European Food Safety Authority

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REASONED OPINION

Review of the existing maximum residue levels (MRLs) for cyromazine according to Article 12 of Regulation (EC) No 396/2005[1]

European Food Safety Authority[2, 3]

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SUMMARY

Cyromazine was included in Annex I to Directive 91/414/EEC on 01 January 2010, which is after 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(1) of afore mentioned regulation. In order to collect the relevant pesticide residues data, EFSA asked Greece, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile) and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 05 July 2010 and, after having considered several comments made by EFSA, the RMS provided on 26 October 2010 a revised PROFile and evaluation report.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, on the scientific opinion of EFSA on melamine in food and feed, and on the additional information provided by the RMS, EFSA issued on 25 February 2011 a draft reasoned opinion that was circulated to Member State experts for consultation. Comments received by 29 April 2011 were considered for finalisation of this reasoned opinion. The following conclusions are derived.

The toxicological profile of cyromazine was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.06 mg/kg bw/d and an ARfD of 0.1 mg/kg bw. The toxicological profile of melamine was evaluated in the scientific opinion on melamine in food and feed, which resulted in a TDI of 0.2 mg/kg bw/d.

Primary crop metabolism of cyromazine was investigated in two different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for risk assessment in fruits and leafy vegetables could be defined as cyromazine and melamine separately. For enforcement purposes it is proposed to define the relevant residue as the parent compound only because melamine may originate from other sources (such as veterinary use, packaging, flame retardants,…) and because the parent compound is an adequate indicator for the pesticide use of cyromazine. A validated analytical method for enforcement of this residue definition with a LOQ of 0.05 mg/kg in high water content commodities is also available. Considering that the

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use of cyromazine is also supported in peas (with pods) and beans (with pods), an additional metabolism study is required in order to confirm the proposed residue definition for pulses and oilseeds as well.

The available residues data are considered acceptable to derive MRL proposals as well as risk assessment values for parent cyromazine in all commodities under evaluation except for lettuce and rucola where MRLs and risk assessment values were derived from a tentative extrapolation. In most of the crops, residue trials were also appropriate to derive risk assessment values and, in case risk managers would have the intention to establish specific melamine MRLs reflecting the pesticide use of cyromazine, optional MRLs for melamine. For lettuce, lamb's lettuce, scarole, rucola and celery however, where residues trials measuring melamine were not available, no MRL could be proposed. For this reason, cyromazine MRL proposals for these 5 crops are considered tentative. For beans (with pods) and peas (with pods), all calculated values are also considered tentative because a confirmatory metabolism study is still required for these two crops.

In processed commodities, levels of cyromazine were shown to be stable during pasteurisation baking, boiling, brewing and sterilisation. Studies investigating the magnitude of residues in some processed products are also available but they only allowed EFSA to derive indicative processing factors. With regard to the risk assessment, further processing studies are not required because they are not expected to affect the outcome of the risk assessment. However, if there would be the intention from risk managers to derive more processing factors for enforcement purposes, additional processing studies might be required.

Occurrence of residues in rotational crops was already investigated during the peer review of cyromazine. It was concluded that in practice no significant residues of cyromazine or melamine are expected in rotational crops.

Based on the uses reported by the RMS, no significant intake resulting from the pesticide use of cyromazine was calculated for dairy ruminant, meat ruminant, poultry and pig. In consequence there is no need to propose a residue definition and to set MRL for animal products at this stage. However, this point has to be reconsidered if further uses are envisaged on crops fed to animals. EFSA also points out that livestock may be exposed to melamine originating from others sources (contaminants, veterinary drugs and food contact materials) but this point is not considered in the context of this MRL review.

Both chronic and acute consumer exposure were calculated for cyromazine and melamine resulting from the pesticide uses of cyromazine reported in the framework of this review. The highest chronic exposure for cyromazine was calculated for French toddlers, representing 3.4 % of the ADI and an exceedance of the ARfD was identified for scarole, representing 114.5 % of the ARfD. A second exposure calculation was therefore performed, excluding this crop. According to the results of this second calculation, the highest chronic exposure remained unchanged; the highest acute exposure is then calculated for cucumbers, representing 76 % of the ARfD. The highest chronic exposure for the melamine metabolite was calculated for the WHO cluster diet B, representing 0.3% of the ADI and highest acute intakes represent 19 % of the ARfD for melon. Although the consumer exposure to melamine resulting from the pesticide use of cyromazine was found to be limited compared to the exposure of cyromazine itself and compared to the overall melamine exposure resulting from other sources of melamine, it is highlighted that the consumer exposure to melamine through the pesticide use of cyromazine on lamb's lettuce, lettuce, scarole, rucola and celery could not be finalised.

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 (see table below for a summary). All MRL values for cyromazine listed in the table as 'Recommended' are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values for cyromazine

listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain tentative MRLs still need to be confirmed by the following data :

- a representative metabolism study for pulses and oilseeds;
- 8 residue trials supporting the indoor GAP on lettuce and rucola;
- 4 residue trials supporting the respective GAPs on lamb's lettuce and celery.

If this data gap is not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the 'Recommended' MRLs or on the national authorisations. Investigation of storage stability for a period of 30 months in commodities with high water content is therefore considered desirable but not essential.

Regarding the MRL proposals for melamine, EFSA points out that melamine might originate from different sources. The presence of melamine in the food chain is regulated by different pieces of legislation (i.e. contaminants, veterinary drugs and food contact materials). Likewise, EFSA highlights that MRLs could not be derived for melamine in leafy vegetables and that MRLs established for cyromazine are already good indicators for monitoring the use of cyromazine as a pesticide. If it is appropriate to establish MRLs for melamine reflecting the pesticide use of cyromazine in the framework of Regulation (EC) No 396/2005, the MRL proposals listed in the table would be the most appropriate.

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Result of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition 1 : cyromazine					
231010	Tomatoes	1	1	0.6	Recommended[(1)]
231020	Peppers	1	1	1.5	Recommended[(1)]
231030	Aubergines (egg plantes)	1	1	0.6	Recommended[(1)]
232010	Cucumbers	1	2	2	Recommended[(1)]
232020	Gherkins	1	-	2	Recommended[(1)]
232030	Courgettes	1	2	2	Recommended[(1)]
233010	Melons	0.3	0.5	0.4	Recommended[(1)]
233020	Pumpkins	0.05*	-	0.4	Recommended[(1)]
233030	Watermelons	0.3	-	0.4	Recommended[(1)]
251010	Lamb's lettuce	15	-	15	Further consideration needed[(2)]
251020	Lettuce	3	4	3	Further consideration needed[(2)]
251030	Scarole	0.05*	-	-	Further consideration needed[(4)]
251060	Rocket, rucola	15	-	3	Further consideration needed[(2)]
260010	Beans (fresh with pods)	5	1	5	Further consideration needed[(3)]
260030	Peas (fresh with pods)	5	-	5	Further consideration needed[(3)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Result of the review	
				MRL (mg/kg)	Comment
270030	Celery	2	4	3	Further consideration needed(2)
280010	Cultivated fungi	5	7	10	Recommended(1)
-	Others products of plant and animal origins	See appendix C.1	See appendix C.2	-	Further consideration needed(5)
Enforcement residue definition 2 : melamine (optional)					
231010	Tomatoes	-	-	0.2	Further consideration needed(6)
231020	Peppers	-	-	0.4	Further consideration needed(6)
231030	Aubergines (egg plantes)	-	-	0.2	Further consideration needed(6)
232010	Cucumbers	-	-	0.8	Further consideration needed(6)
232020	Gherkins	-	-	0.8	Further consideration needed(6)
232030	Courgettes	-	-	0.8	Further consideration needed(6)
233010	Melons	-	-	0.4	Further consideration needed(6)
233020	Pumpkins	-	-	0.4	Further consideration needed(6)
233030	Watermelons	-	-	0.4	Further consideration needed(6)
251010	Lamb's lettuce	-	-	-	Further consideration needed(7)
251020	Lettuce	-	-	-	Further consideration needed(7)
251030	Scarole	-	-	-	Further consideration needed(7)
251060	Rocket, rucola	-	-	-	Further consideration needed(7)
260010	Beans (fresh with pods)	-	-	0.3	Further consideration needed(8)
260030	Peas (fresh with pods)	-	-	0.3	Further consideration needed(8)
270030	Celery	-	-	-	Further consideration needed(7)
280010	Cultivated fungi	-	-	1	Further consideration needed(6)
-	Others products of plant and animal origins	-	-	-	Further consideration needed(9)

(1): 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 or, if available, not compatible with EU residue definitions for risk assessment (combination G-I in Appendix D).

(2): Tentative MRL is derived from a GAP evaluated at EU level; no risk to consumers could be identified with regard to cyromazine but EFSA was not able to perform the risk assessment related to melamine; no CXL is available or, if available, not compatible with EU residue definitions for risk assessment (combination E-I in Appendix D).

(3): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified (assuming the existing residue definition); no CXL is available or, if available, not compatible with EU residue definitions for risk assessment (combination E-I in Appendix D).

(4): GAP evaluated at EU level is not fully supported by data and a risk to consumers cannot be excluded; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix D).

(5): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available or, if available, not compatible with EU residue definitions for risk assessment. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

(6): If MRLs for melamine are considered nevessary by risk managers, this calculated value 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.

(7): Residue levels for melamine resulting from the pesticide use of cyromazine are not available for this crop; MRL cannot be derived and EU MRLs or CXLs are currently not available. Although exposure to melamine levels is expected to be less critical than to cyromazine itself, risk assessment can also not be finalised.
(8): If MRLs for melamine are considered nevessary by risk managers, this tentative value is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified (assuming the existing residue definition); no CXL is available.
(9): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. If MRLs for melamine are considered nevessary by risk managers, either the specific LOQ or the default MRL of 0.01 mg/kg may be considered.

KEY WORDS

Cyromazine, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, triazine, insecticide, melamine.

TABLE OF CONTENTS

BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting as well as the review of pesticide MRLs at Community level. Article 12(1) of that regulation lays down that EFSA shall provide within 12 months from the date of the inclusion or non-inclusion of an active substance in Annex I to Directive 91/414/EEC[5] a reasoned opinion on the review of the existing MRLs for that active substance. As cyromazine was included in Annex I to the above mentioned directive on 01 January 2010, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2010-00184 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 for all uses authorised within the EC as well as uses authorised in third countries having a significant impact on international trade. The information included in the assessment report prepared under Directive 91/414/EEC is therefore insufficient for the assessment of all existing MRLs for a given active substance.

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

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

Greece, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for cyromazine and to prepare a supporting evaluation report. The requested information was submitted to EFSA on 05 July 2010 and subsequently checked for completeness. On 26 October 2010, after having clarified some issues with EFSA, the RMS provided a revised PROFile and evaluation report.

A draft reasoned opinion was issued by EFSA on 25 February 2011 and submitted to Member States (MS) for commenting. All MS comments received by 29 April 2011 were evaluated by EFSA. The conclusions of this meeting were considered by EFSA for finalization 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.

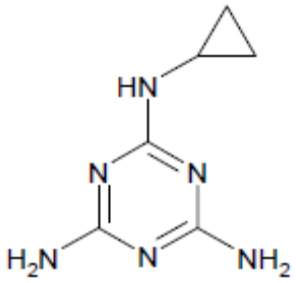
TERMS OF REFERENCE

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

Cyromazine is the ISO common name for N-cyclopropyl-1,3,5-triazine-2,4,6-triamine (IUPAC).



Cyromazine belongs to the group of triazine compounds which are used as insecticide. Cyromazine is a dipteran moulting disruptor. It is a systemic compound which inhibits larval growth and development and prevents the adult emergence from the pupae.

Cyromazine was evaluated in the framework of Directive 91/414/EEC with Greece being the designated rapporteur Member State (RMS). The representative use supported for the peer review process was the indoor foliar treatment of tomatoes at a rate of 0.300 kg as./ha, with up to 4 applications in both northern and southern Europe. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2009/77/EC[6], entering into force on 01 January 2010. The Annex I inclusion of cyromazine is restricted to uses as insecticide in greenhouses only.

EU MRLs for cyromazine in products of plant and animal origin have been set for the first time in 2002 by means of Directive 2002/79/EC[7] and modified in 2005 and 2008, by means of Directives 2005/76/EC[8] and 2008/17/EC[9] respectively. These MRLs have been transferred to Annex II of Regulation (EC) No 396/2005 and will be modified as from 1 January 2012 by means of Regulation (EU) No 559/2011[10]. Additional MRLs for commodities that were not covered by the former European MRL legislation are established in Annex III B of the Regulation. These temporary MRLs were derived from the MRLs that have been set at national level before the Regulation entered into force. All existing EU MRLs, which are established for the parent compound only are summarized in Appendix C.1 to this document. CXLs for cyromazine were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to parent compound only.

For the purpose of this MRL review, the critical uses of cyromazine currently authorized within the EU have been collected by the RMS and reported in the PROFile. A detailed overview of the critical GAPs is available in Appendix A to this document. They include up to three indoor foliar applications in several crops with a maximum application rate of 300 g a.s/ha. Some other critical GAPs which include an outdoor foliar application were reported in the PROFile with up to 2 applications at a rate of 65 g a.s./ha in northern Europe. At last, another GAP concerns a soil treatment in cultivated fungi in Europe with one application at a rate of 4.05 kg a.s/ha performed from before inoculation of spores to before fruit body development.

[6] Commission Directive 2009/77/EC of 1 July 2009, OJ L 172, 2.7.2009, p. 23-33.
[7] Commission Directive 2002/79/EC of 2 October 2002, OJ L 291, 28.10.2002, p. 1-19.
[8] Commission Directive 2005/76/EC of 8 November 2005, OJ L 293, 09.11.2005, p. 14-22.
[9] Commission Directive 2008/17/EC of 19 February 2008, OJ L 50, 23.02.2008, p. 17-48.
[10] Commission Regulation (EU) No 559/2011 of 7 June 2011, OJ L 152 of 11.6.2011, p. 1-21.

ASSESSMENT

EFSA based its assessment on the PROFile submitted the RMS, the evaluation report accompanying the PROFile (Greece, 2010), the conclusion on the peer review of the pesticide risk assessment of the active substance cyromazine (EFSA, 2008), the JMPR Evaluation report (FAO, 2007), the scientific opinion of EFSA on melamine in food and feed (EFSA, 2010) and the evaluation reports submitted during the Member States consultation (Belgium, 2011; The Netherlands, 2011). The assessment was performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products set out in Annex VI to Council Directive 91/414/EEC 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, 2004, 2010, 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, a method using LC-LC-UV and its ILV was evaluated and adequately validated for the determination of cyromazine and its metabolite melamine in plant matrices with a LOQ of 0.05 mg/kg in high water content (tomatoes, beans, potatoes), high fat content (sunflower seeds) and acidic (orange) commodities. The LOQ applies to each compound separately and a confirmatory method has been submitted (Greece, 2007; EFSA, 2008).

Hence it is concluded that cyromazine and melamine can be enforced in food of plant origin with, for each compound, a LOQ of 0.05 mg/kg in high water content, high fat content and acidic commodities.

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

During the peer review under Directive 91/414/EEC, a method using HPLC-MS/MS and its ILV were evaluated and found validated for the determination of cyromazine and its metabolite melamine in food of animal origin with a LOQ of 0.01 mg/kg in bovine muscle, bovine milk, chicken egg, ovine kidney and ovine liver. The LOQ applies to each compound separately (Greece, 2007; EFSA, 2008).

Nevertheless, in food of animal origin, no residue definition or MRLs were derived due to the low exposure of livestock to cyromazine residues (section 3.2). Therefore, an analytical method for enforcement of residues in food of animal origin is in principle not necessary.

2. Mammalian toxicology

The toxicological assessment of cyromazine was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by EFSA (2008). These toxicological reference values are summarized in Table 2-1.

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Parent compound : cyromazine					
ADI	EFSA	2008	0.06 mg/kg bw/d	1-year dog study supported by 2- year mouse study	100
ARfD	EFSA	2008	0.1 mg/kg bw	Developmental study in rabbit	100

The ADI of cyromazine is derived from a semi-chronic study in dogs supported by a long-term study in mice. The critical effects include decreased body weight gain, liver weight changes and haematological and clinical chemistry changes in dogs and decreased body weight gain in mice.

The toxicological profile of melamine (as a plant and more specifically as a groundwater metabolite) was initially addressed by means of an extensive literature review prepared by the RMS (Greece, 2007). During the peer review under Directive 91/414/EEC, it was agreed also that melamine is not genotoxic, it is of low acute toxicity and has no toxicological relevance for groundwater (EFSA, 2008); furthermore since melamine is a major rat metabolite (found in urine at a level of up to 10.7 %), it was agreed, as a worst case assumption, that the ADI of the parent (cyromazine) should be considered relevant for melamine risk assessment.

On the other hand, the CONTAM and CEF panels issued an assessment of melamine in food and feed (EFSA,2010). In sub-chronic toxicity studies the kidney was found to be the main target organ of melamine toxicity in rodent animals. Melamine can form complexes with urinary uric acid in some conditions of pH and uric acid concentration. This critical effect is considered relevant for short term exposure assessment. The panel concluded that the 13-week NTP studies with dietary exposure of male rats provided the best basis for dose response modelling. The Panel identified, for a 10 % increase in urinary bladder crystals, a benchmark dose (BMD10) of 41 mg/kg b.w. per day and its lower confidence limit (BMDL10) of 19 mg/kg b.w. per day. The Panel considered an uncertainty factor of 100 and established a TDI of 0.2 mg/kg bw/d.

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 cyromazine has been investigated using ^{14}C-cyromazine labelled on the triazine ring in celery, lettuce and tomatoes representing two groups of plants: leafy and fruit crop groups. The information is sufficient with regard to these representative uses and are presented in table 3-1.

All these studies confirm that parent cyromazine and melamine represent the major part of the TRR, accounting for 37.1 - 74.0 % and 10.9 – 45.4 % respectively. For celery and lettuce, it was pointed out that the part of the uncharacterised/unidentified radioactivity accounting for 7 to 17 % of the TRR may represent an absolute residue level up to 0.5 mg/kg, taking into account the high total radioactivity levels observed at certain PHI (5.8 mg/kg in celery stems, 4.05 mg/kg in lettuce leaves).

However the RMS confirmed that at GAP application rates, any unidentified fraction would contain any individual compound above 0.01 mg/kg (EFSA, 2008).

In addition to the foliar application, a study was performed where ^{14}C-cyromazine was applied as a soil treatment at a rate of 1 000 g a.s./ha in order to maximise the potential uptake of the active substance and its potential soil metabolites into rotational crops. Celery plants were grown for 6 or 12 weeks after soil application. A similar metabolic pathway was observed at harvest 12 weeks after planting. Parent cyromazine and melamine metabolite appeared to be the main compounds of concern, accounting for 42.9 % and 29.6 % of the TRR respectively (EFSA, 2008).

The submitted studies suggest a common metabolism pathway in the two plant groups covered with a simple metabolic transformation in leaves and fruits to yield the dealkylated product melamine. No metabolites were identified resulting from further breakdown of the triazine ring over the post-treatment time periods investigated (0 – 14 days).

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

Group	Crop	Label position	Method, F or G [(a)]	Application details			
				Rate	No	Sampling	Remarks
Fruits and fruiting vegetable	Tomato	[Triazine-U-^{14}C]-cyromazine	Foliar treatment (F)	280 g as/ha	6	0, 7, and 14 days after the fourth and sixth applications	
Leafy vegetables	Celery	[Triazine-U-^{14}C]-cyromazine	Foliar treatment (G)	280 g as/ha	6	7 days after the third application and 14 days after the last application	
Leafy vegetables	Lettuce	[Triazine-U-^{14}C]-cyromazine	Foliar treatment (G)	280 g as/ha	4	7 days after the second application and 7 days after the last application	
Leafy vegetables	Celery	[Triazine-U-^{14}C]-cyromazine	Soil treatment (G)	140 g as/ha[b]	12	42 and 84 DAT	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): In this study ^{14}C-cyromazine was applied to a celery crop as a soil top dressing in order to maximise the potential uptake of the active substance and metabolites from soil into the target crop (celery) and subsequent rotational crops. The application rate reflected the maximum expected run-off from a celery crop treated 12 x at 0.14 kg a.s./ha. The calculated run-off was based on the stage of celery growth at the time of spraying, and was estimated to be 90 % for the first 4 sprays, 60 % for the next 4 sprays and 30 % for the final 4 sprays, giving a total run-off of 1 kg a.s./ha over the growing season.

Foliar studies were also conducted in the US on celery, lettuce, tomatoes, carrots and mushroom with unlabelled material and exaggerated agricultural practices (up to 19 applications and 5 320 g a.s./ha). Only parent cyromazine and melamine were analysed for in the samples collected in these trials. During the peer review, it was concluded that these studies were not acceptable because analytical methods were not fully valitaded. Consequently they were not taken into account for setting residue definition. They only gave indivative information on the residue levels of cyromazine and melamine observed in crops (EFSA, 2008).

Though it was mentioned that consumer exposure to melamine may be possible through other sources (plastics, colorant, flame retardants, veterinary drugs…), EFSA initially decided to include melamine in the residue definition for risk assessment based on the high melamine residue levels observed in the treated crops and the worst-case assumption that melamine had the same toxicological profile as the parent (EFSA, 2008). The following residue definitions for fruits and leafy crops were proposed:

- For enforcement: cyromazine;
- For risk assessment: sum of cyromazine and melamine, expressed as cyromazine.

However, the notifier submitted to the RMS, in the framework of this MRL review, a position paper to exclude melamine from the RA residue definition for plant commodities. According to the notifier, cyromazine and melamine do not have the same toxicological endpoints and should be considered as two different compounds (Greece, 2010). This statement is further corroborated by the toxicological assessment that was carried out by EFSA's CONTAM and CEF panels (see section 2 for detailed information). EFSA therefore agrees that melamine and cyromazine require a separate risk assessment.

Regarding the enforcement of cyromazine residues, EFSA highlights that the parent compound is already a good indicator for the pesticide use of cyromazine. Also considering that the presence of melamine in the food chain is already regulated by different pieces of legislation (*i.e.* contaminants, veterinary drugs and food contact materials), it might not be appropriate to enforce occurence of melamine in the framework of the pesticide legislation. Consequently, the following residues definitions are proposed:

- For enforcement: cyromazine;
- For risk assessment: cyromazine and melamine separately.

These residue definitions reflect the views of EFSA but they are different from JMPR Evaluation report (FAO, 2007), where the relevant residue for risk assessment was defined in plants as cyromazine only.

Based on the available metabolism data, EFSA also concludes that the proposed residue definitions are applicable to all commodities under evaluation, except beans (with pods) and peas (with pods). Indeed, a data gap is identified and a representative metabolism study is needed for pulses and oilseeds in order to confirm applicability of the proposed residue definition in these two crops. It is noted that metabolism in cultivated fungi was also not investigated but in this case assumed to be covered by the available studies in fruit and leafy crops.

3.1.1.2. Magnitude of residues

The use of cyromazine was reported on several crops by the RMS (Appendix A). Supervised residue trials supporting these uses were initially reported by the RMS (Greece, 2010) but additional data were submitted during the Member State consultation (Belgium, 2011; The Netherlands, 2011). In all reported trials, both parent cyromazine and its metabolite melamine were measured, except for lamb's lettuce, scarole and celery where only the parent compound was measured. The results of the residue trials are summarized in Table 3-2:.

The number of residue trials and extrapolations were evaluated in view of 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:

- For the use of cyromazine on tomatoes, residue trials were performed with 4 applications instead of 3. These trials were already reported in the EFSA conclusion in support of the reprensentative use for the peer review (which involved 4 applications) and, although the

active substance does not demonstrate rapid decline when applied on tomatoes, EFSA accepted residue trials data as representative for the authorized use, since the first applications on tomatoes are done at earlier growth stages. The impact on the residue at harvest is therefore not considered critical.

- For the uses of cyromazine on lamb's lettuce, most of the trials were carried out with more applications than authorised. This higher number of applications was considered acceptable because it can be considered as a worst case and no significant correlaation between residue levels of cyromazine and the number of application was identified. Considering however that available trials for lamb's lettuce did not analyse for melamine, available trials are not fully complying with the proposed residue definitions for risk assessment (cyromazine and melamine separately) and 4 additional trials analyzing for both compounds are still required for each GAP. Consequently, the MRL proposal on lamb's lettuce is only tentative.

- For the uses of cyromazine on lettuce, scarole and rucola, only 4 trials on scarole compliant with the indoor GAP are available. As scarole is morphologically closely related to open leaf varieties of lettuce, EFSA is of the opinion that trials can be extrapolated to lettuce and rucola but on a tentative basis. In fact, this tentative extrapolation is exceptionally accepted since no data are available on lettuce and additional data are anyhow required. It can therefore not be generalized. Moreover, only cyromazine was measured in the available residue trials and residue values are therefore not fully complying with the proposed residue definitions for risk assessment (cyromazine and melamine separately). Consequently, 8 additional residue trials on lettuce (including at least 4 open leaf varieties) measuring both compounds are required; MRL proposals on lettuce, scarole and rucola are only tentative.

- For the use of cyromazine on celery, only cyromazine was measured in the available residue trials. These values are therefore not fully complying with the proposed residue definitions for risk assessment (cyromazine and melamine separately) and 4 residue trials measuring melamine are required for this GAP. Consequently, the MRL proposal on celery is only tentative.

Storage stability of cyromazine and melamine was demonstrated for a period of 24 months at -18 °C in high water content commodities (tomatoes and potatoes), hereby covering all crops evaluated in the framework of this review. All the residue trial samples were stored in accordance with these conditions, except for 4 trials on lamb's lettuce where samples were stored for approximately 29 months. Considering that storage stability was demonstrated for a long period and that no degredation was observed, these additional 5 months are not expected to impact significantly on the storage stability. Degradation of parent cyromazine and its metabolite melamine during storage of the trial samples is therefore not expected but investigation of storage stability for a period of 30 months in commodities with high water content is still considered desirable.

Consequently, the available residues data are considered acceptable to derive MRL proposals as well as risk assessment values for parent cyromazine in all commodities under evaluation (see table 3-1) except for lettuce and rucola, where MRLs and risk assessment values were derived from a tentative extrapolation. In most of the crops, residue trials were also appropriate to derive risk assessment values and, in case risk managers would have the intention to establish specific melamine MRLs reflecting the pesticide use of cyromazine, optional MRLs for melamine. For lettuce, lamb's lettuce, scarole, rucola and celery however, where residues trials measuring melamine were not available, no MRL could be proposed. For this reason, cyromazine MRL proposals for these 5 crops are considered tentative. For beans (with pods) and peas (with pods), all calculated values are also considered tentative because a confirmatory metabolism study is still required for these two crops (see section 3.1.1.1). In case where several uses are supported for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in the table.

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

Commodity	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	Risk assessment					
First residue definition for enforcement and risk assessment: cyromazine									
Tomatoes/ Aubergines (egg plants)	EU	Indoor	0.05; 0.05; 0.11; 0.13; 0.15; 0.16; 0.19; 0.19; 0.21; 0.22; 0.25; 0.29; 0.30; 0.34	0.05; 0.05; 0.11; 0.13; 0.15; 0.16; 0.19; 0.19; 0.21; 0.22; 0.25; 0.29; 0.30; 0.34	0.19	0.34	0.6	1.00	GAP compliant residue trials in tomatoes (10) and aubergines (4) from SEU and NEU were combined. Extrapolation of residue data to aubergines is supported. R_{ber}= 0.52 mg/kg R_{max}= 0.42 mg/kg
Peppers	EU	Indoor	0.11; 0.24; 0.25; 0.29; 0.30; 0.33; 0.35; 0.35; 0.36; 0.49; 0.52; 0.66; 0.78; 0.85	0.11; 0.24; 0.25; 0.29; 0.30; 0.33; 0.35; 0.35; 0.36; 0.49; 0.52; 0.66; 0.78; 0.85	0.35	0.85	1.5	1.00	GAP compliant residue trials on peppers from SEU and NEU uses combined. R_{ber}= 1.11 mg/kg R_{max}= 0.98 mg/kg
Cucumbers/ Gherkins/ Courgettes	EU	Indoor	0.32; 0.35; 0.43; 0.46; 0.47; 0.50; 0.51; 0.54; 0.56; 0.79; 0.96; 1.07; 1.30	0.32; 0.35; 0.43; 0.46; 0.47; 0.50; 0.51; 0.54; 0.56; 0.79; 0.96; 1.07; 1.30	0.51	1.30	2	1.00	GAP compliant residue trials on cucumbers from NEU and SEU were combined. The residue data extrapolation to gherkins and courgettes is supported. R_{ber}= 1.75 mg/kg R_{max}= 1.44 mg/kg
Melons/ Pumpkins/ Watermelons	EU	Indoor	0.06; 0.09; 0.10; 0.12; 0.13; 0.16; 0.16; 0.17; 0.18	0.06; 0.09; 0.10; 0.12; 0.13; 0.16; 0.16; 0.17; 0.18	0.13	0.18	0.4	1.00	GAP compliant residue trials on melons from NEU and SEU were combined. Residue data extrapolation to pumpkins and watermelons is supported. R_{ber}= 0.33 mg/kg R_{max}= 0.25 mg/kg

Commodity	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	Risk assessment					
Lamb's lettuce	NEU	Outdoor	0.22; 0.22[e]; 0.58; 0.65[e]	0.22; 0.22[e]; 0.58; 0.65[e]	0.40	0.65	2	1.00	Four trials on lamb's lettuce supporting the northern outdoor GAP although three trials were carried with 3 or 4 applications instead of 2. Rber = 1.27 mg/kg Rmax = 1.6 mg/kg (Belgium, 2011; The Netherlands, 2011).
	EU	Indoor	0.20; 0.75[e]; 3.42; 6.24[e]	0.20; 0.75[e]; 3.42; 6.24[e]	**2.09**	**6.24**	**15** (tentative)	**1.00**	Four trials on lamb's lettuce supporting the indoor GAP although three residue trials were carried out with 3 applications instead of 2. Rber = 11.07 mg/kg Rmax = 16.92 mg/kg (Belgium, 2011; The Netherlands, 2011).
Lettuce Scarole (broad leaf endive) Rocket (rucola)	NEU	Outdoor	0.06; 0.57	0.06; 0.57	-	-	-	1.00	Trials on scarole compliant with the outdoor GAP but not sufficient to derive robust MRL and risk assessment values. Outdoor GAP not authorised for lettuce and rocket (Belgium, 2011; The Netherlands, 2011).
	EU	Indoor	0.16; 0.19; 0.24; 1.31	0.16; 0.19; 0.24; 1.31	0.22	1.31	3 (tentative)	1.00	Trials on scarole compliant with the indoor GAP. Tentative extrapolation to lettuce and rocket is acceptable. In fact, this tentative extrapolation is an exceptional case and can not be generalized. Rber = 2.08 mg/kg Rmax = 3.34 mg/kg (Belgium, 2011; The Netherlands, 2011).

Commodity	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	Risk assessment					
Beans (fresh with pods)/ Peas (fresh with pods)	EU	Indoor	0.65; 0.96; 1.4; 1.4; 1.5; 2.3; 2.35; 2.54	0.65; 0.96; 1.4; 1.4; 1.5; 2.3; 2.35; 2.54	1.45	2.54	5	1.00	GAP compliant residue trials on fresh beans (with pods) for SEU use submitted. Extrapolation to fresh peas (with pods) supported. R_{ber}= 4.68 mg/kg R_{max}= 3.84 mg/kg
Celery	EU	Indoor	0.14; 0.145; 0.489; 0.87	0.14; 0.145; 0.489; 0.87	0.32	0.87	3 (tentative)	1.00	Trials on celery compliant with the indoor GAP. Rber = 1.55 mg/kg Rmax = 2.2 mg/kg (Belgium, 2011; The Netherlands, 2011).
Cultivated fungi	EU	Indoor	0.44; 1.63; 2.80; 4.30	0.44; 1.63; 2.80; 4.30	2.22	4.30	10	1.00	GAP compliant residue trials on fungi submitted. R_{ber}= 7.85 mg/kg R_{max}= 10.78 mg/kg
Second residue definition for risk assessment: melamine (enforcement of this residue definition is considered optional)									
Tomatoes/ Aubergines (egg plants)	EU	Indoor	<0.05; 0.05; 0.05; 0.05; 0.06; 0.06; <0.07; 0.07; 0.07; 0.09; 0.05; 0.07; 0.09; 0.10	<0.05; 0.05; 0.05; 0.05; 0.06; 0.06; <0.07; 0.07; 0.07; 0.09; 0.05; 0.07; 0.09; 0.10	0.07	0.10	0.2	1.00	GAP compliant residue trials in tomatoes (10) and aubergines (4) from SEU and NEU were combined. Extrapolation of residue data from tomatoes and aubergines supported. R_{ber}= 0.15 mg/kg R_{max}= 0.11 mg/kg
Peppers	EU	Indoor	<0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; 0.06; 0.08; 0.09; 0.10; 0.11; 0.31	<0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; <0.05; 0.06; 0.08; 0.09; 0.10; 0.11; 0.31	0.05	0.31	0.4	1.00	GAP compliant residue trials on peppers from NEU and SEU combined. R_{ber}= 0.19 mg/kg R_{max}= 0.26 mg/kg

Commodity	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	Risk assessment					
Cucumbers/ Gherkins/ Courgettes	EU	Indoor	0.07; 0.08; 0.08; 0.08; 0.08; 0.13; 0.21; 0.23; 0.28; 0.29; 0.35; 0.53; 0.60	0.07; 0.08; 0.08; 0.08; 0.08; 0.13; 0.21; 0.23; 0.28; 0.29; 0.35; 0.53; 0.60	0.21	0.60	0.8	1.00	GAP compliant residue trials on cucumbers from NEU and SEU were combined. The residue data extrapolation to gherkins and courgettes is supported. R_{ber}= 0.64 mg/kg R_{max}= 0.70 mg/kg
Melons/ Pumpkins/ Watermelons	EU	Indoor	0.05; 0.05; 0.06; 0.11; 0.13; 0.16; 0.17; 0.23; 0.25	0.05; 0.05; 0.06; 0.11; 0.13; 0.16; 0.17; 0.23; 0.25	0.13	0.25	0.4	1.00	GAP compliant residue trials on melons from NEU and SEU were combined. Residue data extrapolation to pumpkins and watermelons is supported. R_{ber}= 0.40 mg/kg R_{max}= 0.36 mg/kg
Lamb's lettuce	NEU	Outdoor	-	-	-	-	-	-	Residues trials available (see above) but levels of melamine were not measured (Belgium, 2011; The Netherlands, 2011).
	EU	Indoor	-	-	-	-	-	-	Residues trials available (see above) but levels of melamine were not measured (Belgium, 2011; The Netherlands, 2011).
Lettuce Scarole (broad leaf endive) Rocket (rucola)	NEU	Outdoor	-	-	-	-	-	-	Residues trials available (see above) but levels of melamine were not measured (Belgium, 2011; The Netherlands, 2011).
	EU	Indoor	-	-	-	-	-	-	Residues trials available (see above) but levels of melamine were not measured (Belgium, 2011; The Netherlands, 2011).

Commodity	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	Risk assessment					
Beans (fresh with pods)/ Peas (fresh with pods)	EU	Indoor	0.05; 0.07; 0.08; 0.09; 0.13; 0.13; 0.14; 0.19	0.05; 0.07; 0.08; 0.09; 0.13; 0.13; 0.14; 0.19	0.11	0.19	0.3 (tentative)	1.00	GAP compliant residue trials on fresh beans (with pods) for SEU use submitted. Extrapolation to fresh peas (with pods) supported. R_{ber}= 0.28 mg/kg R_{max}= 0.26 mg/kg
Celery	EU	Indoor	-	-	-	-	-	-	Residues trials available (see above) but levels of melamine were not measured (Belgium, 2011; The Netherlands, 2011).
Cultivated fungi	EU	Indoor	0.22; 0.22; 0.36	0.22; 0.22; 0.36	0.22	0.36	1	1.00	GAP compliant residue trials on fungi submitted. One residue trial (3.07 mg/kg) was disregarded as high melamine residues were identified in control samples, indicating possible contamination from other sources than from the use of cyromazine. Rber= n.a. Rmax= 0.89 mg/kg

(a): NEU, SEU, EU or Import (country code). In the case of indoor uses there is no necessity to differentiate between NEU and SEU.
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residue trial.
(e): Residues trials samples were stored approximately for 29 months.
n.a.: not applicable

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of cyromazine was investigated in the framework of the peer review. A study was conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 120°C, pH 6), boiling/brewing/baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 90°C, pH 4). This study meets the requirements to determine the effect of normal processing (cooking) on high water content commodities (hereby tomatoes, peppers, aubergines, cucurbits with edible peel, cucurbits with inedible peel, beans and peas with pods, and mushrooms). This study showed that cyromazine is hydrolytically stable under these conditions and that no formation of toxicologically relevant metabolites occurs (Greece, 2007; EFSA, 2008).

However, the effect of processing on the nature of melamine was not investigated. Since melamine metabolite denotes a similar chemical structure and the parent cyromazine remains stable to industrial processing and household preparation (recoveries for cyromazine 99.0 to 101.1% depending on conditions), it is agreed that there is no need for a new processing study including melamine (EFSA, 2008).

Additionally, a full processing study on tomatoes has been carried out to determine the magnitude of residues in processed tomato commodities. Processing factors for residues from the RAC to the processed product were calculated (EFSA, 2008). In addition, some residues trials on melons reported residue levels in peel and pulp (Greece, 2010), which allowed EFSA to derive processing factors for peeling. An overview of all available processing studies is available in Table 3-3:.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Indicative processing factors (limited data sets)				
First residue definition for enforcement and risk assessment: cyromazine				
Tomatoes, peeled and canned	2	0.50	1.00	Mean processing factors reported (Greece, 2007).
Tomatoes, sauce	2	1.20	1.00	
Tomatoes, paste	2	2.10	1.00	
Tomatoes, ketchup	2	0.84	1.00	
Tomatoes, juice	2	0.75	1.00	
Melons, peleed Pumpkins, peeled Watermelons, peeled	2	0.61	1.00	Mean peeling factor derived from melon residue trials; extrapolation to pumpkins and watermelons possible. In both studies residues in pulp below the LOQ of 0.05 mg/kg.
Second residue definition for risk assessment: melamine (enforcement of this residue definition is considered optional)				
Melons, peleed Pumpkins, peeled Watermelons, peeled	2	1.00	1.00	Mean peeling factor derived from melon residue trials; extrapolation to pumpkins and watermelons possible.

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

All processing factors reported should be considered indicative as they are not sufficiently supported by studies; a minimum of 3 processing studies is normally required. With regard to the risk assessment, further processing studies are not required as they are not expected to affect the outcome of the risk assessment. However, if there would be the intention to derive more robust processing factors, in particular for enforcement purposes, additional processing studies would be required.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Cyromazine is authorised for use in differents crops, where rotation may occur. Moreover, it was also demonstrated in several laboratory degradation studies that the DT_{90} value for cyromazine may exceed the trigger value of 100 days and reaches up to a maximum of 186 days (EFSA, 2008). Therefore cyromazine uses require further consideration of residues in rotational crops.

3.1.2.2. Nature of residues

Two metabolism crop studies were performed in the US for all five representative crops : fruits and fruiting vegetables, root and tuber vegetables, leafy vegetables, pulses and oilseeds as well as cereals. These studies are carried out with [triazine-U-^{14}C]-cyromazine in indoor (glasshouse) and outdoor (field) conditions at representative rates. As the TRR in rotational crops was too low for characterization, no residue definition is proposed in rotational crops (EFSA, 2008).

3.1.2.3. Magnitude of residues

Two rotational crop studies performed in the US have been submitted. Following multiple applications (12-15) of unlabelled cyromazine on a primary crop (celery or tomato), sweet corn, radish and lettuce were planted as rotational crops at different plant-back intervals of 1 to 8 weeks after the harvest of the primary crop. Due to the high application rates used in these trials, it was concluded that the US data are acceptable and that no significant residues of cyromazine or melamine are expected in practice in rotational crops (EFSA, 2008).

3.2. Nature and magnitude of residues in livestock

Cyromazine is not authorised for use on crops that might be fed to livestock. Further investigation on the occurrence of cyromazine residues in commodities of animal origin is therefore not required and the setting of MRLs in these commodities is not considered necessary.

Although not required, several studies on the metabolism of cyromazine in lactating goats and laying hens using [triazine-U-^{14}C]-cyromazine were submitted and evaluated in the framework of Directive 91/414/EEC (Greece, 2007). However, also in the framework of the peer review, no residue definition or MRLs were derived due to the low exposure of livestock to cyromazine residues (EFSA, 2008). This point has to be reconsidered if further uses are envisaged on crops fed to animals.

EFSA points out also that livestock may be exposed to melamine originating from others sources (contaminants, veterinary drugs and food contact materials) but this point is not considered in the context of this MRL review.

4. Consumer risk assessment

Considering that two different residue definitions were derived for the risk assessment, separate exposure calculations were carried out for cyromazine and melamine.

Moreover, in the framework of this review, only the uses of cyromazine reported by the RMS in Appendix A were considered but the use of cyromazine was previously also assessed by the JMPR (FAO, 2007). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure is usually calculated both with and without consideration of the existing CXLs (see Appendix C.2). In this case, however, EFSA was not able to consider the CXLs for cyromazine because the JMPR did not report on the levels of melamine resulting from the use of cyromazine. Indeed, inclusion of a cyromazine CXLs in EU risk assessment should always go together with the assessment of melamine levels in parallel.

4.1. Consumer risk assessment for parent cyromazine

Chronic and acute exposure calculations for parent cyromazine in 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 intake calculations were derived in compliance with Appendix D and are summarized in table 4-1. The median residue and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities. As melons, pumpkins and watermelons are commonly peeled before consumption, the relevant processing factors reported in table 3-3 were considered as well. For lettuce and rucola, residue trials were not available and it was not possible to derive reliable median residue and highest residue. EFSA therefore decided to include the median residue and highest residue of scarole, based on a tentative extrapolation for indicative risk assessment.

The calculated exposures were compared with the toxicological reference values derived for cyromazine (see table 2-1); detailed results of the calculations are presented as EU scenario 1 in Appendix B.1. The highest chronic exposure was calculated for French toddlers, representing 3.4 % of the ADI. With regard to the acute exposure, however, an exceedance of the ARfD was identified for scarole, representing 114.5 % of the ARfD. Since the data supporting the outdoor GAP on scarole are not sufficient to propose a fall-back MRL, a second exposure calculation was performed excluding this crop. According to the results of this second calculation (see Appendix B.2 – EU scenario 2), the highest chronic exposure remained almost unchanged (3.3 % of the ADI for French toddlers); the highest acute exposure is then calculated for cucumbers, representing 76 % of the ARfD.

Table 4-1: Input values for the consumer risk assessment of cyromazine

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 1 : cyromazine				
Tomatoes	0.19	Median residue(1)	0.34	Highest residue(1)
Peppers	0.35	Median residue(1)	0.85	Highest residue(1)
Aubergines (egg plantes)	0.19	Median residue(1)	0.34	Highest residue(1)
Cucumbers	0.51	Median residue(1)	1.30	Highest residue(1)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Gherkins	0.51	Median residue(1)	1.30	Highest residue(1)
Courgettes	0.51	Median residue(1)	1.30	Highest residue(1)
Melons	0.08	Median x PF(1)	0.11	Highest x PF(1)
Pumpkins	0.08	Median x PF(1)	0.11	Highest x PF(1)
Watermelons	0.08	Median x PF(1)	0.11	Highest x PF(1)
Lamb's lettuce	2.09	Median residue(2)	6.24	Highest residue(2)
Lettuce	0.22	Median residue(2)	1.31	Median residue(2)
Scarole	0.22	Median residue(2)	1.31	Highest residue(2)
Rocket, Rucola	0.22	Median residue(2)	1.31	Median residue(2)
Beans (fresh with pods)	1.45	Median residue(2)	2.54	Highest residue(2)
Peas (fresh with pods)	1.45	Median residue(2)	2.54	Highest residue(2)
Celery	0.32	Median residue(2)	0.87	Highest residue(2)
Cultivated fungi	2.22	Median residue(1)	4.30	Highest residue(1)

(1): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(2): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations (also assuming the existing residue definition).

4.2. Consumer risk assessment for melamine

Chronic and acute exposure calculations for melamine in 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 intake calculations were derived in compliance with Appendix D and are summarized in table 4-2. The median residue and highest residue values selected for chronic and acute intake calculations are based on the residue levels in the raw agricultural commodities. As melons, pumpkins and watermelons are commonly peeled before consumption, the relevant processing factors reported in table 3-3 were considered as well but it is not expected to impact on the outcome as a PF of 1 was derived for melamine in these commodities. For lamb's lettuce, lettuce, scarole, rucola and celery, no residue trials were available to derive reliable median and highest residue values; EU MRLs are also available. Consequently, EFSA was not able to consider these uses for the exposure calculations which need to be considered indicative only.

The calculated exposures were compared with the toxicological reference values derived for melamine (see section 2); detailed results of the calculations are presented as the EU scenario 3 in Appendix B.3. The highest chronic exposure for the melamine metabolite was calculated for the WHO cluster diet B, representing 0.3 % of the TDI and the highest acute exposure was calculated for melon, representing 19 % of the TDI. Although this calculation does not consider the melamine levels in several leafy vegetables, it is not expected that the exposure calculation for melamine would be more critical than for cyromazine because toxicological reference values for cyromazine are lower than for melamine and residue levels of melamine were found to be generally lower than for cyromazine. Nevertheless this still needs to be confirmed by fulfilling the data gaps identified in section 3.

Moreover, the above indicative risk assessment is only relevant for melamine related to the pesticide use of cyromazine. In its scientific opinion on melamine in food and feed, EFSA also assessed the exposure to melamine resulting from all sources such as contamination, veterinary drugs and food contact materials. Based on a large number of samples, EFSA estimated the background exposure to melamine and, for adult high consumers, the dietary exposure estimates to melamine in different EU countries based on the upper bound occurrence values is below 11 µg/kg bw/d (approximately 5 % of the TDI). In the case of melamine migration from packaging to food and bevrages, melamine exposures ranged from 30 µg/kg bw/d to 230 µg/kg bw/d (approximately 15-115% of the TDI) (EFSA, 2010).

Consequently, the chronic exposure calculated in Appendix B.3 (up to 0.3% of the TDI) indicates that contribution of the cyromazine pesticide use to the background melamine exposure (up to 5 % of the TDI) is limited. EFSA notes that the acute exposure for melamine resulting from the pesticide use (19 % of the TDI) is rather high compared to the background exposure to melamine. However, this can be explained by the high variability of residue levels that is assumed when performing acute intake calculations for pesticide residues. Due to the pesticide application methods, a sample taken from a treated plot may exhibit a very high variability of residue levels within that sample. Acute exposure calculations for pesticides take into consideration this potential variability of residues, reflecting the very specific situation where a high consumer is incidentally exposed to a very high residue level resulting from this intra-sample variability (EFSA, 2007). The outcome of the acute exposure calculation for melamine is therefore to be considered as an exceptional event resulting from the pesticide use of cyromazine only and cannot be compared or cumulated with the different melamine exposure scenario's calculated by EFSA in 2010. It is for example very unlikely that on a same day a consumer will be exposed to high level of melamine resulting from the pesticide use of cyromazine and to a high level of melamine residues originating from a food contact material.

Table 4-2: Input values for the consumer risk assessment of melamine

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition 2 : melamine				
Tomatoes	0.07	Median residue(1)	0.10	Highest residue(1)
Peppers	0.05	Median residue(1)	0.31	Highest residue(1)
Aubergines (egg plantes)	0.07	Median residue(1)	0.10	Highest residue(1)
Cucumbers	0.21	Median residue(1)	0.60	Highest residue(1)
Gherkins	0.21	Median residue(1)	0.60	Highest residue(1)
Courgettes	0.21	Median residue(1)	0.60	Highest residue(1)
Melons	0.13	Median x PF(1)	0.25	Highest x PF(1)
Pumpkins	0.13	Median x PF(1)	0.25	Highest x PF(1)
Watermelons	0.13	Median x PF(1)	0.25	Highest x PF(1)
Lamb's lettuce(3)	-	-	-	-
Lettuce(3)	-	-	-	-
Scarole(3)	-	-	-	-
Rocket, Rucola(3)	-	-	-	-
Beans (fresh with pods)	0.11	Median residue(2)	0.19	Highest residue(2)

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Peas (fresh with pods)	0.11	Median residue(2)	0.19	Highest residue(2)
Celery(3)	-	-	-	-
Cultivated fungi	0.22	Median residue(1)	0.36	Highest residue(1)

(1): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(2): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations (also assuming the existing residue definition).
(3): Use reported is not supported by data for melamine; as EU MRLs are also not available for melamine,use cannot be taken into account for risk assessment.

4.3. Final considerations

Based on the above calculations, EFSA concludes that the use of cyromazine on crops fully supported by data (footnote 1 in Table 4-1), is acceptable with regard to consumer. For beans with pods and peas with pods, major uncertainties remain due to the data gaps identified in section 3, in particular with regard to the residue definition, but including the tentative MRLs in the exposure calculation did not indicate any risk to consumers. For the remaining crops (lamb's lettuce, lettuce, scarole, rucola, and celery), major uncertainties remain especially with regard to residue level of melamine. Including the tentative MRLs in the exposure calculation for cyromazine did not indicate any risk to consumers, except for scarole. In addition, although the exposure to melamine is generally expected to be less critical than the exposure to cyromazine, the consumer exposure to melamine resulting from the pesticide use of cyromazine on these crops could not be assessed.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of cyromazine was evaluated in the framework of Directive 91/414/EEC, which resulted in an ADI of 0.06 mg/kg bw/d and an ARfD of 0.1 mg/kg bw. The toxicological profile of melamine was evaluated in the scientific opinion on melamine in food and feed, which resulted in a TDI of 0.2 mg/kg bw/d.

Primary crop metabolism of cyromazine was investigated in two different crop groups following foliar application. Metabolic patterns in the different studies were shown to be similar and the relevant residue for risk assessment in fruits and leafy vegetables could be defined as cyromazine and melamine separately. For enforcement purposes it is proposed to define the relevant residue as the parent compound only because melamine may originate from other sources (such as veterinary use, packaging, flame retardants,…) and because the parent compound is an adequate indicator for the pesticide use of cyromazine. A validated analytical method for enforcement of this residue definition with a LOQ of 0.05 mg/kg in high water content commodities is also available. Considering that the use of cyromazine is also supported in peas (with pods) and beans (with pods), an additional metabolism study is required in order to confirm the proposed residue definition for pulses and oilseeds as well.

The available residues data are considered acceptable to derive MRL proposals as well as risk assessment values for parent cyromazine in all commodities under evaluation except for lettuce and rucola where MRLs and risk assessment values were derived from a tentative extrapolation. In most of the crops, residue trials were also appropriate to derive risk assessment values and, in case risk managers would have the intention to establish specific melamine MRLs reflecting the pesticide use of cyromazine, optional MRLs for melamine. For lettuce, lamb's lettuce, scarole, rucola and celery however, where residues trials measuring melamine were not available, no MRL could be proposed. For this reason, cyromazine MRL proposals for these 5 crops are considered tentative. For beans (with pods) and peas (with pods), all calculated values are also considered tentative because a confirmatory metabolism study is still required for these two crops.

In processed commodities, levels of cyromazine were shown to be stable during pasteurisation baking, boiling, brewing and sterilisation. Studies investigating the magnitude of residues in some processed products are also available but they only allowed EFSA to derive indicative processing factors. With regard to the risk assessment, further processing studies are not required because they are not expected to affect the outcome of the risk assessment. However, if there would be the intention from risk managers to derive more processing factors for enforcement purposes, additional processing studies might be required.

Occurrence of residues in rotational crops was already investigated during the peer review of cyromazine. It was concluded that in practice no significant residues of cyromazine or melamine are expected in rotational crops.

Based on the uses reported by the RMS, no significant intake resulting from the pesticide use of cyromazine was calculated for dairy ruminant, meat ruminant, poultry and pig. In consequence there is no need to propose a residue definition and to set MRL for animal products at this stage. However, this point has to be reconsidered if further uses are envisaged on crops fed to animals. EFSA also points out that livestock may be exposed to melamine originating from others sources (contaminants, veterinary drugs and food contact materials) but this point is not considered in the context of this MRL review.

Both chronic and acute consumer exposure were calculated for cyromazine and melamine resulting from the pesticide uses of cyromazine reported in the framework of this review. The highest chronic exposure for cyromazine was calculated for French toddlers, representing 3.4 % of the ADI and an exceedance of the ARfD was identified for scarole, representing 114.5 % of the ARfD. A second exposure calculation was therefore performed, excluding this crop. According to the results of this second calculation, the highest chronic exposure remained unchanged; the highest acute exposure is then calculated for cucumbers, representing 76 % of the ARfD. The highest chronic exposure for the melamine metabolite was calculated for the WHO cluster diet B, representing 0.3% of the ADI and highest acute intakes represent 19 % of the ARfD for melon. Although the consumer exposure to melamine resulting from the pesticide use of cyromazine was found to be limited compared to the exposure of cyromazine itself and compared to the overall melamine exposure resulting from other sources of melamine, it is highlighted that the consumer exposure to melamine through the pesticide use of cyromazine on lamb's lettuce, lettuce, scarole, rucola and celery could not be finalised.

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 (see table below for a summary). All MRL values for cyromazine listed in the table as 'Recommended' are sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values for cyromazine listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see table footnotes for details). In particular, certain tentative MRLs still need to be confirmed by the following data :

- a representative metabolism study for pulses and oilseeds;
- 8 residue trials supporting the indoor GAP on lettuce and rucola;
- 4 residue trials supporting the respective GAPs on lamb's lettuce and celery.

If this data gap is not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the 'Recommended' MRLs or on the national authorisations. Investigation of storage stability for a period of 30 months in commodities with high water content is therefore considered desirable but not essential.

Regarding the MRL proposals for melamine, EFSA points out that melamine might originate from different sources. The presence of melamine in the food chain is regulated by different pieces of legislation (i.e. contaminants, veterinary drugs and food contact materials). Likewise, EFSA highlights that MRLs could not be derived for melamine in leafy vegetables and that MRLs established for cyromazine are already good indicators for monitoring the use of cyromazine as a pesticide. If it is appropriate to establish MRLs for melamine reflecting the pesticide use of cyromazine in the framework of Regulation (EC) No 396/2005, the MRL proposals listed in the table would be the most appropriate.

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Result of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition 1 : cyromazine					
231010	Tomatoes	1	1	0.6	Recommended(1)
231020	Peppers	1	1	1.5	Recommended(1)
231030	Aubergines (egg plantes)	1	1	0.6	Recommended(1)
232010	Cucumbers	1	2	2	Recommended(1)
232020	Gherkins	1	-	2	Recommended(1)
232030	Courgettes	1	2	2	Recommended(1)
233010	Melons	0.3	0.5	0.4	Recommended(1)
233020	Pumpkins	0.05*	-	0.4	Recommended(1)
233030	Watermelons	0.3	-	0.4	Recommended(1)
251010	Lamb's lettuce	15	-	15	Further consideration needed(2)
251020	Lettuce	3	4	3	Further consideration needed(2)
251030	Scarole	0.05*	-	-	Further consideration needed(4)
251060	Rocket, rucola	15	-	3	Further consideration needed(2)
260010	Beans (fresh with pods)	5	1	5	Further consideration needed(3)
260030	Peas (fresh with pods)	5	-	5	Further consideration needed(3)
270030	Celery	2	4	3	Further consideration needed(2)
280010	Cultivated fungi	5	7	10	Recommended(1)
-	Others products of plant and animal origins	See appendix C.1	See appendix C.2	-	Further consideration needed(5)
Enforcement residue definition 2 : melamine (optional)					
231010	Tomatoes	-	-	0.2	Further consideration needed(6)
231020	Peppers	-	-	0.4	Further consideration needed(6)
231030	Aubergines (egg plantes)	-	-	0.2	Further consideration needed(6)
232010	Cucumbers	-	-	0.8	Further consideration needed(6)
232020	Gherkins	-	-	0.8	Further consideration needed(6)
232030	Courgettes	-	-	0.8	Further consideration needed(6)
233010	Melons	-	-	0.4	Further consideration needed(6)
233020	Pumpkins	-	-	0.4	Further consideration needed(6)
233030	Watermelons	-	-	0.4	Further consideration needed(6)
251010	Lamb's lettuce	-	-	-	Further consideration needed(7)
251020	Lettuce	-	-	-	Further consideration needed(7)
251030	Scarole	-	-	-	Further consideration needed(7)
251060	Rocket, rucola	-	-	-	Further consideration needed(7)
260010	Beans (fresh with pods)	-	-	0.3	Further consideration needed(8)

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Result of the review	
				MRL (mg/kg)	Comment
260030	Peas (fresh with pods)	-	-	0.3	Further consideration needed(8)
270030	Celery	-	-	-	Further consideration needed(7)
280010	Cultivated fungi	-	-	1	Further consideration needed(6)
-	Others products of plant and animal origins	-	-	-	Further consideration needed(9)

(1): 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 or, if available, not compatible with EU residue definitions for risk assessment (combination G-I in Appendix D).
(2): Tentative MRL is derived from a GAP evaluated at EU level; no risk to consumers could be identified with regard to cyromazine but EFSA was not able to perform the risk assessment related to melamine; no CXL is available or, if available, not compatible with EU residue definitions for risk assessment (combination E-I in Appendix D).
(3): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified (assuming the existing residue definition); no CXL is available or, if available, not compatible with EU residue definitions for risk assessment (combination E-I in Appendix D).
(4): GAP evaluated at EU level is not fully supported by data and a risk to consumers cannot be excluded; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination D-I in Appendix D).
(5): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available or, if available, not compatible with EU residue definitions for risk assessment. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(6): If MRLs for melamine are considered nevessary by risk managers, this calculated value 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.
(7): Residue levels for melamine resulting from the pesticide use of cyromazine are not available for this crop; MRL cannot be derived and EU MRLs or CXLs are currently not available. Although exposure to melamine levels is expected to be less critical than to cyromazine itself, risk assessment can also not be finalised.
(8): If MRLs for melamine are considered nevessary by risk managers, this tentative value is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers could be identified (assuming the existing residue definition); no CXL is available.
(9): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. If MRLs for melamine are considered nevessary by risk managers, either the specific LOQ or the default MRL of 0.01 mg/kg may be considered.

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on cyromazine prepared by the rapporteur Member State Greece in the framework of Article 12 of Regulation (EC) No 396/2002. Submitted to EFSA on 05 July 2010. Last updated on 26 October 2010.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

European Food Safety Authority

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.					
Lamb's lettuce	*Valerianella locusta*	NEU	Outdoor	BE	Larvae leaf miners	SL	100,0	g/L	Foliar treatment - spraying			1	2		14	0,07	0,07	kg a.i./ha	14	
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU	Outdoor	BE	Larvae leaf miners	SL	100,0	g/L	Foliar treatment - spraying			1	2		14	0,07	0,07	kg a.i./ha	14	

n.a.: not applicable

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
							Content			Growth stage		Number		Interval (days)						
Common name	Scientific name					Type	Conc.	Unit	Method	From BBCH	Until BBCH	Min.	Max.	Min.	Max.	Min. rate	Max. rate	Rate Unit		
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	NL cGAP with foliar application (3 x 0,15 kg a.s./ha, PHI 1 day) and residue level lower than EU cGAP exists. And another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Peppers	*Capsicum annuum, var grossum and var. longum*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	NL cGAP with foliar application (3 x 0,15 kg a.s./ha, PHI 1 day) and residue level lower than EU cGAP exists. And another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Aubergines (egg plants)	*Solanum melongena*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	NL cGAP with foliar application (3 x 0,15 kg a.s./ha, PHI 1 day) and residue level lower than EU cGAP exists. And another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Cucumbers	*Cucumis sativus*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Gherkins	*Cucumis sativus*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Courgettes	*Cucurbita pepo var. melopepo*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Melons	*Cucumis melo*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Pumpkins	*Cucurbita maxima*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Watermelons	*Citrullus lanatus*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Lamb's lettuce	*Valerianella locusta*	NEU/SEU	Indoor	BE, NL	Larvae leaf miners	SL	100,0	g/L	Foliar treatment - spraying			1	2	7	14	0,07	0,07	kg a.i./ha	14	
Lettuce	*Lactuca sativa*	NEU/SEU	Indoor	BE, NL	Larvae leaf miners	SL	100,0	g/L	Foliar treatment - spraying			1	2	7	14	0,07	0,07	kg a.i./ha	14	
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU/SEU	Indoor	BE	Larvae leaf miners	SL	100,0	g/L	Foliar treatment - spraying			1	2			0,07	0,07	kg a.i./ha	14	
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	NEU/SEU	Indoor	BE	Larvae leaf miners	SL	100,0	g/L	Foliar treatment - spraying			1	2			0,07	0,07	kg a.i./ha	14	
Beans (with pods)	*Phaseolus vulgaris,*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Peas (with pods)	*Pisum sativum*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Foliar treatment - spraying	12	89	1	3	7	7	0,30	0,30	kg a.i./ha	3	and another less critical GAP with a drench/dip application to soil (crop growth stage of BBCH 12-89, 1-3 x 0.188 kg a.s./ha).
Celery	*Apium graveolens var. dulce*	NEU/SEU	Indoor	BE, NL	Larvae leaf miners	SL	100,0	g/L	Foliar treatment - spraying			1	3	7	14	0,07	0,07	kg a.i./ha	14	
Cultivated fungi	*Not specified*	NEU/SEU	Indoor	EU	Liriomyza sp.	WP	750,0	g/kg	Soil treatment - spraying			1	1			4,05	4,05	kg a.i./ha	n.a.	growth stage as specified in the GAP:"before inoculation of spores to -before fruit body development"

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario 1 : PRIMo including all cyromazine levels resulting from the GAPs of cyromazine reported by the RMS

Appendix B.2 – EU scenario 2 : PRIMo including demonstrated safe cyromazine levels resulting from the GAPs of cyromazine reported by the RMS

Appendix B.3 – EU scenario 3 : PRIMo including all melamine levels resulting from the GAPs of cyromazine reported by the RMS

APPENDIX B.1 – EU SCENARIO 1 : PRIMO INCLUDING ALL CYROMAZINE LEVELS RESULTING FROM THE GAPS OF CYROMAZINE REPORTED BY THE RMS

Cyromazine			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,06**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
0	3

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)
3,4	FR toddler	2,7	Beans (with pods)	0,4	Courgettes	0,2	Tomatoes	
3,2	WHO Cluster diet B	1,0	Tomatoes	0,8	Beans (with pods)	0,3	Peppers	
2,7	FR infant	2,0	Beans (with pods)	0,6	Courgettes	0,0	Tomatoes	
2,3	NL child	1,2	Beans (with pods)	0,5	Cultivated fungi	0,2	Cucumbers	
2,3	IE adult	0,9	Cultivated fungi	0,4	Beans (with pods)	0,2	Peas (with pods)	
2,2	WHO regional European diet	0,6	Peas (with pods)	0,5	Beans (with pods)	0,3	Tomatoes	
2,0	DK child	1,4	Cucumbers	0,2	Tomatoes	0,2	Cultivated fungi	
1,9	WHO cluster diet E	0,7	Beans (with pods)	0,4	Peas (with pods)	0,3	Cultivated fungi	
1,6	DE child	0,5	Cucumbers	0,3	Tomatoes	0,3	Cultivated fungi	
1,5	ES adult	0,6	Beans (with pods)	0,2	Tomatoes	0,2	Cultivated fungi	
1,4	IT adult	0,4	Tomatoes	0,4	Beans (with pods)	0,2	Cultivated fungi	
1,4	SE general population 90th percentile	0,3	Cucumbers	0,2	Tomatoes	0,2	Beans (with pods)	
1,4	NL general	0,6	Beans (with pods)	0,3	Cultivated fungi	0,1	Tomatoes	
1,3	ES child	0,6	Beans (with pods)	0,3	Tomatoes	0,1	Lettuce	
1,2	IT kids/toddler	0,5	Tomatoes	0,2	Beans (with pods)	0,2	Courgettes	
1,1	UK vegetarian	0,5	Cultivated fungi	0,2	Tomatoes	0,2	Beans (with pods)	
1,0	WHO cluster diet D	0,3	Tomatoes	0,2	Cucumbers	0,2	Gherkins	
0,9	PL general population	0,5	Cultivated fungi	0,3	Tomatoes	0,1	Cucumbers	
0,9	WHO Cluster diet F	0,2	Tomatoes	0,2	Peas (with pods)	0,1	Lettuce	
0,8	FR all population	0,3	Beans (with pods)	0,1	Tomatoes	0,1	Courgettes	
0,7	UK Toddler	0,2	Cultivated fungi	0,2	Tomatoes	0,1	Beans (with pods)	
0,7	DK adult	0,2	Cucumbers	0,2	Cultivated fungi	0,1	Tomatoes	
0,6	UK Adult	0,2	Cultivated fungi	0,1	Tomatoes	0,1	Beans (with pods)	
0,6	LT adult	0,3	Cucumbers	0,2	Tomatoes	0,0	Lettuce	
0,5	FI adult	0,2	Cucumbers	0,1	Tomatoes	0,1	Beans (with pods)	
0,4	PT General population	0,3	Tomatoes	0,1	Peppers	0,0	Cucumbers	
0,3	UK Infant	0,1	Tomatoes	0,1	Beans (with pods)	0,0	Cultivated fungi	

Conclusion:

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1):		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**1**	**No of commodities for which ARfD/ADI is exceeded (IESTI 1):**		**---**	**No of commodities for which ARfD/ADI is exceeded (IESTI 2):**		**---**
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
114,5	Scarole (broad-leaf	1,31 / 1,14	114,5	Scarole (broad-leaf	1,31 / 1,14	35,1	Courgettes	1,3 / -	26,4	Courgettes	1,3 / -
76,0	Cucumbers	1,3 / -	76,0	Cucumbers	1,3 / -	25,6	Cucumbers	1,3 / -	25,6	Cucumbers	1,3 / -
60,4	Courgettes	1,3 / -	43,2	Courgettes	1,3 / -	20,0	Celery	0,87 / -	14,8	Celery	0,87 / -
53,5	Peppers	0,85 / -	39,9	Celery	0,87 / -	14,4	Lettuce	1,31 / -	13,5	Beans (with pods)	2,54 / -
39,9	Celery	0,87 / -	38,2	Peppers	0,85 / -	13,9	Peppers	0,85 / -	12,6	Cultivated fungi	4,3 / -
No of critical MRLs (IESTI 1)		1				**No of critical MRLs (IESTI 2)**		1			

Processed commodities

No of commodities for which ARfD/ADI is exceeded:		**---**				**No of commodities for which ARfD/ADI is exceeded:**		**---**			
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
5,9	Tomato juice	0,34 / -				0,6	Tomato (preserved-	0,34 / -			

*) 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 Cyromazine IESTI 1 and IESTI 2 were calculated for food commodities for which pTMRLs were submitted and for which consumption data are available.
The estimated short term intake (IESTI 1) exceeded the ARfD/ADI for 1 commodities.
Also the IESTI 2 calculation, using less conservative variability factors, resulted in exceedances of the ARfD/ADI for 1 commodities.
For processed commodities, no exceedance of the ARfD/ADI was identified.

APPENDIX B.2 – EU SCENARIO 2 : PRIMO INCLUDING DEMONSTRATED SAFE CYROMAZINE LEVELS RESULTING FROM THE GAPS OF CYROMAZINE REPORTED BY THE RMS

Cyromazine			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,06**	ARfD (mg/kg bw):	**0,1**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2008**	Year of evaluation:	**2008**

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
0	3
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)
3,3	FR toddler	2,7	Beans (with pods)	0,4	Courgettes	0,2	Tomatoes	
3,2	WHO Cluster diet B	1,0	Tomatoes	0,8	Beans (with pods)	0,3	Peppers	
2,7	FR infant	2,0	Beans (with pods)	0,6	Courgettes	0,0	Tomatoes	
2,3	IE adult	0,9	Cultivated fungi	0,4	Beans (with pods)	0,2	Peas (with pods)	
2,2	NL child	1,2	Beans (with pods)	0,5	Cultivated fungi	0,2	Cucumbers	
2,1	WHO regional European diet	0,6	Peas (with pods)	0,5	Beans (with pods)	0,3	Tomatoes	
2,0	DK child	1,4	Cucumbers	0,2	Tomatoes	0,2	Cultivated fungi	
1,9	WHO cluster diet E	0,7	Beans (with pods)	0,4	Peas (with pods)	0,3	Cultivated fungi	
1,6	DE child	0,5	Cucumbers	0,3	Tomatoes	0,3	Cultivated fungi	
1,5	ES adult	0,6	Beans (with pods)	0,2	Tomatoes	0,2	Cultivated fungi	
1,4	IT adult	0,4	Tomatoes	0,4	Beans (with pods)	0,2	Cultivated fungi	
1,4	SE general population 90th percentile	0,3	Cucumbers	0,2	Tomatoes	0,2	Beans (with pods)	
1,3	ES child	0,6	Beans (with pods)	0,3	Tomatoes	0,1	Lettuce	
1,3	NL general	0,6	Beans (with pods)	0,3	Cultivated fungi	0,1	Tomatoes	
1,2	IT kids/toddler	0,5	Tomatoes	0,2	Beans (with pods)	0,2	Courgettes	
1,1	UK vegetarian	0,5	Cultivated fungi	0,2	Tomatoes	0,2	Beans (with pods)	
1,0	WHO cluster diet D	0,3	Tomatoes	0,2	Cucumbers	0,2	Gherkins	
0,9	PL general population	0,5	Cultivated fungi	0,3	Tomatoes	0,1	Cucumbers	
0,9	WHO Cluster diet F	0,2	Tomatoes	0,2	Peas (with pods)	0,1	Lettuce	
0,8	FR all population	0,3	Beans (with pods)	0,1	Tomatoes	0,1	Courgettes	
0,7	UK Toddler	0,2	Cultivated fungi	0,2	Tomatoes	0,1	Beans (with pods)	
0,7	DK adult	0,2	Cucumbers	0,2	Cultivated fungi	0,1	Tomatoes	
0,6	UK Adult	0,2	Cultivated fungi	0,1	Tomatoes	0,1	Beans (with pods)	
0,6	LT adult	0,3	Cucumbers	0,2	Tomatoes	0,0	Lettuce	
0,5	FI adult	0,2	Cucumbers	0,1	Tomatoes	0,1	Beans (with pods)	
0,4	PT General population	0,3	Tomatoes	0,1	Peppers	0,0	Cucumbers	
0,3	UK Infant	0,1	Tomatoes	0,1	Beans (with pods)	0,0	Cultivated fungi	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	*)	**)	**IESTI 2**	*)	**)	**IESTI 1**	*)	**)	**IESTI 2**	*)	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
76,0	Cucumbers	1,3 / -	76,0	Cucumbers	1,3 / -	35,1	Courgettes	1,3 / -	26,4	Courgettes	1,3 / -
60,4	Courgettes	1,3 / -	43,2	Courgettes	1,3 / -	25,6	Cucumbers	1,3 / -	25,6	Cucumbers	1,3 / -
53,5	Peppers	0,85 / -	39,9	Celery	0,87 / -	20,0	Celery	0,87 / -	14,8	Celery	0,87 / -
39,9	Celery	0,87 / -	38,2	Peppers	0,85 / -	14,4	Lettuce	1,31 / -	13,5	Beans (with pods)	2,54 / -
36,3	Cultivated fungi	4,3 / -	36,3	Cultivated fungi	4,3 / -	13,9	Peppers	0,85 / -	12,6	Cultivated fungi	4,3 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
		***)						***)			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
5,9	Tomato juice	0,34 / -				0,6	Tomato (preserved-	0,34 / -			

*) 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 Cyromazine 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.

APPENDIX B.3 – EU SCENARIO 3 : PRIMO INCLUDING ALL MELAMINE LEVELS RESULTING FROM THE GAPS OF CYROMAZINE REPORTED BY THE RMS

Melamine (from cyromazine)			
Status of the active substance:	**Included**	Code no.	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	**0,2**	ARfD (mg/kg bw):	**0,2**
Source of ADI:	**EFSA**	Source of ARfD:	**EFSA**
Year of evaluation:	**2010**	Year of evaluation:	**2010**

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	WHO Cluster diet B	0,1	Tomatoes	0,0	Watermelons	0,0	Melons	
0,2	DK child	0,2	Cucumbers	0,0	Tomatoes	0,0	Melons	
0,2	IE adult	0,1	Melons	0,0	Cultivated fungi	0,0	Courgettes	
0,1	WHO cluster diet D	0,0	Tomatoes	0,0	Watermelons	0,0	Cucumbers	
0,1	FR toddler	0,1	Beans (with pods)	0,1	Courgettes	0,0	Tomatoes	
0,1	DE child	0,1	Cucumbers	0,0	Tomatoes	0,0	Watermelons	
0,1	FR infant	0,1	Courgettes	0,0	Beans (with pods)	0,0	Pumpkins	
0,1	WHO regional European diet	0,0	Tomatoes	0,0	Melons	0,0	Peas (with pods)	
0,1	SE general population 90th percentile	0,0	Cucumbers	0,0	Tomatoes	0,0	Gherkins	
0,1	NL child	0,0	Beans (with pods)	0,0	Cucumbers	0,0	Tomatoes	
0,1	IT adult	0,0	Tomatoes	0,0	Courgettes	0,0	Melons	
0,1	IT kids/toddler	0,0	Tomatoes	0,0	Courgettes	0,0	Melons	
0,1	WHO cluster diet E	0,0	Tomatoes	0,0	Beans (with pods)	0,0	Gherkins	
0,1	ES child	0,0	Tomatoes	0,0	Beans (with pods)	0,0	Watermelons	
0,1	ES adult	0,0	Tomatoes	0,0	Melons	0,0	Beans (with pods)	
0,1	WHO Cluster diet F	0,0	Tomatoes	0,0	Cucumbers	0,0	Cucumbers	
0,1	LT adult	0,0	Cucumbers	0,0	Tomatoes	0,0	Courgettes	
0,1	UK vegetarian	0,0	Tomatoes	0,0	Cultivated fungi	0,0	Cucumbers	
0,1	FR all population	0,0	Tomatoes	0,0	Melons	0,0	Courgettes	
0,1	NL general	0,0	Tomatoes	0,0	Beans (with pods)	0,0	Cucumbers	
0,1	DK adult	0,0	Cucumbers	0,0	Tomatoes	0,0	Melons	
0,1	PL general population	0,0	Tomatoes	0,0	Cultivated fungi	0,0	Cucumbers	
0,0	UK Toddler	0,0	Tomatoes	0,0	Cucumbers	0,0	Cultivated fungi	
0,0	FI adult	0,0	Cucumbers	0,0	Tomatoes	0,0	Beans (with pods)	
0,0	PT General population	0,0	Tomatoes	0,0	Melons	0,0	Peppers	
0,0	UK Adult	0,0	Tomatoes	0,0	Cultivated fungi	0,0	Cucumbers	
0,0	UK Infant	0,0	Tomatoes	0,0	Beans (with pods)	0,0	Melons	

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

Acute risk assessment /children - refined calculations	Acute risk assessment / adults / general population - refined calculations

The acute risk assessment is based on the ARfD.

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

In the **IESTI 1** calculation, the variability factors were 10, 7 or 5 (according to JMPR manual 2002), for lettuce a variability factor of 5 was used.
In the **IESTI 2** calculations, the variability factors of 10 and 7 were replaced by 5. For lettuce the calculation was performed with a variabilty factor of 3.

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

Unprocessed commodities

No of commodities for which ARfD/ADI is exceeded (IESTI 1): ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 1):** ---			**No of commodities for which ARfD/ADI is exceeded (IESTI 2):** ---		
IESTI 1	***)**	****)**	**IESTI 2**	***)**	****)**	**IESTI 1**	***)**	****)**	**IESTI 2**	***)**	**)
Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)	Highest % of ARfD/ADI	Commodities	pTMRL/ threshold MRL (mg/kg)
19,0	Melons	0.25 / -	19,0	Melons	0.25 / -	8,1	Courgettes	0.6 / -	6,6	Pumpkins	0.25 / -
17,5	Cucumbers	0.6 / -	17,5	Cucumbers	0.6 / -	6,6	Pumpkins	0.25 / -	6,1	Courgettes	0.6 / -
15,3	Watermelons	0.25 / -	15,3	Watermelons	0.25 / -	5,9	Cucumbers	0.6 / -	5,9	Cucumbers	0.6 / -
13,9	Courgettes	0.6 / -	10,0	Courgettes	0.6 / -	5,1	Watermelons	0.25 / -	5,1	Watermelons	0.25 / -
9,8	Peppers	0.31 / -	7,0	Peppers	0.31 / -	4,9	Melons	0.25 / -	4,9	Melons	0.25 / -
No of critical MRLs (IESTI 1) ---						**No of critical MRLs (IESTI 2)** ---					

Processed commodities

No of commodities for which ARfD/ADI is exceeded: ---						**No of commodities for which ARfD/ADI is exceeded:** ---					
		*****)**						*****)**			
Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)				Highest % of ARfD/ADI	Processed commodities	pTMRL/ threshold MRL (mg/kg)			
0,9	Tomato juice	0.1 / -				0,1	Tomato (preserved-	0.1 / -			

*) 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 Melamine (from cyromazine) 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.

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

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs (File created on 08/06/2011 14:25)

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyromazine
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0,05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0,05*
110030	Lemons (Citron, lemon)	0,05*
110040	Limes	0,05*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	0,05*
110990	Others	0,05*
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	0,05*
130010	Apples (Crab apple)	0,05*
130020	Pears (Oriental pear)	0,05*
130030	Quinces	0,05*
130040	Medlar	0,05*
130050	Loquat	0,05*
130990	Others	0,05*
140000	(iv) Stone fruit	0,05*
140010	Apricots	0,05*
140020	Cherries (sweet cherries, sour cherries)	0,05*
140030	Peaches (Nectarines and similar hybrids)	0,05*
140040	Plums (Damson, greengage, mirabelle, sloe)	0,05*
140990	Others	0,05*
150000	(v) Berries & small fruit	0,05*
151000	(a) Table and wine grapes	0,05*
151010	Table grapes	0,05*
151020	Wine grapes	0,05*
152000	(b) Strawberries	0,05*
153000	(c) Cane fruit	0,05*
153010	Blackberries	0,05*
153020	Dewberries (Loganberries, boysenberries, and cloudberries)	0,05*
153030	Raspberries (Wineberries, arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x idaeus))	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries)	0,05*
154020	Cranberries (Cowberries (red bilberries))	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) (Kiwiberry (Actinidia arguta))	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, buckthom (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, limequats (Citrus aurantifolia x Fortunella spp.))	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry Surinam cherry (grumichama Eugenia uniflora),)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi), mangosteen)	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	0,05*
163010	Avocados	0,05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0,05*
163030	Mangoes	0,05*
163040	Papaya	0,05*
163050	Pomegranate	0,05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop), llama and other medium sized Annonaceae)	0,05*
163070	Guava (Red pitaya or dragon fruit (Hylocereus undatus))	0,05*
163080	Pineapples	0,05*
163090	Bread fruit (Jackfruit)	0,05*
163100	Durian	0,05*
163110	Soursop (guanabana)	0,05*
163990	Others	0,05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	1
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	
213010	Beetroot	0,05*
213020	Carrots	1
213030	Celeriac	0,05*
213040	Horseradish (Angelica roots, lovage roots, gentiana roots,)	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (Cyperus esculentus))	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
220010	Garlic	0,05*
220020	Onions (Silverskin onions)	0,05*
220030	Shallots	0,05*
220040	Spring onions (Welsh onion and similar varieties)	0,05*
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	1

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyromazine
231010	Tomatoes (Cherry tomatoes, tree tomato, Physalis, gojiberry, wolfberry (Lycium barbarum and L. chinense))	1
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	1
231040	Okra, lady's fingers	1
231990	Others	1
232000	(b) Cucurbits - edible peel	1
232010	Cucumbers	1
232020	Gherkins	1
232030	Courgettes (Summer squash, marrow (patisson))	1
232990	Others	1
233000	(c) Cucurbits-inedible peel	
233010	Melons (Kiwano)	0.3
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,3
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
242020	Head cabbage (Pointed head cabbage, red cabbage, savoy cabbage, white cabbage)	0,05*
242990	Others	0,05*
243000	(c) Leafy brassica	0,05*
243010	Chinese cabbage (Indian (Chinese) mustard, pak choi, Chinese flat cabbage (tai goo choi), choi sum, peking cabbage (pe-tsai),)	0,05*
243020	Kale (Borecole (curly kale), collards, Portuguese Kale, Portuguese cabbage, cow cabbage)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	
251010	Lamb´s lettuce (Italian cornsalad)	15
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	3[a]
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	0,05*[a]
251040	Cress	15
251050	Land cress	15
251060	Rocket, Rucola (Wild rocket)	15
251070	Red mustard	0.05*
251080	Leaves and sprouts of Brassica spp (Mizuna, leaves of peas and radish and other babyleaf brassica crops (crops harvested up to 8 true leaf stage))	0,05*
251990	Others	15
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, amaranthus spinach)	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth, Agretti (Salsola soda))	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	20
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	15
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	15
256010	Chervil	15
256020	Chives	15
256030	Celery leaves (Fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea leaves)	15
256040	Parsley	15
256050	Sage (Winter savory, summer savory,)	15
256060	Rosemary	15
256070	Thyme (Marjoram, oregano)	15
256080	Basil (Balm leaves, mint, peppermint)	15
256090	Bay leaves (laurel)	15
256100	Tarragon (Hyssop)	15
256990	Others (Edible flowers)	15
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	5
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0.05*
260030	Peas (with pods) (Mangetout (sugar peas, snow peas))	5
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	2
270040	Fennel	0,05*
270050	Globe artichokes	2
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	5
280020	Wild (Chanterelle, Truffle, Morel, Cep)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,05*
300020	Lentils	0,05*
300030	Peas (Chickpeas, field peas, chickling vetch)	0,05*
300040	Lupins	0,05*
300990	Others	0,05*
400000	4. OILSEEDS AND OILFRUITS	0,05*
401000	(i) Oilseeds	0,05*
401010	Linseed	0,05*
401020	Peanuts	0,05*
401030	Poppy seed	0,05*
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 (Other seeds of cucurbitacea)	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat (Amaranthus, quinoa)	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*
500090	Wheat (Spelt, triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,05*
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*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyromazine
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers (Elderflowers (Sambucus nigra))	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves (Ginkgo 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*
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	0,05*
	(Long pepper, pink pepper)	
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	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	
1013010	Meat	
1013020	Fat	
1013030	Liver	
1013040	Kidney	
1013050	Edible offal	
1013990	Others	
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
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	0,02*
1020010	Cattle	0,02*
1020020	Sheep	0,02*
1020030	Goat	0,02*
1020040	Horse	0,02*
1020990	Others	0,02*
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	0,2
1030010	Chicken	0,2
1030020	Duck	0,2
1030030	Goose	0,2
1030040	Quail	0,2
1030990	Others	0,2
1040000	(iv) Honey (Royal jelly, pollen)	0,02*[(a)]
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,02*[(a)]
1060000	(vi) Snails	0,02*[(a)]
1070000	(vii) Other terrestrial animal products	0,02*[(a)]

(*) Indicates lower limit of analytical determination
(a): Value voted during SCFCAH (SANCO/10108/2010), and integrated into regulation No 559/2011, which shall apply from 1 January 2012

APPENDIX C.2 – EXISTING CXLS

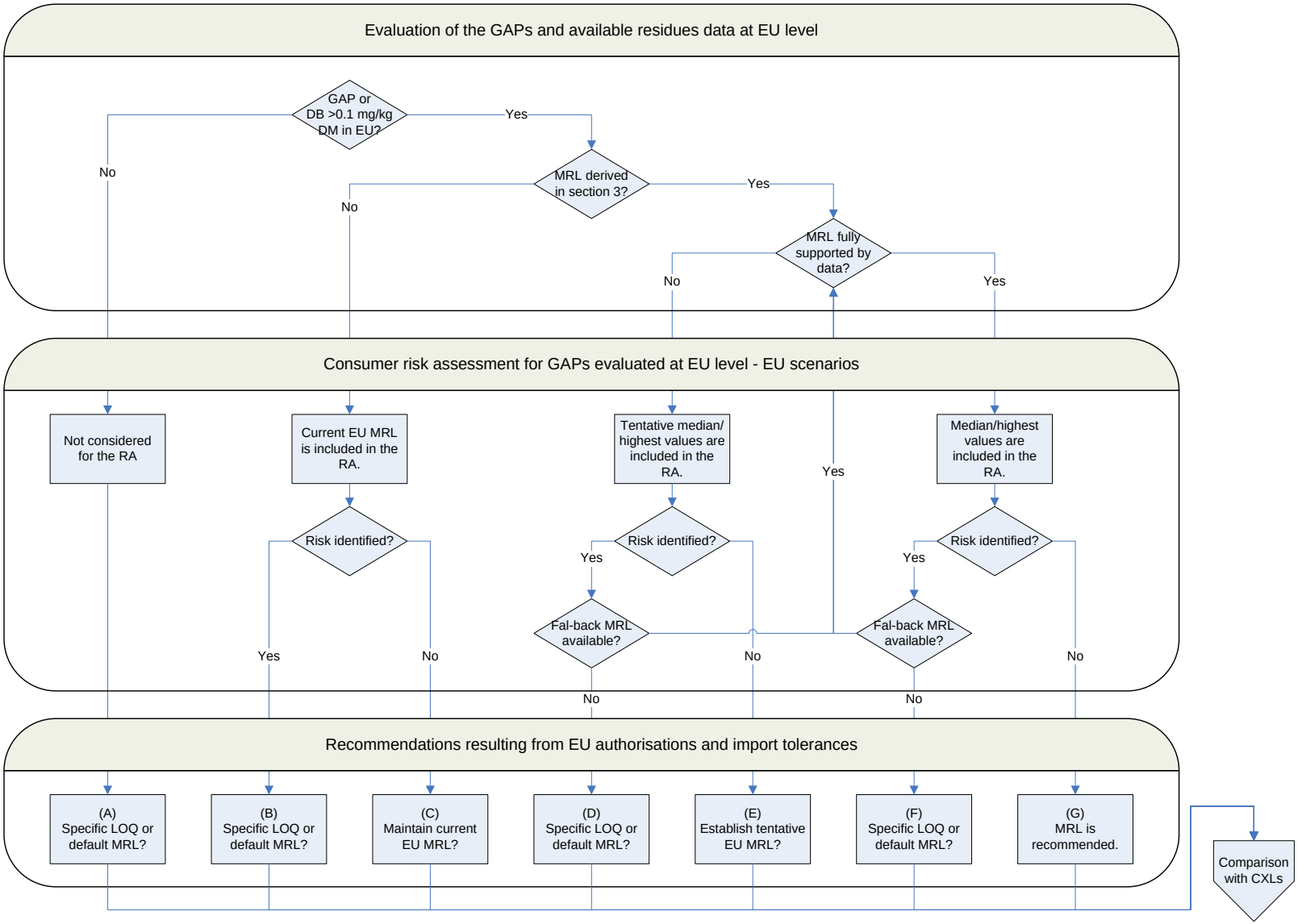
Summary of CXLs for cyromazine in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
163030	Mangoes	Cyromazine	0,5	Cyromazine	0,125	0,25	3	n.c.	0,125	0,25	n.a.	1	2007	no	Trials conducted in mexico according to GAP
220020	Onions	Cyromazine	0,1	Cyromazine	0,05	0,07	3	n.c.	0,05	0,07	n.a.	1	2007	no	Trials conducted in USA according to GAP
220040	Spring onions	Cyromazine	3	Cyromazine	0,345	1,7	1	n.c.	0,345	1,7	n.a.	1	2007	no	Trials conducted in USA according to GAP
231010	Tomatoes	Cyromazine	1	Cyromazine	0,16	0,58	3	n.c.	0,16	0,58	n.a.	1	2007	yes	Trials conducted in the EU according to GAP. Data on tomato and eggplant combined.
231020	Peppers	Cyromazine	1	Cyromazine	0,16	0,58	1	n.c.	0,16	0,58	n.a.	1	2007	no	Trials conducted in USA according to GAP
231030	Aubergines (egg plants)	Cyromazine	1	Cyromazine	0,16	0,58	3	n.c.	0,16	0,58	n.a.	1	2007	yes	See comment for tomato.
231040	Okra, lady's fingers	Cyromazine	1	Cyromazine	0,16	0,58	1	n.c.	0,16	0,58	n.a.	1	2007	yes	Extrapolated from tomato and eggplant data.
232010	Cucumbers	Cyromazine	2	Cyromazine	0,48	1,3	3	n.c.	0,48	1,3	n.a.	1	2007	No	Trials were conducted in the EU and US according to GAP.
232030	Courgettes	Cyromazine	2	Cyromazine	0,16	1	3	n.c.	0,16	1	n.a.	1	2007	No	Trials were conducted in the EU and US according to GAP.
233010	Melons	Cyromazine	0,5	Cyromazine	0,04	0,19	3	n.c.	0,09	0,45	2,5	1	2007	No	Trials were conducted in the EU and US according to GAP.
241010	Broccoli	Cyromazine	1	Cyromazine	0,15	0,51	3	n.c.	0,15	0,51	n.a.	1	2007	No	Trials were conducted in the US according to GAP.
243010	Chinese cabbage	Cyromazine	10	Cyromazine	2,7	7,4	1	n.c.	2,7	7,4	n.a.	1	2007	No	Based on a use for mustard greens. Trials were conducted in the US according to GAP.
251020	Lettuce	Cyromazine	4	Cyromazine	0,34	2	3	n.c.	0,34	2	n.a.	1	2007	Yes	Uses from outside of the EU led to an unacceptable acute intake for children and therefore only the more protective EU GAP was permitted.
260010	Beans (fresh, with pods)	Cyromazine	1	Cyromazine	0,23	0,58	1	n.c.	0,23	0,58	n.a.	1	2007	No	Based on a use for lima beans. Trials were conducted in the US according to GAP.
270030	Celery	Cyromazine	4	Cyromazine	0,58	2,3	3	n.c.	0,58	2,3	n.a.	1	2007	Yes	Trials were conducted in France and Spain according to GAP.
270050	Globe artichokes	Cyromazine	3	Cyromazine	1	1,3	3	n.c.	1	1,3	n.a.	1	2007	Yes	Trials were conducted in Spain according to GAP.
280010	Cultivated fungi	Cyromazine	7	Cyromazine	2,2	4,2	1	n.c.	2,2	4,2	n.a.	1	2007	No	Trials were conducted in both EU and non-EU contries according to GAP.
300010	Beans (dry)	Cyromazine	3	Cyromazine	1	n.c.	1	n.c.	1	1,8	n.a.	1	2007	No	Trials were conducted in the US according to GAP.

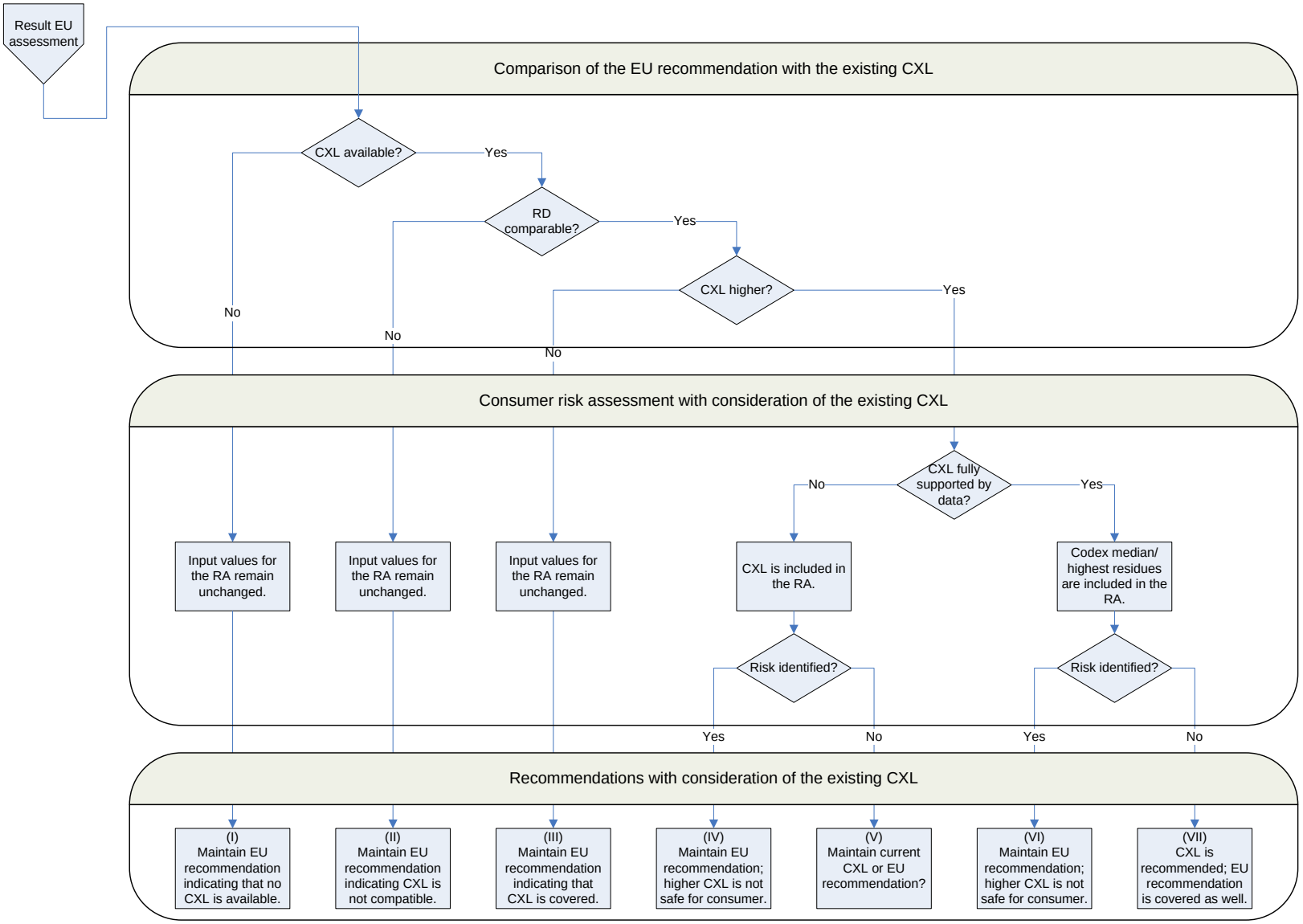
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

Summary of CXLs for cyromazine in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Cyromazine	no	0,3	Cyromazine	0,01	0,2	2007	yes	Critical intakes arise from the EU diet. Dietary burdens of 0.57 mg/kg and 8.5 mg/kg calculated for estimation of STMR and MRLs respectively.
1011030	Swine liver	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1011040	Swine kidney	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1011050	Swine edible offal	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1012010	Bovine meat	Cyromazine	no	0,3	Cyromazine	0,01	0,2	2007	yes	Critical intakes arise from the EU diet. Dietary burdens of 0.57 mg/kg and 8.5 mg/kg calculated for estimation of STMR and MRLs respectively.
1012030	Bovine liver	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1012040	Bovine kidney	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1012050	Bovine edible offal	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1013010	Sheep meat	Cyromazine	no	0,3	Cyromazine	0,01	0,2	2007	yes	Critical intakes arise from the EU diet. Dietary burdens of 0.57 mg/kg and 8.5 mg/kg calculated for estimation of STMR and MRLs respectively.
1013030	Sheep liver	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1013040	Sheep kidney	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1013050	Sheep edible offal	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1014010	Goat meat	Cyromazine	no	0,3	Cyromazine	0,01	0,2	2007	yes	Critical intakes arise from the EU diet. Dietary burdens of 0.57 mg/kg and 8.5 mg/kg calculated for estimation of STMR and MRLs respectively.
1014030	Goat liver	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1014040	Goat kidney	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1014050	Goat edible offal	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1015010	Horses, asses, mules or hinnies meat	Cyromazine	no	0,3	Cyromazine	0,01	0,2	2007	yes	Critical intakes arise from the EU diet. Dietary burdens of 0.57 mg/kg and 8.5 mg/kg calculated for estimation of STMR and MRLs respectively.
1015030	Horses, asses, mules or hinnies liver	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1015040	Horses, asses, mules or hinnies kidney	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1015050	Horses, asses, mules or hinnies edible offal	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1016010	Poultry meat	Cyromazine	no	0,1	Cyromazine	0,05	0,05	2007	yes	Based on a high and mean dietary burdens (EU diet) of 2.4 and 0.14 mg/kg respectively.
1016030	Poultry liver	Cyromazine	n.a.	0,2	Cyromazine	0,065	0,08	2007	yes	
1016040	Poultry kidney	Cyromazine	n.a.	0,2	Cyromazine	0,065	0,08	2007	yes	
1016050	Poultry edible offal	Cyromazine	n.a.	0,2	Cyromazine	0,065	0,08	2007	yes	
1017010	Other farm animals meat	Cyromazine	no	0,3	Cyromazine	0,01	0,2	2007	yes	Critical intakes arise from the EU diet. Dietary burdens of 0.57 mg/kg and 8.5 mg/kg calculated for estimation of STMR and MRLs respectively.
1017030	Other farm animals liver	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1017040	Other farm animals kidney	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1017050	Other farm animals edible offal	Cyromazine	n.a.	0,3	Cyromazine	0,01	0,19	2007	yes	
1020010	Cattle milk	Cyromazine	no	0,01	Cyromazine	0,005	n.c.	2007	yes	Critical intakes arise from the EU diet. Dietary burdens of 0.57 mg/kg and 8.5 mg/kg calculated for estimation of STMR and MRLs respectively.
1020020	Sheep milk	Cyromazine	no	0,01	Cyromazine	0,005	n.c.	2007	yes	
1020030	Goat milk	Cyromazine	no	0,01	Cyromazine	0,005	n.c.	2007	yes	
1020040	Horse milk	Cyromazine	no	0,01	Cyromazine	0,005	n.c.	2007	yes	
1030000	Birds' eggs	Cyromazine	n.a.	0,3	Cyromazine	0,07	0,16	2007	yes	Based on a high and mean dietary burdens (EU diet) of 2.4 and 0.14 mg/kg respectively.

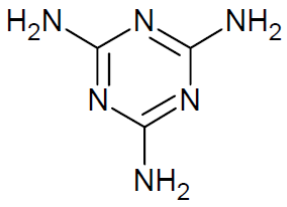
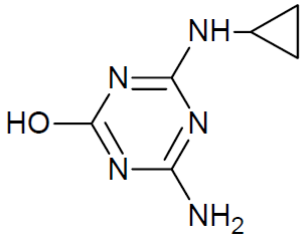
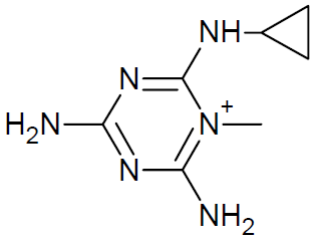
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

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 fully 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.

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
Melamine CGA 235129	1,3,5-triazine-2,4,6-triamine	
Hydroxy-cyromazine	4-amino-6-(cyclopropylamino)-1,3,5-triazin-2-ol	
1-methyl cyromazine	2,4-diamino-6-(cyclopropylamino)-1-methyl-1,3,5-triazin-1-ium	

ABBREVIATIONS

a.s.	active substance
a.i.	active ingredient
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
BMD10	Benchmark dose 10
BMDL	Benchmark dose lower confidence limit
bw	body weight
CCPR	Codex Committee on Pesticide Residues
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
DT_{90}	period required for 90 percent dissipation (define method of estimation)
dw	dry weight
EC	European Community
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GLP	Good Laboratory Practice
ha	hectare
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry

JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
MS	mass spectrometry detection or detector
MS/MS	tandem mass spectrometry
NEU	northern European Union
NTP	National Toxicology Programme
OECD	Organization for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
QuEChERS	Quick, Easy, Cheap, Effective, Rugged, and Safe (method)
R_{ber}	statistical calculation of the MRL by using a non-parametric method
R_{max}	statistical calculation of the MRL by using a parametric method
RA	risk assessment
RAC	raw agricultural commodity
RMS	rapporteur Member State
RSD	relative standard deviation
SEU	Southern European Union
TDI	Tolerable Daily Intake
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
tMRL	temporay MRL
US	United State

UV	ultra-violet detection
WHO	World Health Organisation
WP	wettable powder