European Food Safety Authority

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REASONED OPINION

Reasoned opinion on the review of the existing maximum residue levels (MRLs) for flurtamone according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance flurtamone. In order to assess the occurrence of flurtamone residues in plants, processed commodities, rotational crops and livestock, EFSA considered the conclusions derived in the framework of Directive 91/414/EEC as well as the European authorisations reported by Member States (incl. the supporting residues data). Based on the assessment of the available data, MRL proposals were derived and a consumer risk assessment was carried out. No information required by the regulatory framework was found to be missing and no risk to consumers was identified.

KEY WORDS

flurtamone, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, pyridazinone, herbicide.

[1] On request from EFSA, Question No EFSA-Q-2008-551, approved on 04 December 2012.

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SUMMARY

Flurtamone was included in Annex I to Directive 91/414/EEC on 01 January 2004, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the afore mentioned regulation. In order to collect the relevant pesticide residues data, EFSA asked France, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 23 June 2009 and, after having considered several comments made by EFSA, the RMS provided on 23 April 2010 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC and the additional information provided by the RMS, EFSA issued on 20 June 2012 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 24 August 2012 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of flurtamone was already evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.03 mg/kg bw per d. An ARfD was not deemed necessary.

The metabolism of flurtamone was investigated for pre-emergence and early post-emergence applications in barley and wheat and for pre-emergence applications in sunflower and peanut. In all studies, flurtamone was demonstrated to be extensively degraded through several hydrolytic and oxidative steps to finally form trifluoromethyl benzoate with incorporation into natural plant sugars or triglycerides. As residues of this metabolite are not expected above 0.01 mg/kg the relevant residue for enforcement and risk assessment in cereals, pulses and oilseeds is defined as the parent compound only. Validated analytical methods are available for enforcement of this residue definition in food of plant origin with a LOQ of 0.01 mg/kg in dry and high oil content commodities.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residue trials are available for the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive tentative MRLs.

As quantifiable residues of flurtamone are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing. In addition, the chronic exposure does not exceed 10 % of the ADI.

Following Annex I inclusion, a rotational crop metabolism study, which was carried out on radish, lettuce and wheat, was evaluated by the RMS and demonstrated that degradation of residues in primary crops and rotational crops will proceed through a similar pattern and residues exceeding 0.01 mg/kg are also not expected.

Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Chronic consumer exposure resulting from the authorisations reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. Considering these crops, the highest chronic exposure represented 0.3 % of the ADI (Danish child). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with

the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

It is highlighted that some of the MRLs derived result from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gap which is not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- 8 residues trials analysing for flurtamone residues in straw and supporting the southern outdoor GAP on cereals.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Residue definition for risk assessment: flurtamone				
300030	Peas (dry)	0.02*	0.01*	Recommended [(a)]
401050	Sunflower seed	0.05*	0.01*	Recommended [(a)]
500010	Barley grain	0.02*	0.01*	Recommended [(a)]
500050	Oats grain	0.02*	0.01*	Recommended [(a)]
500070	Rye grain	0.02*	0.01*	Recommended [(a)]
500090	Wheat grain	0.02*	0.01*	Recommended [(a)]
-	Other products of plant and animal origin	See App C	-	Further consideration needed [(b)]

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As flurtamone was included in Annex I to the above mentioned directive on 01 January 2004, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-551 was included in the EFSA Register of Questions.

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

In order to gain an overview of the pesticide residues data that have been considered for the setting of the existing MRLs, EFSA developed the Pesticide Residues Overview File (PROFile). The PROFile is an inventory of all pesticide residues data relevant to the risk assessment and MRL setting for a given active substance. This includes data on:

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

France, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for flurtamone. The requested information was submitted to EFSA on 23 June 2009 and subsequently checked for completeness. On 23 April 2010, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 20 June 2012 and submitted to Member States (MS) for commenting. All MS comments received by 24 August 2012 were considered by EFSA in the finalisation of the reasoned opinion.

[4] Commission Regulation (EC) No 396/2005 of 23 February 2005. OJ L 70, 16.3.2005, p. 1-16.
[5] Council Directive 91/414/EEC of 15 July 1991, OJ L 230, 19.8.1991, p. 1-32.

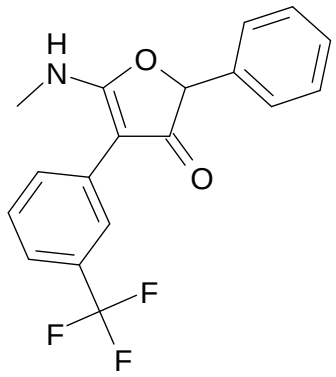
TERMS OF REFERENCE

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

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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Flurtamone is the ISO common name for (2*RS*)-5-methylamino-2-phenyl-4-(α,α,α-trifluoro-*m*-tolyl)furan-3(2*H*)-one (IUPAC).



Flurtamone belongs to the group of pyridazinone compounds which are used as herbicides. It is used pre-emergence or post-emergence for the control of broad-leaved and grass weeds in cereals, pulses and oilseeds by blocking carotenoid biosynthesis via the inhibition of phytoene desaturase causing chlorophyll depletion.

Flurtamone was evaluated in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process was the outdoor treatment of cereals (barley, wheat, rye, and triticale) at 125-250 g as/ha with a PHI of 150 days, in northern and southern Europe. Following the peer review a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2003/84/EC[6], which entered into force on 01 January 2004. According to Regulation (EU) No 540/2011[7], flurtamone is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as a herbicide only. As EFSA was not yet involved in the peer review of flurtamone, an EFSA Conclusion on this active substance is not available.

[6] Directive 2003/84/EC of 25 September 2003, OJ L 247, 30.9.2003, p. 20-25.
[7] Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.
[8] Regulation (EC) No 1107/2009 of 21 October 2009, OJ 309, 24.11.2009, p. 1–50.

The EU MRLs for flurtamone are established in Annexes II and IIIB of Regulation (EC) No 396/2005. All existing EU MRLs, which are established for the parent compound only are summarised in Appendix C to this document. CXLs for flurtamone are not available.

For the purpose of this MRL review, the critical uses of flurtamone currently authorised within the EU have been collected by the RMS and reported in the PROFile (see Appendix A). According to the reported GAPs there have been no extensions of use beyond the representative uses supported for the peer review process, except for the additional use on oats. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) prepared under Council Directive 91/414/EEC (France, 1997), the Review Report on flurtamone (EC, 2003) and the Evaluation Reports submitted during the Member State Consultation (France, 2012 and Germany, 2012). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[9] and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD was evaluated and validated for the determination of flurtamone in dry commodities with a LOQ of 0.01 mg/kg in cereal grain and 0.05 mg/kg in cereal straw (France, 1997). In addition, after Annex I inclusion an ILV was evaluated by the RMS and was found to be satisfactory for cereal grains and sunflower seeds with an LOQ of 0.01 mg/kg (France, 2012).

In addition, after Annex I inclusion, the RMS also evaluated a GC-MS method, confirmed by GC-MS/MS, and its ILV, which was validated for the determination of flurtamone with a LOQ of 0.01 mg/kg in high water content, high fat content, acidic and dry commodities (lettuce, sunflower seed, orange and wheat grain respectively). An acceptable ILV was also reported (France, 2012; Germany, 2012).

The multi-residue QuEChERS method in combination with HPLC-MS/MS, as described by CEN (2008), is also reported for analysis of flurtamone only with a LOQ of 0.01 mg/kg mg/kg in high water content, acidic and dry commodities (EURL, 2012).

Hence it is concluded that flurtamone can be enforced in food of plant origin with a LOQ of 0.01 mg/kg in high water content, high fat content, acidic and dry commodities.

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD (no ILV) was evaluated and validated for the determination of flurtamone in food of animal origin with an LOQ of 0.01 mg/kg in milk and 0.05 mg/kg in meat, fat, and eggs (France, 1997).

[9] Regulation (EU) No 546/2011 of 10 June 2011. OJ L 155, 11.06.2011, p. 127-175.

However, considering that there is no significant intake of residues by livestock, no residue definition and no MRLs are proposed for commodities of animal origin (section 3.2). Therefore, an analytical method for enforcement of residues in food of animal origin is not necessary.

2. Mammalian toxicology

The toxicological assessment of flurtamone was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2003). These toxicological reference values are summarised in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Flurtamone					
ADI	EC	2003	0.03 mg/kg bw per d	Rat, 2-year study	100
ARfD	EC	2003	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

Metabolism of flurtamone was investigated for pre-emergence and early post-emergence treatment on cereals (barley) and pre-emergence on pulses and oilseeds (sunflower) using [U-^{14}C-phenyl]-labelled flurtamone (France, 1997). Following the Annex I inclusion, the RMS received and evaluated additional metabolism studies on wheat with flurtamone radiolabelled on the trifluoromethyl phenyl ring and peanut with flurtamone radiolabelled on both the phenyl and trifluoromethylphenyl rings (France, 2012). The characteristics of these studies are summarised in Table 3-1.

In barley grain, residues were too low for identification (0.04 mg eq./kg for the post-emergence treatment). The highest total radioactive residue levels (TRR) were found in straw (5.17 mg eq./kg for the post-emergence treatment), where the major component of the TRR was parent flurtamone (19.5 % TRR), all other components being below 10 % of the TRR. A further 10 % of the radioactivity was due to the incorporation of radioactive carbon into natural plant sugars.

In sunflowers the highest TRR was found in the seeds (0.09 - 0.33 mg eq./kg). In forage, parent flurtamone constituted the most important component of the residue (18.9 % TRR; 0.03 mg eq./kg). In the seed the parent compound was almost completely degraded. Trifluoromethyl benzoate was the main component of the TRR in the seed, accounting for 19.3 % (0.06 mg eq./kg). All other components were present at levels below 10 % of the TRR (including mandelamide at 1.8 % TRR and mandelic acid at 0.5 % TRR). A further 12.1 % of the radioactivity was due to the incorporation of radioactive carbon into glycerides.

Table 3-1: Summary of available metabolism studies in plants

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (g a.s./ha)	No	Sampling (DAT)	Remarks
Pulses and oilseeds	Sunflower	[U-^{14}C-trifluro-methyl-phenyl]-labelled	Spray, G	42 (pre-emergence)	1	46 and 114	Samples: forage and seed
				84 (pre-emergence)	1	46 and 114	
	Peanut	[U-^{14}C-phenyl]-labelled	Soil applic-ation, G	1121 (pre-planting)	1	120	Samples: foliage, stems, kernels and hulls
		[U-^{14}C-trifluoro-methyl-phenyl]-labelled				121	
Cereals	Barley	[U-^{14}C-trifluoro-methyl-phenyl]-labelled	Spray, G	65 (pre-emergence)	1	111	Samples: grain and straw
				650 (post-emergence)	1	not stated	
	Wheat	[U-^{14}C-phenyl]-labelled	Spray	375 (pre-emergence)	1	not stated	Samples: forage, grain, chaff and straw
				375 (post-emengence)	1	not stated	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

In wheat grain, residues were also too low for identification (<0.015 mg eq./kg for the post-emergence treatment) but were found to consist entirely of polar material. The highest total radioactive residue levels (TRR) were found in straw (<0.16 mg eq./kg for the pre-emergence treatment), where the major component of the TRR was parent flurtamone (20.0-29.5 % TRR in forage, straw and chaff). The proportion of other components (demethylated and hydroxylated metabolites) was lower but the quantification was not reported. Unidentified radioactivity was found to be highly polar and there was evidence of the incorporation of radioactive carbon into natural plant sugars.

In peanuts the highest TRR was found in the foliage (1.32 and 5.81 mg eq./kg for the phenyl and trifluoromethylphenyl radiolabels respectively). Residues in the kernels were lower (0.54 and 0.42 mg eq./kg for the phenyl and trifluoromethylphenyl radiolabels respectively). The majority of the radioactivity after solvent extraction was found to be polar in nature and further radioactivity was extracted by reflux with strong acid and base. Following cleavage mandelamide, mandelic acid and trifluoromethyl benzoate were identified at low levels similar to sunflowers and barley and further radioactivity was due to the incorporation of radioactive carbon into glycerides. Quantification of the metabolic components was not reported but the residues were qualitatively similar to the other studies.

In all studies, flurtamone was demonstrated to be extensively degraded through several hydrolytic and oxidative steps to finally form trifluoromethyl benzoate. This metabolite then undergoes further hydroxylation and decarboxylation to CO_2 with subsequent incorporation in natural plant materials.

Trifluoromethyl benzoate is encountered in the rat metabolism and considered covered by the toxicological profile of flurtamone. This metabolite was not recovered in either of the cereal metabolism studies except as a minor metabolite in barley straw (<5.8 % TRR in straw treated post-emergence). Although identified in peanut the overall TRR was low and therefore this metabolite was not further quantified. The metabolite was present as a major metabolite in sunflower seed (19.3 % TRR; 0.06 mg eg./kg), however this study was conducted at greater than 2N and under protected conditions intended to maximise the residue uptake (controlled watering and sampling) indicating that following more realistic use conditions this metabolite would be found at lower levels. Consequently, the residue for enforcement and risk assessment in cereals and pulses and oilseeds is defined as flurtamone only. A validated analytical method for enforcement of the proposed residue definition in high fat content and dry commodities is available.

3.1.1.2. Magnitude of residues

According to the RMS, the active substance flurtamone is authorised in northern and southern Europe for pre-emergence and early post-emergence treatment of cereals (barley, oats, wheat and rye), peas (dry) and sunflower seed under outdoor conditions (see Appendix A). To assess the magnitude of flurtamone residues resulting from these GAPs, EFSA considered all residues trials reported in the PROFile, including residues trials evaluated in the framework of the peer review (France, 1997). All available residues trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

The number of residues trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). A sufficient number of trials complying with the GAP was reported by the RMS for all crops under assessment, except in the following cases:

- Peas (dry) (SEU), sunflower seed (NEU) and cereal grain (SEU): The number of residues trials supporting these outdoor GAPs is not compliant with the data requirements for these crops. However, the reduced number of residues trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residues trials are therefore not required.

- Cereal straw (SEU): No residue trials complying with the southern outdoor GAP are available. Considering that a large number of residues trials were carried out in Northern Europe, of which seven analysed for flurtamone residues in straw, it is likely that residues will be below the LOQ of 0.05 mg/kg but this should be confirmed by southern residues trials analysing for flurtamone residues in straw.

Table 3-2: Overview of the available residues trials data

Commodity	Residue region [(a)]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [(b)]	Highest residue (mg/kg) [(c)]	MRL proposal (mg/kg)	Median CF [(d)]	Comments
			Enforcement (flurtamone)	Risk assessment (flurtamone)					
Peas (dry)	NEU	Outdoor	17 x <0.01	17 x <0.01	0.01	0.01	0.01*	1.0	Trials compliant with GAP.
	SEU	Outdoor	2 x <0.01	2 x <0.01	0.01	0.01	0.01*	1.0	Trials compliant with GAP.
Sunflower seed	NEU	Outdoor	4 x <0.01, 3 x <0.02	4 x <0.01, 3 x <0.02	0.01	0.01	0.01*	1.0	Trials compliant with GAP.
	SEU	Outdoor	3 x <0.01, 14 x <0.02	3 x <0.01, 14 x <0.02	0.01	0.01	0.01*	1.0	Trials compliant with GAP.
Barley, oats, rye, wheat (grain)	NEU	Outdoor	8 x <0.01	8 x <0.01	0.01	0.01	0.01*	1.0	Combined dataset on wheat (4), barley (2) and rye (2) compliant with the GAP.
	SEU	Outdoor	2 x <0.01	2 x <0.01	0.01	0.01	0.01*	1.0	Trials on wheat compliant with the GAP. Not authorised for rye and oats in SEU.
Barley, oats, rye, wheat (straw)	NEU	Outdoor	7 x <0.05	7 x <0.05	0.05	0.05	0.05*	1.0	Combined dataset on wheat (4), barley (1) and rye (2) compliant with the GAP.
	SEU	Outdoor	-	-	-	-	-	-	No trials compliant with the GAP. Not authorised for rye and oats in SEU.

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).
(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.

The potential degradation of residues during storage of the residues trials samples was also assessed. In the framework of the peer review, storage stability of flurtamone was demonstrated for a period of 12 months at -20 °C in commodities with high oil content (sunflower seeds) and dry commodities (barley grain and straw) (France, 1997). Following the Annex I inclusion, the RMS received and evaluated an additional storage stability study that demonstrated the stability of flurtamone for a period of 18 months at -18 °C in commodities with high oil content (sunflower seeds) and dry commodities (wheat grain) (France, 2012). Residues trials samples for peas (dry) and cereals were stored in compliance with the storage conditions reported above (Germany, 2012). No information is available on the storage period in sunflower however it is considered that the storage stability data provided will be sufficient to cover the maximum period for which the samples were likely to have been stored. Degradation of residues during storage of the trial samples is therefore not expected.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation (see also Table 3-2). Tentative MRLs were also derived for feed crops (cereal straw) in view of the future need to set MRLs in feed items.

3.1.1.3. Effect of industrial processing and/or household preparation

As quantifiable residues of flurtamone are not expected in the treated crops and the chronic exposure does not exceed 10 % of the ADI (see also section 4), there is no need to investigate the effect of industrial and/or household processing.

Nevertheless, analyses of flurtamone residues in sunflower oil and meal reported in the DAR demonstrated that residues were below the LOQ and therefore do not concentrate in these processed commodities (France, 1997).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

All crops under consideration may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, the DT_{90} value of flurtamone is expected to be higher than the trigger value of 100 days (152-216 days in the field) (France, 1997). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is required.

3.1.2.2. Nature and magnitude of residues

The metabolism of flurtamone in rotational crops – lettuce, radish, wheat - has been evaluated (France, 2012). One confined rotational crop study investigating the nature of residues following different plant-back intervals is available. The characteristics of these studies are summarised in Table 3-4.

Table 3-3: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Leafy vegetables	Lettuce	[U-^{14}C-phenyl]-labelled	Soil spraying, F	2 x 250	30, 120, 365	BBCH 41 and 49 (maturity)	
Root and tuber vegetables	Radish	[U-^{14}C-phenyl]-labelled	Soil spraying, F	2 x 250	30, 120, 365	BBCH 41 and 49 (maturity)	
Cereals	Wheat	[U-^{14}C-trifluoro-methyl-phenyl]-labelled	Soil spraying, F	2 x 250	30, 120, 365	BBCH 51-65 and 89 (maturity)	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Following application to the soil residues resulting from the phenyl radiolabel were low in all mature lettuce and radish at all sowing intervals (<0.01 mg eq./kg). Analysis of the extracts showed the radioactivity to comprise parent flurtamone and polar material. Residues in wheat treated with the trifluoromethylphenyl radiolabel were higher (<0.076 mg eq./kg in grain and <0.205 mg eq./kg in straw). The soil metabolite trifluoroacetic acid was the main component of the TRR in the grain, accounting for 79.9 % of the TRR (0.061 mg eq./kg; 0.021 mg/kg) and straw, accounting for 33.8 % of the TRR (0.069 mg eq./kg; 0.024 mg/kg) after the 30 day sowing interval. Since the studies are overdosed (1.3N) and represent a worst case in terms of expected residues due to the bare soil application, residues of the metabolite are not expected to exceed 0.01 mg/kg in rotational crops following realistic practice.. Other metabolites identified at lower levels (<0.01 mg eq./kg) were consistent with those found in the primary crop metabolism studies.

Consequently, metabolism in primary and rotational crops was found to be similar and a specific residue definition for rotational crops is not deemed necessary. Residues exceeding 0.01 mg/kg are also not expected, provided that flurtamone is applied according to the reported GAPs.

3.2. Nature and magnitude of residues in livestock

Flurtamone is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-3. For cereal bran a default processing factor of 8 has been included in the calculation in order to consider the potential concentration of residues in this commodity. A processing factor for sunflower seed meal was not used since the available processing information indicated that residues above the LOQ were not expected (see section 3.1.1.3).

Table 3-4: Input values for the dietary burden calculation

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Residue definition for risk assessment: flurtamone				
Peas (dry)	0.01	Median residue	0.01	Median residue
Sunflower seed	0.01	Median residue	0.01	Median residue
Sunflower seed meal	0.01	Median residue	0.01	Median residue
Cereal grain	0.01	Median residue	0.01	Median residue
Cereal bran	0.08	Median residue x 8	0.08	Median residue x 8
Cereal straw	0.05	Median residue	0.05	Highest residue

The results of the calculations are reported in Table 3-4. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Table 3-5: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Residue definition for risk assessment: flurtamone					
Dairy ruminants	0.0013	0.0013	Wheat bran	0.036	N
Meat ruminants	0.0022	0.0022	Wheat straw	0.050	N
Poultry	0.0011	0.0011	Wheat bran	0.018	N
Pigs	0.0010	0.0010	Wheat bran	0.025	N

4. Consumer risk assessment

Chronic exposure calculations for all crops supported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the exposure calculations were derived in compliance with Appendix D and are summarised in Table 4-1. The median residue values selected for chronic intake calculations are based on the residue levels in the raw agricultural commodities reported in section 3. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation. Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Table 4-1: Input values for the consumer risk assessment (without consideration of CXLs)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	**Comment**
Residue definition for risk assessment: flurtamone		
Peas (dry)	0.01*	Median residue [(a)]
Sunflower seeds	0.01*	Median residue [(a)]
Cereal grains (barley, oats, rye, wheat)	0.01*	Median residue [(a)]

(*): Indicates that the input value is set at or below the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment value derived in section 3 are used for the exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for flurtamone (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for Danish children, representing 0.3 % of the ADI.

Based on the above calculations, EFSA concludes that the use of flurtamone on all crops is fully supported by data and is acceptable with regard to consumer exposure.

It is noted by EFSA that the above risk assessment was performed disregarding the possible impact of plant or livestock metabolism on the isomer ratio of the active substance. Considering however that the active substance is a racemic mixture, a change of isomer ratios in the residue might in the worst case situation lead to a duplication of the toxicological burden of the residue. Since the exposure calculations represent much less than 50% of the ADI, EFSA concludes that the potential change of isomer ratios in the final residue will not be of concern for the uses supported in the framework of this review. In case future uses of flurtamone would lead to a higher consumer exposure, further information regarding the impact of plant and livestock metabolism on the isomer ratio might be required.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of flurtamone was already evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI being established at 0.03 mg/kg bw per d. An ARfD was not deemed necessary.

The metabolism of flurtamone was investigated for pre-emergence and early post-emergence applications in barley and wheat and for pre-emergence applications in sunflower and peanut. In all studies, flurtamone was demonstrated to be extensively degraded through several hydrolytic and oxidative steps to finally form trifluoromethyl benzoate with incorporation into natural plant sugars or triglycerides. As residues of this metabolite are not expected above 0.01 mg/kg the relevant residue for enforcement and risk assessment in cereals, pulses and oilseeds is defined as the parent compound only. Validated analytical methods are available for enforcement of this residue definition in food of plant origin with a LOQ of 0.01 mg/kg in dry and high oil content commodities.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residue trials are available for the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive tentative MRLs.

As quantifiable residues of flurtamone are not expected in the treated crops, there is no need to investigate the effect of industrial and/or household processing. In addition, the chronic exposure does not exceed 10 % of the ADI.

Following Annex I inclusion, a rotational crop metabolism study, which was carried out on radish, lettuce and wheat, was evaluated by the RMS and demonstrated that degradation of residues in primary crops and rotational crops will proceed through a similar pattern and residues exceeding 0.01 mg/kg are also not expected.

Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Chronic consumer exposure resulting from the authorisations reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. Considering these crops, the highest chronic exposure represented 0.3 % of the ADI (Danish child). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation.

It is highlighted that some of the MRLs derived result from a GAP in one climatic zone only, while other GAPs reported by the RMS were not fully supported by data. EFSA therefore identified the following data gap which is not expected to impact on the validity of the MRLs derived but which might have an impact on national authorisations:

- 8 residues trials analysing for flurtamone residues in straw and supporting the southern outdoor GAP on cereals.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Residue definition for risk assessment: flurtamone				
300030	Peas (dry)	0.02*	0.01*	Recommended [(a)]
401050	Sunflower seed	0.05*	0.01*	Recommended [(a)]
500010	Barley grain	0.02*	0.01*	Recommended [(a)]
500050	Oats grain	0.02*	0.01*	Recommended [(a)]
500070	Rye grain	0.02*	0.01*	Recommended [(a)]
500090	Wheat grain	0.02*	0.01*	Recommended [(a)]
-	Other products of plant and animal origin	See App C	-	Further consideration needed [(b)]

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

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).
(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on flurtamone prepared by the rapporteur Member State France in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 23 June 2009. Last updated on 23 April 2010.

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EC (European Commission), 1997a. Appendix A. Metabolism and distribution in plants. 7028/IV/95-rev.3.

EC (European Commission), 1997b. Appendix B. General recommendations for the design, preparation and realization of residue trials. Annex 2. Classification of (minor) crops not listed in the Appendix of Council Directive 90/642/EEC. 7029/VI/95-rev.6. EC (European Commission), 1997c. Appendix C. Testing of plant protection products in rotational crops. 7524/VI/95-rev.2.

EC (European Commission), 1997d. Appendix E. Processing studies. 7035/VI/95-rev.5. EC (European Commission), 1997e. Appendix F. Metabolism and distribution in domestic animals. 7030/VI/95-rev.3.

EC (European Commission), 1997f. Appendix H. Storage stability of residue samples. 7032/VI/95-rev.5.

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France, 1997. Draft assessment report on the active substance flurtamone prepared by the rapporteur Member State France in the framework of Council Directive 91/414/EEC, March 1997.

France, 2012. Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005. Additional data to be considered for the review of the existing MRLs for flurtamone, 24 August 2012.

Germany, 2012. Additional Evaluation Report prepared under Article 12 of Regulation (EC) No 396/2005.Authorised uses to be considered for the review of the existing MRLs for flurtamone, 20 August 2012.

APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Peas (dry)	*Pisum sativum*	NEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	94.0	g/L	Soil treatment - spraying	0	9		1				376.00	g a.i./ha	n.a.	
Sunflower seed	*Helianthus annuus*	NEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	94.0	g/L	Soil treatment - spraying	0	9		1				376.00	g a.i./ha	n.a.	
Barley	*Hordeum spp.*	NEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	250.0	g/L	Foliar treatment - spraying	10	29		1				250.00	g a.i./ha	90	
Oats	*Avena fatua*	NEU	Outdoor	IE	Broad leaved weeds and some grasses	SC	250.0	g/L	Foliar treatment - spraying	0	32		1				250.00	g a.i./ha	n.a.	
Rye	*Secale cereale*	NEU	Outdoor	IE	Broad leaved weeds and some grasses	SC	250.0	g/L	Foliar treatment - spraying	0	32		1				250.00	g a.i./ha	n.a.	
Wheat	*Triticum aestivum*	NEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	250.0	g/L	Foliar treatment - spraying	10	29		1				250.00	g a.i./ha	90	

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Peas (dry)	*Pisum sativum*	SEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	94.0	g/L	Soil treatment - spraying	0	9		1				376.00	g a.i./ha	n.a.	
Sunflower seed	*Helianthus annuus*	SEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	94.0	g/L	Soil treatment - spraying	0	9		1				376.00	g a.i./ha	n.a.	
Barley	*Hordeum spp.*	SEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	250.0	g/L	Foliar treatment - spraying	10	29		1				250.00	g a.i./ha	90	
Wheat	*Triticum aestivum*	SEU	Outdoor	FR	Broad leaved weeds and some grasses	SC	250.0	g/L	Foliar treatment - spraying	10	29		1				250.00	g a.i./ha	90	

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Flurtamone			
Status of the active substance:	Included	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	n.n.
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2003	Year of evaluation:	2003

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI
minimum - maximum

No of diets exceeding ADI: ---

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	pTMRLs at LOQ (in % of ADI)
0.3	DK child	0.2	Wheat	0.1	Rye	0.0	Oats	
0.3	WHO Cluster diet B	0.3	Wheat	0.0	Sunflower seed	0.0	Barley	
0.3	WHO cluster diet D	0.2	Wheat	0.0	Sunflower seed	0.0	Rye	
0.2	IT kids/toddler	0.2	Wheat	0.0	Sunflower seed	0.0	Barley	
0.2	WHO cluster diet E	0.1	Wheat	0.0	Barley	0.0	Rye	
0.2	WHO Cluster diet F	0.1	Wheat	0.0	Rye	0.0	Barley	
0.2	DE child	0.1	Wheat	0.0	Rye	0.0	Oats	
0.2	NL child	0.2	Wheat	0.0	Rye	0.0	Oats	
0.2	ES child	0.1	Wheat	0.0	Peas	0.0	Sunflower seed	
0.1	PT General population	0.1	Wheat	0.0	Sunflower seed	0.0	Rye	
0.1	IE adult	0.1	Wheat	0.0	Barley	0.0	Peas	
0.1	IT adult	0.1	Wheat	0.0	Peas	0.0	Sunflower seed	
0.1	UK Toddler	0.1	Wheat	0.0	Oats	0.0	Peas	
0.1	FR all population	0.1	Wheat	0.0	Sunflower seed	0.0	Barley	
0.1	WHO regional European diet	0.1	Wheat	0.0	Barley	0.0	Sunflower seed	
0.1	SE general population 90th percentile	0.1	Wheat	0.0	Rye		FRUIT (FRESH OR FROZEN)	
0.1	ES adult	0.1	Wheat	0.0	Barley	0.0	Sunflower seed	
0.1	UK Infant	0.1	Wheat	0.0	Oats		FRUIT (FRESH OR FROZEN)	
0.1	DK adult	0.1	Wheat	0.0	Rye	0.0	Oats	
0.1	FR toddler	0.1	Wheat	0.0	Sunflower seed		FRUIT (FRESH OR FROZEN)	
0.1	NL general	0.1	Wheat	0.0	Barley	0.0	Rye	
0.1	LT adult	0.0	Rye	0.0	Wheat	0.0	Oats	
0.1	UK vegetarian	0.1	Wheat	0.0	Oats	0.0	Peas	
0.1	FI adult	0.0	Wheat	0.0	Rye	0.0	Oats	
0.1	UK Adult	0.1	Wheat	0.0	Barley	0.0	Oats	
0.0	FR infant	0.0	Wheat	0.0	Sunflower seed		FRUIT (FRESH OR FROZEN)	
0.0	PL general population	0.0	Peas	0.0	Sunflower seed		FRUIT (FRESH OR FROZEN)	

Conclusion:

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

APPENDIX C – EXISTING EU MAXIMUM RESIDUE LIMITS (MRLS) AND CODEX LIMITS (CXLS)

(Pesticides - Web Version - EU MRLs (File created on 07/04/2012 14:05)

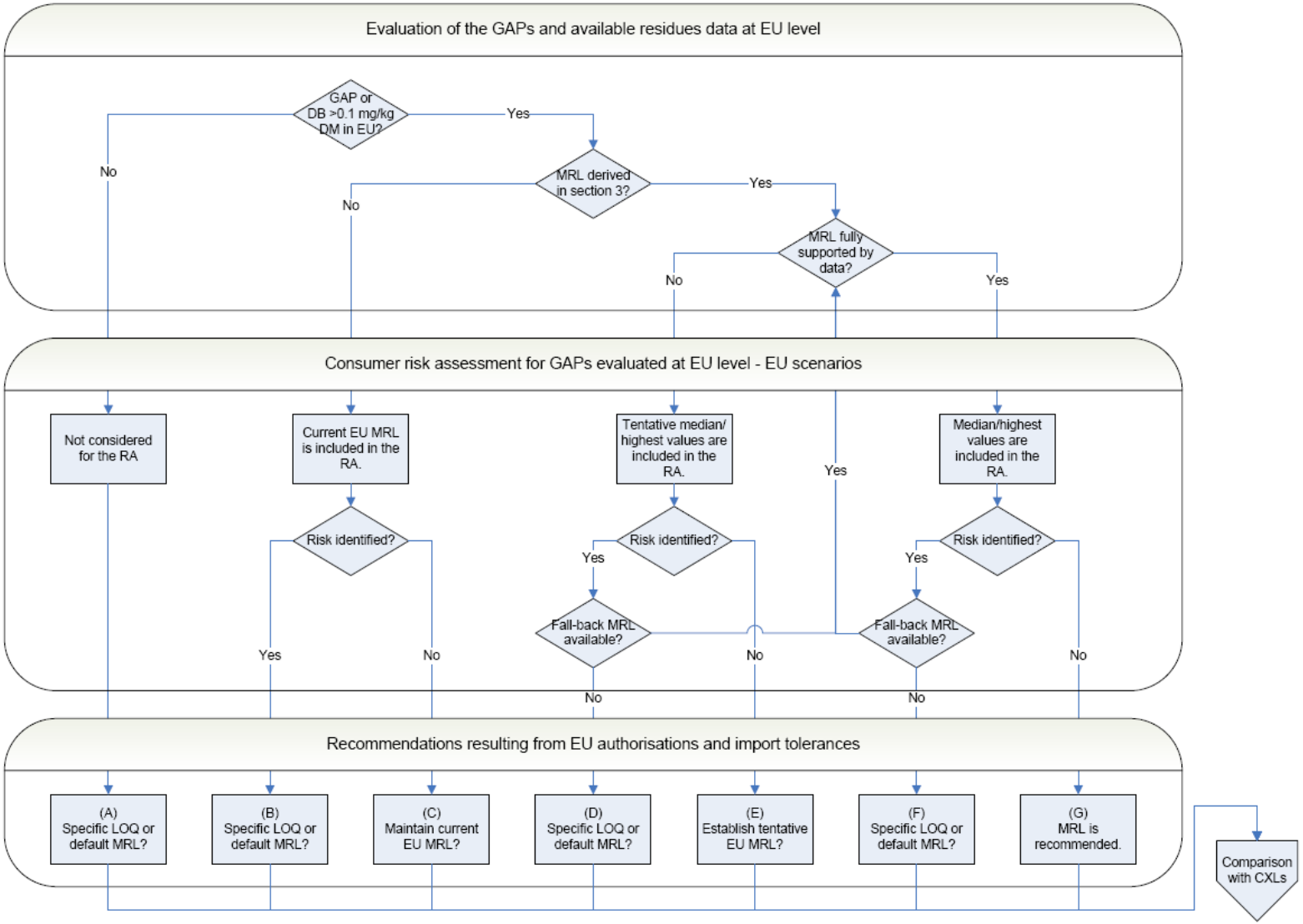
Code number	Groups and examples of individual products to which the MRLs apply (a)	Flurtamone
100000	1. FRUIT FRESH OR FROZEN; NUTS	0.02*
110000	(i) Citrus fruit	0.02*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, ugli and other hybrids)	0.02*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.02*
110030	Lemons (Citron, lemon)	0.02*
110040	Limes	0.02*
110050	Mandarins (Clementine, tangerine and other hybrids)	0.02*
110990	Others	0.02*
120000	(ii) Tree nuts (shelled or unshelled)	0.02*
120010	Almonds	0.02*
120020	Brazil nuts	0.02*
120030	Cashew nuts	0.02*
120040	Chestnuts	0.02*
120050	Coconuts	0.02*
120060	Hazelnuts (Filbert)	0.02*
120070	Macadamia	0.02*
120080	Pecans	0.02*
120090	Pine nuts	0.02*
120100	Pistachios	0.02*
120110	Walnuts	0.02*
120990	Others	0.02*
130000	(iii) Pome fruit	0.02*
130010	Apples (Crab apple)	0.02*
130020	Pears (Oriental pear)	0.02*
130030	Quinces	0.02*
130040	Medlar	0.02*
130050	Loquat	0.02*
130990	Others	0.02*
140000	(iv) Stone fruit	0.02*
140010	Apricots	0.02*
140020	Cherries (sweet cherries, sour cherries)	0.02*
140030	Peaches (Nectarines and similar hybrids)	0.02*
140040	Plums (Damson, greengage, mirabelle)	0.02*
140990	Others	0.02*
150000	(v) Berries & small fruit	0.02*
151000	(a) Table and wine grapes	0.02*
151010	Table grapes	0.02*
151020	Wine grapes	0.02*
152000	(b) Strawberries	0.02*
153000	(c) Cane fruit	0.02*
153010	Blackberries	0.02*
153020	Dewberries (Loganberries, Boysenberries, and cloudberries)	0.02*
153030	Raspberries (Wineberries)	0.02*
153990	Others	0.02*
154000	(d) Other small fruit & berries	0.02*
154010	Blueberries (Bilberries cowberries (red bilberries))	0.02*
154020	Cranberries	0.02*
154030	Currants (red, black and white)	0.02*
154040	Gooseberries (Including hybrids with other ribes species)	0.02*
154050	Rose hips	0.02*
154060	Mulberries (arbutus berry)	0.02*
154070	Azarole (mediteranean medlar)	0.02*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	0.02*
154990	Others	0.02*
160000	(vi) Miscellaneous fruit	0.02*
161000	(a) Edible peel	0.02*
161010	Dates	0.02*
161020	Figs	0.02*
161030	Table olives	0.02*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0.02*
161050	Carambola (Bilimbi)	0.02*
161060	Persimmon	0.02*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (grumichama), Surinam cherry)	0.02*
161990	Others	0.02*
162000	(b) Inedible peel, small	0.02*
162010	Kiwi	0.02*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0.02*
162030	Passion fruit	0.02*
162040	Prickly pear (cactus fruit)	0.02*
162050	Star apple	0.02*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.02*
162990	Others	0.02*
163000	(c) Inedible peel, large	0.02*
163010	Avocados	0.02*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.02*
163030	Mangoes	0.02*
163040	Papaya	0.02*
163050	Pomegranate	0.02*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.02*
163070	Guava	0.02*
163080	Pineapples	0.02*
163090	Bread fruit (Jackfruit)	0.02*
163100	Durian	0.02*
163110	Soursop (guanabana)	0.02*
163990	Others	0.02*
200000	2. VEGETABLES FRESH OR FROZEN	0.02*
210000	(i) Root and tuber vegetables	0.02*
211000	(a) Potatoes	0.02*
212000	(b) Tropical root and tuber vegetables	0.02*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0.02*
212020	Sweet potatoes	0.02*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0.02*
212040	Arrowroot	0.02*
212990	Others	0.02*
213000	(c) Other root and tuber vegetables except sugar beet	0.02*
213010	Beetroot	0.02*
213020	Carrots	0.02*
213030	Celeriac	0.02*
213040	Horseradish	0.02*
213050	Jerusalem artichokes	0.02*
213060	Parsnips	0.02*
213070	Parsley root	0.02*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0.02*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0.02*
213100	Swedes	0.02*
213110	Turnips	0.02*
213990	Others	0.02*
220000	(ii) Bulb vegetables	0.02*
220010	Garlic	0.02*
220020	Onions (Silverskin onions)	0.02*
220030	Shallots	0.02*
220040	Spring onions (Welsh onion and similar varieties)	0.02*
220990	Others	0.02*
230000	(iii) Fruiting vegetables	0.02*
231000	(a) Solanacea	0.02*
231010	Tomatoes (Cherry tomatoes,)	0.02*
231020	Peppers (Chilli peppers)	0.02*
231030	Aubergines (egg plants) (Pepino)	0.02*
231040	Okra, lady's fingers	0.02*
231990	Others	0.02*
232000	(b) Cucurbits - edible peel	0.02*
232010	Cucumbers	0.02*
232020	Gherkins	0.02*
232030	Courgettes (Summer squash, marrow (patisson))	0.02*
232990	Others	0.02*
233000	(c) Cucurbits-inedible peel	0.02*

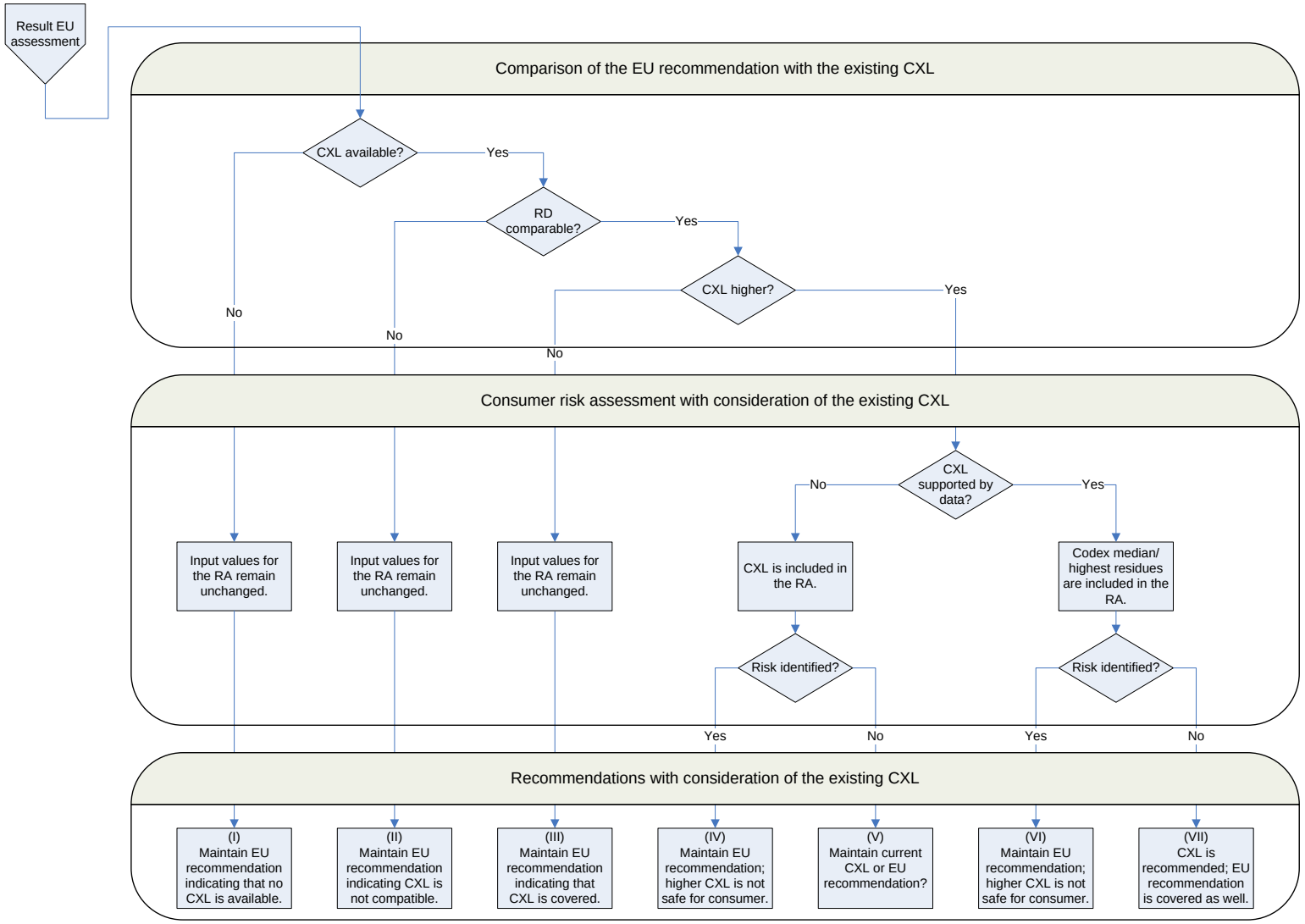
Code number	Groups and examples of individual products to which the MRLs apply (a)	Flurtamone
233010	Melons (Kiwano)	0.02*
233020	Pumpkins (Winter squash)	0.02*
233030	Watermelons	0.02*
233990	Others	0.02*
234000	(d) Sweet corn	0.02*
239000	(e) Other fruiting vegetables	0.02*
240000	(iv) Brassica vegetables	0.02*
241000	(a) Flowering brassica	0.02*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0.02*
241020	Cauliflower	0.02*
241990	Others	0.02*
242000	(b) Head brassica	0.02*
242010	Brussels sprouts	0.02*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0.02*
242990	Others	0.02*
243000	(c) Leafy brassica	0.02*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), peking cabbage (pe-tsai), cow cabbage)	0.02*
243020	Kale (Borecole (curly kale), collards)	0.02*
243990	Others	0.02*
244000	(d) Kohlrabi	0.02*
250000	(v) Leaf vegetables & fresh herbs	0.02*
251000	(a) Lettuce and other salad plants including Brassicacea	0.02*
251010	Lamb´s lettuce (Italian cornsalad)	0.02*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0.02*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0.02*
251040	Cress	0.02*
251050	Land cress	0.02*
251060	Rocket, Rucola (Wild rocket)	0.02*
251070	Red mustard	0.02*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0.02*
251990	Others	0.02*
252000	(b) Spinach & similar (leaves)	0.02*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0.02*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth)	0.02*
252030	Beet leaves (chard) (Leaves of beetroot)	0.02*
252990	Others	0.02*
253000	(c) Vine leaves (grape leaves)	0.02*
254000	(d) Water cress	0.02*
255000	(e) Witloof	0.02*
256000	(f) Herbs	0.02*
256010	Chervil	0.02*
256020	Chives	0.02*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0.02*
256040	Parsley	0.02*
256050	Sage (Winter savory, summer savory,)	0.02*
256060	Rosemary	0.02*
256070	Thyme (marjoram, oregano)	0.02*
256080	Basil (Balm leaves, mint, peppermint)	0.02*
256090	Bay leaves (laurel)	0.02*
256100	Tarragon (Hyssop)	0.02*
256990	Others	0.02*
260000	(vi) Legume vegetables (fresh)	0.02*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0.02*
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.02*
260030	Peas (with pods) (Mangetout (sugar peas))	0.02*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0.02*
260050	Lentils	0.02*
260990	Others	0.02*
270000	(vii) Stem vegetables (fresh)	0.02*
270010	Asparagus	0.02*
270020	Cardoons	0.02*
270030	Celery	0.02*
270040	Fennel	0.02*
270050	Globe artichokes	0.02*
270060	Leek	0.02*
270070	Rhubarb	0.02*
270080	Bamboo shoots	0.02*
270090	Palm hearts	0.02*
270990	Others	0.02*
280000	(viii) Fungi	0.02*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0.02*
280020	Wild (Chanterelle, Truffle, Morel ,)	0.02*
280990	Others	0.02*
290000	(ix) Sea weeds	0.02*
300000	3. PULSES, DRY	0.02*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0.02*
300020	Lentils	0.02*
300030	Peas (Chickpeas, field peas, chickling vetch)	0.02*
300040	Lupins	0.02*
300990	Others	0.02*
400000	4. OILSEEDS AND OILFRUITS	
401000	(i) Oilseeds	0.05*
401010	Linseed	0.05*
401020	Peanuts	0.05*
401030	Poppy seed	0.05*
401040	Sesame seed	0.05*
401050	Sunflower seed	0.05*
401060	Rape seed (Bird rapeseed, turnip rape)	0.05*
401070	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	
402010	Olives for oil production	0.02*
402020	Palm nuts (palmoil kernels)	0.05*
402030	Palmfruit	0.05*
402040	Kapok	0.05*
402990	Others	0.05*
500000	5. CEREALS	0.02*
500010	Barley	0.02*
500020	Buckwheat	0.02*
500030	Maize	0.02*
500040	Millet (Foxtail millet, teff)	0.02*
500050	Oats	0.02*
500060	Rice	0.02*
500070	Rye	0.02*
500080	Sorghum	0.02*
500090	Wheat (Spelt Triticale)	0.02*
500990	Others	0.02*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0.05*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.05*
620000	(ii) Coffee beans	0.05*
630000	(iii) Herbal infusions (dried)	0.05*
631000	(a) Flowers	0.05*
631010	Camomille flowers	0.05*
631020	Hybiscus flowers	0.05*
631030	Rose petals	0.05*
631040	Jasmine flowers	0.05*
631050	Lime (linden)	0.05*
631990	Others	0.05*
632000	(b) Leaves	0.05*
632010	Strawberry leaves	0.05*
632020	Rooibos leaves	0.05*
632030	Maté	0.05*
632990	Others	0.05*
633000	(c) Roots	0.05*
633010	Valerian root	0.05*
633020	Ginseng root	0.05*
633990	Others	0.05*
639000	(d) Other herbal infusions	0.05*
640000	(iv) Cocoa (fermented beans)	0.05*
650000	(v) Carob (st johns bread)	0.05*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0.05*
800000	8. SPICES	0.05*
810000	(i) Seeds	0.05*
810010	Anise	0.05*
810020	Black caraway	0.05*
810030	Celery seed (Lovage seed)	0.05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Flurtamone
810040	Coriander seed	0.05*
810050	Cumin seed	0.05*
810060	Dill seed	0.05*
810070	Fennel seed	0.05*
810080	Fenugreek	0.05*
810090	Nutmeg	0.05*
810990	Others	0.05*
820000	(ii) Fruits and berries	0.05*
820010	Allspice	0.05*
820020	Anise pepper (Japan pepper)	0.05*
820030	Caraway	0.05*
820040	Cardamom	0.05*
820050	Juniper berries	0.05*
820060	Pepper, black and white (Long pepper, pink pepper)	0.05*
820070	Vanilla pods	0.05*
820080	Tamarind	0.05*
820990	Others	0.05*
830000	(iii) Bark	0.05*
830010	Cinnamon (Cassia)	0.05*
830990	Others	0.05*
840000	(iv) Roots or rhizome	0.05*
840010	Liquorice	0.05*
840020	Ginger	0.05*
840030	Turmeric (Curcuma)	0.05*
840040	Horseradish	0.05*
840990	Others	0.05*
850000	(v) Buds	0.05*
850010	Cloves	0.05*
850020	Capers	0.05*
850990	Others	0.05*
860000	(vi) Flower stigma	0.05*
860010	Saffron	0.05*
860990	Others	0.05*
870000	(vii) Aril	0.05*
870010	Mace	0.05*
870990	Others	0.05*
900000	9. SUGAR PLANTS	0.02*
900010	Sugar beet (root)	0.02*
900020	Sugar cane	0.02*
900030	Chicory roots	0.02*
900990	Others	0.02*
1000000	10. PRODUCTS OF ANIMAL ORIGIN- TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	
1011010	Meat	
1011020	Fat free of lean meat	
1011030	Liver	
1011040	Kidney	
1011050	Edible offal	
1011990	Others	
1012000	(b) Bovine	
1012010	Meat	
1012020	Fat	
1012030	Liver	
1012040	Kidney	
1012050	Edible offal	
1012990	Others	
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	
1014010	Meat	
1014020	Fat	
1014030	Liver	
1014040	Kidney	
1014050	Edible offal	
1014990	Others	
1015000	(e) Horses, asses, mules or hinnies	
1015010	Meat	
1015020	Fat	
1015030	Liver	
1015040	Kidney	
1015050	Edible offal	
1015990	Others	
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl- , ostrich, pigeon	
1016010	Meat	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offal	
1016990	Others	
1017000	(g) Other farm animals (Rabbit, Kangaroo)	
1017010	Meat	
1017020	Fat	
1017030	Liver	
1017040	Kidney	
1017050	Edible offal	
1017990	Others	
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others	
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	
1030010	Chicken	
1030020	Duck	
1030030	Goose	
1030040	Quail	
1030990	Others	
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

(*) Indicates lower limit of analytical determination
(a): Table footnote

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




Result EU assessment
Comparison of the EU recommendation with the existing CXL
CXL available?
Yes
No
RD comparable?
Yes
No
CXL higher?
Yes
No
Consumer risk assessment with consideration of the existing CXL
CXL supported by data?
No
Yes
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
Input values for the RA remain unchanged.
CXL is included in the RA.
Codex median/ highest residues are included in the RA.
Risk identified?
Risk identified?
Yes
No
Yes
No
Recommendations with consideration of the existing CXL
(I) Maintain EU recommendation indicating that no CXL is available.
(II) Maintain EU recommendation indicating CXL is not compatible.
(III) Maintain EU recommendation indicating that CXL is covered.
(IV) Maintain EU recommendation; higher CXL is not safe for consumer.
(V) Maintain current CXL or EU recommendation?
(VI) Maintain EU recommendation; higher CXL is not safe for consumer.
(VII) CXL is recommended; EU recommendation is covered as well.

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detector
GC-MS	gas chromatography with mass spectrometry
GC-MS/MS	gas chromatography with tandem mass spectrometry
ha	hectare
hL	hectolitre
ILV	independent laboratory validation

ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
L	litre
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residue Overview File
RA	risk assessment
RAC	raw agricultural commodity
RD	residue definition
RMS	rapporteur Member State
SCFCAH	Standing Committee on the Food Chain and Animal Health
SEU	Southern European Union
TRR	total radioactive residue