

REASONED OPINION OF EFSA

Modification of the existing MRL for cyprodinil in spinach¹

Prepared by the Pesticides Unit (PRAPeR)

(Question No EFSA-Q-2009-00206)

Issued on 6 March 2009

SUMMARY

Portugal received an application from the Iberian Salads Agricultura SA to modify the existing MRL for cyprodinil in spinach. The current MRL for spinach is set at the LOQ of 0.05 mg/kg and the applicant proposes to raise it to 10 mg/kg by extrapolation from lettuce. The Evaluating Member State Portugal according to Article 9 of the Regulation drafted the evaluation report on this subject which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report prepared by the Evaluating Member State Portugal and the EFSA conclusion prepared in the framework of the peer review:

The toxicological profile of the active substance was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.03 mg/kg bw/d. An ARfD was considered not necessary.

In the peer review it was concluded that the metabolic pattern of cyprodinil is similar in all crops assessed and the residue definitions for monitoring and risk assessment can be established as parent cyprodinil only in all plant commodities. In potatoes the metabolic pattern was slightly different resulting from the translocation of degradation products through the plant from the soil metabolism of cyprodinil; no parent cyprodinil and no major fraction was identified. Regarding leafy vegetables, the metabolic pathway is comparable to the crop groups considered under the peer review and no additional metabolism studies are necessary.

Adequate analytical methods are available to enforce a MRL in spinach.

The submitted supervised residues field trials on lettuce were adequate to derive an MRL proposal for spinach. EFSA concludes that a MRL of 8 mg/kg would be required.

The effect of processing on the nature of cyprodinil residues has been investigated under the peer review in hydrolysis studies. Cyprodinil is considered stable under hydrolytic processing conditions and no formation of toxicologically significant metabolites is expected. It should

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be taken into account that spinach are mainly consumed processed. The applicant has not submitted processing data for spinach. Although the trigger value of 10% of the TMDI for spinach is not exceeded (6.4% for French toddler diet), the deriving of processing factors is recommended, considering that the current estimated long term dietary intake of products containing cyprodinil is close to 100% of the ADI.

As concluded in the peer review, the metabolism in rotational crops proceeds in a slightly different pathway than in primary crops yielding two plant metabolites in measurable levels in succeeding crops for the short plant back intervals (30 DAT). The metabolites, however, were not included in the residue definition for plants, but the need for fixing the plant back intervals for succeeding crops was considered in the peer review. It is therefore recommended that Portugal before granting an authorization for the use of cyprodinil on spinach should consider the need of establishing the plant back intervals.

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

Consumer risk assessment was performed with the EFSA PRIMo rev. 2 using the existing MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR value derived for the intended use on spinach. For several crops the STMR values were available to refine the intake calculations. No chronic intake concerns were identified for any of European diets since TMDI values ranged from 17-98% of the ADI. Acute risk assessment was not performed as no ARfD value is established.

EFSA recommendations resulting from the assessment are summarized in the table below.

Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Cyprodinil			
Spinach	0.05*	8 ^a	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.

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

^a – applicant proposed 10 mg/kg, however, 8 mg/kg is the MRL proposal derived from the MRL calculations

Key words: Spinach, MRL application, Regulation (EC) No 396/2005, pyrimidinamines

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BACKGROUND

Regulation (EC) No 396/2005 establishes the rules governing the setting of pesticide MRLs at Community level. Article 6 of that regulation lays down that a party requesting an authorisation for the use of a plant protection product in accordance with Directive 91/414/EEC, shall submit to a Member State, when appropriate, an application to set or modify an MRL in accordance with the provisions of Article 7 of that regulation.

Portugal, hereafter referred to as an Evaluating Member State (EMS), received an application from the Iberian Salads Agricultura SA² on the modification of the existing MRL for cyprodinil in spinach by an extrapolation from lettuce. This application was notified to the European Commission and EFSA and subsequently evaluated by the EMS in accordance with Article 8 of the Regulation.

After completion, the evaluation report of the EMS was submitted to the European Commission who forwarded the application, the evaluation report and the supporting dossier to EFSA on 14 January 2009. The application was included in the EFSA Register of Question with the reference number EFSA-Q-2009-00206 and the following subject:

Cyprodinil - Application to modify the existing MRL for cyprodinil in spinach from 0.05 mg/kg to 10 mg/kg*

EFSA then proceeded with the assessment of the application as required by Article 10 of the Regulation.

TERMS OF REFERENCE

According to Article 10 of Regulation (EC) No 396/2005, EFSA shall, based on the evaluation report provided by the Evaluating Member State, provide a reasoned opinion on the risks to the consumer associated with the application.

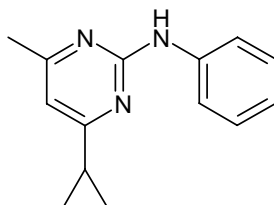
According to Article 11 of that Regulation, the reasoned opinion shall be provided as soon as possible and at the latest within 3 months from the date of receipt of the application. Where EFSA requests supplementary information, the time limit laid down shall be suspended until that information has been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

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

² Iberian Salads Agricultura SA, Quinta dos Cativos – Boavista dos Pinheiros, 7630-033, Odemira, Portugal

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cyprodinil is the ISO common name for (4-cyclopropyl-6-methyl-pyrimidin-2-yl)-phenylamine and it has the following structure:



Cyprodinil is a broad spectrum fungicide for foliar applications on a wide range of different crops. It belongs to the chemical class of pyrimidinamines (or anilinopyrimidines). Cyprodinil is a systemic fungicide having good uptake in plants after foliar applications. Cyprodinil is active against fungi from the classes *Ascomycetes*, *Basidiomycetes* and *Deuteromycetes*.

Cyprodinil is effective by inhibiting the penetration and mycelial growth of target pathogens on the surface and inside leaves. It is widely used against foliar diseases in crops like small grain cereals, pome and stone fruits, grapes, strawberries, field crops and vegetables. It is also developed as a seed treatment fungicide in barley.

Cyprodinil has been peer reviewed under the Directive 91/414/EEC and is included in the Annex I of this Directive by the Commission Directive 2006/64/EC for the uses as fungicide only. The representative uses evaluated under the peer review refers to the foliar application of cyprodinil on winter wheat (1 x 750 g a.s./ha) and on apples (4 x 225 g a.s./ha).

In the European Community the MRLs for cyprodinil are established in Annex IIIA of the Regulation (EC) No 396/2005 and are summarized in Appendix B. The current EC MRL for spinach is set at the LOQ of 0.05 mg/kg. Codex Alimentarius has established CXLs for several crops, but no CXL is set for spinach.

Portugal requested an authorization for an outdoor and indoor use of cyprodinil on spinach at an application rate of 2 x 0.056-0.225 kg a.s./ha. The minimum waiting period is 14 days. The information on the interval between applications is not specified. The GAP is provided in Appendix A.

ASSESSMENT

1. Methods of analysis

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

The analytical methods for the determination of cyprodinil in the foodstuffs of plant origin were evaluated in the framework of the peer review of Directive 91/414/EEC (France, 2003). In general, for the determination of cyprodinil in matrices with high water content, three analytical methods are sufficiently validated:

- 1) Multi residue method DFG S19 where samples are analysed by GS-MSD. The validated LOQ is 0.02 mg/kg for commodities with high water content (tomatoes)
- 2) Single residue method REM 141.01, where samples are analysed by HLPC UV. The validated LOQ is 0.01 mg/kg for commodities with high water content (apples)
- 3) Single residue method REM 141.09, where samples are analysed by HLPC-MS/MS with and LOQ of 0.01 mg/kg for commodities with high water content (lettuce, radish tubers).

It is concluded that there are adequate analytical methods available for the enforcement of the proposed MRL for spinach.

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

Since spinach are not used as a livestock feed, analytical methods for the products of animal origin are not of relevance for the proposed MRL.

2. Mammalian toxicology

The toxicological reference values for cyprodinil were derived in the peer review process of Directive 91/414/EEC (EFSA, 2005) and are compiled in Table 2-1. Since cyprodinil does not exhibit acute toxicological properties, no ARfD value was established.

Table 2-1. Overview of the toxicological reference values

	Source	Year	Value (mg/kg bw/d)	Study relied upon	Safety factor
ADI	EFSA	2005	0.03	2 yr rat	100
ARfD	EFSA	2005	n.n.	n.n.	n.n.

n.n.- not necessary

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

During the peer review of Directive 91/414/EEC the metabolism of cyprodinil was investigated in the following crop categories (France, 2003):

- root and tuber vegetables (potatoes)- foliar spray 3 x 0.56 kg a.s./ha
- fruits and fruiting vegetables (apples, peach, tomatoes); tomatoes - foliar spray 2x 0.75 kg a.s./ha; apples- foliar spray 3 x 0.05 kg a.s./hl
- cereals (wheat)- foliar spray, 2 x 0.5-0.75 kg a.s/ha (field) and 1x 0.75 g a.s/ha

Two radiolabelled forms of cyprodinil were used – phenyl and pyrimidine labels. The metabolism proceeds mainly by hydroxylation of the phenyl and pyrimidine rings followed by sugar conjugation. Cyprodinil is comparatively persistent and up to 60 days after application the parent compound remains the dominant residue except in potato tubers where the metabolic pattern results from the translocation of degradation products through the plant from the soil metabolism of cyprodinil. The metabolism in crops where there is a direct contact of cyprodinil with the edible part, demonstrates that cyprodinil represents the largest part of the residue. In potato tubers where the edible part of the crop is not exposed to the fungicide spray the residues were very low with no parent identified and no major fraction. In the peer review it was concluded that metabolism is similar in all crops and the residue definition for both risk assessment and monitoring should be established as cyprodinil (parent compound only).

Regarding leafy vegetables, no metabolism studies are available. Considering that metabolism of cyprodinil in leafy crops is similar in the crops directly exposed to the spray, it can be assumed that metabolic pathway in leafy vegetables proceeds in a similar pattern than demonstrated in cereals and fruit vegetables. This assumption is confirmed by the findings in metabolism studies with potatoes and tomatoes where the results on leaves were comparable with the results from fruit and wheat metabolism study.

3.1.1.2. Magnitude of residues

In support of the proposed GAP on spinach, the applicant referred to the supervised residues field trials on lettuce as reported in the FAO/WHO JMPR Evaluation 2003. In total 14 supervised residues field trials are available on different lettuce varieties. Nine trials were submitted reflecting the indoor use of cyprodinil and five trials were on the outdoor use of cyprodinil in Southern Europe (FAO/WHO, 2003). In all supervised field trials cyprodinil was applied three times on the lettuce therefore not complying with the proposed GAP where two applications are envisaged. However, the residue decline data demonstrated that the most critical application regarding residue levels in the crop is the last application. EFSA therefore concludes that the data on supervised residue field trials are representative for the intended GAP and sufficient for deriving an MRL proposal.

The residue levels measured in the indoor trials are higher than the levels measured in outdoor trials therefore the MRL proposals and risk assessment values are derived from the indoor trials. The summary of residue field trials data and the derived MRL proposals and risk assessment values are summarized in Table 3-1. The MRL proposals were derived using the statistical methodologies agreed at European level. The extrapolation from lettuce to spinach is acceptable.

The storage stability of cyprodinil residues in treated crops has been evaluated under the peer review of Directive 91/414/EEC (France, 2003). The stability of cyprodinil has been demonstrated for at least 24 months under deep freezer storage conditions in commodities with high acid and high water content and in dry commodities. The residue data was considered valid both in the means of analytical performance and storage stability (FAO/WHO, 2003).

It should be noted that during the evaluation process the number of applications and the PHI were modified by the EMS which resulted in new parameters of the GAP matching the available residues trials. EFSA is not in the position to judge whether the number of applications and the PHI were altered for the means of efficiency.

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

Commodity	Region (a)	Outdoor /Indoor	Individual trial results (mg/kg)		STMR (mg/kg) ^(b)	HR (mg/kg) ^(c)	MRL proposal (mg/kg)	Median CF ^(d)	Comments
			Enforcement	Risk assessment					
Enforcement residue definition: Cyprodinil									
Spinach	SEU	Outdoor	<0.02; 0.06; 0.18; 1.0; 1.1	<0.02; 0.06; 0.18; 1.0; 1.1	0.18	1.1	3.00	1.00	Trials were performed on lettuce and can be extrapolated to spinach. MRL proposal and risk assessment values are based on the indoor use, considering that it is the most critical (indicated in bold). $R_{\max}(\text{indoor}) = 7.7 \text{ mg/kg}$ $R_{\text{ber}}(\text{indoor}) = 7.0 \text{ mg/kg}$ $R_{\max}(\text{outdoor}) = 2.7 \text{ mg/kg}$ $R_{\text{ber}}(\text{outdoor}) = 2.1 \text{ mg/kg}$
	EU	Indoor	1.1; 1.3; 2.0; 2.2; 2.7; 2.8; 2.9; 4.1; 6.4	1.1; 1.3; 2.0; 2.2; 2.7; 2.8; 2.9; 4.1; 6.4	2.7	6.4	8.00	1.00	

(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

Under the peer review the effect of processing on the nature of cyprodinil residues was investigated in hydrolysis study (EFSA, 2005), stimulating pasteurization (90°C, 20 min.), baking, brewing, boiling (100°C, 60 min.) and sterilization (120°C, 20 min.). No breakdown or reaction products were formed and the residue of concern in processed crop commodities and fractions is parent cyprodinil only.

No specific processing data has been submitted. Although the trigger value of 10% of the TMDI for spinach is not exceeded (6.4% for French toddler diet), the deriving of processing factors is recommended, considering that the current estimated long term dietary intake of products containing cyprodinil is close to 100% of the ADI (see Appendix C).

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Spinach can be grown in rotation with other crops. The rate of degradation of cyprodinil was investigated in the peer review of Directive 91/414/EEC. Since the highest DT₉₀ value of cyprodinil based on the field study amounts for up to 814 days in acidic soils (EFSA, 2005), investigation of residues in rotational crops is required.

3.1.2.2. Nature of residues

The nature of cyprodinil residues was investigated during the peer review in four confined studies to address the potential uptake of cyprodinil and cyprodinil related metabolites into succeeding crops (France, 2003). In the confined studies cyprodinil was radio-labelled in phenyl or pyrimidinyl rings and applied to bare soil or crops at an application rates ranging from 1.25 -3.6 kg a.s./ha. When radiolabelled cyprodinil was applied on a primary crop at an application rate of 1.25 kg a.s./ha, no significant cyprodinil residues were found in any of the edible parts of the succeeding crops tested. When cyprodinil was applied to bare soil the studies identified four cyprodinil metabolites in the succeeding crops: 4-cyclopropyl-6-methyl-pyrimidin-2-ol (CGA 321915), 4-cyclopropyl-6-methyl-pyrimidine-2-yl-amine (CGA 249287), (2-amino-6-cyclopropyl-pyrimidin-4-yl) methanol (NOA 422054), and N-phenyl-guanidine. The metabolism of cyprodinil in rotational crops is elucidated. In all confined studies the application rates were much higher than in the GAPs under consideration, therefore EFSA decided to focus on the field studies.

3.1.2.3. Magnitude of residues

The available field studies were performed at an application rates ranging from 0.75 kg a.s./ha to 2.24 kg a.s./ha. These studies confirmed the occurrence of two plant metabolites (2-amino-6-cyclopropyl-pyrimidin-4-yl) methanol (NOA 422054) and 4-cyclopropyl-6-methyl-pyrimidin-2-ol (CGA 321915) which were also identified in the radiolabelled study. Both metabolites were encountered in measurable levels in the tested succeeding crops for the short plant back intervals (30 DAT). Cyprodinil itself occurred very rarely. Residues of NOA 422054 were up to 0.14 mg/kg in radish tops, 0.04 mg/kg in lettuces and 0.07 mg/kg in wheat forage from 30 DAT and with the total application rate of 0.75 kg a.s./ha. The maximum residues of CGA 321915 in this case were 0.03 mg/kg in radish leaves. However, in the peer

review it was concluded not to include these metabolites in the residue definition for plants because they occur in very specific crops/conditions. The need for fixing the plant back intervals for succeeding crops was considered in the EFSA conclusion of the peer review. The decision on whether the plant back intervals for rotational crops should be set following the proposed use of cyprodinil on spinach, should be considered by the Member State before granting an authorization of cyprodinil containing plant protection products.

3.2. Nature and magnitude of residues in livestock

Nature and magnitude of cyprodinil residues in livestock were not assessed with regard to the current application since spinach are not normally fed to livestock.

4. Consumer risk assessment

Consumer risk assessment was performed with the EFSA PRIMo rev. 2 using the existing MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR values derived for the intended use on spinach. In addition, for beet leaves, herbs and beetroots the STMR values were used as obtained in the EFSA reasoned opinion on the modification of the existing MRLs for cyprodinil in various crops (EFSA, 2009). For several other commodities the STMR values were available from the MRL proposals submitted to the EC during the MRL setting for cyprodinil. Input values are summarized in Table 4-1.

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

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: Cyprodinil				
Spinach	2.7	STMR (Portugal, 2009)	Acute risk assessment was not performed since no ARfD is established for cyprodinil	
Beet leaves(chard), herbs	3.00	STMR (EFSA, 2009)		
Beetroots	0.41	STMR (EFSA, 2009)		
Apples	0.49	STMR (France, 2007)		
Cherries	0.17	STMR (France, 2007)		
Carrots, parsley roots, salsify, parsnips, horseradish	0.51	STMR (France, 2007)		
Peppers	0.24	STMR (France, 2007)		
Beans (with pods), peas (with pods)	0.6	STMR (France, 2007)		
Pulses, dry	0.05	STMR (France, 2007)		
Barley	0.75	STMR (France, 2007)		

The summary of intake calculations can be found in Appendix C. No chronic intake concerns were identified for any of European diets since TMDI values ranged from 17-98% of the ADI. The highest contribution of spinach was for French toddler diet (6.4% of the ADI). Acute risk assessment was not performed since no ARfD value is established. It is concluded that the intended use of cyprodinil on spinach is acceptable with regard to consumer safety.

CONCLUSIONS AND RECOMMENDATIONS

Portugal received an application from the Iberian Salads Agricultura SA to modify the existing MRL for cyprodinil in spinach. The current MRL for spinach is set at the LOQ of 0.05 mg/kg and the applicant proposes to raise it to 10 mg/kg by extrapolation from lettuce. The Evaluating Member State Portugal according to Article 9 of the Regulation drafted the evaluation report on this subject which was submitted to the European Commission and forwarded to EFSA on 14 January 2009.

EFSA derives the following conclusions regarding the application, based on the Evaluation Report prepared by the Evaluating Member State Portugal and the EFSA conclusion prepared in the framework of the peer review:

The toxicological profile of the active substance was investigated in the peer review and the data were sufficient to conclude on an ADI value of 0.03 mg/kg bw/d. An ARfD was considered not necessary.

In the peer review it was concluded that the metabolic pattern of cyprodinil is similar in all crops assessed and the residue definitions for monitoring and risk assessment can be established as parent cyprodinil only in all plant commodities. In potatoes the metabolic pattern was slightly different resulting from the translocation of degradation products through the plant from the soil metabolism of cyprodinil; no parent cyprodinil and no major fraction was identified. Regarding leafy vegetables, the metabolic pathway is comparable to the crop groups considered under the peer review and no additional metabolism studies are necessary.

Adequate analytical methods are available to enforce a MRL in spinach.

The submitted supervised residues field trials on lettuce were adequate to derive an MRL proposal for spinach. EFSA concludes that a MRL of 8 mg/kg would be required.

The effect of processing on the nature of cyprodinil residues has been investigated under the peer review in hydrolysis studies. Cyprodinil is considered stable under hydrolytic processing conditions and no formation of toxicologically significant metabolites is expected. It should be taken into account that spinach are mainly consumed processed. The applicant has not submitted processing data for spinach. Although the trigger value of 10% of the TMDI for spinach is not exceeded (6.4% for French toddler diet), the deriving of processing factors is recommended, considering that the current estimated long term dietary intake of products containing cyprodinil is close to 100% of the ADI.

As concluded in the peer review, the metabolism in rotational crops proceeds in a slightly different pathway than in primary crops yielding two plant metabolites in measurable levels in succeeding crops for the short plant back intervals (30 DAT). The metabolites, however, were not included in the residue definition for plants, but the need for fixing the plant back intervals for succeeding crops was considered in the peer review. It is therefore recommended that Portugal before granting an authorization for the use of cyprodinil on spinach should consider the need of establishing the plant back intervals.

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

Consumer risk assessment was performed with the EFSA PRIMo rev. 2 using the existing MRLs as established in Annex III of Regulation (EC) No 396/2005 as well as the STMR value derived for the intended use on spinach. For several crops the STMR values were available to refine the intake calculations. No chronic intake concerns were identified for any

of European diets since TMDI values ranged from 17-98% of the ADI. Acute risk assessment was not performed as no ARfD value is established.

EFSA recommendations resulting from the assessment are summarized in the table below.

Table 5-1. Overview of the proposed EC MRLs

Commodity	Existing EC MRL (mg/kg)	Proposed EC MRL (mg/kg)	Justification for the proposal
Cyprodinil			
Spinach	0.05*	8 ^a	The MRL proposal is supported by data and no risk for consumers was identified for the proposed uses.

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

^a – applicant proposed 10 mg/kg , however, 8 mg/kg is the MRL proposal derived from the MRL calculations

DOCUMENTATION PROVIDED TO EFSA

1. Evaluation report on the modification of the existing MRL for cyprodinil in spinach under Regulation (EC) No 396/2005 prepared the Evaluating member State Portugal. Received in EFSA on 15 December 2008. Updated on 27 February, 2009.

REFERENCES

- EFSA, 2005. Conclusion of EFSA prepared by the PRAPeR regarding the peer review of the pesticide risk assessment of cyprodinil. December, 2005, 1-78.
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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPs)

Crop and / or Situation	Field, Glasshouse or Indoor	Formulation		Application		Application rate per treatment			PHI (days)	Remarks
		Type	Conc. of a.s.	method, kind	number (range)	kg a.s./hl	water l/ha	kg a.s./ha		
Spinach	Field/ Glasshouse	WG	37,5%	spraying	2	0,01875- 0,0225	300-1000	0,0563-0,225	14	In mixture with fludioxonil 25%: 0,0125-0,015 kg/hl

APPENDIX B – EXISTING EC MRLs

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
100000	1. FRUIT FRESH OR FROZEN; NUTS	
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	1
130010	Apples (Crab apple)	1
130020	Pears (Oriental pear)	1
130030	Quinces	1
130040	Medlar	1
130050	Loquat	1
130990	Others	1
140000	(iv) Stone fruit	
140010	Apricots	2
140020	Cherries (sweet cherries, sour cherries)	1
140030	Peaches (Nectarines and similar hybrids)	2

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
140040	Plums (Damson, greengage, mirabelle)	2
140990	Others	0,5
150000	(v) Berries & small fruit	
151000	(a) Table and wine grapes	5
151010	Table grapes	5
151020	Wine grapes	5
152000	(b) Strawberries	5
153000	(c) Cane fruit	
153010	Blackberries	10
153020	Dewberries (Loganberries, Boysenberries, and cloudberrries)	0,05*
153030	Raspberries (Wineberries)	10
153990	Others	0,05*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries cowberries (red bilberries))	5
154020	Cranberries	2
154030	Currants (red, black and white)	5
154040	Gooseberries (Including hybrids with other ribes species)	5
154050	Rose hips	2
154060	Mulberries (arbutus berry)	2
154070	Azarole (mediteranean medlar)	2
154080	Elderberries (Black chokeberry (appleberry), mountain ash, azarole, buckthorn (sea sallowthorn), hawthorn, service berries, and other treeberries)	2
154990	Others	2
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*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
161040	Kumquats (Marumi kumquats, nagami kumquats)	0,05*
161050	Carambola (Bilimbi)	0,05*
161060	Persimmon	0,05*
161070	Jambolan (java plum) (Java apple (water apple), pomegranate, rose apple, Brazilian cherry (grumichama), Surinam cherry)	0,05*
161990	Others	0,05*
162000	(b) Inedible peel, small	0,05*
162010	Kiwi	0,05*
162020	Lychee (Litchi) (Pulasan, rambutan (hairy litchi))	0,05*
162030	Passion fruit	0,05*
162040	Prickly pear (cactus fruit)	0,05*
162050	Star apple	0,05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0,05*
162990	Others	0,05*
163000	(c) Inedible peel, large	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*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	0,05*
211000	(a) Potatoes	0,05*
212000	(b) Tropical root and tuber vegetables	0,05*
212010	Cassava (Dasheen, eddoe (Japanese taro), tannia)	0,05*
212020	Sweet potatoes	0,05*
212030	Yams (Potato bean (yam bean), Mexican yam bean)	0,05*
212040	Arrowroot	0,05*
212990	Others	0,05*
213000	(c) Other root and tuber vegetables except sugar beet	0,05*
213010	Beetroot	0,05*
213020	Carrots	2
213030	Celeriac	0,05*
213040	Horseradish	2
213050	Jerusalem artichokes	0,05*
213060	Parsnips	2
213070	Parsley root	2
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties)	0,05*
213090	Salsify (Scorzonera, Spanish salsify (Spanish oysterplant))	2
213100	Swedes	0,05*
213110	Turnips	0,05*
213990	Others	0,05*
220000	(ii) Bulb vegetables	
220010	Garlic	0,3
220020	Onions (Silverskin onions)	0,3
220030	Shallots	0,3
220040	Spring onions (Welsh onion and similar varieties)	1
220990	Others	0,05*
230000	(iii) Fruiting vegetables	
231000	(a) Solanacea	
231010	Tomatoes (Cherry tomatoes,)	1

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	1
231040	Okra, lady`s fingers	0,5
231990	Others	0,5
232000	(b) Cucurbits - edible peel	0,5
232010	Cucumbers	0,5
232020	Gherkins	0,5
232030	Courgettes (Summer squash, marrow (patisson))	0,5
232990	Others	0,5
233000	(c) Cucurbits-inedible peel	0,05*
233010	Melons (Kiwano)	0,05*
233020	Pumpkins (Winter squash)	0,05*
233030	Watermelons	0,05*
233990	Others	0,05*
234000	(d) Sweet corn	0,05*
239000	(e) Other fruiting vegetables	0,05*
240000	(iv) Brassica vegetables	0,05*
241000	(a) Flowering brassica	0,05*
241010	Broccoli (Calabrese, Chinese broccoli, Broccoli raab)	0,05*
241020	Cauliflower	0,05*
241990	Others	0,05*
242000	(b) Head brassica	0,05*
242010	Brussels sprouts	0,05*
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*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	10
251010	Lamb`s lettuce (Italian cornsalad)	10
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	10
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	10
251040	Cress	10
251050	Land cress	10
251060	Rocket, Rucola (Wild rocket)	10
251070	Red mustard	10
251080	Leaves and sprouts of Brassica spp (Mizuna)	10
251990	Others	10
252000	(b) Spinach & similar (leaves)	
252010	Spinach (New Zealand spinach, turnip greens (turnip tops))	0,05*
252020	Purslane (Winter purslane (miner`s lettuce), garden purslane, common purslane, sorrel, glassworth)	10
252030	Beet leaves (chard) (Leaves of beetroot)	0,05*
252990	Others	0,05*
253000	(c) Vine leaves (grape leaves)	0,05*
254000	(d) Water cress	0,05*
255000	(e) Witloof	0,05*
256000	(f) Herbs	0,05*
256010	Chervil	0,05*
256020	Chives	0,05*
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	0,05*
256040	Parsley	0,05*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
256050	Sage (Winter savory, summer savory,)	0,05*
256060	Rosemary	0,05*
256070	Thyme (marjoram, oregano)	0,05*
256080	Basil (Balm leaves, mint, peppermint)	0,05*
256090	Bay leaves (laurel)	0,05*
256100	Tarragon (Hyssop)	0,05*
256990	Others	0,05*
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	2
260020	Beans (without pods) (Broad beans, Flageolets, jack bean, lima bean, cowpea)	0,5
260030	Peas (with pods) (Mangetout (sugar peas))	2
260040	Peas (without pods) (Garden pea, green pea, chickpea)	0,1
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	5
270040	Fennel	0,2
270050	Globe artichokes	0,05*
270060	Leek	0,05*
270070	Rhubarb	0,05*
270080	Bamboo shoots	0,05*
270090	Palm hearts	0,05*
270990	Others	0,05*
280000	(viii) Fungi	0,05*
280010	Cultivated (Common mushroom, Oyster mushroom, Shi-take)	0,05*
280020	Wild (Chanterelle, Truffle, Morel ,)	0,05*
280990	Others	0,05*
290000	(ix). Sea weeds	0,05*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
300000	3. PULSES, DRY	0,2
300010	Beans (Broad beans, navy beans, flageolets, jack beans, lima beans, field beans, cowpeas)	0,2
300020	Lentils	0,2
300030	Peas (Chickpeas, field peas, chickling vetch)	0,2
300040	Lupins	0,2
300990	Others	0,2
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	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	
500010	Barley	3
500020	Buckwheat	0,05*
500030	Maize	0,05*
500040	Millet (Foxtail millet, teff)	0,05*
500050	Oats	2
500060	Rice	0,05*
500070	Rye	0,5
500080	Sorghum	0,05*
500090	Wheat (Spelt Triticale)	0,5

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
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 <i>Camellia sinensis</i>)	0,05*
620000	(ii) Coffee beans	0,05*
630000	(iii) Herbal infusions (dried)	0,05*
631000	(a) Flowers	0,05*
631010	Camomille flowers	0,05*
631020	Hybiscus flowers	0,05*
631030	Rose petals	0,05*
631040	Jasmine flowers	0,05*
631050	Lime (linden)	0,05*
631990	Others	0,05*
632000	(b) Leaves	0,05*
632010	Strawberry leaves	0,05*
632020	Rooibos leaves	0,05*
632030	Maté	0,05*
632990	Others	0,05*
633000	(c) Roots	0,05*
633010	Valerian root	0,05*
633020	Ginseng root	0,05*
633990	Others	0,05*
639000	(d) Other herbal infusions	0,05*
640000	(iv) Cocoa (fermented beans)	0,05*
650000	(v) Carob (st johns bread)	0,05*
700000	7. HOPS (dried), including hop pellets and unconcentrated powder	0,05*
800000	8. SPICES	0,05*
810000	(i) Seeds	0,05*
810010	Anise	0,05*
810020	Black caraway	0,05*
810030	Celery seed (Lovage seed)	0,05*
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*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
820010	Allspice	0,05*
820020	Anise pepper (Japan pepper)	0,05*
820030	Caraway	0,05*
820040	Cardamom	0,05*
820050	Juniper berries	0,05*
820060	Pepper, black and white (Long pepper, pink pepper)	0,05*
820070	Vanilla pods	0,05*
820080	Tamarind	0,05*
820990	Others	0,05*
830000	(iii) Bark	0,05*
830010	Cinnamon (Cassia)	0,05*
830990	Others	0,05*
840000	(iv) Roots or rhizome	0,05*
840010	Liquorice	0,05*
840020	Ginger	0,05*
840030	Turmeric (Curcuma)	0,05*
840040	Horse-radish	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	0,05*
1010000	(i) Meat, preparations of meat, offals, blood, animal fats fresh chilled or frozen, salted, in brine, dried or smoked or processed as flours or meals other processed products such as sausages and food preparations based on	0,05*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
	these	
1011000	(a) Swine	0,05*
1011010	Meat	0,05*
1011020	Fat free of lean meat	0,05*
1011030	Liver	0,05*
1011040	Kidney	0,05*
1011050	Edible offal	0,05*
1011990	Others	0,05*
1012000	(b) Bovine	0,05*
1012010	Meat	0,05*
1012020	Fat	0,05*
1012030	Liver	0,05*
1012040	Kidney	0,05*
1012050	Edible offal	0,05*
1012990	Others	0,05*
1013000	(c) Sheep	0,05*
1013010	Meat	0,05*
1013020	Fat	0,05*
1013030	Liver	0,05*
1013040	Kidney	0,05*
1013050	Edible offal	0,05*
1013990	Others	0,05*
1014000	(d) Goat	0,05*
1014010	Meat	0,05*
1014020	Fat	0,05*
1014030	Liver	0,05*
1014040	Kidney	0,05*
1014050	Edible offal	0,05*
1014990	Others	0,05*
1015000	(e) Horses, asses, mules or hinnies	0,05*
1015010	Meat	0,05*
1015020	Fat	0,05*
1015030	Liver	0,05*
1015040	Kidney	0,05*
1015050	Edible offal	0,05*
1015990	Others	0,05*
1016000	(f) Poultry -chicken, geese, duck, turkey and Guinea fowl-, ostrich, pigeon	0,05*
1016010	Meat	0,05*
1016020	Fat	0,05*
1016030	Liver	0,05*
1016040	Kidney	0,05*
1016050	Edible offal	0,05*
1016990	Others	0,05*

Code No	Groups and examples of individual products to which the MRLs apply (a)	Cyprodinil
1017000	(g) Other farm animals (Rabbit, Kangaroo)	0,05*
1017010	Meat	0,05*
1017020	Fat	0,05*
1017030	Liver	0,05*
1017040	Kidney	0,05*
1017050	Edible offal	0,05*
1017990	Others	0,05*
1020000	(ii) Milk and cream, not concentrated, nor containing added sugar or sweetening matter, butter and other fats derived from milk, cheese and curd	0,05*
1020010	Cattle	0,05*
1020020	Sheep	0,05*
1020030	Goat	0,05*
1020040	Horse	0,05*
1020990	Others	0,05*
1030000	(iii) Birds eggs, fresh preserved or cooked Shelled eggs and egg yolks fresh, dried, cooked by steaming or boiling in water, moulded, frozen or otherwise preserved whether or not containing added sugar or sweetening matter	0,05*
1030010	Chicken	0,05*
1030020	Duck	0,05*
1030030	Goose	0,05*
1030040	Quail	0,05*
1030990	Others	0,05*
1040000	(iv) Honey (Royal jelly, pollen)	0,05*
1050000	(v) Amphibians and reptiles (Frog legs, crocodiles)	0,05*
1060000	(vi) Snails	0,05*
1070000	(vii) Other terrestrial animal products	0,05*

APPENDIX C – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Cyprodinil			
Status of the active substance:	pending	Code no.	42
LOQ (mg/kg bw):		proposed LOQ:	0.05
Toxicological end points			
ADI (mg/kg bw/day):	0.03	ARfD (mg/kg bw):	n.n.
Source of ADI:	EFSA	Source of ARfD:	EFSA
Year of evaluation:	2005	Year of evaluation:	2005

For chronic RA - STMR values for spinach -2.7, beet leaves and leaf herbs- 3.00 mg/kg; beetroots - 0.41 mg/kg; apples- 0.49; cherries-0.17; carrots, parsley roots, parsnips, salsify, horseradish - 0.51; peppers-0.24; beans (with pods), peas (with pods)-0.6; pulses (dry)-0.05; barley-0.75 mg/kg

Chronic risk assessment - refined calculations

		TMDI (range) in % of ADI minimum - maximum							
		17 98							
		No of diets exceeding ADI:							

Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet		2nd contributor to MS diet		3rd contributor to MS diet		pTMRs at LOQ	
		(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	Commodity / group of commodities	(in % of ADI)	(in % of ADI)
97.96	WHO Cluster diet B	29.9	Wine grapes	14.2	Wheat	11.9	Lettuce		
93.5	FR all population	66.7	Wine grapes	6.3	Other lettuce and other salad plants	5.5	Wheat		
87.2	DE child	21.2	Table grapes	19.7	Apples	8.2	Strawberries		
76.0	NL child	12.7	Table grapes	10.3	Apples	7.9	Wheat		
69.3	IE adult	20.8	Wine grapes	4.3	Table grapes	4.1	Strawberries		
66.1	PT General population	41.5	Wine grapes	6.5	Wheat	4.6	Table grapes		
61.1	WHO cluster diet E	26.8	Wine grapes	6.6	Wheat	3.1	Lettuce		
51.9	FR toddler	10.4	Strawberries	6.6	Milk and cream,	6.4	Spinach		
46.9	DK child	9.2	Wheat	7.4	Rye	4.7	Lettuce		
43.5	ES adult	17.9	Lettuce	6.9	Wine grapes	3.9	Wheat		
43.1	IT kids/toddler	11.1	Wheat	9.7	Lettuce	4.8	Tomatoes		
43.0	WHO Cluster diet F	10.0	Lettuce	9.9	Wine grapes	6.0	Wheat		
42.5	WHO regional European diet	12.6	Lettuce	4.9	Wheat	3.8	Wine grapes		
42.2	IT adult	12.6	Lettuce	6.9	Wheat	5.3	Other lettuce and other salad		
40.2	NL general	10.5	Wine grapes	4.0	Lettuce	3.9	Scarole (broad-leaf endive)		
39.0	ES child	13.9	Lettuce	7.4	Wheat	3.3	Tomatoes		
38.5	UK Toddler	6.5	Wheat	4.1	Table grapes	3.8	Sugar beet (root)		
38.0	DK adult	23.2	Wine grapes	3.4	Wheat	1.4	Tomatoes		
37.0	WHO cluster diet D	10.8	Wheat	6.0	Wine grapes	3.4	Tomatoes		
34.3	FR infant	8.1	Strawberries	4.5	Carrots	4.3	Milk and cream,		
33.0	UK vegetarian	13.6	Wine grapes	4.7	Lettuce	3.4	Wheat		
32.9	UK Adult	18.1	Wine grapes	3.9	Lettuce	2.8	Wheat		
30.5	UK Infant	6.5	Milk and cream,	4.4	Wheat	3.6	Strawberries		
26.2	SE general population 90th percentile	5.3	Wheat	2.8	Strawberries	2.6	Tomatoes		
20.2	FI adult	5.1	Wine grapes	2.6	Lettuce	1.6	Wheat		
18.6	PL general population	5.3	Table grapes	3.3	Apples	2.9	Tomatoes		
16.8	LT adult	3.0	Apples	2.1	Lettuce	2.1	Tomatoes		

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

GLOSSARY / ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
bw	body weight
CAC	Codex Alimentarius Commission
CXL	codex maximum residue limit
d	day
DAR	Draft Assessment Report (prepared under Directive 91/414/eec)
DAT	days after treatment
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
EC	European Community
EFSA	European Food Safety Authority
EMS	Evaluating Member State
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
ha	hectare
hL	hectolitre
HPLC	high performance liquid chromatography
HR	highest residue
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
L	litre
LC	liquid chromatography
LC-MS	liquid chromatography-mass spectrometry
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NOAEL	no observed adverse effect level

PF	processing factor
PHI	pre harvest interval
ppm	parts per million (10^{-6})
PRIMo	Pesticide Residues Intake Model
RMS	Rapporteur Member State
SEU	Southern European Union
STMR	supervised trials median residue
TMDI	theoretical maximum daily intake
TMDI	theoretical maximum daily intake
TRR	total radioactive residue
UVD	ultra-violet detection
WHO	World Health Organisation