

REASONED OPINION

Review of the existing maximum residue levels (MRLs) for cyclanilide according to Article 12 of Regulation (EC) No 396/2005¹

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SUMMARY

Cyclanilide was included in Annex I to Directive 91/414/EEC on 01 November 2001, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of 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). The requested information was submitted to EFSA on 06 March 2009 and, after having considered several comments made by EFSA, the RMS provided on 22 October 2009 a revised PROFile.

Based on the conclusions derived in the framework of Directive 91/414/EEC and the additional information provided by the Greece, EFSA issued on 16 November 2011 a draft reasoned opinion that was circulated to Member State experts for consultation. No comments were received by 27 January 2012 and the following conclusions are derived.

The toxicological profile of cyclanilide was already evaluated in the framework of Directive 91/414/EEC. The ADI and the ARfD were established at 0.0075 mg/kg bw/d and 0.015 mg/kg bw respectively.

Primary crop metabolism of cyclanilide was investigated in cotton and wheat following foliar application. The metabolism study of cyclanilide in cotton showed insignificant total radioactive residues in cotton seeds, which could therefore not be characterised. In cotton foliage and fibers, total radioactive residues were essentially characterised as unchanged parent compound. Unchanged parent compound was also identified as the predominant component of total radioactive residues in wheat. These findings indicate that metabolism of cyclanilide in plants is limited. It is therefore proposed to define the regulated residue in cotton as cyclanilide parent compound alone. Validated analytical method for enforcement of the residue definition in foods of plant origin is available with an LOQ of 0.05 mg/kg in high oil content, commodities.

¹ On request from EFSA, Question No EFSA-Q-2008-517, approved on 02 February 2012.

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³ Acknowledgement: EFSA wishes to thank the rapporteur Member State Greece for the preparatory work on this scientific output.

Regarding the magnitude of residues in cotton, the critical GAP was supported by a sufficient number of supervised residue trials, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive an appropriate MRL.

No study was provided that investigated potential breakdown or reaction products of cyclanilide residues in processed commodities, but considering their low contribution to the chronic exposure and knowing that the overall chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. EFSA did not derive processing factors.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in sorghum, collards and radishes. These studies showed that significant residues in rotational crops are not expected, provided that cyclanilide is applied according to the GAPs supported in the framework of this review.

The dietary burden resulting from the reported uses of cyclanilide was calculated for each type of livestock. As all the calculated intakes represented less than 0.1 mg/kg DM, significant residues in commodities of animal origin are not expected and no MRLs were proposed.

Chronic consumer exposure resulting from the MRLs proposed in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure for cyclanilide was calculated for the Dutch children, representing 0.003 % of the ADI. No acute exposure was identified as no acute consumption data are available for cotton, highlighting the minor contribution of this crop in the EU diet. As the calculated intakes are all well below the toxicological reference values, it is concluded that the proposed MRL is not of concern for the European consumer.

Based on the above assessment, EFSA does not recommend inclusion of this cyclanilide in Annex IV to Regulation (EC) No 396/2005. An MRL recommendation was derived for cotton in compliance with the decision tree reported in Appendix D (see table below for a summary). This MRL value is sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation.

A minor deficiency was identified in the assessment but this deficiency is not expected to impact either on the validity of the 'Recommended' MRL or on the national authorisations. One additional residue trial on cotton to support the reported use in southern Europe is therefore considered desirable but not essential.

It is also highlighted that the above recommendation is based on an authorisation that should be withdrawn by 30 April 2011. However, EFSA still considers the MRL recommendation relevant for the time being considering that a period of grace for this authorisation still applies until 31 October 2013.

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: cyclanilide				
401090	Cotton seed	0.2	0.3	Recommended ^(a)
-	Other products of plant and/or animal origin	See App C	-	Further consideration needed ^(b)

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

KEY WORDS

Cyclanilide, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, plant growth regulator, 2,4-dichloroaniline.

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BACKGROUND

Regulation (EC) No 396/2005⁴ establishes the rules governing the setting as well as the review of pesticide MRLs at European level. Article 12(2) of that regulation lays down that EFSA shall provide by 01 September 2009 a reasoned opinion on the review of the existing MRLs for [all active substances included in Annex I to Directive 91/414/EEC⁵ before 02 September 2008. As cyclanilide was included in Annex I to the above mentioned directive on 01 November 2001, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-517 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 EU 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 cyclanilide. The requested information was submitted to EFSA on 06 March 2009 and subsequently checked for completeness. On 22 October 2009, after having clarified some issues with EFSA, the Greece provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 16 November 2011 and submitted to Member States (MS) for commenting. No comments were received by 27 January 2012.

TERMS OF REFERENCE

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

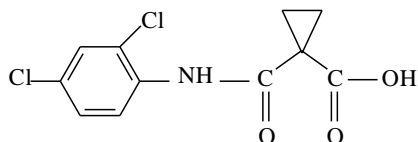
- the inclusion of the cyclanilide in Annex IV to the Regulation, when appropriate;
- the necessity of setting new MRLs for the cyclanilide or deleting/modifying existing MRLs set out in Annex II or III of the Regulation;
- the inclusion of the recommended MRLs in Annex II or III to the Regulation;
-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

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.

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cyclanilide is the ISO common name for 1-(2,4-dichloroanilincarbonyl)cyclopropanecarboxylic acid (IUPAC).



Cyclanilide belongs to the group of unclassified plant growth regulators. It is primarily used in cotton fields in combination with the plant growth regulator ethephon. The mixture of cyclanilide with ethephon promotes boll opening, leaf abscission and inhibits regrowth after defoliation. It inhibits auxin transport from the leaf meristems to the pedicels and thus facilitates the dehiscence by promoting the effect of ethephon (ethylene generator).

Cyclanilide 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 foliar application on cotton in southern Europe at the rate of 0.12 to 0.14 kg a.s./ha with a 7 days PHI. Following the peer review, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2001/87/EC⁶, entering into force on 01 November 2001. According to Regulation (EU) No 540/2011⁷, cyclanilide was deemed to have been approved under Regulation (EC) No 1107/2009⁸ but according to Regulation (EU) No 1022/2011⁹, the approval expired on 31 October 2011 because no application for renewal of this approval was received within the predefined timelines. The approval was restricted to uses as plant growth regulator only. As EFSA was not yet involved in the peer review of cyclanilide, a conclusion of EFSA on this active substance is not available.

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

For the purpose of this MRL review, the critical uses of cyclanilide currently authorized within the EU, have been collected by Greece and reported in the PROFile (see Appendix A). Only the use on cotton supported for the peer review process, but at a slightly higher application rate (0.18 kg a.s./ha) was reported. Although this authorisation should be withdrawn by 30 April 2012, in compliance with Regulation (EU) No 1022/2011, it is noted that a period of grace for disposal, storage and use of existing stocks of plant protection products containing cyclanilide applies until 31 October 2013. The use of cyclanilide on cotton seed until that date can therefore not be excluded and assessment of this GAP is still considered relevant.

The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

⁶ Commission Directive 2001/87/EC of 12 October 2001 OJ L 276, 19.10.2001, p. 17-20

⁷ Regulation (EU) No 540/2011 of 25 May 2011, OJ L 153, 11.6.2011, p. 1-186.

⁸ Regulation (EC) No 1107/2009 of 21 October 2009, OJ L 309, 24.11.2009, p. 1-50.

⁹ Regulation (EU) No 1022/2011 of 14 October 2011, OJ L 270, 15.10.2011, p. 20-21.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (Greece, 1998, 2001) and the Review Report on cyclanilide (EC, 2001). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation of the Authorization of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011¹⁰ and the currently applicable guidance documents relevant for the consumer risk assessment of pesticide residues (EC, 1996, 1997a, 1997b, 1997c, 1997d, 1997e, 1997f, 1997g, 2000, 2010a, 2010b, 2011).

1. Methods of analysis

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

During the peer review under Directive 91/414/EEC, an analytical method using GC-ECD confirmed by the use of a different column and its ILV were evaluated and validated for determination of parent cyclanilide in plant matrices with an LOQ of 0.05 mg/kg in high oil content (cotton seed) commodities (Greece, 1998). However, although not fully demonstrated, this method is expected to convert upon basic hydrolysis all residues to the common moiety 2,4-dichloroaniline which is then derivatized for analysis. Therefore this method is not specific to cyclanilide. The confirmatory method was also not reported in detail.

Nevertheless, the multi-residue DFG S19 method using GC-MS was evaluated and validated for determination of parent cyclanilide in plant matrices with an LOQ of 0.05 mg/kg in high oil content (cotton seed) commodities. This analytical method first converts cyclanilide to its methyl ester by a derivatisation step before analysis (Greece, 2001).

No analytical method is available for high water content, dry and acidic commodities.

Hence it is concluded that cyclanilide can be enforced in high oil content commodities with an LOQ of 0.05 mg/kg.

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

An analytical method for enforcement of residues in food of animal origin is not deemed necessary due to the fact that there is no significant intake of residues by livestock. No residue definition and no MRLs are proposed for commodities of animal origin (see section 3.2).

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

2. Mammalian toxicology

The toxicological assessment of cyclanilide was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the European Commission (2001). 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					
ADI	EC	2001	0.0075 mg/kg bw/d	2-generation rat reproductive study	200
ARfD	EC	2001	0.015 mg/kg/d	Rabbit developmental toxicity study	200

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 cyclanilide was investigated for foliar application on cotton and wheat, using [U-¹⁴C-phenyl] labelled cyclanilide (Greece, 1998). Validated metabolism studies are summarized in Table 3-1.

In wheat, there is no significant metabolism of cyclanilide following application prior to head formation (62-63% TRR - 0.76 to 5.02 mg/kg in straw). In grain, residue was determined to be predominately parent cyclanilide, with residue levels of 0.02 mg/kg (55.19 % TRR). A small portion of the cyclanilide is metabolized by esterification and dechlorination, with probable cyclopropane cleavage and hydrolysis of the anilide linkage. However, the metabolic products associated with these pathways are low enough (< 5% TRR) to be considered minor.

After a single post-emergence spray application to cotton, both lint and foliage contained radioactivity, the seeds from bolls that were both closed and open at the time of treatment, did not contain any quantifiable amounts of radioactivity, indicating that ¹⁴C-cyclanilide does not translocate in cotton plants. The metabolism study of cyclanilide in cotton showed insignificant total radioactive residues in cotton seeds, which could therefore not be characterised. In cotton foliage and fibers, total radioactive residues were essentially characterised as unchanged parent compound (88 % and 100 % TRR respectively). No 2,4-dichloroaniline was found in any of the consumable parts of the crops. Unchanged parent compound was also identified as the predominant component of total radioactive residues in wheat. These findings indicate that metabolism of cyclanilide in plants is limited.

Consequently, the residue definition for enforcement and risk assessment in plants commodities belonging to the group “pulses and oilseed” was defined as parent compound alone. Validated analytical method for enforcement of the proposed residue definition in plants with high oil content is available (see also section 1.1).

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

Group	Crop	Label position	Application and sampling details				
			Method, F or G ^(a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Pulses and oilseeds	Cotton	U- ¹⁴ C-phenyl cyclanilide	Foliar, n.r.	1.4	1	26 (maturity)	
Cereals	Wheat	U- ¹⁴ C-phenyl cyclanilide	Foliar, n.r.	0.090 and 0.340	1	33 to 105	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
n.r.: F or G not reported

3.1.1.2. Magnitude of residues

According to the RMS, the active substance cyclanilide should only be used for foliar treatment of cotton in southern Europe under outdoor conditions (see Appendix A). To assess the magnitude of cyclanilide residues resulting from this GAP, EFSA considered all residues trials reported in the PROFile, including residues trials evaluated in the framework of the peer review (Greece, 1998). All available residues trials that, according to the RMS, comply with the reported GAP, are summarized in Table 3-2.

The number of residues trials was evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). Although appropriate MRL and risk assessment values can be derived from the available data, one additional residue trial on cotton should in principle be submitted to support the reported use. However, the RMS noted that 6 additional trials have been conducted with twice the critical application rate per ha (0.36 kg a.s./ha) and that the residues found in cotton seed were in the range of <0.02 - 0.086 mg/kg. Therefore one additional trial on cotton compliant with the GAP is only considered desirable (minor deficiency).

The storage stability of cyclanilide has been investigated under the peer review. The results showed that fortified cyclanilide residues were stable in cotton seed for twelve months and processed fractions thereof for three months of freezer storage (Greece, 1998). According to RMS, the storage conditions for all available residues trials were in compliance with the storage stability data.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for cotton (see Table 3-2).

Table 3-2: Overview of the available residues 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 (cyclanilide)	Risk assessment (cyclanilide)					
Cotton seed	SEU	Outdoor	<0.024; 2x<0.028; <0.033; <0.038; 0.061; 0.210	<0.024; 2x<0.028; <0.033; <0.038; 0.061; 0.210	0.03	0.21	0.3	1	Trials compliant with the GAP. Rber = 0.12 Rmax = 0.29

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

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

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

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

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

3.1.1.3. Effect of industrial processing and/or household preparation

No study was provided that investigated potential breakdown or reaction products of cyclanilide residues in processed commodities. However, based on the low contribution of cotton seed to the chronic exposure, such information is not considered necessary.

A processing study investigating the magnitude of residues in crude oil, refined oil and press cake, was reported in the DAR. In this study, no residues were found in crude oil, refined oil and meal/press cake although residue level in cotton seed amounted to 0.88 mg/kg. Hence a loss of residues occurred during the process that could not be explained. It also seems unlikely that cyclanilide was hydrolysed to breakdown products because the processes for oil extraction are mainly mechanical processes. EFSA is therefore of the opinion that this study is not appropriate and should not be used for deriving any processing factor.

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Cotton evaluated in the framework of this review might be grown in rotation with other crops. During the peer review under Directive 91/414/EEC, it was demonstrated in several degradation field studies that the DT₉₀ value for cyclanilide is in the range of 37 - 151 days (mean: 94 days), close to the trigger value of 100 days. According to the European guidelines on rotational crops (EC, 1997b), further investigations of residues in rotational crops are required.

3.1.2.2. Nature of residues

Nature of residues in rotational crops was investigated (Greece, 1998). The available studies are summarized in Table 3-4.

Confined rotational crops - radish, collards and sorghum - were grown in soil treated with [U-¹⁴C-phenyl] labelled cyclanilide. Crops that were planted 30, 120 and 359 days after treatment of the soil were radioassayed at maturity (except for sorghum forage). Due to the low residues (<0.01 mg/kg) in the collards and radishes at the 120d plant-back interval, only the sorghum was planted at the 359 d plant back interval.

Parent comprised the bulk of the organosoluble residue of the examined aerial crops and 2,4-dichloroaniline was the major residue in the examined root sample. In the 30d plant back interval samples, the largest metabolite in radish root was 2,4-dichloroaniline (38% of TRR – 0.034 mg/kg); in sorghum stalk, parent accounted for 11 % of the TRR, (0.009 mg/kg). In collard at each sampling date and in all crops at later sampling dates, residue levels were too low (<0.01 mg/kg cyclanilide equivalent) to be identified.

Although 2,4-dichloroaniline constituted the most important component of the residue in radish at the 30d plant-back interval, cyclanilide was applied on a bare soil at an overdosed rate (1.5N); residues are therefore expected to be very low in practice. Moreover, such a short rotation is not to be expected after an established cotton crop. A specific residue definition for rotational crops is not deemed necessary due to the very low residue levels expected.

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

Crop group	Crop	Label position	Application and sampling details				Remarks
			Method, F or G ^(a)	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	
Leafy vegetables	Collard (<i>Brassica oleracea</i>)	U- ¹⁴ C-phenyl cyclanilide	Soil treatment	0.280	30, 120, 360	n.r. maturity	
Root and tuber vegetables	Radish (<i>Raphanus sativus</i>),	U- ¹⁴ C-phenyl cyclanilide	Soil treatment	0.280	30, 120, 360	n.r. maturity	
Cereals	Sorghum (<i>Sorghum vulgare</i>)]	U- ¹⁴ C-phenyl cyclanilide	Soil treatment	0.280	30, 120, 360	n.r. maturity	

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
n.r.: DAT not reported

3.1.2.3. Magnitude of residues

According to the studies reported in section 3.1.2.2., the total radioactive residues in the edible parts of succeeding crops were very low for all plant back intervals. There is no accumulation of cyclanilide or its degradation products (including 2,4-dichloroaniline) in the parts of plants used for human or animal consumption and restrictions related to the use on cotton are therefore not required.

3.2. Nature and magnitude of residues in livestock

Cyclanilide is authorised for use on cotton, a crop that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarized in Table 3-5. For cotton seed meal, a default processing factor of 1.3 has been included in the calculation in order to consider potential concentration of residues in this commodity.

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

Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: cyclanilide				
Cotton seed	0.03	Median residue	0.03	Median residue
Cotton seed meal	0.04	Median residue x 1.3	0.04	Median residue x 1.3

The results of the calculations are reported in Table 3-6. Since the calculated dietary burdens for all groups of livestock were found to be below the trigger value of 0.1 mg/kg DM, further investigation of residues as well as the setting of MRLs in commodities of animal origin is not necessary.

Table 3-5: Results of the dietary burden calculation

	Maximum dietary burden (mg/kg bw/d)	Median dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: cyclanilide					
Dairy ruminants	0.0005	0.0005	Cotton seed	0.015	No
Meat ruminants	0.0006	0.0006	Cotton seed	0.015	No
Poultry	0.0003	0.0003	Cotton seed	0.005	No
Pigs	0.0004	0.0004	Cotton seed	0.010	No

4. Consumer risk assessment

Chronic and acute exposure calculations for all crops supported in the framework of this review were performed using revision 2 of the EFSA Pesticide Residues Intake Model (PRIMo) (EFSA, 2007). Input values for the intake calculations were derived in compliance with Appendix D and are summarized in Table 4-1. The contributions of other commodities, for which no GAP was reported in the framework of this review, were not included in the calculation.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: cyclanilide				
Cotton seed	0.03	Median residue ^(a)	0.21	Highest residue ^(a)

(a): 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.

The calculated exposures were compared with the toxicological reference values derived for cyclanilide (see Table 2-1); detailed results of the calculations are presented in Appendix B. The highest chronic exposure was calculated for Dutch children, representing 0.003% of the ADI, and no acute exposure was identified linked to the use on cotton as no acute consumption data are available for this crop. The lack of acute consumption data for cotton seed highlights the minor contribution of this crop to the diet of European consumers.

Based on the above calculations, EFSA concludes that the use of cyclanilide on cotton, is acceptable with regard to consumer exposure.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The toxicological profile of cyclanilide was already evaluated in the framework of Directive 91/414/EEC. The ADI and the ARfD were established at 0.0075 mg/kg bw/d and 0.015 mg/kg bw respectively.

Primary crop metabolism of cyclanilide was investigated in cotton and wheat following foliar application. The metabolism study of cyclanilide in cotton showed insignificant total radioactive residues in cotton seeds, which could therefore not be characterised. In cotton foliage and fibers, total radioactive residues were essentially characterised as unchanged parent compound. Unchanged parent compound was also identified as the predominant component of total radioactive residues in wheat. These findings indicate that metabolism of cyclanilide in plants is limited. It is therefore proposed to define the regulated residue in cotton as cyclanilide parent compound alone. Validated analytical method for enforcement of the residue definition in foods of plant origin is available with an LOQ of 0.05 mg/kg in high oil content, commodities.

Regarding the magnitude of residues in cotton, the critical GAP was supported by a sufficient number of supervised residue trials, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive an appropriate MRL.

No study was provided that investigated potential breakdown or reaction products of cyclanilide residues in processed commodities, but considering their low contribution to the chronic exposure and knowing that the overall chronic exposure does not exceed 10 % of the ADI, there is no need to investigate the effect of industrial and/or household processing. EFSA did not derive processing factors.

The potential incorporation of soil residues into succeeding and rotational crops was investigated in sorghum, collards and radishes. These studies showed that significant residues in rotational crops are not expected, provided that cyclanilide is applied according to the GAPs supported in the framework of this review.

The dietary burden resulting from the reported uses of cyclanilide was calculated for each type of livestock. As all the calculated intakes represented less than 0.1 mg/kg DM, significant residues in commodities of animal origin are not expected and no MRLs were proposed.

Chronic consumer exposure resulting from the MRLs proposed in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure for cyclanilide was calculated for the Dutch children, representing 0.003 % of the ADI. No acute exposure was identified as no acute consumption data are available for cotton, highlighting the minor contribution of this crop in the EU diet. As the calculated intakes are all well below the toxicological reference values, it is concluded that the proposed MRL is not of concern for the European consumer.

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this cyclanilide in Annex IV to Regulation (EC) No 396/2005. An MRL recommendation was derived for cotton in compliance with the decision tree reported in Appendix D (see table below for a summary). This MRL value is sufficiently supported by data and therefore proposed for inclusion in Annex II to the Regulation.

A minor deficiency was identified in the assessment but this deficiency is not expected to impact either on the validity of the 'Recommended' MRL or on the national authorisations. One additional residue trial on cotton to support the reported use in southern Europe is therefore considered desirable but not essential.

It is also highlighted that the above recommendation is based on an authorisation that should be withdrawn by 30 April 2011. However, EFSA still considers the MRL recommendation relevant for the time being considering that a period of grace for this authorisation still applies until 31 October 2013.

Code number	Commodity	Existing EU MRL (mg/kg)	Outcome of the review	
			MRL (mg/kg)	Comment
Enforcement residue definition: cyclanilide				
401090	Cotton seed	0.2	0.3	Recommended ^(a)
-	Other products of plant and/or animal origin	See App C	-	Further consideration needed ^(b)

(a): MRL is derived from a GAP evaluated at EU level, which is fully supported by data and for which no risk to consumers is identified; no CXL is available (combination G-I in Appendix D).

(b): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either the specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on cyclanilide prepared by the rapporteur Member State Greece in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 06 March 2009. Last updated on 22 October 2009.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Method	Application				Application rate			PHI or waiting period (days)	Comments (max. 250 characters)		
Common name	Scientific name					Type	Content			From BBCH	Until BBCH	Number		Interval (days)		Min. rate			Max. rate	Rate Unit
							Conc.	Unit				Min.	Max.	Min.	Max.					
Cotton seed	<i>Gossypium spp.</i>	SEU	Outdoor	Greece	plant growth regulator	SC	60.0	g/L	Foliar treatment - spraying	88	88	1	1			0.15	0.18	kg a.i./ha	7	The ppp is a mixture of cyclanilide and ethephon

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Cyclanilide			
Status of the active substance:	Included	Code no.:	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.0075	ARfD (mg/kg bw):	0.015
Source of ADI:	COM	Source of ARfD:	COM
Year of evaluation:	2001	Year of evaluation:	2001

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)
0.0	NL child	0.0	Cotton seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
0.0	NL general	0.0	Cotton seed		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	
	DK adult		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)		FRUIT (FRESH OR FROZEN)	

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

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

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

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

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

Threshold MRL is the calculated residue level which would 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)
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)

*) 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 Cyclanilide 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)

(Pesticides - Web Version - EU MRLs (File created on 28 March/2011 12:30))

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
100000	1. FRUIT FRESH OR FROZEN; NUTS	0,05*
110000	(i) Citrus fruit	0,05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo, 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 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)	0,05*
140990	Others	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
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 cloudberry)	0,05*
153030	Raspberries (Wineberries)	0,05*
153990	Others	0,05*
154000	(d) Other small fruit & berries	0,05*
154010	Blueberries (Bilberries cowberries (red bilberries))	0,05*
154020	Cranberries	0,05*
154030	Curants (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	Azrole (mediterranean medlar)	0,05*
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea salallowthorn), hawthorn, service berries, and other treeberries)	0,05*
154990	Others	0,05*
160000	(vi) Miscellaneous fruit	0,05*
161000	(a) Edible peel	0,05*
161010	Dates	0,05*
161020	Figs	0,05*
161030	Table olives	0,05*
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomarac, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammy 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	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	0,05*
210000	(j) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
213010	Beetroot	0,05*
213020	Carrots	0,05*
213030	Celeriac	0,05*
213040	Horseradish	0,05*
213050	Jerusalem artichokes	0,05*
213060	Parsnips	0,05*
213070	Parsley root	0,05*
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	0,05*
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	0,05*
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	0,05*
231000	(a) Solanacea	0,05*
231010	Tomatoes (Cherry tomatoes,)	0,05*
231020	Peppers (Chilli peppers)	0,05*
231030	Aubergines (egg plants) (Pepino)	0,05*
231040	Okra, lady's fingers	0,05*
231990	Others	0,05*
232000	(b) Cucurbits - edible peel	0,05*
232010	Cucumbers	0,05*
232020	Gherkins	0,05*
232030	Courgettes (Summer squash, marrow (patisson))	0,05*
232990	Others	0,05*
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
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), peking cabbage (pe-tsai), cow cabbage)	0,05*
243020	Kale (Borecole (curly kale), collards)	0,05*
243990	Others	0,05*
244000	(d) Kohlrabi	0,05*
250000	(v) Leaf vegetables & fresh herbs	0,05*
251000	(a) Lettuce and other salad plants including Brassicaceae	0,05*
251010	Lamb's lettuce (Italian comsalad)	0,05*
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	0,05*
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curd leave endive, sugar loaf)	0,05*
251040	Cress	0,05*
251050	Land cress	0,05*
251060	Rocket, Rucola (Wild rocket)	0,05*
251070	Red mustard	0,05*
251080	Leaves and sprouts of Brassica spp (Mizuna)	0,05*
251990	Others	0,05*
252000	(b) Spinach & similar (leaves)	0,05*
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glasswort)	0,05*
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves, Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cicely and other Apiacea)	0,05*
256040	Parsley	0,05*
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Taragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	0,05*
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	0,05*
260020	Beans (without pods) (Broad beans, Flageolet, jack bean, lima bean, cowpea)	0,05*
260030	Peas (with pods) (Mangetout (sugar peas))	0,05*
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,05*
260050	Lentils	0,05*
260990	Others	0,05*
270000	(vii) Stem vegetables (fresh)	0,05*
270010	Asparagus	0,05*
270020	Cardoons	0,05*
270030	Celery	0,05*
270040	Fennel	0,05*
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
280020	Wild (Chanterelle, Truffle, Morel)	0,05*
280990	Others	0,05*
290000	(ix) Sea weeds	0,05*
300000	3. PULSES, DRY	0,05*
300010	Beans (Broad beans, navy beans, flageolet, 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 OILFRUITIS	
401000	(i) Oilseeds	
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	0,2
401100	Pumpkin seeds	0,05*
401110	Safflower	0,05*
401120	Borage	0,05*
401130	Gold of pleasure	0,05*
401140	Hempseed	0,05*
401150	Castor bean	0,05*
401990	Others	0,05*
402000	(ii) Oilfruits	0,05*
402010	Olives for oil production	0,05*
402020	Palm nuts (palmoil kernels)	0,05*
402030	Palmfruit	0,05*
402040	Kapok	0,05*
402990	Others	0,05*
500000	5. CEREALS	0,05*
500010	Barley	0,05*
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	0,05*
500060	Rice	0,05*
500070	Rye	0,05*
500080	Sorghum	0,05*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
500090	Wheat (Spelt Triticale)	0,05*
500990	Others	0,05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	0,1*
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0,1*
620000	(ii) Coffee beans	0,1*
630000	(iii) Herbal infusions (dried)	0,1*
631000	(a) Flowers	0,1*
631010	Camomille flowers	0,1*
631020	Hybiscus flowers	0,1*
631030	Rose petals	0,1*
631040	Jasmine flowers	0,1*
631050	Lime (linden)	0,1*
631990	Others	0,1*
632000	(b) Leaves	0,1*
632010	Strawberry leaves	0,1*
632020	Rooibos leaves	0,1*
632030	Maté	0,1*
632990	Others	0,1*
633000	(c) Roots	0,1*
633010	Valerian root	0,1*
633020	Ginseng root	0,1*
633990	Others	0,1*
639000	(d) Other herbal infusions	0,1*
640000	(iv) Cocoa (fermented beans)	0,1*
650000	(v) Carob (st johns bread)	0,1*
700000	7. HOPS (dried) , including hop pellets and unconcentrated powder	0,1*
800000	8. SPICES	0,1*
810000	(i) Seeds	0,1*
810010	Anise	0,1*
810020	Black caraway	0,1*
810030	Celery seed (Lovage seed)	0,1*
810040	Coriander seed	0,1*
810050	Cumin seed	0,1*
810060	Dill seed	0,1*
810070	Fennel seed	0,1*
810080	Fenugreek	0,1*
810090	Nutmeg	0,1*
810990	Others	0,1*
820000	(ii) Fruits and berries	0,1*
820010	Allspice	0,1*
820020	Anise pepper (Japan pepper)	0,1*
820030	Caraway	0,1*
820040	Cardamom	0,1*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
820050	Juniper berries	0,1*
820060	Pepper, black and white (Long pepper, pink pepper)	0,1*
820070	Vanilla pods	0,1*
820080	Tamarind	0,1*
820990	Others	0,1*
830000	(iii) Bark	0,1*
830010	Cinnamon (Cassia)	0,1*
830990	Others	0,1*
840000	(iv) Roots or rhizome	0,1*
840010	Liquorice	0,1*
840020	Ginger	0,1*
840030	Turmeric (Curcuma)	0,1*
840040	Horseradish	0,1*
840990	Others	0,1*
850000	(v) Buds	0,1*
850010	Cloves	0,1*
850020	Capers	0,1*
850990	Others	0,1*
860000	(vi) Flower stigma	0,1*
860010	Saffron	0,1*
860990	Others	0,1*
870000	(vii) Aril	0,1*
870010	Mace	0,1*
870990	Others	0,1*
900000	9. SUGAR PLANTS	0,05*
900010	Sugar beet (root)	0,05*
900020	Sugar cane	0,05*
900030	Chicory roots	0,05*
900990	Others	0,05*
1000000	10. PRODUCTS OF ANIMAL	

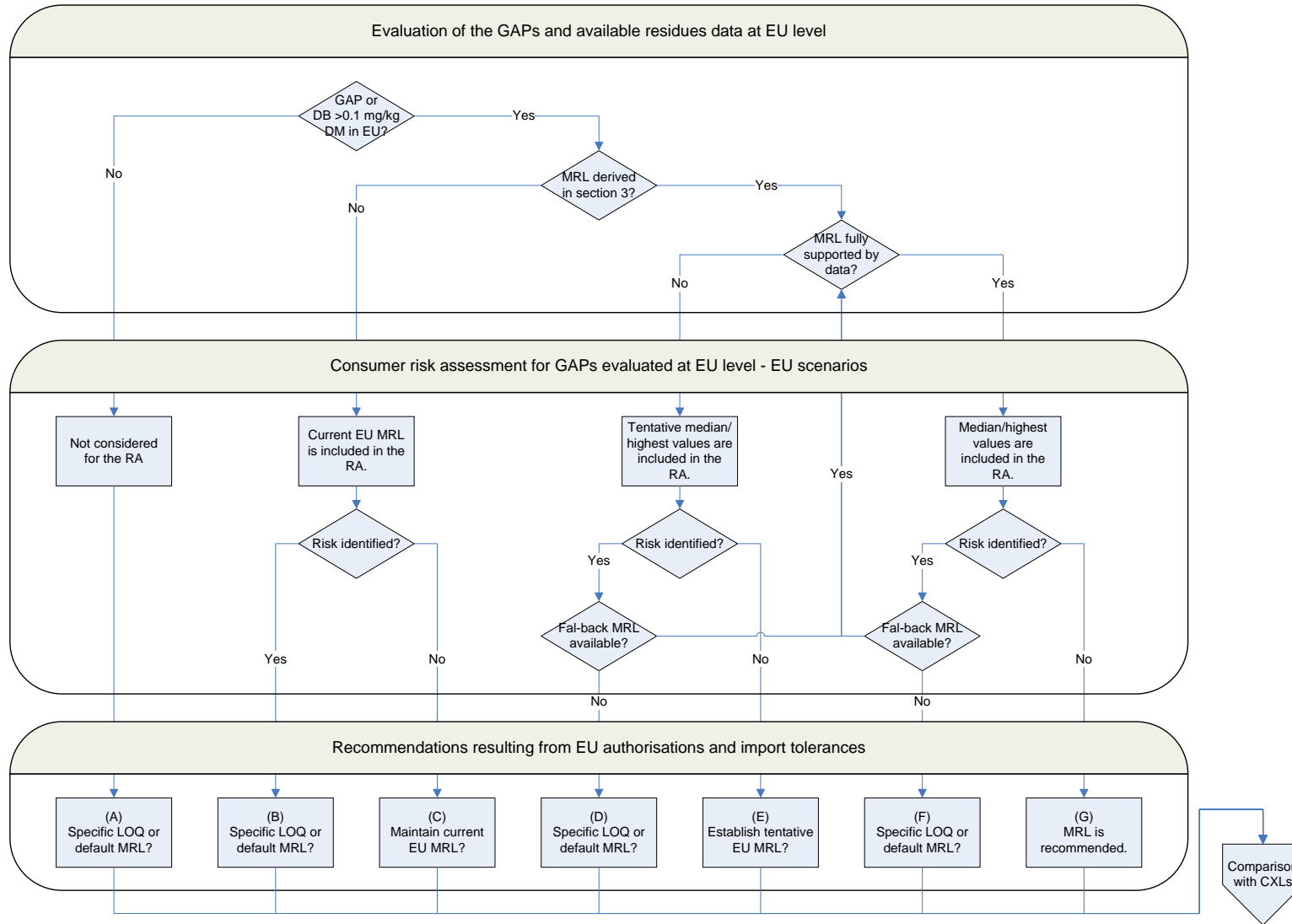
Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
	ORIGIN-TERRESTRIAL ANIMALS	
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on these	0,01*
1011000	(a) Swine	0,01*
1011010	Meat	0,01*
1011020	Fat free of lean meat	0,01*
1011030	Liver	0,01*
1011040	Kidney	0,01*
1011050	Edible offal	0,01*
1011990	Others	0,01*
1012000	(b) Bovine	0,01*
1012010	Meat	0,01*
1012020	Fat	0,01*
1012030	Liver	0,01*
1012040	Kidney	0,01*
1012050	Edible offal	0,01*
1012990	Others	0,01*
1013000	(c) Sheep	0,01*
1013010	Meat	0,01*
1013020	Fat	0,01*
1013030	Liver	0,01*
1013040	Kidney	0,01*
1013050	Edible offal	0,01*
1013990	Others	0,01*
1014000	(d) Goat	0,01*

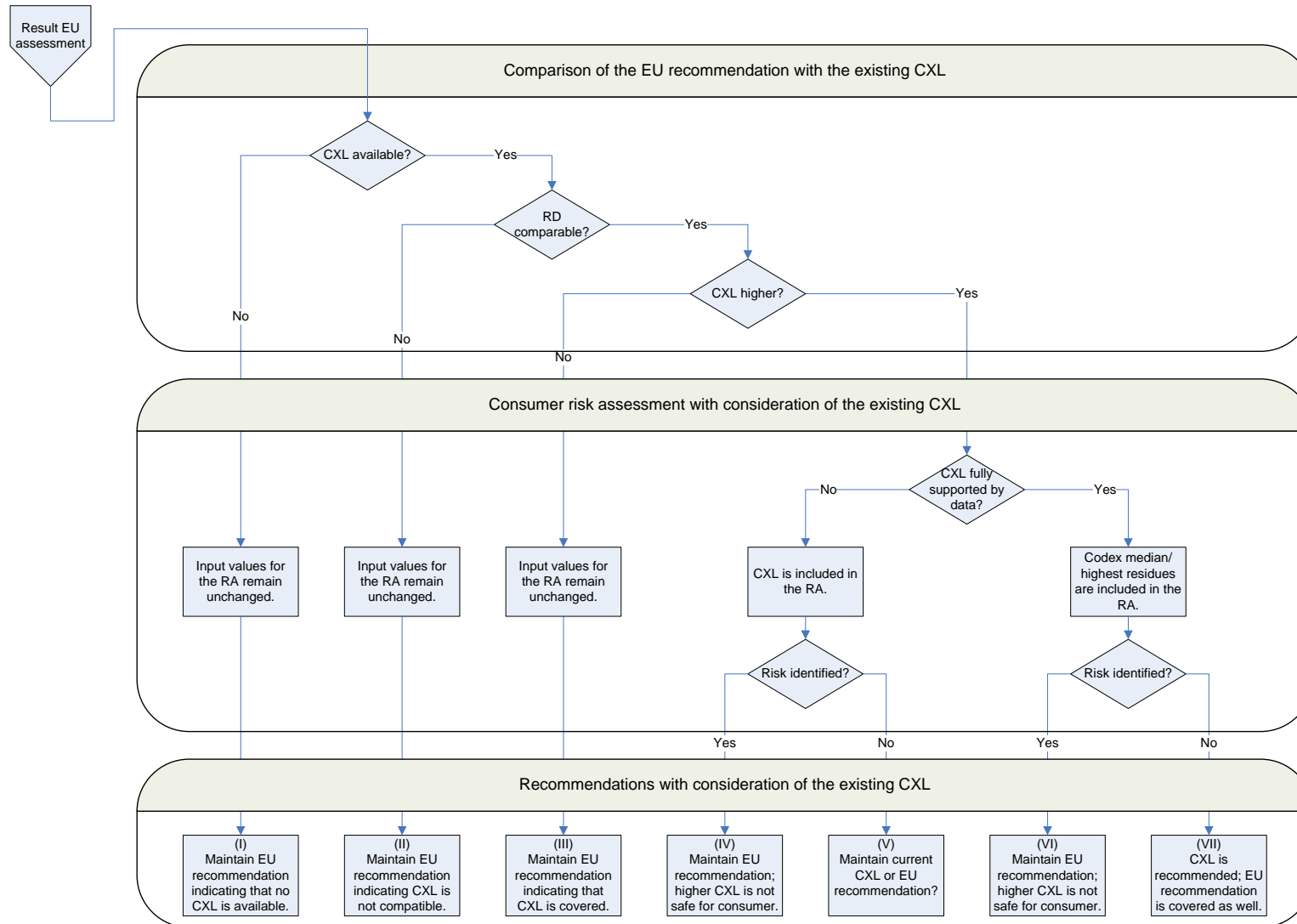
Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
1014010	Meat	0,01*
1014020	Fat	0,01*
1014030	Liver	0,01*
1014040	Kidney	0,01*
1014050	Edible offal	0,01*
1014990	Others	0,01*
1015000	(e) Horses, asses, mules or hinnies	0,01*
1015010	Meat	0,01*
1015020	Fat	0,01*
1015030	Liver	0,01*
1015040	Kidney	0,01*
1015050	Edible offal	0,01*
1015990	Others	0,01*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,01*
1016010	Meat	0,01*
1016020	Fat	0,01*
1016030	Liver	0,01*
1016040	Kidney	0,01*
1016050	Edible offal	0,01*
1016990	Others	0,01*
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,01*
1017010	Meat	0,01*
1017020	Fat	0,01*
1017030	Liver	0,01*
1017040	Kidney	0,01*
1017050	Edible offal	0,01*
1017990	Others	0,01*
1020000	(ii) Milk and cream, not	0,01*

Code number	Groups and examples of individual products to which the MRLs apply (a)	Cyclanilide (F)
	concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	
1020010	Cattle	0,01*
1020020	Sheep	0,01*
1020030	Goat	0,01*
1020040	Horse	0,01*
1020990	Others	0,01*
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	0,01*
1030010	Chicken	0,01*
1030020	Duck	0,01*
1030030	Goose	0,01*
1030040	Quail	0,01*
1030990	Others	0,01*
1040000	(iv) Honey (Royal jelly, pollen)	
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	
1060000	(vi) Snails	
1070000	(vii) Other terrestrial animal products	

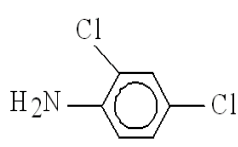
(*) Indicates lower limit of analytical determination

APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS





APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
2,4-dichloroaniline	2,4-dichloroaniline	

ABBREVIATIONS

a.s.	Active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CF	conversion factor for enforcement residue definition to risk assessment residue definition
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Council Directive 91/414/EEC)
DAT	days after treatment
DB	dietary burden
DM	dry matter
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC-ECD	gas chromatography with electron capture detection
GC-MS	gas chromatography with mass spectrometry detection
ha	hectare
ILV	independent laboratory validation
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
LOQ	limit of quantification
MRL	maximum residue limit

MS	Member States
PHI	pre-harvest interval
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residue Overview File
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
RD	residue definition
RMS	rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue