2.0	Oranges	1.3	Apples		
19.2	PT General population	10.0	Wine grapes	2.0	Bananas	1.6	Oranges		
18.4	ES child	6.1	Bananas	5.8	Oranges	1.5	Apples		
18.0	DK child	6.8	Bananas	2.9	Apples	1.6	Cucumbers		
16.6	FR infant	4.3	Bananas	3.2	Apples	2.6	Milk and cream,		
16.1	WHO cluster diet E	6.4	Wine grapes	2.2	Bananas	1.2	Oranges		
14.6	NL general	4.0	Oranges	2.5	Wine grapes	1.9	Bananas		
13.2	WHO Cluster diet F	3.4	Bananas	2.4	Wine grapes	2.3	Oranges		
12.2	DK adult	5.6	Wine grapes	2.3	Bananas	1.0	Apples		
11.8	UK vegetarian	3.3	Wine grapes	2.3	Oranges	2.3	Bananas		
11.7	ES adult	3.4	Oranges	2.2	Bananas	1.7	Wine grapes		
10.9	UK Adult	4.3	Wine grapes	2.1	Bananas	1.5	Oranges		
10.5	WHO regional European diet	2.3	Bananas	1.3	Oranges	0.9	Wine grapes		
9.7	IT kids/toddler	3.2	Bananas	1.3	Oranges	1.1	Apples		
9.1	WHO cluster diet D	1.4	Wine grapes	0.8	Apples	0.8	Table grapes		
8.3	FI adult	2.6	Oranges	1.5	Bananas	1.2	Wine grapes		
7.0	PL general population	2.6	Apples	1.3	Table grapes	1.1	Bananas		
6.6	IT adult	1.2	Bananas	1.0	Apples	1.0	Oranges		
5.5	LT adult	2.4	Apples	0.4	Milk and cream,	0.4	Cucumbers		

Conclusion:

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

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	Federal Biological Research Centre for Agriculture and Forestry (Germany)
bw	body weight
CAC	Codex Alimentarius Commission
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT _{90lab}	period required for 90 percent dissipation (laboratory studies)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
GAP	good agricultural practice
GC	gas chromatography
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	Northern European Union
NOAEL	no observed adverse effect level
PF	processing factor
PHI	pre harvest interval

ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
STM	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WG	water dispersible granule