

## REASONED OPINION OF EFSA

### Modification of the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*)<sup>1</sup>

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00211)

Issued on 15 April 2009

#### SUMMARY

According to Article 6(4) of Regulation (EC) No 396/2005, France received an application from Exponent International Ltd on behalf of BASF to modify the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*). The applicant proposes to raise the existing MRL, which is currently set at the analytical limit of quantification of 0.05 mg/kg, to 15 mg/kg. The subsequent evaluation report drafted by France was forwarded to EFSA on 14/01/2009 according to article 9 of the Regulation.

Based on the evaluation report of France, the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) France under Directive 91/414/EEC, EFSA derives the following conclusion regarding the application:

The metabolism of flufenoxuron was investigated for foliar applications in grapes, tomatoes, apples and Chinese cabbage. In apples, tomatoes and Chinese cabbage flufenoxuron metabolism was similar and flufenoxuron was the main component in samples at harvest. In grapes, besides flufenoxuron three unidentified metabolites were found in concentrations between 7% and 31% of the radioactive residues. Only two crop groups (fruit and leafy vegetable group) are covered by the available studies and since the identity of the metabolites in the grape study and their toxicological relevance is not known, a provisional residue definition was proposed in the DAR: flufenoxuron only. On the basis of the results of the metabolism study on cabbage, which is relevant for tea, it is expected that flufenoxuron is the only relevant component of residues in fresh tea leaves.

The proposed MRL refers to processed green tea. Processing includes steaming, drying and rolling. On the basis of the results on the effect of processing on the nature of residues, flufenoxuron is expected to be the terminal residue in the processed green tea leaves. In absence of information on the effect of fermentation on the nature of residues, which is relevant for other tea types such as black tea, the proposed residue definition for enforcement and risk assessment is only relevant for green tea.

<sup>1</sup> For citation purposes: Reasoned opinion of EFSA prepared by the Pesticides Unit (PRAPeR) on the modification of the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*). *EFSA Scientific Report* (2009) 267, 1-24

An analytical method is available for enforcement of the MRL for flufenoxuron in tea.

A sufficient number of supervised residue trials on green tea is available. EFSA concludes that an MRL of 15 mg/kg would be required to accommodate for the use of flufenoxuron on green tea.

Chronic and acute intake calculations were performed using revision 2 of the EFSA PRIMo. The acute intake calculation for tea did not reveal potential acute health risk.

Long-term intake calculations resulted in ADI exceedances for six European diets (max. 144% of the ADI for the German diet for children). The contribution through intake of tea to the chronic exposure is highest for Irish adults and UK infants (10% and 4.3%). Additional information regarding the established MRLs (e.g. data on registered uses, STMR values for crops with MRLs established above the LOQ or processing factors) would be necessary to finalise the chronic risk assessment and to come to a conclusion whether the proposed MRL of 15 mg/kg for green tea is a consumer health risk.

**Key words: Flufenoxuron, tea, MRL application, Regulation (EC) No 396/2005, consumer risk assessment, benzoylurea insecticides**

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## BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that any party having a legitimate commercial interest may submit to the Rapporteur Member State designated pursuant to Directive 91/414/EEC an application to set an import tolerance in accordance with the provisions of Article 7 of that regulation.

In particular, France, hereafter referred to as the Evaluating Member State (EMS), received an application from Exponent International Ltd<sup>2</sup> on behalf of BASF to modify the existing MRL for the active substance flufenoxuron in tea. 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 Question with the reference number EFSA-Q-2009-00211 and the following subject:

- *Flufenoxuron – Application to modify the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented of Camellia sinensis) from 0.05\* mg/kg to 15 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.

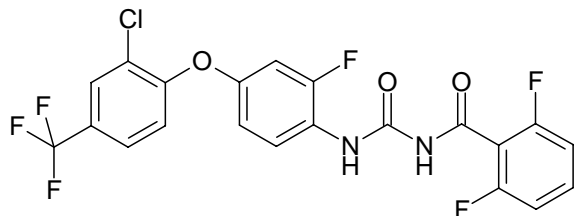
In this particular case the calculated deadline for providing the reasoned opinion is 14 April 2009.

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<sup>2</sup> Exponent International Ltd, The Lenz, Hornbeam Park, HG2 8RE, Harrogate, UK

## THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Flufenoxuron is the ISO common name for N-{4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluorophenyl}-N'-(2,6-difluorobenzoyl)urea (IUPAC).



Flufenoxuron belongs to the class of benzoylurea insecticides. It is an insect growth regulator with acaricidal activity. Flufenoxuron kills pest mites and insects through interference with chitin production during cuticle development in mite and insect juvenile stages. Additionally, eggs laid by treated female adult mites and insects are nonviable and fail to develop.

Flufenoxuron has been evaluated in the framework of Directive 91/414/EEC (stage 3B) with France being the designated Rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar applications on grapes, tomatoes and ornamentals. The notifier voluntarily withdrew, in accordance with Article 11e of Regulation (EC) No 1490/2002, the support for the inclusion of this substance. Therefore, it was decided not to include flufenoxuron in Annex I to Council Directive 91/414/EEC (Commission Decision 2008/934/EC) and the Draft assessment report prepared by France has not been peer reviewed. It is expected that the notifier will submit an application in accordance with the accelerated procedure provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 and that the evaluation will be finalised subsequently.

In the European Community temporary MRLs are currently established for flufenoxuron (see Annex B). These temporary MRLs have been derived from the MRLs established at national level before Regulation EC( No) 396/2005 entered into force. The MRL for tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*) was established at the level of 0.05\* mg/kg for a residue definition which contained the parent compound only.

Exponent International Ltd on behalf of BASF now has made an application for an import tolerance for green tea. A modification of the existing MRL to 15 mg/kg is requested. A detailed overview of the Japanese GAP is available in Appendix A to this document. It concerns foliar applications at a rate of maximal 0.1 kg a.s./ha two times per season and a minimum PHI of 7 days.

In support of the MRL application an evaluation report has been submitted. EFSA also relied on the DAR prepared by France under Directive 91/414/EEC. As the DAR has not been peer reviewed at this stage, conclusions reached in this reasoned opinion are temporary and might be reconsidered after finalization of the evaluation.

## ASSESSMENT

### 1. Methods of analysis

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

An analytical method for enforcement of flufenoxuron MRL in green tea has been evaluated (France 2008). Flufenoxuron and its metabolites are extracted with a mixture of methanol, water and hydrochloric acid and analysed by LC/MS/MS. A LOQ of 0.1 mg/kg was derived for flufenoxuron. The method is also capable to measure residues of certain metabolites or degradation products of flufenoxuron (CL 932338<sup>3</sup>, CL 359882<sup>4</sup> and 2,6-difluorobenzamide), each with an LOQ of 0.01 mg/kg. The method is sufficiently validated for all analytes. An independent laboratory validation of the analytical method for flufenoxuron only is available.

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

The availability of an analytical method for enforcement of residues in food of animal origin was not considered in this application as it is not relevant for an import tolerance on tea.

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<sup>3</sup> N-[4-[2-chloro-4-(trifluoromethyl) phenoxy]-2-fluorophenyl] urea

<sup>4</sup> 4-[2-chloro-4-(trifluoromethyl)phenoxy]-2-fluoro-benzenamine

## 2. Mammalian toxicology

The toxicological properties of flufenoxuron have been evaluated in the DAR prepared under Directive 91/414/EEC (France, 2006) and reference values have been derived. As the notifier voluntarily withdrew the support for the inclusion of this substance the evaluation was not peer-reviewed. It is expected that the notifier will submit an application in accordance with the accelerated procedure provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 and that the evaluation will be finalised subsequently. It is proposed to rely on the conclusions of the RMS in the meantime. The reference values derived by France are summarized in the table below.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	DAR	2006	0.0035	1 year dog study	1000
ARfD	DAR	2006	0.49	28 day rat 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**

Plant metabolism studies have been provided with foliar application of flufenoxuron on grapes, tomatoes, apples and Chinese cabbage. They have been evaluated in the DAR (France, 2006) and a summary was provided in the evaluation to support the MRL application (France, 2008). The studies on all crops were carried out with test substance with a radioactive marker in the fluoroaniline ring. In the grape metabolism also test substance labelled in the benzoyl ring was used.

Whereas radioactive residues were mainly found in the surface wash for fruit crops, a considerable translocation of flufenoxuron into the leaves was observed in the Chinese cabbage study. In the studies on apples, tomatoes and Chinese cabbage, flufenoxuron was the only relevant component of the radioactive residues. In grapes, besides flufenoxuron three unidentified metabolites were found in concentrations between 8% and 31% of TRR. On the basis of the results of these metabolism studies the following provisional residue definition for primary crops was proposed in the DAR: flufenoxuron only. The residue definition is pending the identification of the metabolites found in the grape metabolism study and the evaluation of their toxicological relevance.

The metabolism study on Chinese cabbage which is relevant for the use of flufenoxuron on tea was carried out at the application rate proposed for green tea. Almost 100% of the radioactive residues were identified as flufenoxuron in this study. Therefore, it is expected that flufenoxuron is the only relevant component of residues in fresh tea leaves.

In the residue trials on green tea (see section 3.1.1.2) residues have been analysed in green tea after processing (i.e. steaming, rolling and drying). Therefore, also these processing steps have to be taken into account for the residue definitions relevant for (crude) tea (for details see section 3.1.1.3). On the basis of the information available on metabolism in Chinese cabbage, the effect of processing on the nature of residues and the results from residue trials (see section 3.1.1.2) the following residue definition for enforcement and risk assessment is proposed for tea for the application under evaluation: flufenoxuron only. It is noted that this residue definition also applies to the MRLs for flufenoxuron currently included in Regulation (EC) No 396/2005. However, it might be appropriate to revise the residue definition when further information on the metabolism in grapes and processing are available.

###### **3.1.1.2. Magnitude of residues**

A total of thirteen residue trials carried out in Japan in the growing seasons 1999 (two trials), 2005 (four trials) and 2007 (seven trials) are available and have been evaluated by France (2008). All trials were carried out in accordance with the Japanese GAP. Samples of the processed dry green tea (i.e. tea leaves after steaming, rolling and drying) were analysed for flufenoxuron and in the 2007 trials additionally for CL 932338, CL 359882 and 2,6-difluorobenzamide, which are degradation products which were identified in the processing studies simulating boiling and sterilisation.



Tea samples were processed within 24 hours after harvest. The crude tea was stored frozen for maximal 150 days until analysis. Flufenoxuron residues have been shown to be stable under freezing conditions in crops with high content of water or fat and acid commodities for up to 36 months. No specific study is available regarding storage stability in tea. However, the active substance is stable in different crop groups and no degradation is expected for tea under freezing conditions for 150 days.

The analytical methods used in the residue trials from the 2005 and 2007 growing seasons have been sufficiently validated with acceptable results for all compounds analysed for in the respective trial. The validation of the analytical method used for the residue trials from 1999 was not regarded as sufficient by the EMS, as only two replicates were analysed for each fortification levels. EFSA followed the proposal of the EMS not to use the results of these trials to derive the MRL. However, these trials showed comparable residue levels (7.94 mg/kg and 7.22 mg/kg) and also include information on the transfer of flufenoxuron when infusions are prepared from dried tea leaves. As no other data are available for the transfer of residues into infusions and the recoveries for the two replicates were acceptable, the results were used to derive a processing factor (see sections 3.1.1.3).

The results for flufenoxuron in samples harvested 7 days after the last application from the 2005 and 2007 trials are summarised in table 3.1. The EMS (France, 2008) excluded the highest value (11.8 mg/kg) from the MRL calculation as it was identified as probable outlier by the Dixon test. As no technical (other than statistical) reason was given for the exclusion of this value, EFSA decided not to delete this value from the data base (see table 3-1). Residue levels of CL 932338, CL 359882 and 2,6-difluorobenzamide were found to be below the LOQ of 0.01 mg/kg in all 2007 residue trials.

The calculation carried out by EFSA leads to the conclusion that an MRL of 15 mg/kg would be required to accommodate the use on green tea (see table 3-1).

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (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: <b>flufenoxuron</b>									
Green tea (after steaming, drying and rolling)	Import (Japan)	Outdoor	2.4; 2.5; 4.0; 4.6; 5.8; 6.0; 6.1; 6.2; 6.4; 7.4; 11.8 (**)	2.4; 2.5; 4.0; 4.6; 5.8; 6.0; 6.1; 6.2; 6.4; 7.4; 11.8(**)	6.0	11.8	15	1.0	Rmax = 12.99 Rber = 12.80

(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.

(\*\*) According to the Dixon test, the maximum residue value (11.8 is probably an outlier).

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

In the DAR (France, 2006) studies on the effect of processing on the nature of residues metabolites have been evaluated. Flufenoxuron was shown to be stable under conditions simulating pasteurisation. Under conditions simulating boiling (60 min. at 100°C), 2,6-difluorobenzamide was formed at a level of max. 32%. Under conditions simulating sterilisation (20 min at 120°C), 2,6-difluorobenzoic acid, 2,6-difluorobenzamide and metabolites CL 932338 and CL 359882 were formed. A further metabolite was found at a level of max. 9%. However the chemical identity was not provided in the dossier.

The samples from the residue trials on green tea were analysed after processing which includes steaming, drying and rolling. According to the information provided in the 1999 residue trial study, steaming of green tea is carried out at 100 °C and lasts for 30 seconds. Very low concentrations of the hydrolysis products observed in the study simulating boiling conditions are expected after steaming of green tea because of the short duration of the heat treatment. Furthermore, three of the possible hydrolysis products 2,6-difluorobenzamide, CL 932338 and CL 359882 were analysed in four of the residue trials and residues levels were found to be below the LOQ. Therefore, it is proposed not to include the metabolites in the residue definition for enforcement and risk assessment for the application for green tea under evaluation (see section 3.1.1.1). However, it is noted that the proposed MRL applies also for other types of tea (e.g. black tea) which are processed differently, e.g. by fermentation. No information on the effect of fermenting of tea on the nature of flufenoxuron residues is available.

The 1999 residue trials also included information on residues in infusions prepared from the tea leaves (see section 3.1.1.1). A calculation carried out by EFSA showed that approximately 44% of the residues in the tea leaves were extracted during the preparation of the infusion. A provisional processing factor of 0.44 can be derived from these studies for preparation of tea infusions of green tea. However, a full data set of at least three processing studies and a balance study, carried out using a fully validated analytical method, would be necessary to conclude on a final processing factor.

### 3.1.2. Rotational crops

Occurrence of possible residues of flufenoxuron in rotational crops was not further considered in the framework of this application as it is not relevant for an import tolerance on tea.

## 3.2. Nature and magnitude of residues in livestock

Occurrence of flufenoxuron residues in food of animal origin was not further considered in the framework of this application as tea is not relevant as feed.

## 4. Consumer risk assessment

Chronic and acute intake calculations were carried out using revision 2 of the EFSA PRIMo. The calculation of the chronic exposure is based on the existing temporary MRLs and where available, STMR values provided by Member States in the framework of establishing temporary MRLs in Annex III of Regulation 396/2005. The input values for the refined risk assessment are summarised in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: <b>flufenoxuron</b>				
Citrus fruit	0.05	STMR-P (peeled fruits)	Not relevant	
Pome fruit	0.16	STMR	Not relevant	
Table grapes	0.09	STMR	Not relevant	
Wine grapes	0.01	STMR-P (production of wine)	Not relevant	
Tomatoes, aubergines	0.12	STMR	Not relevant	
Tea	2.6	STMR * PF (preparation of infusion)	5.2	HR * PF (preparation of infusion)
Other crops	MRLs	see Appendix B, no information is available for refined intake calculations	Not relevant	

The results of the refined intake calculations are reported in Appendix C to this document. The acute intake of flufenoxuron via tea is calculated to be 2.2% and 0.7% for children and adults, respectively. Therefore no acute consumer risk is expected regarding the consumption of green tea treated with flufenoxuron.

Long-term intake calculations resulted in ADI exceedances for six European diets (max. 144% of the ADI for the German diet for children). The contribution through intake of tea to the chronic exposure is highest for Irish adults and UK infants (10% and 4.3%). The contribution through intake of crops with the MRL set at the LOQ ranges from 51% to 93% of the ADI. Further information, e.g. information concerning registered uses for crops where MRLs are established at the LOQ level, STMR values for other crops not mentioned in table 4-1 or processing factors have not been provided. Lacking this information, EFSA cannot finalise the chronic risk assessment and a final conclusion whether the proposed MRL for green tea is a consumer health risk can not be derived.

## CONCLUSIONS AND RECOMMENDATIONS

According to Article 6(4) of Regulation (EC) No 396/2005, France received an application from Exponent International Ltd on behalf of BASF to modify the existing MRL for flufenoxuron in tea (dried leaves and stalks, fermented or otherwise of *Camellia sinensis*). The applicant proposes to raise the existing MRL, which is currently set at the analytical limit of quantification of 0.05 mg/kg, to 15 mg/kg. The subsequent evaluation report drafted by France was forwarded to EFSA on 14/01/2009 according to article 9 of the Regulation.

Based on the evaluation report of France, the Draft Assessment Report (DAR) prepared by the Rapporteur Member State (RMS) France under Directive 91/414/EEC, EFSA derives the following conclusion regarding the application:

The metabolism of flufenoxuron was investigated for foliar applications in grapes, tomatoes, apples and Chinese cabbage. In apples, tomatoes and Chinese cabbage flufenoxuron metabolism was similar and flufenoxuron was the main component in samples at harvest. In grapes, besides flufenoxuron three unidentified metabolites were found in concentrations between 7% and 31% of the radioactive residues. Only two crop groups (fruit and leafy vegetable group) are covered by the available studies and since the identity of the metabolites in the grape study and their toxicological relevance is not known, a provisional residue definition was proposed in the DAR: flufenoxuron only. On the basis of the results of the metabolism study on cabbage, which is relevant for tea, it is expected that flufenoxuron is the only relevant component of residues in fresh tea leaves.

The proposed MRL refers to processed green tea. Processing includes steaming, drying and rolling. On the basis of the results on the effect of processing on the nature of residues, flufenoxuron is expected to be the terminal residue in the processed green tea leaves. In absence of information on the effect of fermentation on the nature of residues, which is relevant for other tea types such as black tea, the following residue definition for enforcement and risk assessment is only relevant for green tea.

An analytical method is available for enforcement of the MRL for flufenoxuron in tea.

A sufficient number of supervised residue trials on green tea is available. EFSA concludes that an MRL of 15 mg/kg would be required to accommodate for the use of flufenoxuron on green tea.

Chronic and acute intake calculations were performed using revision 2 of the EFSA PRIMo. The acute intake calculation for tea did not reveal potential acute health risk.

Long- term intake calculations, based on the information provided to EFSA, resulted in ADI exceedances for six European diets (max. 144% of the ADI for the German diet for children). The contribution through intake of tea to the chronic exposure is highest for Irish adults and UK infants (10% and 4.3%). Additional information regarding the established MRLs (e.g. data on registered uses, STMR values for crops with MRLs established above the LOQ or processing factors) would be necessary to finalise the chronic risk assessment and to come to a conclusion whether the proposed MRL of 15 mg/kg for green tea is a consumer health risk.

## DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report submitted by France (October 2008): Draft assessment report prepared in the context of a request of a new MRL on tea leaves: Flufenoxuron – Import tolerance (green tea). Prepared by by the Ministère de l’Agriculture et de la Pêche, Direction Générale de l’Alimentation.
2. Supporting dossier – tea: Reference studies provided by BASF and submitted to EFSA by the Agence Française de Sécurité Sanitaire des Aliments on 30 October 2008.

## REFERENCES

France, 2008. Draft Assessment Report on flufenoxuron prepared by the Ministère de l’Agriculture et de la Pêche, Direction Générale de l’Alimentation under Directive 91/414/EEC. June 2006.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

(a)	Member State, Country or Region	Product name	F G or I	Pests or Group of pests controlled	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days)  (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/ max (k)	interval between applications (min)	g as/hL (l) min – max	water L/ha min – max	g as/ha (l) min – max		
Green tea	Japan	CASCAD E EC	F	<i>Oriental tea tortrix, Smaller tea tortrix, Tea leafroller, Tea green leafroller, Mugwort looper, Yellow tea thrips, Broad mite</i>	EC	10 % w/w  106 g/l	Spray	Newly growing stage (April-October)	2	7-14	0.0025  (25 ppm)	2000-4000	0.05-0.1	7	

- (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse 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. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypry). In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).
- (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) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

**APPENDIX B – LIST OF EXISTING EC MRLs**

**Flufenoxuron (F)**

Pesticide residues and maximum residue levels (mg/kg)

(\*) Indicates lower limit of analytical determination

Pesticides - Web Version - EU MRLs (File created on 05/03/2009 12:40)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0,3
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0,3
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,3
110030	Lemons (Citron, lemon )	0,3
110040	Limes	0,3
110050	Mandarins (Clementine, tangerine and other hybrids)	0,3
110990	Others	0,3
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	0,5
130010	Apples (Crab apple)	0,5
130020	Pears (Oriental pear)	0,5
130030	Quinces	0,5
130040	Medlar	0,5
130050	Loquat	0,5
130990	Others	0,5
140000	(iv) Stone fruit	0,5
140010	Apricots	0,5
140020	Cherries (sweet cherries, sour	0,5

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008
140030	cherries) Peaches (Nectarines and similar hybrids)	0,5
140040	Plums (Damson, greengage, mirabelle)	0,5
140990	Others	0,5
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	
151010	Table grapes	1
151020	Wine grapes	2
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, Boysenberries, and cloudberry)	0,05*
153030	Raspberries (Wineberries )	0,05*
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 sallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
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), pomerac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*



Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008	Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008
162010	Kiwi	0,05*		Japanese radish, small radish and similar varieties)	
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*	213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
162030	Passion fruit	0,05*	213100	Swedes	0,05*
162040	Prickly pear (cactus fruit)	0,05*	213110	Turnips	0,05*
162050	Star apple	0,05*	213990	Others	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*	220000	(ii) Bulb vegetables	0,05*
162990	Others	0,05*	220010	Garlic	0,05*
163000	(c) Inedible peel, large	0,05*	220020	Onions (Silverskin onions)	0,05*
163010	Avocados	0,05*	220030	Shallots	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*	220040	Spring onions (Welsh onion and similar varieties)	0,05*
163030	Mangoes	0,05*	220990	Others	0,05*
163040	Papaya	0,05*	230000	(iii) Fruiting vegetables	
163050	Pomegranate	0,05*	231000	(a) Solanacea	
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*	231010	Tomatoes (Cherry tomatoes, )	0,5
163070	Guava	0,05*	231020	Peppers (Chilli peppers)	0,5
163080	Pineapples	0,05*	231030	Aubergines (egg plants) (Pepino)	0,5
163090	Bread fruit (Jackfruit)	0,05*	231040	Okra, lady' s fingers	0,05*
163100	Durian	0,05*	231990	Others	0,05*
163110	Soursop (guanabana)	0,05*	232000	(b) Cucurbits - edible peel	
163990	Others	0,05*	232010	Cucumbers	0,2
200000	2. VEGETABLES FRESH OR FROZEN		232020	Gherkins	0,05*
210000	(i) Root and tuber vegetables	0,05*	232030	Courgettes (Summer squash, marrow (patisson))	0,05*
211000	(a) Potatoes	0,05*	232990	Others	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*	233000	(c) Cucurbits-inedible peel	
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*	233010	Melons (Kiwano )	0,2
212020	Sweet potatoes	0,05*	233020	Pumpkins (Winter squash)	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*	233030	Watermelons	0,2
212040	Arrowroot	0,05*	233990	Others	0,05*
212990	Others	0,05*	234000	(d) Sweet corn	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*	239000	(e) Other fruiting vegetables	0,05*
213010	Beetroot	0,05*	240000	(iv) Brassica vegetables	0,05*
213020	Carrots	0,05*	241000	(a) Flowering brassica	0,05*
213030	Celeriac	0,05*	241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
213040	Horseradish	0,05*	241020	Cauliflower	0,05*
213050	Jerusalem artichokes	0,05*	241990	Others	0,05*
213060	Parsnips	0,05*	242000	(b) Head brassica	0,05*
213070	Parsley root	0,05*	242010	Brussels sprouts	0,05*
213080	Radishes (Black radish,	0,05*	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,	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008	Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008
	Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)			peppermint)	
243020	Kale (Borecole (curly kale), collards)	0,05*	256090	Bay leaves (laurel)	0,05*
243990	Others	0,05*	256100	Tarragon (Hyssop)	0,05*
244000	(d) Kohlrabi	0,05*	256990	Others	0,05*
250000	(v) Leaf vegetables & fresh herbs		260000	(vi) Legume vegetables (fresh)	
251000	(a) Lettuce and other salad plants including Brassicacea		260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,5
251010	Lamb's lettuce (Italian cornsalad)	0,05*	260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	1	260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*	260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
251040	Cress	0,05*	260050	Lentils	0,05*
251050	Land cress	0,05*	260990	Others	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*	270000	(vii) Stem vegetables (fresh)	0,05*
251070	Red mustard	0,05*	270010	Asparagus	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*	270020	Cardoons	0,05*
251990	Others	0,05*	270030	Celery	0,05*
252000	(b) Spinach & similar (leaves)	0,05*	270040	Fennel	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*	270050	Globe artichokes	0,05*
252020	Purslane (Winter purslane (miner' s lettuce), garden purslane, common purslane, sorrel, glassworth)	0,05*	270060	Leek	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*	270070	Rhubarb	0,05*
252990	Others	0,05*	270080	Bamboo shoots	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*	270090	Palm hearts	0,05*
254000	(d) Water cress	0,05*	270990	Others	0,05*
255000	(e) Witloof	0,05*	280000	(viii) Fungi	
256000	(f) Herbs	0,05*	280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
256010	Chervil	0,05*	280020	Wild (Chanterelle, Truffle, Morel .)	0,1
256020	Chives	0,05*	280990	Others	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*	290000	(ix) Sea weeds	0,05*
256040	Parsley	0,05*	300000	3. PULSES, DRY	0,05*
256050	Sage (Winter savory, summer savory, )	0,05*	300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
256060	Rosemary	0,05*	300020	Lentils	0,05*
256070	Thyme ( marjoram, oregano)	0,05*	300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
256080	Basil (Balm leaves, mint,	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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008	Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008
401030	Poppy seed	0,05*	632990	Others	0,05*
401040	Sesame seed	0,05*	633000	(c) Roots	0,05*
401050	Sunflower seed	0,05*	633010	Valerian root	0,05*
401060	Rape seed (Bird rapeseed, turnip rape)	0,05*	633020	Ginseng root	0,05*
401070	Soya bean	0,05*	633990	Others	0,05*
401080	Mustard seed	0,05*	639000	(d) Other herbal infusions	0,05*
401090	Cotton seed	0,05*	640000	(iv) Cocoa (fermented beans)	0,05*
401100	Pumpkin seeds	0,05*	650000	(v) Carob (st johns bread)	0,05*
401110	Safflower	0,05*	700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,05*
401120	Borage	0,05*	800000	8. SPICES	0,05*
401130	Gold of pleasure	0,05*	810000	(i) Seeds	0,05*
401140	Hempseed	0,05*	810010	Anise	0,05*
401150	Castor bean	0,05*	810020	Black caraway	0,05*
401990	Others	0,05*	810030	Celery seed (Lovage seed)	0,05*
402000	(ii) Oilfruits	0,05*	810040	Coriander seed	0,05*
402010	Olives for oil production	0,05*	810050	Cumin seed	0,05*
402020	Palm nuts (palmoil kernels)	0,05*	810060	Dill seed	0,05*
402030	Palmfruit	0,05*	810070	Fennel seed	0,05*
402040	Kapok	0,05*	810080	Fenugreek	0,05*
402990	Others	0,05*	810090	Nutmeg	0,05*
500000	5. CEREALS	0,05*	810990	Others	0,05*
500010	Barley	0,05*	820000	(ii) Fruits and berries	0,05*
500020	Buckwheat	0,05*	820010	Allspice	0,05*
500030	Maize	0,05*	820020	Anise pepper (Japan pepper)	0,05*
500040	Millet (Foxtail millet, teff)	0,05*	820030	Caraway	0,05*
500050	Oats	0,05*	820040	Cardamom	0,05*
500060	Rice	0,05*	820050	Juniper berries	0,05*
500070	Rye	0,05*	820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
500080	Sorghum	0,05*	820070	Vanilla pods	0,05*
500090	Wheat (Spelt Triticale)	0,05*	820080	Tamarind	0,05*
500990	Others	0,05*	820990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*	830000	(iii) Bark	0,05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,05*	830010	Cinnamon (Cassia )	0,05*
620000	(ii) Coffee beans	0,05*	830990	Others	0,05*
630000	(iii) Herbal infusions (dried)	0,05*	840000	(iv) Roots or rhizome	0,05*
631000	(a) Flowers	0,05*	840010	Liquorice	0,05*
631010	Camomille flowers	0,05*	840020	Ginger	0,05*
631020	Hybiscus flowers	0,05*	840030	Turmeric (Curcuma)	0,05*
631030	Rose petals	0,05*	840040	Horseradish	0,05*
631040	Jasmine flowers	0,05*	840990	Others	0,05*
631050	Lime (linden)	0,05*	850000	(v) Buds	0,05*
631990	Others	0,05*	850010	Cloves	0,05*
632000	(b) Leaves	0,05*	850020	Capers	0,05*
632010	Strawberry leaves	0,05*	850990	Others	0,05*
632020	Rooibos leaves	0,05*	860000	(vi) Flower stigma	0,05*
632030	Maté	0,05*	860010	Saffron	0,05*
			860990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008
870000	(vii) Aril	0,05*
870010	Mace	0,05*
870990	Others	0,05*
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	0,05*
	(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*
1010000	(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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Reg.(EC) N°149/2008
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*
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	

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

Flufenoxuron			
Status of the active substance:		Code no.	
LOQ (mg/kg bw):	0.05	proposed LOQ:	0.05
Toxicological end points			
ADI (mg/kg bw/day):	0.0035	ARfD (mg/kg bw):	0.49
Source of ADI:	DAR	Source of ARfD:	DAR
Year of evaluation:		Year of evaluation:	

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							
		28 - 144							
		<b>No of diets exceeding ADI:</b>		6					
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)	
143.6	DE child	55.2	Apples	20.4	Milk and cream,	5.9	Wheat	51.3	
138.3	NL child	41.9	Milk and cream,	28.9	Apples	8.4	Potatoes	81.4	
122.3	FR toddler	56.6	Milk and cream,	15.8	Beans (with pods)	12.0	Apples	89.2	
114.0	WHO Cluster diet B	12.2	Wheat	10.6	Tomatoes	10.2	Lettuce	51.5	
111.5	UK Infant	55.3	Milk and cream,	14.4	Sugar beet (root)	7.1	Apples	93.2	
103.0	UK Toddler	32.7	Sugar beet (root)	29.5	Milk and cream,	7.8	Apples	85.2	
92.0	IE adult	9.8	Tea (dried leaves and stalks,	8.1	Peaches	5.1	Sweet potatoes	45.3	
86.2	DK child	18.0	Milk and cream,	10.6	Apples	9.4	Cucumbers	48.9	
84.7	FR infant	36.8	Milk and cream,	12.0	Beans (with pods)	11.4	Apples	57.9	
79.5	ES child	17.9	Milk and cream,	11.9	Lettuce	6.3	Wheat	44.4	
68.1	WHO regional European diet	10.8	Lettuce	6.9	Milk and cream,	5.7	Potatoes	32.5	
61.0	WHO cluster diet E	5.6	Wheat	5.5	Potatoes	4.3	Milk and cream,	35.4	
60.7	SE general population 90th percentile	17.7	Milk and cream,	6.0	Potatoes	4.8	Apples	41.8	
58.4	ES adult	15.3	Lettuce	7.1	Milk and cream,	3.5	Apples	23.0	
57.8	WHO cluster diet D	9.3	Wheat	7.2	Milk and cream,	5.8	Potatoes	34.8	
52.5	WHO Cluster diet F	8.6	Lettuce	5.7	Milk and cream,	5.1	Wheat	32.0	
49.3	IT kids/toddler	9.5	Wheat	8.3	Lettuce	5.0	Peaches	17.6	
47.2	NL general	9.4	Milk and cream,	5.4	Apples	3.9	Potatoes	27.6	
46.1	IT adult	10.8	Lettuce	5.9	Wheat	5.4	Peaches	11.6	
41.7	PT General population	7.6	Potatoes	5.6	Wheat	5.1	Peaches	21.9	
39.1	UK vegetarian	5.4	Sugar beet (root)	4.7	Milk and cream,	4.0	Lettuce	21.5	
35.2	LT adult	8.5	Apples	5.7	Milk and cream,	4.5	Potatoes	18.5	
34.7	FR all population	4.7	Wheat	3.8	Milk and cream,	2.6	Lettuce	18.8	
34.0	UK Adult	5.7	Sugar beet (root)	4.3	Milk and cream,	4.0	Tea (dried leaves and stalks,	19.9	
32.6	DK adult	7.7	Milk and cream,	3.6	Apples	2.9	Wheat	20.0	
29.2	PL general population	9.3	Apples	4.9	Potatoes	3.0	Tomatoes	8.1	
28.0	FI adult	8.1	Milk and cream,	2.2	Lettuce	1.8	Apples	18.0	

**Conclusion:**

The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 28 % to 144 % of the ADI. For 6 diets the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk can not be excluded at the moment.

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

Unprocessed commodities	No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):			No of commodities for which ARfD/ADI is exceeded (IESTI 1):			No of commodities for which ARfD/ADI is exceeded (IESTI 2):					
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	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)			
	1.0	Tea	5.2 / -	1.0	Tea	5.2 / -	0.3	Tea	5.2 / -	0.3	Tea	5.2 / -			
<b>No of critical MRLs (IESTI 1)</b>				---				<b>No of critical MRLs (IESTI 2)</b>				---			

Processed commodities	No of commodities for which ARfD/ADI is exceeded:			No of commodities for which ARfD/ADI is exceeded:		
	---			---		
	***)			***)		
	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)

\*) 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 Flufenoxuron 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
CF	conversion factor for enforcement residue definition to risk assessment residue definition
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
GAP	good agricultural practice
ha	hectare
hL	hectolitre
HR	highest residue
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
PHI	pre harvest interval
PF	Processing factor
PRIMo	Pesticide Residues Intake Model
PSD	Pesticide Safety Directorate, United Kingdom
RMS	Rapporteur Member State
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TRR	total radioactive residue