REASONED OPINION

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

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

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

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KEY WORDS

cyprodinil, MRL review, Regulation (EC) No 396/2005, consumer risk assessment, anilinopyrimidine, fungicide

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[2] Correspondence: pesticides.mrl@efsa.europa.eu
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SUMMARY

Cyprodinil was included in Annex I to Directive 91/414/EEC on 01 May 2007, which is before the entry into force of Regulation (EC) No 396/2005 on 02 September 2008. EFSA is therefore required to provide a reasoned opinion on the review of the existing MRLs for that active substance in compliance with Article 12(2) of the aforementioned regulation. In order to collect the relevant pesticide residues data, EFSA asked France, as the designated rapporteur Member State (RMS), to complete the Pesticide Residues Overview File (PROFile). The requested information was submitted to EFSA on 17 August 2009 and, after having considered several comments made by EFSA, the RMS provided on 23 November 2012 a revised PROFile.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the MRLs established by the Codex Alimentarius Commission and the additional information provided by the RMS, EFSA issued on 26 March 2013 a draft reasoned opinion that was circulated to Member States' experts for consultation. Comments received by 31 May 2013 were considered in the finalisation of this reasoned opinion. The following conclusions are derived.

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

Primary crop metabolism was investigated for foliar application in the fruit and fruiting vegetables crop grouping (apple, peaches and tomato) and the root and tuber vegetables grouping (potato) and the cereal grouping (wheat). The studies demonstrate that where there is a direct contact of cyprodinil with the edible part, cyprodinil represents the largest part of the residue, and that metabolism proceeds mainly via hydroxylation of the phenyl and pyrimidine rings followed by sugar conjugation. It was concluded that metabolism is similar in all crops and the residue definition for all the considered uses for both risk assessment and enforcement should be established as cyprodinil (parent compound only). Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.02 mg/kg in high acid content, high water content and dry commodities, covering the authorised uses except high oil content commodities (almonds), and herbal infusions and spices of roots.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residue trials is available for the majority of the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRL proposals, except for apricots and peaches, cherries, and herbal infusions and spices of roots where tentative MRLs are derived.

Residue data on the nature of residues over processing in the form of radiolabelled hydrolysis study is available showing that cyprodinil remained stable and that no breakdown or reaction products were formed. Some studies on the magnitude of residues also allowed deriving robust processing factors for various commodities, whilst for commodities where only a limited number of studies were available some indicative processing factors were derived. Further processing studies are not required as they are not expected to significantly affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

Four confined rotational crop metabolism studies are available to address the potential for residues to occur in rotational crops. Studies on the magnitude of residues in rotational crops confirmed the presence of the plant metabolites NOA 422054 and CGA 321915 at the earliest replanting interval of 30 DAT. Although these metabolites are not expected to be of any particular toxicological concern compared to the parent compound, the possibility of residues arising in rotational crops is likely to depend on the specific crop use and whether close cropping will occur as a result of normal agricultural practice.

Metabolism studies conducted using goats and hens are available investigating the potential for residues to occur in animal products. Both studies show that cyprodinil is extensively metabolised and proceeds predominantly via hydroxylation of the phenyl and pyrimidine rings and conjugation with sulphate or glucuronic acid. The main metabolites identified in the livestock metabolism were all found in the rat metabolism study and the residue definition for enforcement and risk assessment is defined as the sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil, aside from milk where the conjugated form of the metabolite needs to be included both for enforcement and risk assessment purposes. Metabolism data in hens were sufficient to confirm an expectation of insignificant residues in poultry and MRLs can be proposed at the level of the LOQ. A cow feeding study was also available to derive MRLs for swine and ruminant products. Analytical methods were reported to enforce the proposed residues definitions. Considering however that a validated enforcement method for the determination of cyprodinil and CGA 304075 in eggs and a confirmatory method for commodities of animal origin were identified as data gaps, all MRLs for commodities of animal origin are tentative only.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 37.0 % of the ADI (German children). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for cyprodinil. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 38.6 % of the ADI (German children).

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- ILV data for the HPLC-MS/MS method for the determination of cyprodinil in high oil content commodities;
- a validated enforcement method for the determination of cyprodinil in herbal infusions and spices;
- a validated enforcement method for the determination of cyprodinil and CGA 304075 in eggs;
- confirmatory method validation data for the determination of cyprodinil and CGA 304075 in animal products.

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

- 8 residue trials on peaches or apricots (with a minimum of 4 trials on apricots) complying with the northern outdoor GAP and 4 trials on apricots complying with the southern outdoor GAP (southern trials already planned by the notifier and expected for 2015);
- 4 residue trials complying with the northern outdoor GAP on cherries;

- 5 residue trials complying with the northern outdoor GAP on plums;
- 8 residue trials complying with the indoor GAP on grapes;
- 6 residue trials (e.g. on tomatoes) complying with the southern GAP on tomatoes and aubergines (trials already planned by the notifier and expected for 2015);
- 6 additional trials complying with the southern outdoor GAP on peppers (trials already planned by the notifier and expected for 2015);
- 4 additional trials complying with the southern outdoor GAP on cucumbers and courgettes (trials already planned by the notifier and expected for 2015).

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. EFSA recommends in any case that Member States granting authorisations for cyprodinil should consider the need to take the appropriate risk mitigation measures (e.g. definition of pre-plant intervals of at least 120d) in order to avoid the presence of cyprodinil metabolites residues in rotational crops.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- 1 trial complying with the southern outdoor GAP on plums;
- 1 additional trial (e.g. on barley) complying with the southern GAP to support barley and oats grain and straw;
- 1 trial (e.g. on wheat) complying with the southern GAP to support wheat and rye grain and straw.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing and proposed): cyprodinil					
120010	Almonds	0.05*	0.02*	0.02*	Further consideration needed [(a)]
130010	Apples	1	0.05*	1.5	Recommended [(b)]
130020	Pears	1	0.05*	1.5	Recommended [(b)]
130030	Quinces	1	-	1.5	Recommended [(c)]
130040	Medlar	1	-	0.9	Recommended [(c)]
130050	Loquat	1	-	0.9	Recommended [(c)]
140010	Apricots	2	2	2	Recommended [(d)]
140020	Cherries	1	2	2	Recommended [(d)]
140030	Peaches	2	2	2	Recommended [(d)]
140040	Plums	2	2	2	Recommended [(e)]
151000	Table and wine grapes	5	3	3	Recommended [(b)]
152000	Strawberries	5	2	5	Recommended [(b)]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
153010	Blackberries	10	0.5	3	Recommended [b]
153030	Raspberries	10	0.5	3	Recommended [b]
154010	Blueberries	5	-	3	Recommended [c]
154020	Cranberries	2	-	3	Recommended [c]
154030	Currants	5	-	3	Recommended [c]
154040	Gooseberries	5	-	3	Recommended [c]
154050	Rose hips	2	-	3	Recommended [c]
154060	Mulberries	2	-	3	Recommended [c]
154070	Azarole	2	-	3	Recommended [c]
154080	Elderberries	2	-	3	Recommended [c]
213010	Beetroot	1	-	1.5	Recommended [c]
213020	Carrots	2	-	1.5	Recommended [c]
213030	Celeriac	0.3	-	0.3	Recommended [c]
213040	Horseradish	2	-	1.5	Recommended [c]
213060	Parsnips	2	-	1.5	Recommended [c]
213070	Parsley root	2	-	1.5	Recommended [c]
213080	Radishes	0.05*	-	0.08	Recommended [c]
213090	Salsify	2	-	1.5	Recommended [c]
220010	Garlic	0.3	-	0.07	Recommended [c]
220020	Onions	0.3	0.3	0.3	Recommended [e]
220030	Shallots	0.3	-	0.07	Recommended [c]
220040	Spring onions	1	-	0.8	Recommended [c]
231010	Tomatoes	1	0.5	1.5	Recommended [b]
231020	Peppers	1	0.5	1.5	Recommended [b]
231030	Aubergines	1	0.2	1.5	Recommended [b]
232000	Cucurbits – edible peel	0.5	0.2	0.5	Recommended [b]
233000	Cucurbits – inedible peel	0.05*	-	0.6	Recommended [c]
251000	Lettuce and other salad plants including *Brassicacea*	15	10	15	Recommended [b]
252000	Spinach and similar	15	-	15	Recommended [c]
255000	Witloof	0.05*	-	0.06	Recommended [c]
256000	Herbs	15	-	15	Recommended [c]
260010	Beans (with pods)	2	0.5	2	Recommended [b]
260020	Beans (without pods)	0.5	-	0.08	Recommended [c]
260030	Peas (with pods)	2	-	2	Recommended [c]
260040	Peas (without pods)	0.1	-	0.08	Recommended [c]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
270010	Asparagus	0.05*	-	0.02*	Recommended [c]
270040	Fennel	0.2	-	0.3	Recommended [c]
300010	Beans (dry)	0.2	-	0.2	Recommended [c]
300030	Peas (dry)	0.2	-	0.1	Recommended [c]
300040	Lupins (dry)	0.2	-	0.1	Recommended [c]
500010	Barley grain	3	3	4	Recommended [b]
500050	Oats grain	2	-	4	Recommended [c]
500070	Rye grain	0.5	-	0.5	Recommended [c]
500090	Wheat grain	0.5	0.5	0.5	Recommended [b]
633000	Herbal infusions (roots)	1	-	1.5	Further consideration needed [f]
840000	Spices (roots and rhizomes)	1	-	1.5	Further consideration needed [f]
	Other products of plant origin	See App C	-	-	Further consideration needed [g]
Enforcement residue definition (existing): sum of cyprodinil and CGA 304075 **Enforcement residue definition (proposed):** sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil					
1011010	Swine meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1011020	Swine fat (free of lean meat)	0.05*	0.01*	0.02*	Further consideration needed [h]
1011030	Swine liver	0.05*	0.01*	0.02*	Further consideration needed [h]
1011040	Swine kidney	0.05*	0.01*	0.02*	Further consideration needed [h]
1012010	Bovine meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1012020	Bovine fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1012030	Bovine liver	0.05*	0.01*	0.05	Further consideration needed [h]
1012040	Bovine kidney	0.05*	0.01*	0.05	Further consideration needed [h]
1013010	Sheep meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1013020	Sheep fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1013030	Sheep liver	0.05*	0.01*	0.05	Further consideration needed [h]
1013040	Sheep kidney	0.05*	0.01*	0.05	Further consideration needed [h]
1014010	Goat meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1014020	Goat fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1014030	Goat liver	0.05*	0.01*	0.05	Further consideration needed [h]
1014040	Goat kidney	0.05*	0.01*	0.05	Further consideration needed [h]
1016010	Poultry meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1016020	Poultry fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1016030	Poultry liver	0.05*	0.01*	0.02*	Further consideration needed [h]
1030000	Birds' eggs	0.05*	0.01*	0.02*	Further consideration needed [h]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
	Other products of animal origin, except milk products below	See App C	-	-	Further consideration needed (g)
Enforcement residue definition (existing): sum of cyprodinil and CGA 304075 **Enforcement residue definition (proposed):** sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil					
1020010	Cattle milk	0.05*	0.004*	0.02*	Further consideration needed (h)
1020020	Sheep milk	0.05*	0.004*	0.02*	Further consideration needed (h)
1020030	Goat milk	0.05*	0.004*	0.02*	Further consideration needed (h)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(b): 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; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(c): 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).
(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).

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BACKGROUND

Regulation (EC) No 396/2005[4] establishes the rules governing the setting and the review of pesticide MRLs at European level. Article 12(2) of that regulation stipulates that EFSA shall provide by 01 September 2009 or a reasoned opinion on the review of the existing MRLs for all active substances included in Annex I to Directive 91/414/EEC[5] before 02 September 2008. As cyprodinil was included in Annex I to the above mentioned directive on 01 May 2007, EFSA initiated the review of all existing MRLs for that active substance and a task with the reference number EFSA-Q-2008-521 was included in the EFSA Register of Questions.

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

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

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

France, the designated rapporteur Member State (RMS) in the framework of Directive 91/414/EEC, was asked to complete the PROFile for cyprodinil. The requested information was submitted to EFSA on 17 August 2009 and subsequently checked for completeness. On 23 November 2012, after having clarified some issues with EFSA, the RMS provided a revised PROFile.

A draft reasoned opinion was issued by EFSA on 26 March 2013 and submitted to Member States (MS) for commenting. All MS comments received by 31 May 2013 were considered by EFSA in the finalisation of the reasoned opinion.

[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. OJ L 70, 16.3.2005, p. 1-16.

[5] Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market. OJ L 230, 19.8.1991, p. 1-32.

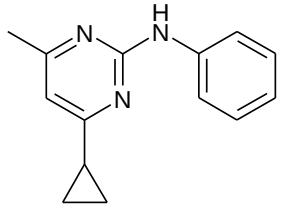
TERMS OF REFERENCE

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

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

THE ACTIVE SUBSTANCE AND ITS USE PATTERN

Cyprodinil is the ISO common name for 4-cyclopropyl-6-methyl-*N*-phenylpyrimidin-2-amine (IUPAC).



Cyprodinil belongs to the group of anilinopyrimidine compounds and is used as a broad spectrum fungicide for foliar applications on a wide range of different crops. Cyprodinil is taken up systemically via leaves and works by inhibiting both the penetration and the mycelial growth of the fungi. It is active against fungi from the classes *Ascomycetes*, *Basidiomycetes* and *Deuteromycetes*. As well as being widely used against foliar diseases in cereal, fruit and vegetable crops, it has also been developed as a cereal fungicidal seed treatment.

Cyprodinil was evaluated in the framework of Directive 91/414/EEC with France being the designated rapporteur Member State (RMS). The representative uses supported for the peer review process were foliar application of cyprodinil on winter wheat and on apples. Following the peer review, which was carried out by EFSA, a decision on inclusion of the active substance in Annex I to Directive 91/414/EEC was published by means of Commission Directive 2006/64/EC[6], which entered into force on 01 May 2007. According to Regulation (EU) No 540/2011[7], cyprodinil is deemed to have been approved under Regulation (EC) No 1107/2009[8]. This approval is restricted to uses as a fungicide only.

The EU MRLs for cyprodinil are established in Annexes IIIA of Regulation (EC) No 396/2005. Since the entry into force of that regulation, EFSA recommended the modification of the existing MRLs for various crops (EFSA, 2009a, 2009b, 2009c, 20010 and 2012) which was legally implemented by

[6] Council Directive 2006/64/EC of 18 July 2006, amending Council Directive 91/414/EEC to include clopyralid, cyprodinil, fosetyl and trinexapac as active substances. OJ L 206, 27.7.2006, p. 107-111.

[7] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances. OJ L 153, 11.6.2011, p. 1-186.

[8] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ 309, 24.11.2009, p. 1-50.

means of several regulations, the latest being Regulation (EC) No 592/2012/EC[9]. EFSA also recommended the modification of the existing MRLs for radishes and cucurbits with inedible peel (EFSA, 2013) which was already approved by the meeting of the Standing Committee on the Food Chain and Animal Health held on 13-14 June 2013 but not yet legally implemented. All existing EU MRLs, which are established for the parent compound only (commodities of plant origin) or sum of cyprodinil and metabolite CGA 304075 (products of animal origin), are summarised in Appendix C.1 to this document. CXLs for cyprodinil were also established by the Codex Alimentarius Commission and are reported in Appendix C.2 to this reasoned opinion. These CXLs refer to parent cyprodinil only for both plant and animal commodities.

For the purpose of this MRL review, the critical uses of cyprodinil currently authorised within the EU, have been collected by the RMS and reported in the PROFile. The additional GAPs reported during the consultation of Member States were also considered (see Appendix A). The GAPs for foliar uses in northern and southern Europe cover a wide range of different crops across all crop groupings. Additionally there are foliar indoor uses for many crops and there is a seed treatment use on barley in northern and southern Europe. The RMS did not report any use authorised in third countries that might have a significant impact on international trade.

ASSESSMENT

EFSA bases its assessment on the PROFile submitted by the RMS, the conclusion on the peer review of the pesticide risk assessment of the active substance cyprodinil (EFSA, 2005), the Draft Assessment Report (DAR) and its addendum prepared under Council Directive 91/414/EEC (France, 2003, 2009), the JMPR Evaluation report (FAO, 2003), the previous reasoned opinions on cyprodinil (EFSA, 2009a, 2009b, 2009c, 2010, 2012, 2013) as well as the evaluation reports submitted during the consultation of Member States (Belgium, 2013; France, 2013a, 2013b; Germany, 2013; Netherlands, 2013). The assessment is performed in accordance with the legal provisions of the Uniform Principles for Evaluation and Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011[10] 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, and OECD, 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 HPLC-UVD was evaluated and validated for the determination of cyprodinil in plant matrices with an LOQ of 0.01 mg/kg in high water content (apple) and acidic commodities (grapes), and with an LOQ of 0.02 mg/kg in dry commodities (wheat grain). Some limited ILV data for this method were available for various high water content crops and wheat with an LOQ of 0.02 mg/kg. Confirmation and ILV for cyprodinil has, however, been achieved by development of this method (for the approach to detection) whereby residues are quantified using HPLC-MS/MS. This was acceptably validated with an LOQ of 0.01 mg/kg in high water content (lettuce and radish roots), acidic (grape), and dry (wheat grain and straw) commodities (France, 2003). The HPLC-MS/MS approach also included validation for commodities of high oil content (rape seed) although the recoveries were low (53 % to 79 %, average 70 %) at the higher fortification level. This method is fully acceptable to support all the authorized uses except high oil content commodities (almonds).

[9] Commission Regulation (EC) No 592/2012 of 4 July 2012 amending Annexes II and III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bifenazate, captan, cyprodinil, fluopicolide, hexythiazox, isoprothiolane, metaldehyde, oxadixyl and phosmet in or on certain products.

[10] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.06.2011, p. 127-175.

Additionally, the multi-residue DFG S19 method using GC-MS was demonstrated to be suitable for the determination of cyprodinil and was validated in high water content (tomatoes), high acid content (oranges), high oil content (rape seed) and dry commodities (wheat grain) with an LOQ of 0.02 mg/kg (France, 2003). The ILV for this method was not accepted by the peer review because both validations were performed in the same laboratory.

In the framework of a previous MRL application, the above validation data were considered sufficient to address enforcement of residues in herbal infusions and spices of roots (EFSA, 2009a); mainly on the basis of the DFG S19 method being validated in the four main crop groups at the same LOQ. EFSA is now aware that the multi residue method (DFG S19) does not have an acceptable ILV and therefore should not have considered the method adequate for the enforcement of the proposed MRLs. A validated analytical method for enforcement of cyprodinil in herbal infusions and spices is therefore still required.

The multi-residue QuEChERS method in combination with HPLC-MS/MS and GC/MS, as described by CEN (CEN, 2008), is also reported for analysis of cyprodinil only with an LOQ of 0.01 mg/kg in high water content, acidic and dry commodities (EURL, 2013). Detailed validation data were not reported as they did not impact on the outcome of the assessment and validation data for high oil content commodities or spices are not available.

Consequently, also considering that a large number of the available residues trials were generated using an LOQ of 0.02 mg/kg, it is concluded that cyprodinil can be enforced in food of plant origin with an LOQ of 0.02 mg/kg in high water content, acidic and dry commodities. Cyprodinil has also been analysed successfully in rape seed however ILV data are not currently available for this high oil content commodity group and this is therefore required. A validated analytical method for enforcement of cyprodinil in spices and herbal infusions is also required.

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

During the peer review under Directive 91/414/EEC, analytical methods were only available for determination of parent cyprodinil using HPLC-UVD and a confirmatory GC technique, although at that time MRLs were not proposed for products of animal origin.

According to the RMS, a more recent enforcement method using HPLC-MS/MS was validated for the determination of cyprodinil and CGA 304075[11] in animal commodities (meat, fat, liver, kidney and milk, but not eggs) with an LOQ for each analyte of 0.01 mg/kg (reported in the PROFile). Evidence that the method includes a hydrolytic step to release the conjugates was provided by France during the Member State consultation (France, 2013a), however confirmatory validation data are not available and this is therefore required.

Hence there are indications that both cyprodinil and CGA 304075 can be enforced in food of animal origin with an LOQ of 0.01 mg/kg (each analyte) in milk, meat, fat, liver and kidney. Data gaps exist with regard to the need for a validated enforcement method for the determination of cyprodinil and CGA 304075 in eggs and confirmatory validation data for determining residues in animal products.

2. Mammalian toxicology

The toxicological assessment of cyprodinil was peer reviewed under Directive 91/414/EEC and toxicological reference values were established by the EFSA (2005). These toxicological reference values are summarised in Table 2-1.

[11] CGA 304075: 4-(4-cyclopropyl-6-methyl-pyrimidine-2-yl-amino)-phenol

Table 2-1: Overview of the toxicological reference values

	Source	Year	Value	Study relied upon	Safety factor
Cyprodinil					
ADI	EFSA	2005	0.03 mg/kg bw per d	Rat, two year	100
ARfD	EFSA	2005	Not necessary		

3. Residues

3.1. Nature and magnitude of residues in plant

3.1.1. Primary crops

3.1.1.1. Nature of residues

Metabolism of cyprodinil was investigated for foliar application on cereals (wheat), on fruits and fruiting vegetables (peach, tomato and apple), and on root and tuber vegetables (potato), using U-^{14}C-phenyl or 2-^{14}C-pyrimidine labelled cyprodinil (France, 2003). The characteristics of these studies are summarised in Table 3-1.

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
Fruits and fruiting vegetable	apple	2-^{14}C-pyrimidine	Foliar, F	0.05 kg a.s./hl	3[b]	61 (fruits and foliage at harvest) [c]	-
	peach	U-^{14}C-phenyl or 2-^{14}C-pyrimidine	Foliar, F	0.27 2.7	4[d]	1 (fruits and foliage)	-
	tomato	U-^{14}C-phenyl or 2-^{14}C-pyrimidine	Foliar, G	0.75	2[e]	14 (fruits and foliage at harvest) [f]	-
Root and tuber vegetables	potato	U-^{14}C-phenyl or 2-^{14}C-pyrimidine	Foliar, G	0.56	3[g]	14 (tubers and foliage at harvest) [h]	-

Group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks
Cereals	wheat	U-^{14}C-phenyl	Foliar, G	0.75	1[(i)]	Whole plant autoradiography and samples taken at 0-35 days	-
	wheat	U-^{14}C-phenyl or 2-^{14}C-pyrimidine	Foliar, F	0.75 + 0.50	2[(j)]	41 (straw, husk and grain at harvest) [(k)]	-

(a): Outdoor/field application (F) or glasshouse/protected/indoor application (G)
(b): Application intervals of ca. 8 and 5 weeks
(c): Additionally sampling of foliage, post each application.
(d): Application to individual branches of separate fruit trees, 21 to 1 day PHI (7 day intervals approx.)
(e): First application when fruits 2 cm diameter; second application 28 days later (14 days before harvest)
(f): Additionally sampling of fruit and foliage after 1st application and after 2nd application
(g): Application intervals of 19/20 days
(h): Additionally foliage sampled day of 1st and 3rd application and tubers sampled after final application
(i): Application at 5-6 leaf stage
(j): 1st application BBCH 16-18 (6-8 leaf stage); 2nd application 22 days later
(k): Additionally whole plant material sampled (after each application and 41 days after 1st application)

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 (18-90% TRR). In these crops, metabolism proceeds mainly via hydroxylation of the phenyl and pyrimidine rings to form metabolites CGA 232449[12], CGA 304076[13], CGA 304075 and CGA 275535[14] followed by sugar conjugation. Of these CGA 232449 was most prevalent in the tomato metabolism, where it was found at 0.63 mg/kg in the fruit (12.6% TRR), and in a much lower amount than the corresponding level of parent cyprodinil in the fruit (63.2% TRR, 3.2 mg/kg). Lower levels of the other hydroxylated metabolites were found (up to 2.8% TRR). Of these, CGA 232449, CGA 304076, and CGA 304075 are encountered in the rat metabolism and considered covered by the toxicological profile of parent cyprodinil.

In potato tubers where the edible part of the crop is not exposed to the fungicide spray, the residues were low with the TRR in potatoes being <0.1 mg/kg for both labels. Metabolite CGA 263208[15] resulting from cleavage of the pyrimdine ring represented 6.7% of the TRR in mature whole tuber; four other metabolites were identified as the free and sugar conjugated forms of N-phenyl-4-(2-hydroxypropyl)-5-hydroxy-6-methyl-2-pyrimidinamine (at up to 13.7% TRR) and N-phenyl-4-(3'-hydroxypropyl)-5-hydroxy-6-methyl-2-pyrimidinamine (at up to 15.9% TRR) with no parent identified and no major fraction; non-identified extractable fractions were present at very low levels and most of the non extractable radioactivity was incorporated in natural cell constituents. These potato metabolites were not found in the rat metabolism, but due to the low absolute levels at which they were found in the potato metabolism study, they are not of toxicological relevance. In potato

[12] CGA 232449: (6-cyclopropyl-2-phenylamino-pyrimidine-4-yl)-methanol
[13] CGA 304076: 4-cyclopropyl-6-methyl-2-phenylamino-pyrimidine-5-ol
[14] CGA 275535: 3-(4-cyclopropyl-6-methyl-pyrimidine-2-yl-amino)-phenol
[15] CGA 263208: N-(4-hydroxyphenyl-4-cyclopropyl-6-methyl-2-pyrimidinamine

leaves/foliage at mature harvest parent cyprodinil was the major component accounting 46-48% of the TRR.

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). However, it was also noted that any use on potatoes should be considered for metabolism, taking into account the application rates and the actual residue levels expected in tubers. There is no GAP for potatoes. EFSA considers that the findings in metabolism study for potatoes could be relevant also for the authorised uses of root and bulb crops (*Allium* species). However, since the application rate for the authorised uses for these crops is less critical compared to the application rate in the potato metabolism study, EFSA concludes that no significant cyprodinil metabolites are expected to occur in root and bulb crops for the currently authorised uses and no additional metabolism studies are necessary at this time. The residue definition might require further consideration for these crops and other root and tuber vegetables, including any uses on potatoes, if higher rates of use are requested in future.

Regarding leafy vegetables and pulses and oilseeds, 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 is clear and 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 the other fruit and wheat metabolism studies. EFSA is of the opinion that the same residue definition can be applied also for the authorised uses of cyprodinil for crops in the oilseeds and pulses metabolism grouping, since metabolism was concluded as essentially similar across the three crop categories and five different crops investigated in the metabolism studies.

Consequently, the residue for enforcement and risk assessment in all plant commodities is defined as cyprodinil only. The conclusions regarding definition of the residue reached by EFSA reflect the views of the RMS and are also in line with those of the JMPR (FAO, 2003). Validated analytical methods for enforcement of the proposed residue definition are available in high water content, acidic and dry commodities but not high oil content commodities. A validated analytical method for enforcement of the proposed residue definition in herbal infusions and spices is also not available (see also section 1.1).

3.1.1.2. Magnitude of residues

According to the RMS, the active substance cyprodinil is authorised in northern and southern Europe for foliar spray treatment in a large number of crops, both under outdoor and indoor conditions (see Appendix A). To assess the magnitude of cyprodinil residues resulting from these GAPs, EFSA considered all residue trials reported in the PROFile, including residue trials evaluated in the framework of the peer review (EFSA, 2005) or in the framework of a previous MRL application (EFSA, 2009a, 2009b, 2009c, 2010, 2012, 2013) and additional data submitted during the consultation of Member States (Belgium, 2013; France, 2013a, 2013b; Germany, 2013; Netherlands, 2013). All available residue trials that, according to the RMS, comply with the authorised GAPs, are summarised in Table 3-2.

The number of residue trials and extrapolations were evaluated in accordance with the European guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs (EC, 2011). For many of the reported GAPs, sufficient trials are available to derive MRLs and risk assessment values. Some of the MRLs are tentative where it is concluded that some further data are outstanding, and this is explained below for each of the crops. The following considerations were made by EFSA:

- Apricots and peaches: No residue trials complying with the northern outdoor GAP are available and only residues trials on peaches were reported for the southern outdoor GAP,

while a minimum of four trials is normally needed on apricots specifically. Although tentative MRL and risk assessment values can be derived from the southern data (and tentative extrapolation from peaches is possible), 8 residue trials on peaches or apricots (with a minimum of 4 trials on apricots) complying with the northern outdoor GAP, and 4 trials on apricots complying with the southern outdoor GAP are required. It is noted that, according to the notifier, 4 southern outdoor residue trials on apricots are planned, with reports expected in 2015.

- Cherries: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop (4 trials instead of 8). Although tentative MRL and risk assessment values can be derived from the northern data, 4 trials complying with the northern GAP (cherries is a major crop in northern Europe) are still required. During the Member State consultation Netherlands submitted an indoor GAP for cherries (Netherlands, 2013) however, when queried, Netherlands informed EFSA that the indoor GAP was no longer authorised.

- Plums: The number of residue trials supporting the northern outdoor GAP is not compliant with the data requirements for this crop. Although appropriate MRL and risk assessment values can be derived from the southern data, 5 trials complying with the northern outdoor GAP are still required. 1 additional trial complying with the southern outdoor GAP is also considered desirable but not essential (minor deficiency). During the Member State consultation Netherlands submitted an indoor GAP for plums (Netherlands, 2013) however, when queried, Netherlands informed EFSA that the indoor GAP was no longer authorised.

- Grapes: During the Member State consultation Netherlands submitted a northern outdoor GAP and indoor GAP for grapes (Netherlands, 2013). The northern outdoor GAP is less critical than that already considered and has therefore not been given further consideration. The indoor GAP on grapes had not previously been considered and was therefore included in this evaluation although no supporting residue trials are available. Although appropriate MRL and risk assessment values can be derived from the northern and southern data, 8 trials complying with the indoor GAP are still required.

- Tomatoes and aubergines: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. Although appropriate MRL and risk assessment values can be derived from the indoor data, 6 trials complying with the southern GAP are still required. EFSA notes that France reported, during the Member State consultation, that 6 residue trials on tomato are planned for 2014, with reports expected in 2015 (it is assumed these would be southern outdoor trials although it was not stated). EFSA also notes that Netherlands submitted a more critical GAP during the Member State consultation (3 × 0.9 kg as/ha, 3 day PHI), however this was not supported by data and therefore was not considered further.

- Peppers: The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop. Although appropriate MRL and risk assessment values can be derived from the indoor data, 6 additional trials complying with the southern outdoor GAP are still required. EFSA notes that France reported, during the Member State consultation, that 6 residue trials complying with southern outdoor GAP on peppers are planned for 2014, with reports expected in 2015.

- Cucumbers and courgettes: The number of residue trials supporting the southern outdoor GAP for cucumber and courgettes is not compliant with the data requirements for these crops. Although appropriate MRL and risk assessment values can be derived from the indoor data, 4 additional trials on cucumbers or courgettes complying with the southern outdoor GAP are still required. EFSA notes that France reported, during the Member State consultation, that 1

trial on cucumbers and 3 trials on courgettes are planned for 2014, with reports expected in 2015 (it is assumed these would be southern outdoor trials although it was not stated).

- Lettuce and other salad plants, spinach and similar, and herbs: In order to extrapolate from lettuce to all other crops, 8 trials on open leaf varieties would in principle be needed for each residue region. For the 7 NEU trials one trial was on an open leaf variety; for the 9 SEU trials it is unclear whether the trials were performed with open leaved varieties; and for the 9 indoor trials (on which the MRL proposal is based) 4 trials were performed using open leaf varieties. The supporting data for the EU indoor use have previously been considered by EFSA (2012) and, although extrapolation was initially not accepted by EFSA, MRLs for lettuce, other salad plants, spinach, beet leaves and herbs were set at 15 mg/kg in Regulation (EC) 592/2012[16], indicating the extrapolation was subsequently accepted by risk managers. Also considering that the results of the residues trials on open leaf varieties are in the same range as those obtained with head forming varieties, EFSA now concludes that appropriate MRL and risk assessment values can be derived from the indoor data; further trials for the outdoor uses are considered unnecessary since the available GAP compliant trials data for the outdoor uses (7 for NEU and 9 for SEU) show that the indoor use represents the critical EU GAP. EFSA notes that Netherlands submitted NEU outdoor and EU indoor GAPs (3 × 0.225 kg as/ha with a 7 day PHI) during the Member State consultation. These GAPs were not supported by data however they were similar to the existing critical GAPs and therefore were not considered further.

- Beans and peas (with pods): The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (7 trials instead of 8). Since it is clear that the SEU GAP is less critical than the indoor GAP, EFSA considers an additional trial complying with the southern outdoor GAP to be unnecessary.

- Asparagus: The number of residue trials supporting the northern outdoor and southern outdoor GAPs is not compliant with the data requirements for this crop. However, the reduced number of residue trials is considered acceptable in this case because all results were below the LOQ and a no residues situation is expected. Further residue trials are therefore not required.

- Barley and oat (grain and straw): The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (7 trials instead of 8). Although appropriate MRL and risk assessment values have been derived from these data (which seem more critical than the trials for the corresponding northern outdoor trials supporting barley and oats), 1 additional trial complying with the southern GAP is considered desirable but not essential (minor deficiency).

- Wheat and rye (grain and straw): The number of residue trials supporting the southern outdoor GAP is not compliant with the data requirements for this crop (7 trials instead of 8). Although appropriate MRL and risk assessment values can be derived from the northern data, 1 additional trial complying with the southern GAP is considered desirable but not essential (minor deficiency).

The potential degradation of residues during storage of the residue trials samples was also assessed. In the framework of the peer review, storage stability of cyprodinil was demonstrated for a period of 26 months at -18°C in commodities with high water content (peaches, apple), and 24 months at -18°C in commodities with high acid content (grapes, strawberries) and in dry commodities (wheat). The storage conditions for some residue trials (pome fruit, stone fruit, table and wine grapes, indoor strawberries, bulb vegetables, tomato, pepper, aubergine, cucumbers, gherkins, courgettes, beans, peas, lupins, fennel) were not reported by the RMS. However, degradation of residues during storage

[16] Regulation (EC) 592/2012 of 4 July 2012, OJ L 176, 6.7.2012, p. 1-37.

of the trial samples is not expected as storage stability has been demonstrated over the long term (two years) in three crop groups.

Consequently, the available residues data are considered sufficient to derive MRL proposals as well as risk assessment values for all commodities under evaluation, except for apricots, peaches and cherries where only tentative MRLs could be derived (see also Table 3-2). The proposed MRLs for herbal infusions and spices of roots are also tentative considering that a validated analytical method for enforcement of these MRLs is still missing. Where several uses are authorised for one commodity, the final MRL proposal was derived from the most critical use and indicated in bold in Table 3-2. MRLs were also derived for wheat, barley, oat and rye straw in view of the future need to set MRLs in feed items.

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

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Apples, pears and quinces	NEU	Outdoor	apples 0.27; 0.32; 0.40; 0.56 pears 0.09; 0.17; 0.25; 0.28	apples 0.27; 0.32; 0.40; 0.56 pears 0.09; 0.17; 0.25; 0.28	0.28	0.56	0.9	1.00	8 GAP compliant trials (PHI of 3 days, application rates range from 0.36 to 0.412 kg as/ha, within 25 % of the GAP), 4 on apples and 4 on pears in NEU (France, 2013a); extrapolation to quinces is possible. R_{max} = 0.75 R_{ber} = 0.76 MRL_{OECD} = 0.88
	SEU	Outdoor	apples 0.39; 0.40; 0.49; 0.74 pears 0.14; 0.26; 0.5; 0.53; 0.88	apples 0.39; 0.40; 0.49; 0.74 pears 0.14; 0.26; 0.5; 0.53; 0.88	**0.49**	**0.88**	**1.5**	**1.00**	9 GAP compliant trials, 4 trials on apples and 5 on pears in SEU (France, 2013a); extrapolation to quinces is possible. R_{max} = 1.17 R_{ber} = 1.27 MRL_{OECD} = 1.44
Medlar and loquat	NEU	Outdoor	apples 0.27; 0.32; 0.40; 0.56 pears 0.09; 0.17; 0.25; 0.28	apples 0.27; 0.32; 0.40; 0.56 pears 0.09; 0.17; 0.25; 0.28	0.28	0.56	0.9	1.00	Extrapolation from trials on apples and pears in NEU. Extrapolation from SEU trials not possible since it is not authorised for use on these crops in SEU.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Apricots and peaches	NEU	Outdoor	-	-	-	-	-	-	No trials available.
	SEU	Outdoor	0.12; 2 × 0.14; 0.15; 2 × 0.20; 0.28; 0.31;0.38; 0.45; 0.50; 0.55; 0.68; 0.71	0.12; 2 × 0.14; 0.15; 2 × 0.20; 0.28; 0.31;0.38; 0.45; 0.50; 0.55; 0.68; 0.71	**0.30**	**0.71**	**1.5** tentative	**1.00**	14 GAP compliant trials on peaches in SEU. Tentative extrapolation to apricots is possible, although a minimum of four trials on apricots are needed. R_{max} = 0.88 R_{ber} = 1.03 MRL_{OECD} = 1.16
Cherries	NEU	Outdoor	2 × 0.16; 0.24; 0.31	2 × 0.16; 0.24; 0.31	**0.20**	**0.31**	**0.7** tentative	**1.00**	4 GAP compliant trials on cherries in NEU (Belgium, 2013). R_{max} = 0.59 R_{ber} = 0.59 MRL_{OECD} = 0.65
	SEU	Outdoor	0.10; 0.13; 0.16; 0.18; 0.20; 0.25	0.10; 0.13; 0.16; 0.18; 0.20; 0.25	0.17	0.25	0.6	1.00	6 GAP compliant trials in SEU. R_{max} = 0.37 R_{ber} = 0.43 MRL_{OECD} = 0.51
Plums	NEU	Outdoor	0.10; 0.11; 0.15	0.10; 0.11; 0.15	0.11	0.15	0.4	1.00	3 GAP compliant trials in NEU (Netherlands, 2013). R_{max} = 0.32 R_{ber} = - MRL_{OECD} = 0.36
	SEU	Outdoor	2 × 0.11; 0.18; 0.19; 0.22; 0.25; 0.50	2 × 0.11; 0.18; 0.19; 0.22; 0.25; 0.50	**0.19**	**0.50**	**0.8**	1.00	7 GAP compliant trials in SEU. R_{max} = 0.67 R_{ber} = 0.50 MRL_{OECD} = 0.75

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Table grapes	NEU	Outdoor	0.12; 0.15; 0.24; 0.31; 2 × 0.33; 0.36; 2 × 0.67; 0.70; 0.72; 0.82; 0.85; 0.88; 1.49; 2.30	0.12; 0.15; 0.24; 0.31; 2 × 0.33; 0.36; 2 × 0.67; 0.70; 0.72; 0.82; 0.85; 0.88; 1.49; 2.30	0.67	**2.30**	**3**	1.00	16 GAP compliant trials on table grapes in NEU. R_{max} = 2.09 R_{ber} = 1.69 MRL_{OECD} = 2.91
	SEU	Outdoor	<0.01; 0.05; 0.06; 0.13; 0.34; 0.42; 2 × 0.48; 0.50; 0.58; 0.64; 0.65; 0.70; 0.72; 0.74; 2 × 0.88; 0.92; 1.0; 1.1; 1.03; 1.27; 1.86; 1.9	<0.01; 0.05; 0.06; 0.13; 0.34; 0.42; 2 × 0.48; 0.50; 0.58; 0.64; 0.65; 0.70; 0.72; 0.74; 2 × 0.88; 0.92; 1.0; 1.1; 1.03; 1.27; 1.86; 1.9	**0.68**	1.90	3	1.00	24 GAP compliant trials on table grapes in SEU. R_{max} = 1.86 R_{ber} = 1.96 MRL_{OECD} = 2.69
	EU	Indoor	-	-	-	-	-	1.00	No trials available.
Wine grapes	NEU	Outdoor	0.12; 0.15; 0.24; 0.31; 2 × 0.33; 0.36; 2 × 0.67; 0.70; 0.72; 0.82; 0.85; 0.88; 1.49; 2.30	0.12; 0.15; 0.24; 0.31; 2 × 0.33; 0.36; 2 × 0.67; 0.70; 0.72; 0.82; 0.85; 0.88; 1.49; 2.30	**0.67**	**2.30**	**3**	1.00	Extrapolation from trials on table grapes in NEU.
	SEU	Outdoor	0.03; 0.30; 0.31; 2 × 0.33; 0.42; 0.45; 0.54; 0.64; 0.67; 0.70; 0.75; 1.12; 2.13	0.03; 0.30; 0.31; 2 × 0.33; 0.42; 0.45; 0.54; 0.64; 0.67; 0.70; 0.75; 1.12; 2.13	0.50	2.13	3	1.00	14 GAP compliant trials on wine grapes in SEU. R_{max} = 1.95 R_{ber} = 1.43 MRL_{OECD} = 2.65
	EU	Indoor	-	-	-	-	-	1.00	No trials available.

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Strawberries	NEU	Outdoor	0.16; 0.29; 0.38; 0.42; 0.45; 0.61; 0.68; 0.97	0.16; 0.29; 0.38; 0.42; 0.45; 0.61; 0.68; 0.97	0.44	0.97	1.5	1.00	All 8 trials (France, 2013a) done with 3 applications, considered GAP compliant. R_{max} = 1.30 R_{ber} = 1.33 MRL_{OECD} = 1.51
	SEU	Outdoor	0.47; 0.49; 0.63; 0.80; 1.17; 1.20; 1.23; 1.90	0.47; 0.49; 0.63; 0.80; 1.17; 1.20; 1.23; 1.90	**0.99**	1.90	3	1.00	All 8 trials (France, 2013a) done with 3 applications, considered GAP compliant. R_{max} = 2.53 R_{ber} = 2.45 MRL_{OECD} = 2.96
	EU	Indoor	0.32; 0.48; 0.50; 0.55; 0.71; 0.62; 0.67; 0.79; 0.92; 1.07; 1.15; 1.31; 1.57; 1.74; 2.98; 3.74	0.32; 0.48; 0.50; 0.55; 0.71; 0.62; 0.67; 0.79; 0.92; 1.07; 1.15; 1.31; 1.57; 1.74; 2.98; 3.74	0.86	**3.74**	**5**	1.00	All trials (France, 2013a) done with 3 applications, considered GAP compliant. R_{max} = 3.58 R_{ber} = 3.01 MRL_{OECD} = 4.97

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Blackberries and raspberries	NEU	Outdoor	0.51; 0.73; 0.81; 1.17; 1.60	0.51; 0.73; 0.81; 1.17; 1.60	**0.81**	**1.60**	**3**	1.00	5 GAP compliant trials on raspberries in NEU (Belgium, 2013). Extrapolation to blackberries is possible. R_{max} = 2.76 R_{ber} = 2.77 MRL_{OECD} = 2.89
	EU	Indoor	0.42; 0.48; 0.79; 0.80	0.42; 0.48; 0.79; 0.80	0.64	0.80	2	1.00	4 GAP compliant trials on indoor raspberries (France, 2013a). Extrapolation to blackberries is possible. R_{max} = 1.66 R_{ber} = 1.60 MRL_{OECD} = 1.87
Blueberries, cranberries, currants (red, black, white), gooseberries, rose hips, mulberries, azarole, elderberries	NEU	Outdoor	blueberries 0.17; 0.31; 0.34; 0.68 black currants 0.69; 0.82; 0.93; 0.93 red currants 1.7	blueberries 0.17; 0.31; 0.34; 0.68 black currants 0.69; 0.82; 0.93; 0.93 red currants 1.7	0.69	1.70	3	1.00	9 GAP compliant trials (Germany, 2013). Extrapolation to other small fruits and berries is possible. R_{max} = 2.12 R_{ber} = 1.86 MRL_{OECD} = 2.56

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Beetroot, carrots, horseradish, parsnips, parsley root, salsify	NEU	Outdoor	0.21; 0.27; 0.33; 0.41; 0.48; 0.51; 0.53; 1.04	0.21; 0.27; 0.33; 0.41; 0.48; 0.51; 0.53; 1.04	**0.45**	**1.04**	**1.5**	1.00	8 GAP compliant trials on carrots in NEU. One of these trials (1.04) submitted during Member State consultation (France, 2013a). Extrapolation to all these other root crops in the group is possible (EFSA, 2009a). R_{max} = 1.29 R_{ber} = 1.05 MRL_{OECD} = 1.50
	SEU	Outdoor	0.04; 0.06; 0.08; 0.09; 0.11; 0.14; 0.18; 0.50	0.04; 0.06; 0.08; 0.09; 0.11; 0.14; 0.18; 0.50	0.10	0.50	0.8	1.00	8 GAP compliant trials on carrots in SEU (France, 2013a); extrapolation to salsify is possible. Not authorised on beetroot, horseradish, parsnips, and parsley root in SEU. R_{max} = 0.62 R_{ber} = 0.34 MRL_{OECD} = 0.74
Celeriac	NEU	Outdoor	0.051; 0.075; 0.092; 0.11	0.051; 0.075; 0.092; 0.11	0.08	0.11	0.3	1.00	4 GAP compliant trials on celeriac in NEU (EFSA, 2009c). R_{max} = 0.21 R_{ber} = 0.21 MRL_{OECD} = 0.25
Radish	EU	Indoor	0.013; 0.016; 0.03; 0.04	0.013; 0.016; 0.03; 0.04	0.023	0.04	0.08	1	4 GAP compliant indoor trials on radish (EFSA, 2013). R_{max} = 0.09 R_{ber} = 0.08 MRL_{OECD} = 0.08

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Garlic, onions, and shallots	NEU	Outdoor	5 × <0.02; 0.02; 0.03; 0.05	5 × <0.02; 0.02; 0.03; 0.05	0.02	0.05	0.07 (garlic and shallots)	1.00	8 GAP compliant trials on onions in NEU. Extrapolation to garlic and shallot is possible. R_{max} = 0.06 R_{ber} = 0.06 MRL_{OECD} = 0.07 MRL proposal based on SEU data (below) except for garlic and shallots.
	SEU	Outdoor	5 × <0.02; 0.04; 0.09; 0.10	5 × <0.02; 0.04; 0.09; 0.10	**0.02**	**0.10**	**0.2** (onions)	1.00	8 GAP compliant trials on onions in SEU (France, 2013a). Not authorised on garlic or shallots in SEU. R_{max} = 0.15 R_{ber} = 0.16 MRL_{OECD} = 0.18
Spring onions	NEU	Outdoor	0.05; 0.07; 0.10; 0.14; 0.19; 0.24; 0.32; 0.43	0.05; 0.07; 0.10; 0.14; 0.19; 0.24; 0.32; 0.43	**0.17**	**0.43**	**0.8**	1.00	8 GAP compliant trials on spring onions in NEU (France, 2013a; Germany, 2013). R_{max} = 0.61 R_{ber} = 0.60 MRL_{OECD} = 0.72
	SEU	Outdoor	0.02; 0.05; 0.05; 0.07	0.02; 0.05; 0.05; 0.07	0.05	0.07	0.15	1.00	4 GAP compliant trials on spring onions in SEU (France, 2013a). R_{max} = 0.15 R_{ber} = 0.13 MRL_{OECD} = 0.14

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Tomatoes and aubergines	SEU	Outdoor	0.17; 0.64	0.17; 0.64	-	-	-	1.00	2 GAP compliant trials on tomato in SEU (France, 2013a). Insufficient data to calculate MRL.
	EU	Indoor	0.08; 0.10; 3 x 0.12; 0.15; 2 x 0.16; 2 x 0.17; 0.20; 2 x 0.22; 0.25; 0.26; 0.34; 0.37; 0.80; 0.97	0.08; 0.10; 3 x 0.12; 0.15; 2 x 0.16; 2 x 0.17; 0.20; 2 x 0.22; 0.25; 0.26; 0.34; 0.37; 0.80; 0.97	**0.17**	**0.97**	**1.5**	1.00	19 GAP compliant indoor trials on tomato (Germany, 2013; France, 2013a). Extrapolation to aubergine is possible. R_{max} = 0.83 R_{ber} = 0.52 MRL_{OECD} = 1.20
Peppers	SEU	Outdoor	0.02; 0.09	0.02; 0.09	-	-	-	1.00	2 GAP compliant trials on pepper in SEU. Insufficient data to calculate MRL.
	EU	Indoor	0.09; 0.15; 0.22; 0.23; 0.24; 0.32; 0.33; 0.39; 0.78	0.09; 0.15; 0.22; 0.23; 0.24; 0.32; 0.33; 0.39; 0.78	**0.24**	**0.78**	**1.5**	1.00	9 GAP compliant indoor trials on pepper. R_{max} = 0.91 R_{ber} = 0.72 MRL_{OECD} = 1.11

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Cucumbers, gherkins and courgettes	SEU	Outdoor	cucumber 0.03; 0.15; 0.17 courgette 0.10	cucumber 0.03; 0.15; 0.17 courgette 0.10	0.13	0.17	0.5	1.00	4 GAP compliant trials on cucumbers and courgettes in SEU. No authorisation on gherkins in SEU (outdoor). R_{max} = 0.43 R_{ber} = 0.33 MRL_{OECD} = 0.36
	EU	Indoor	cucumber 2 × 0.07; 2 × 0.08; 0.09; 0.11; 3 × 0.13; 0.18; 2 × 0.19; 0.29; 0.36 courgette 0.07; 0.11; 3 × 0.13; 0.15; 0.17; 0.19	cucumber 2 × 0.07; 2 × 0.08; 0.09; 0.11; 3 × 0.13; 0.18; 2 × 0.19; 0.29; 0.36 courgette 0.07; 0.11; 3 × 0.13; 0.15; 0.17; 0.19	**0.13**	**0.36**	**0.5**	1.00	22 GAP compliant indoor trials on cucumbers and courgettes. Extrapolation to gherkins is possible. R_{max} = 0.31 R_{ber} = 0.37 MRL_{OECD} = 0.43
Melons, pumpkins, watermelons	EU	Indoor	0.04; 2 × 0.06; 2 × 0.08; 0.11; 0.16; 0.25; 0.36	0.04; 2 × 0.06; 2 × 0.08; 0.11; 0.16; 0.25; 0.36	0.08	0.36	0.6	1.00	8 GAP compliant indoor trials on melons and 1 on watermelon (0.25) Extrapolation to pumpkins and watermelons is possible (EFSA, 2013). R_{max} = 0.46 R_{ber} = 0.41 MRL_{OECD} = 0.56

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Lettuce and other salad plants including *Brassicacea* Spinach and similar Herbs	NEU	Outdoor	0.19; 0.22; 0.3; 0.3[(e)]; 0.67; 0.74; 2.07	0.19; 0.22; 0.3; 0.3[(e)]; 0.67; 0.74; 2.07	0.30	2.07	4	1.00	7 GAP compliant trials on lettuce in NEU incl. 1 trial on an open leaf variety (EFSA, 2009a, EFSA, 2012). Extrapolation to other salad plants, spinach and similar, and herbs is possible. R_{max} = 2.91 R_{ber} = 1.48 MRL_{OECD} = 3.31
	SEU	Outdoor	3 × <0.02; 0.04; 0.06; 0.16; 0.39; 0.62; 1.05	3 × <0.02; 0.04; 0.06; 0.16; 0.39; 0.62; 1.05	0.06	1.05	2	1.00	9 GAP compliant trials on lettuce in SEU (France, 2013a) (not known if any were on open leaf varieties). Extrapolation to other salad plants and spinach is possible; not authorised for purslane, beet leaves and herbs in SEU. R_{max} = 1.36 R_{ber} = 1.01 MRL_{OECD} = 1.71
	EU	Indoor	1.8; 1.9[(e)]; 2.06[(e)]; 2.2; 3.1; 5.0; 5.31[(e)]; 7.89; 8.9[(e)]	1.8; 1.9[(e)]; 2.06[(e)]; 2.2; 3.1; 5.0; 5.31[(e)]; 7.89; 8.9[(e)]	**3.10**	**8.90**	**15**	1.00	9 GAP compliant indoor trials on lettuce incl. 4 trials on open leaf varieties (EFSA, 2009a, EFSA, 2012). Extrapolation to other salad plants, spinach and similar, and herbs is possible. R_{max} = 12.43 R_{ber} = 13.20 MRL_{OECD} = 15.05

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Witloof	EU	Indoor	2 × <0.02; 0.02; 0.03	2 × <0.02; 0.02; 0.03	0.02	0.03	0.06	1.00	4 GAP compliant indoor trials on witloof. R_{max} = 0.05 R_{ber} = 0.06 MRL_{OECD} = 0.05
Beans and peas (with pods)	NEU	Outdoor	0.06; 3 × 0.10; 0.11; 0.13; 0.15; 2 × 0.19; 0.32	0.06; 3 × 0.10; 0.11; 0.13; 0.15; 2 × 0.19; 0.32	0.12	0.32	0.5	1.00	10 GAP compliant trials on beans (with pods) in NEU. Extrapolation to peas (with pods) is possible. R_{max} = 0.36 R_{ber} = 0.38 MRL_{OECD} = 0.44
	SEU	Outdoor	0.08; 0.11; 0.13; 0.14; 0.18; 0.19; 0.20	0.08; 0.11; 0.13; 0.14; 0.18; 0.19; 0.20	0.14	0.20	0.5	1.00	7 GAP compliant trials on beans (with pods) in SEU (France, 2013a). Extrapolation to peas (with pods) is possible. R_{max} = 0.30 R_{ber} = 0.38 MRL_{OECD} = 0.44
	EU	Indoor	0.34; 0.47; 0.54; 0.58; 0.60; 0.61; 0.75; 0.83; 1.15	0.34; 0.47; 0.54; 0.58; 0.60; 0.61; 0.75; 0.83; 1.15	**0.60**	**1.15**	**2**	1.00	9 GAP compliant indoor trials on beans (with pods). Although GAPs are different, extrapolation to peas (with pods) is possible because the application rates fall within the 25% deviation. R_{max} = 1.36 R_{ber} = 1.58 MRL_{OECD} = 1.96

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Beans and peas (without pods)	NEU	Outdoor	5 × <0.02; 0.02; 0.03; 2 × 0.05	5 × <0.02; 0.02; 0.03; 2 × 0.05	0.02	0.05	0.08	1.00	9 GAP compliant trials on peas (without pods) in NEU (EFSA, 2010); extrapolation to beans (without pods) is possible. R_{max} = 0.07 R_{ber} = 0.08 MRL_{OECD} = 0.08
Asparagus	NEU	Outdoor	2 × <0.02	2 × <0.02	**0.02**	**0.02**	**0.02***	1.00	2 GAP compliant trials on asparagus in NEU.
	SEU	Outdoor	2 × <0.01	2 × <0.01	0.01	0.01	0.02*	1.00	2 GAP compliant trials on asparagus in SEU.
Fennel	SEU	Outdoor	0.06; 2 × 0.07; 0.12	0.06; 2 × 0.07; 0.12	0.07	0.12	0.3	1.00	4 GAP compliant trials on fennel in SEU. R_{max} = 0.22 R_{ber} = 0.22 MRL_{OECD} = 0.24
Beans (dry) Peas (dry) Lupins	NEU	Outdoor	beans 0.01; 2 × 0.02; 0.03 peas <0.02; 0.02; 0.03; 0.07	beans 0.01; 2 × 0.02; 0.03 peas <0.02; 0.02; 0.03; 0.07	**0.02**	**0.07**	**0.1 (peas and lupins)**	**1.00**	8 GAP compliant trials, 4 on beans and 4 on peas in NEU. Extrapolation to all dry pulses is possible. R_{max} = 0.09 R_{ber} = 0.06 MRL_{OECD} = 0.10
	SEU	Outdoor	beans 0.02; 0.03; 0.05; 0.11 peas 0.04; 2 x 0.06; 0.07	beans 0.02; 0.03; 0.05; 0.11 peas 0.04; 2 x 0.06; 0.07	**0.06**	**0.11**	**0.2 (beans only)**	**1.00**	8 GAP compliant trials, 4 on beans and 4 on peas in SEU. Extrapolation to beans (dry) is possible; not authorised for use on other pulses in SEU. R_{max} = 0.14 R_{ber} = 0.14 MRL_{OECD} = 0.17

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Barley and oat grain	NEU	Outdoor	0.09; 0.21; 0.43; 0.67; 0.73; 0.74; 0.75; 1.07; 1.09; 1.10; 1.34; 1.41; 1.74	0.09; 0.21; 0.43; 0.67; 0.73; 0.74; 0.75; 1.07; 1.09; 1.10; 1.34; 1.41; 1.74	**0.75**	1.74	3	1.00	13 trials considered supportive of the GAP (PHIs range from 43-49 days for application rates close to 0.6 kg as/ha and 43-50 days for rates close to 0.75 kg as/ha) on barley in NEU (France, 2013a). Extrapolation to oat is possible. R_{max} = 2.15 R_{ber} = 2.44 MRL_{OECD} = 2.79
	SEU	Outdoor	<0.02; 0.15; 0.20; 0.61; 1.08; 1.13; 1.81	<0.02; 0.15; 0.20; 0.61; 1.08; 1.13; 1.81	0.61	**1.81**	**4**	1.00	7 trials considered supportive of the GAP (PHIs range from 42-47 days for application rates close to 0.6 kg as/ha and 49 days for rates close 0.75 kg as/ha) on barley in SEU (France, 2013a). Extrapolation to oat is possible. R_{max} = 2.95 R_{ber} = 2.26 MRL_{OECD} = 3.34
Wheat and rye grain	NEU	Outdoor	0.02; 0.03; 0.05; 0.05; 0.06; 0.09; 0.13; 0.14; 0.17; 0.17; 0.26; 0.32	0.02; 0.03; 0.05; 0.05; 0.06; 0.09; 0.13; 0.14; 0.17; 0.17; 0.26; 0.32	0.11	0.32	0.5	1.00	12 GAP compliant trials on wheat in NEU (France, 2013a). Extrapolation from wheat to rye is possible. R_{max} = 0.38 R_{ber} = 0.34 MRL_{OECD} = 0.50
	SEU	Outdoor	0.05; 0.08; 0.10; 2 × 0.13; 0.16; 0.32	0.05; 0.08; 0.10; 2 × 0.13; 0.16; 0.32	**0.13**	**0.32**	**0.5**	1.00	7 GAP compliant trials on wheat in SEU (France, 2013a). Extrapolation from wheat to rye is possible. R_{max} = 0.44 R_{ber} = 0.32 MRL_{OECD} = 0.49

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Barley and oat straw	NEU	Outdoor	0.12; 0.15; 0.25; 0.33; 0.39; 0.50; 0.64; 1.99	0.12; 0.15; 0.25; 0.33; 0.39; 0.50; 0.64; 1.99	0.36	1.99	3	1.00	8 trials considered supportive of the GAP (PHIs range from 43-49 days for application rates close to 0.6 kg as/ha and 43-50 days for rates close to 0.75 kg as/ha) on barley in NEU. Extrapolation to oats is possible. R_{max} = 2.49 R_{ber} = 1.21 MRL_{OECD} = 2.98
	SEU	Outdoor	0.19; 0.24; 0.45; 0.46; 1.24; 1.52; 2.45	0.19; 0.24; 0.45; 0.46; 1.24; 1.52; 2.45	**0.46**	**2.45**	**5**	1.00	7 trials considered supportive of the GAP (PHIs range from 42-47 days for application rates close to 0.6 kg as/ha and 49 days for rates close 0.75 kg as/ha) on barley in SEU (France, 2013a). Extrapolation to oats is possible. R_{max} = 3.79 R_{ber} = 3.04 MRL_{OECD} = 4.29
Wheat and rye straw	NEU	Outdoor	0.06; 0.14; 0.18; 0.26; 0.28; 0.31; 0.53; 0.65; 0.95; 0.96; 1.66; 2.57	0.06; 0.14; 0.18; 0.26; 0.28; 0.31; 0.53; 0.65; 0.95; 0.96; 1.66; 2.57	0.42	2.57	4	1.00	12 GAP compliant trials on wheat in NEU (France, 2013a). Extrapolation from wheat to rye is acceptable as the GAP on wheat is more critical. R_{max} = 2.75 R_{ber} = 1.92 MRL_{OECD} = 3.69
	SEU	Outdoor	0.16; 0.22; 0.26; 0.58; 1.06; 2.5; 5.78	0.16; 0.22; 0.26; 0.58; 1.06; 2.5; 5.78	**0.58**	**5.78**	**10**	1.00	7 GAP compliant trials on wheat in SEU (France, 2013a). Extrapolation from wheat to rye is possible. R_{max} = 8.50 R_{ber} = 5.00 MRL_{OECD} = 9.73

Commodity	Residue region [a]	Outdoor /Indoor	Individual trial results (mg/kg)		Median residue (mg/kg) [b]	Highest residue (mg/kg) [c]	MRL proposal (mg/kg)	Median CF [d]	Comments
			Enforcement (cyprodinil)	Risk assessment (cyprodinil)					
Herbal infusions (roots) and spices (roots and rhizomes)	NEU	Outdoor	0.21; 0.27; 0.33; 0.41; 0.48; 0.51; 0.53; 1.04	0.21; 0.27; 0.33; 0.41; 0.48; 0.51; 0.53; 1.04	0.45	1.04	1.5 [f] tentative	1.00	Extrapolation from carrots is possible (EFSA, 2009a), including the additional trial on carrot (1.04) submitted during Member State consultation (France, 2013a). R_{max} = 1.29 R_{ber} = 1.05 MRL_{OECD} = 1.5

(a): NEU (Northern and Central Europe), SEU (Southern Europe and Mediterranean), EU (i.e outdoor use) or Import (country code) (EC, 2011).
(b): Median value of the individual trial results according to the enforcement residue definition.
(c): Highest value of the individual trial results according to the enforcement residue definition.
(d): The median conversion factor for enforcement to risk assessment is obtained by calculating the median of the individual conversion factors for each residues trial.
(e): Trial was carried out on an open leaf lettuce variety.
(f): MRL proposal considered tentative because a validated analytical method for enforcement of these MRLs is still missing.
(*): Indicates that the MRL is set at the limit of analytical quantification.

3.1.1.3. Effect of industrial processing and/or household preparation

The effect of processing on the nature of cyprodinil was investigated in the framework of the peer review. Studies were conducted simulating representative hydrolytic conditions for pasteurisation (20 minutes at 90°C, pH 4), boiling, brewing, baking (60 minutes at 100°C, pH 5) and sterilisation (20 minutes at 120°C, pH 6). From these studies, as no breakdown or reaction products were formed, it was concluded that processing by pasteurisation, baking/brewing/boiling and sterilisation is not expected to have a significant impact on the composition of residues in matrices of plant origin (France, 2003). The relevant residue for enforcement and risk assessment in processed commodities is therefore expected to be the same as for primary crops.

Studies investigating the magnitude of residues in processed commodities were generally not reported in the framework of the peer review (France, 2003), aside from data on apple juice and apple pomace but additional processing trials were reported in the JMPR evaluation of cyprodinil (FAO, 2003). Some processing trials were reported during the MS consultation (France, 2013b) but they were already considered by JMPR as well. An overview of all available processing studies is available in Table 3-3 and median processing factors for enforcement and risk assessment were recalculated by EFSA for a number of commodities as indicated in Table 3-3. No robust processing factors for enforcement and risk assessment could be derived for some other commodities as they were not supported by a sufficient number of studies; a minimum of 3 processing studies is normally required. These processing factors should therefore be considered as indicative only.

Further processing studies are not required as they are anyhow not expected to significantly affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

Table 3-3: Overview of the available processing studies

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Processing factors recommended (sufficiently supported by data)				
apples, juice	13	0.25	1	France, 2003
apples, wet pomace	4	1.25	1	France, 2003
plums, dried (prunes)	7	1.46	1	FAO, 2003
table grapes, dried (raisins)	15	2.00	1	FAO, 2003
wine grapes, juice	22	0.14	1	FAO, 2003
wine grapes, must	19	0.35	1	FAO, 2003
wine grapes, red wine (unheated)	18	0.06	1	FAO, 2003
strawberries, jam	3	0.52	1	FAO, 2003
strawberries, canned	3	0.77	1	FAO, 2003
barley, brewing malt	25	1.15	1	FAO, 2003
barley, beer	19	0.03	1	FAO, 2003
barley, pot/pearl	7	0.48	1	FAO, 2003
wheat, white flour	4	0.49	1	FAO, 2003; extrapolated to rye, white flour
wheat, bran	4	2.20	1	FAO, 2003; extrapolated to rye, bran

Processed commodity	Number of studies	Median PF [(a)]	Median CF [(b)]	Comments
Indicative processing factors (limited dataset)				
wine grapes, wet pomace	1	3.47	1	FAO, 2003
tomatoes, unpeeled and canned	2	0.10	1	FAO, 2003
tomatoes, paste	2	0.84	1	FAO, 2003
tomatoes, juice	2	0.20	1	FAO, 2003
tomatoes, juice	2	0.20	1	FAO, 2003
beans (fresh, with pods), cooked	1	0.85	1	FAO, 2003
wheat, wholemeal flour	1	0.87	1	FAO, 2003; extrapolated to rye, wholemeal flour
wheat, wholemeal bread	1	0.50	1	FAO, 2003; extrapolated to rye, wholemeal bread

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

3.1.2. Rotational crops

3.1.2.1. Preliminary considerations

Many of the crops under consideration, except permanent crops (for example apples, pears, cherries, and grapes), may be grown in rotation. According to the soil degradation studies evaluated in the framework of the peer review, the highest DT_{90} value of cyprodinil based on the field study amounts for up to 814 days in acidic soils, which is higher than the trigger value of 100 days (France, 2003). According to the European guidelines on rotational crops (EC, 1997b), further investigation of residues in rotational crops is relevant.

3.1.2.2. Nature of residues

The metabolism of cyprodinil in four confined rotational crops studies investigating the nature of residues following different plant-back intervals has been evaluated and reported under the peer review (France, 2003). In these studies cyprodinil radiolabelled in phenyl or pyrimidinyl rings was applied to bare soil or crops at application rates ranging from 1.25-3.6 kg a.s./ha (0.83N/1.1N to approximately 3N the intended total seasonal application rate). The characteristics of these studies are summarised in Table 3-4.

Table 3-4: Summary of available metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Study 1 (Switzerland)							
Leafy vegetables	lettuce	U-^{14}C-phenyl	F	0.75 + 0.5	43	not reported	applied to a primary crop of

Crop group	Crop	Label position	Application and sampling details				
			Method, F or G [(a)]	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks
Root and tuber vegetables	sugar beet	U-^{14}C-phenyl	F	0.75 + 0.5	272	not reported	spring wheat
Cereals	wheat maize	U-^{14}C-phenyl	F	0.75 + 0.5	106 302	not reported	
Study 2 (Switzerland)							
Leafy vegetables	lettuce	U-^{14}C-pyrimidine	F	0.75 + 0.5	43	77 96	applied to a primary crop of spring wheat
Root and tuber vegetables	sugar beet	U-^{14}C-pyrimidine	F	0.75 + 0.5	272	365 398 483	
Cereals	wheat maize	U-^{14}C-pyrimidine	F	0.75 + 0.5	106 302	317 365 398 365 398 483	
Study 3 (California, USA)							
Pulses and oilseeds	mustard	U-^{14}C-phenyl and 2-^{14}C-pyrimidine	F	3.2-3.6	42 130 283 365	not reported	applied to bare soil
Root and tuber vegetables	radish	U-^{14}C-phenyl and 2-^{14}C-pyrimidine	F	3.2-3.6	42 130 283 365	not reported	
Cereals	wheat	U-^{14}C-phenyl and 2-^{14}C-pyrimidine	F	3.2-3.6	42 130 283 365	not reported	
Study 4 (Switzerland)							
Leafy vegetables	lettuce	2-^{14}C-pyrimidine	F	1.25	29 124 365	'mat-urity'	applied to bare soil
Root and tuber vegetables	radish	2-^{14}C-pyrimidine	F	1.25	29 124 365	'mat-urity'	
Cereals	wheat	2-^{14}C-pyrimidine	F	1.25	29 180 365	'interim samples and maturity'	

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

When radiolabelled cyprodinil was applied on a primary crop (spring wheat) at an application rate of 1.25 kg a.s./ha, no significant cyprodinil residues (TRR<0.01 mg/kg) were found in any of the edible parts of the succeeding crops tested (lettuce, sugar beet, maize and winter wheat). When cyprodinil was applied to bare soil, the studies identified four major cyprodinil metabolites in the succeeding crops (wheat, lettuce and radishes) sown at any of the replant intervals: CGA 321915[17] (up to 0.013, 0.012, and 0.066 mg/kg in 124 DAT head lettuce, 124 DAT radish top and 29 DAT wheat straw, respectively), CGA 249287[18] (up to 0.001, 0.48 and 0.20 mg/kg in 29 DAT lettuce head, 130 DAT wheat straw and 130 DAT mustard leaves, respectively), NOA 422054[19] (major metabolite representing up to 12.6% of the TRR (0.007 mg/kg), 46.2% of the TRR (0.71 mg/kg) and 12.8% of the TRR (1.5 mg/kg) in 29 DAT lettuce head, 365 DAT radish leaves and 130 DAT wheat straw, respectively), and CGA 263208 (up to 0.38 and 0.064 mg/kg in 130 DAT mustard leaves and 42 DAT wheat straw, respectively).

It is concluded that the metabolism of cyprodinil in rotational crops is sufficiently elucidated. Studies on the magnitude of residues in rotational crops confirmed the presence of the plant metabolites NOA 422054 and CGA 321915 which were found at measurable levels at the earliest replanting interval of 30 DAT, whilst parent cyprodinil occurred rarely (see section 3.1.2.3 below). However, as none of these metabolites were found to be of toxicological concern, it was concluded in the peer review not to include these metabolites in the residue definition for plants assuming that short plant-back intervals were not expected to occur in practice for the crops supported in the framework of the peer review (EFSA, 2005).

3.1.2.3. Magnitude of residues

In addition to the confined rotational crop studies, five rotational crop field trials performed at application rates ranging from 0.75 kg a.s./ha to 2.24 kg a.s./ha (from 0.5N to 5N the intended rate depending on the GAP) were evaluated in the framework of the peer review (France, 2003).

In the first field study performed in California (USA) cyprodinil was applied to bare soil at 4 x 0.56 kg a.s./ha (a total of 2.24 kg a.s./ha) and lettuce, turnips and wheat were sown or planted as succeeding crops 30, 90, 150 and 210 DAT. Samples were analysed for cyprodinil parent only. No cyprodinil residues were found above the LOQ in any of the samples 30 DAT, and the samples for the longer plant back intervals were therefore not analysed.

In the other four studies, performed in Northern Europe, cyprodinil was applied once to wheat at 0.75 kg/ha. Wheat, lettuce and radishes were planted as succeeding crops 28-30 or 35-37 DAT. Lettuce and radishes were also planted 112-114 or 120 DAT while wheat was additionally planted 314-315 or 331-370 DAT. Crop samples were analysed for parent cyprodinil and for the metabolites CGA 321915 and NOA 422054. These studies confirmed the occurrence of the two plant metabolites NOA 422054 and CGA 321915 which were also identified in the radiolabelled studies. 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 and only at the earliest replanting interval at 0.01 mg/kg. 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 corresponding maximum residue of CGA 321915 was 0.03 mg/kg in radish leaves. These metabolites were rarely found at the later replanting timings, and at lower levels when found (up to 0.02 mg/kg).

Although CGA 321915 and NOA 422054 are not expected to be of any particular toxicological concern compared to the parent compound, the possibility of residues of these metabolites arising in rotational crops is likely to be dependant on the specific crop use and whether close cropping will occur as a result of normal agricultural practice. In order to address all possible crop rotations with

[17] CGA 321915: 4-cyclopropyl-6-methyl-pyrimidin-2-ol
[18] CGA 249287: 4-cyclopropyl-6-methyl-pyrimidine-2-yl-amine
[19] NOA 422054: (2-amino-6-cyclopropyl-pyrimidin-4-yl)-methanol

primary crops reported in the framework of this review, EFSA concludes that Member States granting authorisations for cyprodinil should consider the need to take the appropriate risk mitigation measures (e.g. definition of pre-plant intervals of at least 120d) in order to avoid the presence of cyprodinil metabolites residues in rotational crops.

3.2. Nature and magnitude of residues in livestock

3.2.1. Dietary burden of livestock

Cyprodinil is authorised for use on several crops that might be fed to livestock. The median and maximum dietary burdens were therefore calculated for different groups of livestock using the agreed European methodology (EC, 1996). The input values for all relevant commodities have been selected according to the recommendations of JMPR (FAO, 2009) and are summarised in Table 3-5. For apple pomace, wheat and rye bran, the processing factors recommended under Section 3.1.1.3 have been included in the calculation.

Table 3-5: 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: cyprodinil				
Apple, pomace	0.61	Median residue × PF	0.61	Median residue × PF
Wheat grain	0.13	Median residue	0.13	Median residue
Barley grain	0.75	Median residue	0.75	Median residue
Rye grain	0.13	Median residue	0.13	Median residue
Oat grain	0.75	Median residue	0.75	Median residue
Wheat bran	0.29	Median residue × PF	0.29	Median residue × PF
Rye bran	0.29	Median residue × PF	0.29	Median residue × PF
Wheat straw	0.58	Median residue	5.78	Highest residue
Barley straw	0.46	Median residue	2.45	Highest residue
Rye straw	0.58	Median residue	5.78	Highest residue
Oat straw	0.46	Median residue	2.45	Highest residue
Peas (dry)	0.02	Median residue	0.02	Median residue
Beans (dry)	0.06	Median residue	0.06	Median residue
Lupins (dry)	0.02	Median residue	0.02	Median residue

The results of the calculations are reported in Table 3-6. The calculated dietary burdens for all groups of livestock were found to exceed the trigger value of 0.1 mg/kg DM. Further investigation of residues is therefore required in all commodities of animal origin.

Table 3-6: Results of the dietary burden calculation

	Median dietary burden (mg/kg bw per d)	Maximum dietary burden (mg/kg bw per d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Risk assessment residue definition: cyprodinil					
Dairy ruminants	0.0277	0.0717	Wheat straw	2.0	Y
Meat ruminants	0.0604	0.1857	Wheat straw	4.3	Y
Poultry	0.0398	0.0398	Barley grain	0.63	Y
Pigs	0.0284	0.0284	Barley grain	0.71	Y

3.2.2. Nature of residues

The nature of cyprodinil residues in commodities of animal origin was investigated in the framework of Directive 91/414/EEC (France, 2003). Reported metabolism studies include three studies in lactating goats and two studies in laying hens using [U-^{14}C- phenyl] and [2-^{14}C-pyrimidine] labelled cyprodinil. The characteristics of these studies are summarised in Table 3-7.

Table 3-7: Summary of available metabolism studies in livestock

Group	Species	Label position	No of animal	Application details		Sample details	
				Rate (mg/kg bw per d)	Duration (days)	Commodity	Time
Lactating ruminants	Goat study 1 and 2	U-^{14}C-phenyl	2	0.2 , 9.94 (a)	4	Milk	Twice daily
						Urine and faeces	Daily
						Tissues	After sacrifice (f)
		2-^{14}C-pyrimidine	2	0.2, 9.8 (b)	4	Milk	Twice daily
						Urine and faeces	Daily
						Tissues	After sacrifice (f)
	Goat study 3	U-^{14}C-phenyl	2	4.11 (c)	4	Milk	Twice daily
						Urine and faeces	Daily
						Tissues	After sacrifice (f)
Laying hens	Hen	U-^{14}C-phenyl	6	0.4, 18.9 (d)	4	Eggs	Daily
						Excreta	Daily
						Tissues	After sacrifice (f)
		2-^{14}C-pyrimidine	6	0.4, 19.2 (e)	4	Eggs	Daily
						Excreta	Daily
						Tissues	After sacrifice (f)

(a): U-^{14}C-phenyl cyprodinil was administered to a single goat at a dose level of 0.2 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and a second goat at a dose level of 9.94 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(b): 2-^{14}C-pyrimidine cyprodinil was administered to a single goat at a dose level of 0.2 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and a second goat at a dose level of 9.8 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(c): U-^{14}C-phenyl cyprodinil was administered to a single goat at a dose level of 4.11 mg/kg bw (nominal dose rate of 100 mg/kg in the diet).

(d): U-^{14}C-phenyl cyprodinil was administered to two hens at a dose level 0.4 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and to four hens at a dose level of 18.9 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(e): 2-^{14}C-pyrimidine cyprodinil was administered to two hens at a dose level of 0.4 mg/kg bw (nominal dose rate of 5 mg/kg in the diet) and to four hens at a dose level of 19.2 mg/kg bw (nominal dose rate of 250 mg/kg in the diet).
(f): 6 h after the last dose

Lactating goats were dosed with 0.2-9.94 mg/kg bw per d of cyprodinil, corresponding to approximately 3-140 times the exposure of dairy ruminants and 1-53 times the exposure of meat ruminants. At the 5 mg/kg nominal dose rate (0.2 mg/kg bw per d), 27-39 % of the administered dose was excreted in the urine and 19.1-29 % in the faeces. At the higher nominal dose rate of 250 mg/kg (9.94 mg/kg bw per d) 27.4-29 % TRR was excreted in the urine and 40-47 % in the faeces. Highest TRR for U-^{14}C-phenyl and 2-^{14}C-pyrimidine cyprodinil were found in milk (3.22 mg eq/kg and 1.47 mg eq/kg respectively, goat study 1), liver (12.73 mg eq/kg and 9.62 mg eq/kg respectively, goat study 1) and kidney (9.21 mg eq/kg and 5.21 mg eq/kg respectively, goat study 1) at the nominal dose rate of 250 mg/kg in the diet (9.94 mg/kg bw per d).

Characterisation of residues was conducted at both the 5 mg/kg (0.2 mg/kg bw per d, goat study 1) and 100 mg/kg (4.11 mg/kg bw per d, goat study 3) nominal dose levels. At the lower dose level, parent cyprodinil was only observed in the liver representing 1.5 % TRR (0.003 mg/kg) and 5.7 % TRR (0.016 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively. CGA 304075 was the main metabolite observed in the kidney representing 18.3 % TRR (0.041 mg/kg) and 17.7 % TRR (0.038 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively. The glucuronic acid conjugate of CGA 304075 was observed in milk at 15.2 % TRR (0.003 mg/kg) and 27.3 % TRR (0.013 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively. The sulphate conjugate of CGA 304076 (which itself is formed from hydroxylation in the 5 position of the pyrimidine ring) was found in milk at 11.7 % TRR (0.002 mg/kg) and 19.1 % TRR (0.009 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively. The pyrimidine metabolite CGA 249287, resulting from the cleavage of the amino bridge between the phenyl and pyrimidine ring was observed in milk at 2.1 % TRR (0.001 mg/kg), liver at 4.2 %TRR (0.012 mg/kg) and kidney at 5.8 % TRR (0.013 mg/kg).

At the higher dose level, animals were dosed with U-^{14}C-phenyl cyprodinil only. In fat, parent cyprodinil was the major residue in fat, representing 68 % of the TRR (0.05 mg/kg). It was present to a lesser extent in muscle (2.4 % TRR, 0.0012 mg/kg) and liver (9.4 % TRR, 0.023 mg/kg). In milk, the glucuronide conjugate of CGA 304075 was the major metabolite accounting for 55.2 % TRR (0.39 mg/kg). CGA 304075 was the major component in liver, kidney and muscle accounting for 30 % TRR (0.746 mg/kg), 39 % TRR (1.113 mg/kg) and 14.5 % TRR (0.0075 mg/kg) respectively. The metabolite CGA 304076, both sulphate and glucuronide, was present in all tissues and milk. The sulphate conjugate represented 4.4 % TRR (0.023 mg/kg) in muscle, 6.5 % TRR (0.162 mg/kg) in liver, 10.3 % TRR in kidneys (0.312 mg/kg) and 15.6 % (0.11 mg/kg) in milk whilst the glucuronide metabolite represented 1.8 % TRR (0.0009 mg/kg) in muscle, 5.8 % TRR (0.144 mg/kg) in liver, 10.8 % TRR (0.312 mg/kg) in kidneys and 4.1 % TRR(0.029 mg/kg) in milk. CGA 232449 resulting from the oxidation of the methyl group on the pyrimidine ring represented 12.1 % TRR (0.352 mg/kg) in liver.

Laying hens were dosed with 0.4-19.2 mg/kg bw per d of cyprodinil, corresponding to approximately 10-500 times the exposure of poultry. Excretion was the major route of elimination, accounting for 92-96 % of the total administered dose at sacrifice. Highest TRR for U-^{14}C-phenyl and 2-^{14}C-pyrimidine cyprodinil were found in egg yolks (0.293 mg eq/kg and 0.53 mg eq/kg respectively), liver (5.75 mg eq/kg and 5.53 mg eq/kg respectively) and kidney (2.4 mg eq/kg and 2.94 mg eq/kg respectively) at the nominal dose rate of 250 mg/kg in the diet (18.9-19.2 mg/kg bw per d). TRR in meat accounted for 0.066 mg/kg and 0.09 mg/kg at the higher dose level (250 mg/kg, 18.9-19.2 mg/kg bw per d).

No attempt was made to characterise the radioactivity in meat but characterisation of radioactive residues was conducted in eggs liver and kidney for both radiolabels at the nominal dose rates of 250 mg/kg, 18.9-19.2 mg/kg bw per d (eggs) and 5 mg/kg, 0.4 mg/kg bw per d (kidney and liver).

The main metabolites in egg yolk were the sulphate (representing 15.8 % TRR (0.022 mg/kg) and 19.3 % TRR (0.034 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively) and glucuronide (representing 8.1 % TRR (0.011 mg/kg) and 6.8 % TRR (0.012 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively) conjugates of CGA 304075. The presence of the label specific metabolite CGA 249287 at 6.0% TRR (0.011 mg/kg) and an unknown metabolite I7b (3.7% TRR; 0.006 mg/kg) were the only metabolites that indicated the cleavage of the amino bridge between the two ring systems (these were also observed in lower amounts in egg white, liver and kidney). In egg white, parent cyprodinil represented 12.9 % (0.002 mg/kg) and 13.4 % TRR (0.003 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively. The unknown metabolite I7b was found for the 2-^{14}C-pyrimidine labelled treatment at 11.6 % TRR (0.003 mg/kg). In kidney, parent cyprodinil represented 2.4 % TRR (0.001 mg/kg) and was identified for the U-^{14}C-phenyl labelled treatment only. The main metabolite identified was the sulphate conjugate of CGA 304075 representing 15.4 % TRR (0.007 mg/kg) and 22 % (0.009 mg/kg) for the U-^{14}C-phenyl and 2-^{14}C-pyrimidine labelled treatments respectively. In liver, parent cyprodinil was not identified. The main metabolite identified was the sulphate conjugate of CGA 304075 representing 10.4 % TRR (0.010 mg/kg) and 5.6 %TRR (0.007 mg/kg) for the 2-^{14}C-pyrimidine and U-^{14}C-phenyl labelled treatment respectively.

The metabolism studies in both ruminants and poultry show that cyprodinil is extensively metabolised and proceeds predominantly via hydroxylation of the phenyl and pyrimidine rings and conjugation with sulphate or glucuronic acid. The majority of the radioactivity was eliminated in the urine and faeces. In the peer review it was concluded that because of the similarity between ruminant, poultry and rat metabolism a metabolism study in pigs is not necessary (EFSA, 2005).

Based on the above findings, and that the metabolites CGA 304075, CGA 304076, CGA 232449, and CGA 249287 were all found in the rat metabolism study, EFSA concludes that the residue definition should include parent cyprodinil and CGA 304075. The question of whether the conjugate of CGA 304075 needs to be included in the residue definition is relevant and it is noted that it is not clear whether the cow feeding study (section 3.2.3) included a hydrolysis step to enable the determination of residues present as conjugate. Whilst conjugation does occur in hens, no significant residues in poultry are expected. In the goat metabolism whilst the free CGA 304075 was the main metabolite in liver and kidney, the glucuronide conjugate was the main metabolite found in milk. The cow feeding studies (section 3.2.3) confirmed the presence of CGA 304075 (and parent cyprodinil to a lesser extent in kidney and liver); as might be expected free CGA 304075 was not detected in the milk in the feeding study, but is questionable whether the analytical methodology used would have released the glucuronide conjugate of CGA 304075 if present.

Therefore EFSA proposes that for the residues enforcement and risk assessment in all commodities of animal origin is defined as the sum of cyprodinil and CGA 304075 expressed as cyprodinil, except for milk where it is proposed that the residues for enforcement and risk assessment is defined as the sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil. It is also considered that the residue definition might require further consideration in the future if the dietary burden of poultry is increased.

Validated analytical methods for enforcement of the proposed residue definition are available (see also section 1.1), although a data gap exists for a validated enforcement method for the determination of cyprodinil and CGA 304075 in eggs and confirmatory validation data for determining residues in animal products.

Although log $P_{o/w}$ of cyprodinil is higher than 3 (France, 2003), the distribution of CGA 304075 in animal tissues indicates that the metabolite does not accumulate in fat tissues. Furthermore, the results

of the cow feeding study (section 3.2.3 below) show that residues of either cyprodinil or CGA 304075 were not found in milk and fat and an exaggerated dose rate, although it is possible that the glucuronide conjugate of CGA 304075 could be present in milk, indicating that residues of cyprodinil are not necessarily expected to accumulate in fat tissues. EFSA therefore concludes that the residue in commodities of animal origin is not fat soluble.

3.2.3. Magnitude of residues

According to the above mentioned hen metabolism studies, it is concluded that, after exposure to the maximum dietary burden (at least 10 times lower than the lowest dose level of the metabolism studies; see also section 3.2.1), residue levels in poultry commodities are expected to remain below the enforcement LOQ of 0.01 mg/kg in poultry products, including muscle, fat, eggs, liver and kidney. Hence, no livestock feeding study for poultry is needed; MRLs and risk assessment values for the relevant commodities in poultry can be established at the LOQ level.

Regarding other types of livestock, the magnitude of cyprodinil residues in ruminants was investigated during the peer review under Directive 91/414/EEC in a feeding study with lactating cows (France, 2003). However the metabolite CGA 304075 was not determined and it was not possible to propose MRLs on the basis of this study. In an addendum to the DAR an additional feeding study with lactating cows was reported (France, 2009) where the magnitude of residues of cyprodinil and CGA 304075 were investigated.

Four groups of lactating cows, one group consisting of a control and a back-up animal and the remaining three groups consisting of three cow each, were dosed for 29-30 consecutive days with cyprodinil at levels of 2 (1X), 15 (7.5X) and 50 (25X) mg/kg in the diet (equivalent to 0.07, 0.54 and 1.81 mg/kg bw per d). The samples were analysed for cyprodinil and the metabolite CGA 304075. Results of ruminant livestock feeding studies are summarised in Table 3-7. In milk, residues of cyprodinil and CGA 304075 were <LOQ at the 25 X dose level. When found in liver and kidney (at the 7.5X and 25X dose rates only), residues were mostly analysed as CGA 304075, although parent cyprodinil was still found as an isolated occurrence at the highest dosing rate in liver (where a residue of 0.02 mg/kg cyprodinil and a residue of 0.07 mg/kg CGA 304075 was analysed).

The storage stability of cyprodinil residues in animal products was evaluated under the peer review of Directive 91/414/EEC (France, 2003). Studies demonstrated storage stability of cyprodinil in milk, muscle, fat, liver and kidney, eggs for up to 19 months when stored deep frozen. According to the RMS, all samples reported in the PROFile were stored in compliance with the above reported storage conditions. Degradation of parent cyprodinil during storage of the samples is not expected.

In an addendum to the DAR, an additional report was submitted investigating the storage stability of the metabolite CGA 304075 in dairy cow tissues and milk under freezer conditions (approximately -20°C) over a storage period of 3 months. Residues of free CGA 304075 fortified onto matrix were found to be stable in milk (88 % recovery) but unstable in liver (40 % recovery), kidney (16 % recovery), muscle (2 % recovery) and fat (36 % recovery) after 3 months in frozen storage. Incurred residues of CGA 304075 were found to be stable in kidney and liver samples (114 % and 113 % recoveries respectively) following frozen storage for at least 6 months when studied in the context of the livestock feeding study involving CGA 304075. As the feeding study samples were stored frozen for a maximum period of 3 months and as residues were not found in muscle, fat or milk samples at the highest dose rate (25X), it is considered unlikely that the validity of the results is compromised by frozen storage, even though the stability data have shown conflicting information for liver and kidney and there are limited stability data available for muscle, milk and fat showing instability. EFSA accepts that there is some uncertainty with these data but do not consider that a new feeding study should be generated.

Consequently, the available data are considered sufficient for deriving MRLs in ruminants and pigs. These MRLs were derived in compliance with the latest recommendations on this matter (FAO, 2009)

and are summarised in Table 3-8. Significant residues in kidney and liver of ruminants are expected and MRLs for these animal commodities can be proposed. MRLs and risk assessment values for swine products and for ruminant muscle, milk and fat can be established at the LOQ level.

Considering that a data gap for a validated enforcement method for the determination of cyprodinil and CGA 304075 in eggs and a confirmatory method for enforcement purposes in commodities of animal origin was identified, all MRLs for commodities of animal origin are tentative only.

Table 3-8: Overview of the values derived from the livestock feeding studies

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	MRL proposal (mg/kg)[(d)]	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[(a)]	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Enforcement and risk assessment residue definition: sum of cyprodinil and CGA 304075 expressed as cyprodinil												
Pig muscle/meat [(e)]	0.0284	0.0284	0.0720	3	n.r.	n.r.	n.r.	n.r.	0.02	0.02	0.02*	1.00
			0.5450	3	n.r.	n.r.	n.r.	n.r.				
			1.8100	3	<0.02	<0.02	<0.02	<0.02				
Pig fat	0.0284	0.0284	0.0720	3	n.r.	n.r.	n.r.	n.r.	0.02	0.02	0.02*	1.00
			0.5450	3	n.r.	n.r.	n.r.	n.r.				
			1.8100	3	<0.02	<0.02	<0.02	<0.02				
Pig liver	0.0284	0.0284	0.0720	3	<0.02	<0.02	<0.02	<0.02	0.02	0.02	0.02*	1.00
			0.5450	3	0.03	0.03	0.03	0.03				
			1.8100	3	0.09	0.09	0.09	0.09				
Pig kidney	0.0284	0.0284	0.0720	3	<0.02	<0.02	<0.02	<0.02	0.02	0.02	0.02*	1.00
			0.5450	3	0.04	0.04	0.04	0.04				
			1.8100	3	0.13	0.13	0.13	0.13				
Ruminant muscle/meat [(e)]	0.0604	0.1857	0.0720	3	n.r.	n.r.	n.r.	n.r.	0.02	0.02	0.02*	1.00
			0.5450	3	n.r.	n.r.	n.r.	n.r.				
			1.8100	3	<0.02	<0.02	<0.02	<0.02				
Ruminant fat	0.0604	0.1857	0.0720	3	n.r.	n.r.	n.r.	n.r.	0.02	0.02	0.02*	1.00
			0.5450	3	n.r.	n.r.	n.r.	n.r.				
			1.8100	3	<0.02	<0.02	<0.02	<0.02				

Commodity	Dietary burden		Results of the livestock feeding study						Median residue (mg/kg)[(b)]	Highest residue (mg/kg)[(c)]	MRL proposal (mg/kg)[(d)]	CF for RA
	Med. (mg/kg bw per d)	Max. (mg/kg bw per d)	Dose Level (mg/kg bw per d)[(a)]	No	Result for enf.		Result for RA					
					Mean (mg/kg)	Max. (mg/kg)	Mean (mg/kg)	Max. (mg/kg)				
Ruminant liver	0.0604	0.1857	0.0720	3	<0.02	<0.02	<0.02	<0.02	0.02	0.022	0.05	1.00
			0.5450	3	0.03	0.03	0.03	0.03				
			1.8100	3	0.09	0.09	0.09	0.09				
Ruminant kidney	0.0604	0.1857	0.0720	3	<0.02	<0.02	<0.02	<0.02	0.02	0.025	0.05	1.00
			0.5450	3	0.04	0.04	0.04	0.04				
			1.8100	3	0.13	0.13	0.13	0.13				
Enforcement and risk assessment residue definition: sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil												
Milk	0.0277	0.0717	0.0720	84[(f)]	n.r.	n.a.	n.r.	n.a.	0.02	0.02	0.02*	1.00
			0.5450	84[(f)]	n.r.	n.a.	n.r.	n.a.				
			1.8100	84[(f)]	<0.02	n.a.	<0.02	n.a.				

n.a.: Not applicable – only the mean values are considered for calculating MRLs in milk
n.r.: Not reported but residues at higher dosing levels were already demonstrated to be <0.02 mg/kg
(a): Based on a 550 kg animal consuming 20 kg feed DM/day.
(b): Median residue value according to the enforcement residue definition, derived by interpolation/extrapolation from the feeding study for the median dietary burden (FAO, 2009).
(c): Highest residue value (tissues, eggs) or mean residue value (milk) according to the enforcement residue definition, derived by interpolation/extrapolation of the maximum dietary burden between the relevant feeding groups of the study (FAO, 2009).
(d): The median conversion factor for enforcement to risk assessment.
(e): While the results of the livestock feeding study refer to the muscle, the MRL proposal and risk assessment values are applicable to the meat.
(f): Mean residue level from day 0 until day 28 (3 cows, 28 sampling days).
(*): Indicates that the MRL is set at the limit of analytical quantification.

4. Consumer risk assessment

In the framework of this review, only the uses of cyprodinil reported by the RMS in Appendix A were considered, however the use of cyprodinil was previously also assessed by the JMPR (FAO, 2003). The CXLs, resulting from this assessment by JMPR and adopted by the CAC, are now international recommendations that need to be considered by European risk managers when establishing MRLs. In order to facilitate consideration of these CXLs by risk managers, the consumer exposure was calculated both with and without consideration of the existing CXLs (see Appendix C.2).

4.1. Consumer risk assessment without consideration of the existing CXLs

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

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

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: cyprodinil		
Apples, pears and quinces	0.49	Median residue [a]
Medlar and loquat	0.28	Median residue [a]
Apricots	0.30	Median residue (tentative) [b]
Cherries	0.20	Median residue (tentative) [b]
Peaches	0.30	Median residue (tentative) [b]
Plums	0.19	Median residue [a]
Table grapes	0.68	Median residue [a]
Wine grapes	0.67	Median residue [a]
Strawberries	0.99	Median residue [a]
Blackberries and raspberries	0.81	Median residue [b]
Other small fruit and berries	0.69	Median residue [a]
Beetroot, carrots, horseradish, parsnips, parsley root and salsify	0.45	Median residue [a]
Celeriac	0.08	Median residue [a]
Radishes	0.02	Median residue [a]
Garlic, onions and shallot	0.02*	Median residue [a]
Spring onions	0.17	Median residue [a]
Tomatoes and aubergines	0.17	Median residue [a]
Peppers	0.24	Median residue [a]
Cucurbits with edible peel	0.13	Median residue [a]

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Cucurbits with inedible peel	0.08	Median residue [a]
Lettuce and other salad plants including *Brassicacea*	3.1	Median residue [a]
Spinach and similar	3.1	Median residue [a]
Herbs	3.1	Median residue [a]
Witloof	0.02	Median residue [a]
Beans and peas (with pods)	0.6	Median residue [a]
Beans and peas (without pods)	0.02	Median residue [a]
Asparagus	0.02*	Median residue [a]
Fennel	0.07	Median residue [a]
Beans (dry)	0.06	Median residue [a]
Peas (dry) and lupins	0.02	Median residue [a]
Barley and oats grain	0.75	Median residue [a]
Wheat and rye grain	0.13	Median residue [a]
Herbal infusions (dried roots)	0.45	Median residue (tentative) [b]
Spices (roots and rhizome)	0.45	Median residue (tentative) [b]
Risk assessment residue definition: sum of cyprodinil and CGA 304075 expressed as cyprodinil		
Swine meat	0.02*	Median residue (tentative) [c]
Swine fat (free of lean meat)	0.02*	Median residue (tentative) [c]
Swine liver	0.02*	Median residue (tentative) [c]
Swine kidney	0.02*	Median residue (tentative) [c]
Ruminant meat	0.02*	Median residue (tentative) [c]
Ruminant fat (free of lean meat)	0.02*	Median residue (tentative) [c]
Ruminant liver	0.02*	Median residue (tentative) [c]
Ruminant kidney	0.02*	Median residue (tentative) [c]
Poultry products (meat, fat, liver and eggs)	0.02*	Median residue (tentative) [c]
Risk assessment residue definition: sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil		
Milk	0.02*	Median residue (tentative) [c]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

The calculated exposures were compared with the toxicological reference value derived for cyprodinil (see Table 2-1); detailed results of the calculations are presented as the EU scenario in Appendix B.1. The highest chronic exposure was calculated for German children, representing 37.1% of the ADI.

Based on the above calculations, EFSA concludes that the use of cyprodinil on crops fully supported by data (footnotes a in Table 4-1), is acceptable with regard to consumer exposure. For the other crops, uncertainties remain due to the data gaps identified in section 3, but considering tentative MRLs in the exposure calculation did not indicate a risk to consumers.

4.2. Consumer risk assessment with consideration of the existing CXLs

In order to include the CXLs in the calculations of the consumer exposure, all data relevant to the consumer exposure assessment have been collected from JMPR evaluations and reported in Appendix C.2 to this document. These CXLs were compared with the EU MRL proposals in compliance with Appendix D and input values resulting from this comparison are summarised in Table 4-2.

EFSA notes that a CXL was established for almonds which belong to the group of high oil content commodities while a validated analytical method for enforcement of this crop group is not available. The CXL for almonds is therefore considered not to be adequately supported by data.

Furthermore, the residue definition derived by JMPR for commodities of animal origin only includes parent cyprodinil while a different residue definition is derived by EFSA. Considering however that only few CXLs for plant commodities are higher than the MRL proposals derived by EFSA to cover EU authorisations, and that none of the commodities concerned is expected to be fed to livestock, the livestock dietary burden generated by CXLs is already covered by the livestock dietary burden calculated for the EU authorisation. There is therefore no need to take into consideration the existing CXLs for commodities of animal origin.

Table 4-2: Input values for the consumer risk assessment (with consideration of CXLs)

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Risk assessment residue definition: cyprodinil		
Almonds	0.02*	Median residue (CXL, tentative) [(d)]
Apples, pears and quinces	0.49	Median residue [(a)]
Medlar and loquat	0.28	Median residue [(a)]
Stone fruits	0.68	Median residue (CXL) [(c)]
Table grapes	0.68	Median residue [(a)]
Wine grapes	0.67	Median residue [(a)]
Strawberries	0.99	Median residue [(a)]
Blackberries and raspberries	0.81	Median residue [(a)]
Other small fruit and berries	0.69	Median residue [(a)]
Beetroot, carrots, horseradish, parsnips, parsley root and salsify	0.45	Median residue [(a)]
Celeriac	0.08	Median residue [(a)]
Radishes	0.02	Median residue [(a)]
Onions	0.07	Median residue (CXL) [(c)]
Garlic and shallot	0.02*	Median residue [(a)]
Spring onions	0.17	Median residue [(a)]
Tomatoes and aubergines	0.17	Median residue [(a)]

Commodity	Chronic risk assessment	
	Input value (mg/kg)	Comment
Peppers	0.24	Median residue [a]
Cucurbits with edible peel	0.13	Median residue [a]
Cucurbits with inedible peel	0.08	Median residue [a]
Lettuce and other salad plants including *Brassicacea*	3.1	Median residue [a]
Spinach and similar	3.1	Median residue [a]
Herbs	3.1	Median residue [a]
Witloof	0.02	Median residue [a]
Beans and peas (with pods)	0.6	Median residue [a]
Beans and peas (without pods)	0.02	Median residue [a]
Asparagus	0.02*	Median residue [a]
Fennel	0.07	Median residue [a]
Beans (dry)	0.06	Median residue [a]
Peas (dry) and lupins	0.02	Median residue [a]
Barley and oats grain	0.75	Median residue [a]
Wheat and rye grain	0.13	Median residue [a]
Herbal infusions (dried roots)	0.45	Median residue (tentative) [b]
Spices (roots and rhizome)	0.45	Median residue (tentative) [b]
Risk assessment residue definition: sum of cyprodinil and CGA 304075 expressed as cyprodinil		
Swine meat	0.02*	Median residue (tentative) [e]
Swine fat (free of lean meat)	0.02*	Median residue (tentative) [e]
Swine liver	0.02*	Median residue (tentative) [e]
Swine kidney	0.02*	Median residue (tentative) [e]
Ruminant meat	0.02*	Median residue (tentative) [e]
Ruminant fat (free of lean meat)	0.02*	Median residue (tentative) [e]
Ruminant liver	0.02*	Median residue (tentative) [e]
Ruminant kidney	0.02*	Median residue (tentative) [e]
Poultry products (meat, fat, liver and eggs)	0.02*	Median residue (tentative)[e]
Risk assessment residue definition: sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil		
Milk	0.02*	Median residue (tentative) [e]

(*): Indicates that the input value is proposed at the limit of analytical quantification.
(a): At least one relevant GAP reported by the RMS is fully supported by data for this commodity; the risk assessment values derived in section 3 are used for the exposure calculations.
(b): Use reported by the RMS is not fully supported by data but the risk assessment values derived in section 3 are used for indicative exposure calculations.
(c): CXL is supported by data; the corresponding risk assessment values are used for the exposure calculations.
(d): CXL is not sufficiently supported by data; the corresponding risk assessment value is used for indicative exposure calculations.
(e): Dietary burden relevant to this commodity of animal origin, resulting from the GAPs reported by the RMS, is not fully supported by data; the risk assessment values derived in section 3 are used for indicative exposure calculations.

Chronic calculations were also performed using revision 2 of the EFSA PRIMo and calculated exposures were compared with the toxicological reference value derived for cyprodinil (see Table 2-1); detailed results of the calculations are presented as the EU/Codex scenario in Appendix B.2. The highest chronic exposure was calculated for German children, representing 38.6 % of the ADI.

Based on the above calculations, EFSA concludes that the CXLs supported by data (footnote c in Table 4-2) are not expected to be of concern for European consumers. For the CXL on almonds, uncertainties remain as it is not well supported by data. Nevertheless, inclusion of this CXL in the exposure calculation did not indicate any risk to European consumers.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

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

Primary crop metabolism was investigated for foliar application in the fruit and fruiting vegetables crop grouping (apple, peaches and tomato) and the root and tuber vegetables grouping (potato) and the cereal grouping (wheat). The studies demonstrate that where there is a direct contact of cyprodinil with the edible part, cyprodinil represents the largest part of the residue, and that metabolism proceeds mainly via hydroxylation of the phenyl and pyrimidine rings followed by sugar conjugation. It was concluded that metabolism is similar in all crops and the residue definition for all the considered uses for both risk assessment and enforcement should be established as cyprodinil (parent compound only). Validated analytical methods for enforcement of this residue definition are available with an LOQ of 0.02 mg/kg in high acid content, high water content and dry commodities, covering the authorised uses except high oil content commodities (almonds), and herbal infusions and spices of roots.

Regarding the magnitude of residues in primary crops, a sufficient number of supervised residue trials is available for the majority of the GAPs reported by the RMS, which allowed EFSA to estimate the expected residue concentrations in the relevant plant commodities and to derive appropriate MRL proposals, except for apricots and peaches, cherries, and herbal infusions and spices of roots where tentative MRLs are derived.

Residue data on the nature of residues over processing in the form of radiolabelled hydrolysis study is available showing that cyprodinil remained stable and that no breakdown or reaction products were formed. Some studies on the magnitude of residues also allowed deriving robust processing factors for various commodities, whilst for commodities where only a limited number of studies were available some indicative processing factors were derived. Further processing studies are not required as they are not expected to significantly affect the outcome of the risk assessment. However, if more robust processing factors were to be required by risk managers, in particular for enforcement purposes, additional processing studies would be needed.

Four confined rotational crop metabolism studies are available to address the potential for residues to occur in rotational crops. Studies on the magnitude of residues in rotational crops confirmed the presence of the plant metabolites NOA 422054 and CGA 321915 at the earliest replanting interval of 30 DAT. Although these metabolites are not expected to be of any particular toxicological concern compared to the parent compound, the possibility of residues arising in rotational crops is likely to depend on the specific crop use and whether close cropping will occur as a result of normal agricultural practice.

Metabolism studies conducted using goats and hens are available investigating the potential for residues to occur in animal products. Both studies show that cyprodinil is extensively metabolised and proceeds predominantly via hydroxylation of the phenyl and pyrimidine rings and conjugation with

sulphate or glucuronic acid. The main metabolites identified in the livestock metabolism were all found in the rat metabolism study and the residue definition for enforcement and risk assessment is defined as the sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil, aside from milk where the conjugated form of the metabolite needs to be included both for enforcement and risk assessment purposes. Metabolism data in hens were sufficient to confirm an expectation of insignificant residues in poultry and MRLs can be proposed at the level of the LOQ. A cow feeding study was also available to derive MRLs for swine and ruminant products. Analytical methods were reported to enforce the proposed residues definitions. Considering however that a validated enforcement method for the determination of cyprodinil and CGA 304075 in eggs and a confirmatory method for commodities of animal origin were identified as data gaps, all MRLs for commodities of animal origin are tentative only.

Chronic consumer exposure resulting from the authorised uses reported in the framework of this review was calculated using revision 2 of the EFSA PRIMo. The highest chronic exposure represented 37.0 % of the ADI (German children). Acute exposure calculations were not carried out because an ARfD was not deemed necessary for this active substance.

Apart from the MRLs evaluated in the framework of this review, internationally recommended CXLs have also been established for cyprodinil. Additional calculations of the consumer exposure, considering these CXLs, were therefore carried out and the highest chronic exposure represented 38.6 % of the ADI (German children).

RECOMMENDATIONS

Based on the above assessment, EFSA does not recommend inclusion of this active substance in Annex IV to Regulation (EC) No 396/2005. MRL recommendations were derived in compliance with the decision tree reported in Appendix D of the reasoned opinion (see summary table). All MRL values listed as 'Recommended' in the table are sufficiently supported by data and are therefore proposed for inclusion in Annex II to the Regulation. The remaining MRL values listed in the table are not recommended for inclusion in Annex II because they require further consideration by risk managers (see summary table footnotes for details). In particular, some tentative MRLs or existing EU MRLs need to be confirmed by the following data:

- ILV data for the HPLC-MS/MS method for the determination of cyprodinil in high oil content commodities;
- a validated enforcement method for the determination of cyprodinil in herbal infusions and spices;
- a validated enforcement method for the determination of cyprodinil and CGA 304075 in eggs;
- confirmatory method validation data for the determination of cyprodinil and CGA 304075 in animal products.

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

- 8 residue trials on peaches or apricots (with a minimum of 4 trials on apricots) complying with the northern outdoor GAP and 4 trials on apricots complying with the southern outdoor GAP (southern trials already planned by the notifier and expected for 2015);
- 4 residue trials complying with the northern outdoor GAP on cherries;

- 5 residue trials complying with the northern outdoor GAP on plums;
- 8 residue trials complying with the indoor GAP on grapes;
- 6 residue trials (e.g. on tomatoes) complying with the southern GAP on tomatoes and aubergines (trials already planned by the notifier and expected for 2015);
- 6 additional trials complying with the southern outdoor GAP on peppers (trials already planned by the notifier and expected for 2015);
- 4 additional trials complying with the southern outdoor GAP on cucumbers and courgettes (trials already planned by the notifier and expected for 2015).

If the above reported data gaps are not addressed in the future, Member States are recommended to withdraw or modify the relevant authorisations at national level. EFSA recommends in any case that Member States granting authorisations for cyprodinil should consider the need to take the appropriate risk mitigation measures (e.g. definition of pre-plant intervals of at least 120d) in order to avoid the presence of cyprodinil metabolites residues in rotational crops.

Minor deficiencies were also identified in the assessment but these deficiencies are not expected to impact either on the validity of the MRLs derived or on the national authorisations. The following data are therefore considered desirable but not essential:

- 1 trial complying with the southern outdoor GAP on plums;
- 1 additional trial (e.g. on barley) complying with the southern GAP to support barley and oats grain and straw;
- 1 trial (e.g. on wheat) complying with the southern GAP to support wheat and rye grain and straw.

SUMMARY TABLE

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
Enforcement residue definition (existing and proposed): cyprodinil					
120010	Almonds	0.05*	0.02*	0.02*	Further consideration needed [a]
130010	Apples	1	0.05*	1.5	Recommended [b]
130020	Pears	1	0.05*	1.5	Recommended [b]
130030	Quinces	1	-	1.5	Recommended [c]
130040	Medlar	1	-	0.9	Recommended [c]
130050	Loquat	1	-	0.9	Recommended [c]
140010	Apricots	2	2	2	Recommended [d]
140020	Cherries	1	2	2	Recommended [d]
140030	Peaches	2	2	2	Recommended [d]
140040	Plums	2	2	2	Recommended [e]
151000	Table and wine grapes	5	3	3	Recommended [b]
152000	Strawberries	5	2	5	Recommended [b]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
153010	Blackberries	10	0.5	3	Recommended [b]
153030	Raspberries	10	0.5	3	Recommended [b]
154010	Blueberries	5	-	3	Recommended [c]
154020	Cranberries	2	-	3	Recommended [c]
154030	Currants	5	-	3	Recommended [c]
154040	Gooseberries	5	-	3	Recommended [c]
154050	Rose hips	2	-	3	Recommended [c]
154060	Mulberries	2	-	3	Recommended [c]
154070	Azarole	2	-	3	Recommended [c]
154080	Elderberries	2	-	3	Recommended [c]
213010	Beetroot	1	-	1.5	Recommended [c]
213020	Carrots	2	-	1.5	Recommended [c]
213030	Celeriac	0.3	-	0.3	Recommended [c]
213040	Horseradish	2	-	1.5	Recommended [c]
213060	Parsnips	2	-	1.5	Recommended [c]
213070	Parsley root	2	-	1.5	Recommended [c]
213080	Radishes	0.05*	-	0.08	Recommended [c]
213090	Salsify	2	-	1.5	Recommended [c]
220010	Garlic	0.3	-	0.07	Recommended [c]
220020	Onions	0.3	0.3	0.3	Recommended [e]
220030	Shallots	0.3	-	0.07	Recommended [c]
220040	Spring onions	1	-	0.8	Recommended [c]
231010	Tomatoes	1	0.5	1.5	Recommended [b]
231020	Peppers	1	0.5	1.5	Recommended [b]
231030	Aubergines	1	0.2	1.5	Recommended [b]
232000	Cucurbits – edible peel	0.5	0.2	0.5	Recommended [b]
233000	Cucurbits – inedible peel	0.05*	-	0.6	Recommended [c]
251000	Lettuce and other salad plants including *Brassicacea*	15	10	15	Recommended [b]
252000	Spinach and similar	15	-	15	Recommended [c]
255000	Witloof	0.05*	-	0.06	Recommended [c]
256000	Herbs	15	-	15	Recommended [c]
260010	Beans (with pods)	2	0.5	2	Recommended [b]
260020	Beans (without pods)	0.5	-	0.08	Recommended [c]
260030	Peas (with pods)	2	-	2	Recommended [c]
260040	Peas (without pods)	0.1	-	0.08	Recommended [c]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
270010	Asparagus	0.05*	-	0.02*	Recommended [c]
270040	Fennel	0.2	-	0.3	Recommended [c]
300010	Beans (dry)	0.2	-	0.2	Recommended [c]
300030	Peas (dry)	0.2	-	0.1	Recommended [c]
300040	Lupins (dry)	0.2	-	0.1	Recommended [c]
500010	Barley grain	3	3	4	Recommended [b]
500050	Oats grain	2	-	4	Recommended [c]
500070	Rye grain	0.5	-	0.5	Recommended [c]
500090	Wheat grain	0.5	0.5	0.5	Recommended [b]
633000	Herbal infusions (roots)	1	-	1.5	Further consideration needed [f]
840000	Spices (roots and rhizomes)	1	-	1.5	Further consideration needed [f]
	Other products of plant origin	See App C	-	-	Further consideration needed [g]
Enforcement residue definition (existing): sum of cyprodinil and CGA 304075 **Enforcement residue definition (proposed):** sum of cyprodinil and CGA 304075 (free) expressed as cyprodinil					
1011010	Swine meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1011020	Swine fat (free of lean meat)	0.05*	0.01*	0.02*	Further consideration needed [h]
1011030	Swine liver	0.05*	0.01*	0.02*	Further consideration needed [h]
1011040	Swine kidney	0.05*	0.01*	0.02*	Further consideration needed [h]
1012010	Bovine meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1012020	Bovine fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1012030	Bovine liver	0.05*	0.01*	0.05	Further consideration needed [h]
1012040	Bovine kidney	0.05*	0.01*	0.05	Further consideration needed [h]
1013010	Sheep meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1013020	Sheep fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1013030	Sheep liver	0.05*	0.01*	0.05	Further consideration needed [h]
1013040	Sheep kidney	0.05*	0.01*	0.05	Further consideration needed [h]
1014010	Goat meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1014020	Goat fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1014030	Goat liver	0.05*	0.01*	0.05	Further consideration needed [h]
1014040	Goat kidney	0.05*	0.01*	0.05	Further consideration needed [h]
1016010	Poultry meat	0.05*	0.01*	0.02*	Further consideration needed [h]
1016020	Poultry fat	0.05*	0.01*	0.02*	Further consideration needed [h]
1016030	Poultry liver	0.05*	0.01*	0.02*	Further consideration needed [h]
1030000	Birds' eggs	0.05*	0.01*	0.02*	Further consideration needed [h]

Code number	Commodity	Existing EU MRL (mg/kg)	Existing CXL (mg/kg)	Outcome of the review	
				MRL (mg/kg)	Comment
	Other products of animal origin, except milk products below	See App C	-	-	Further consideration needed (g)
Enforcement residue definition (existing): sum of cyprodinil and CGA 304075 **Enforcement residue definition (proposed):** sum of cyprodinil and CGA 304075 (free and conjugated) expressed as cyprodinil					
1020010	Cattle milk	0.05*	0.004*	0.02*	Further consideration needed (h)
1020020	Sheep milk	0.05*	0.004*	0.02*	Further consideration needed (h)
1020030	Goat milk	0.05*	0.004*	0.02*	Further consideration needed (h)

(*): Indicates that the MRL is set at the limit of analytical quantification.
(a): MRL is derived from the existing CXL, which is not sufficiently supported by data but for which no risk to consumers is identified; there are no relevant authorisations or import tolerances reported at EU level (combination A-V in Appendix D).
(b): 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; existing CXL is covered by the recommended MRL (combination G-III in Appendix D).
(c): 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).
(d): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is not fully supported by data, leads to a lower tentative MRL (combination E-VII in Appendix D).
(e): MRL is derived from the existing CXL, which is supported by data and for which no risk to consumers is identified; GAP evaluated at EU level, which is also fully supported by data, leads to a lower MRL (combination G-VII in Appendix D).
(f): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; no CXL is available (combination E-I in Appendix D).
(g): There are no relevant authorisations or import tolerances reported at EU level; no CXL is available. Either a specific LOQ or the default MRL of 0.01 mg/kg may be considered (combination A-I in Appendix D).
(h): Tentative MRL is derived from a GAP evaluated at EU level, which is not fully supported by data but for which no risk to consumers was identified; CXL is not compatible with EU residue definitions (combination E-II in Appendix D).

DOCUMENTATION PROVIDED TO EFSA

1. Pesticide Residues Overview File (PROFile) on cyprodinil prepared by the rapporteur Member State France in the framework of Article 12 of Regulation (EC) No 396/2005. Submitted to EFSA on 17 August 2009. Last updated on 23 November 2012.

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APPENDIX A – GOOD AGRICULTURAL PRACTICES (GAPS)

Critical Outdoor GAPs for Northern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	NEU	Outdoor	NL	Botryotinia fuckeliana	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	2	3	10	14	0.06	0.45	kg a.i./ha	3	NL GAP submitted at MSC stage. Rate is 0.03 kg as/hL.
Pears	*Pyrus communis*	NEU	Outdoor	NL	Stemphylium vesicarium	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	2	3	10	14	0.06	0.45	kg a.i./ha	3	NL GAP submitted at MSC stage. Rate is 0.03 kg as/hL.
Quinces	*Cydonia oblonga*	NEU	Outdoor	FR, UK	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.30	kg a.i./ha	3	Data origin : applicant. Extrapolation from apples and pears.
Medlar	*Mespilus germanica*	NEU	Outdoor	FR, UK	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.30	kg a.i./ha	3	Extrapolation from apples and pears.
Loquat	*Eriobotrya japonica*	NEU	Outdoor	FR, UK	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.30	kg a.i./ha	3	Extrapolation from apples and pears.
Apricots	*Prunus armeniaca*	NEU	Outdoor	DE	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	81	n.a.	2	12	14	n.a.	0.34	kg a.i./ha	14	Application rate is 0.113 kg a.i./ha and per m crown height (for standard tree of 3 m height equivalent to 0.34 kg a.i./ha).
Cherries	*Prunus cerasus, Prunus avium*	NEU	Outdoor	BE	n.a.	WG	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.38	kg a.i./ha	4	BE GAP submitted at MSC stage. NL GAP also submitted GAP at MSC stage (3 × 0.45 kg a.i./ha, 7 day PHI) - considered less critical than the BE GAP on the basis of residue trials data.
Peaches	*Prunus persica*	NEU	Outdoor	DE	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	81	n.a.	2	12	14	n.a.	0.34	kg a.i./ha	14	Application rate is 0.113 kg a.i./ha and per m crown height (for standard tree of 3 m height equivalent to 0.34 kg a.i./ha).
Plums	*Prunus domestica*	NEU	Outdoor	NL	Botryotinia fuckeliana	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	10	14	n.a.	0.45	kg a.i./ha	7	NL GAP submitted at MSC stage.
Table grapes	*Vitis euvitis*	NEU	Outdoor	FR	n.a.	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.45	kg a.i./ha	21	
Wine grapes	*Vitis euvitis*	NEU	Outdoor	FR	n.a.	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.45	kg a.i./ha	21	
Strawberries	*Fragaria x ananassa*	NEU	Outdoor	NL	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	7	14	n.a.	0.38	kg a.i./ha	1	FR outdoor NEU GAP submitted at MSC stage is same as outdoor SEU. NL GAP is slightly more critical with 3 applications. "Application rate" : the value is rounded to 2 numbers after the comma.
Blackberries	*Rubus fruticosus*	NEU	Outdoor	BE	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	7	n.a.	0.75	kg a.i./ha	7	"Application rate": the value is rounded to 2 numbers after the comma.
Raspberries	*Rubus idaeus*	NEU	Outdoor	BE	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	7	n.a.	0.75	kg a.i./ha	7	"Application rate": the value is rounded to 2 numbers after the comma.
Blueberries	*Vaccinium corymbosum*	NEU	Outdoor	DE, FR, IE	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	51	89	n.a.	3	n.a.	10	n.a.	0.38	kg a.i./ha	7	"Application rate" : the value is rounded to 2 numbers after the comma.
Cranberries	*Vaccinium macrocarpon*	NEU	Outdoor	DE, IE	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	10	n.a.	0.38	kg a.i./ha	7	IE : data applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Currants (red, black and white)	*Ribes nigrum, rubrum*	NEU	Outdoor	DE, FR, IE	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	51	89	n.a.	3	n.a.	10	n.a.	0.38	kg a.i./ha	7	"Application rate": the value is rounded to 2 numbers after the comma.
Gooseberries	*Ribes uva-crispa*	NEU	Outdoor	DE, FR, IE	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	51	89	n.a.	3	n.a.	10	n.a.	0.38	kg a.i./ha	7	"Application rate" : the value is rounded to 2 numbers after the comma.
Rose hips	*Rosa canina*	NEU	Outdoor	DE	n.a.	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.38	kg a.i./ha	7	Mentioned use: "Other small fruits and berries". "Application rate" : the value is rounded to 2 numbers after the comma.

Mulberries	*Morus spp;*	NEU	Outdoor	DE	n.a.	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.38	kg a.i./ha	7	Mentioned use : "Other small fruits and berries". "Application rate": the value is rounded to 2 numbers after the comma.
Azarole (mediteranean medlar)	*Crataegus azarolus*	NEU	Outdoor	DE	n.a.	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.38	kg a.i./ha	7	Mentioned use : "Other small fruits and berries". "Application rate" : the value is rounded to 2 numbers after the comma.
Elderberries	*Sambucus nigra*	NEU	Outdoor	DE	n.a.	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.38	kg a.i./ha	7	Mentioned use : "Other small fruits and berries". "Application rate" : the value is rounded to 2 numbers after the comma.
Beetroot	*Beta vulgaris subsp. Vulgaris*	NEU	Outdoor	UK	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.		3				0.30	kg a.i./ha	7	EFSA Scientific report (2009)240
Carrots	*Daucus carota*	NEU	Outdoor	UK	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	2	12	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Celeriac	*Apium graveolens var. rapaceum*	NEU	Outdoor		Fungus	WG			Foliar treatment - ultra low volume spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.38	kg a.i./ha	14	EFSA Scientific report (2009) 325
Horseradish	*Armoracia rusticana*	NEU	Outdoor	UK	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	3	12	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Parsnips	*Pastinaca sativa*	NEU	Outdoor	UK	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	3	12	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Parsley root	*Petroselinum crispum*	NEU	Outdoor	UK	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	3	12	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Salsify	*Tragopogon porrifolius*	NEU	Outdoor	UK	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	3	12	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Garlic	*Allium sativum*	NEU	Outdoor	DE	Botrytis squamosa	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	10	14	n.a.	0.38	kg a.i./ha	14	Mentioned use : bulb vegetables (fresh).
Onions	*Allium cepa*	NEU	Outdoor	AT, FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	20	47	n.a.	3	n.a.	14	n.a.	0.38	kg a.i./ha	14	AT GAP: interval is 21 days, GS at application not stated. "Application rate": the value is rounded to 2 numbers after the comma.
Shallots	*Allium ascalonicum (Allium cepa var. aggregatum)*	NEU	Outdoor	DE	Botrytis squamosa, Botrytis allii	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	10	14	n.a.	0.38	kg a.i./ha	14	Mentioned use : "Bulb vegetables (fresh)".
Spring onions	*Allium cepa*	NEU	Outdoor	DE, FR	Botrytis squamosa	WG	375.0	g/kg	Foliar treatment - spraying	20	47	n.a.	3	10	14	n.a.	0.38	kg a.i./ha	14	DE GAP: GS at application not stated. "Application rate" : the value is rounded to 2 numbers after the comma.
Lamb's lettuce	*Valerianella locusta*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Lettuce	*Lactuca sativa*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1). NL has a similar GAP: 3 × 0.225 kg as/ha, 7 day PHI.
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1). NL has a similar GAP: 3 × 0.225 kg as/ha, 7 day PHI.
Cress	*Lepidium sativum*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Land cress	*Barbarea verna*	NEU	Outdoor	IE	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.26	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	NEU	Outdoor	IE	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Red mustard	*Brassica juncea var. rugosa*	NEU	Outdoor	SE	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Leaves and sprouts of Brassica spp	*Brassica spp*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Spinach	*Spinacia oleracea*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Purslane	*Portulaca oleracea*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	GAP submitted by UK during MSC. Extrapolation from lettuce.
Beet leaves (chard)	*Beta vulgaris*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Chervil	*Anthriscus cerefolium*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Chives	*Allium schoenoprasum*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Celery leaves	*Apium graveolens var. seccalinum*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Parsley	*Petroselinum crispum*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Sage	*Salvia officinalis*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Rosemary	*Rosmarinus officinalis*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Thyme	*Thymus spp.*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Basil	*Ocimum basilicum*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Bay leaves (laurel)	*Laurus nobilis*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240

Tarragon	*Artemisia dracunculus*	NEU	Outdoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Beans (with pods)	*Phaseolus vulgaris,*	NEU	Outdoor	AT, DE, FR, SE, UK	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	51	79	n.a.	2	10	14	n.a.	0.38	kg a.i./ha	14	SE : BBCH 51-79, 10-14 d. between applications. DE : BBCH 60. AT : 10 d. between applications. FR, DE : product = Switch (WG, 375 g/kg). "Application rate" : the value is rounded to 2 numbers after the comma.
Beans (without pods)	*Phaseolus vulgaris*	NEU	Outdoor	AT, DE, FR, SE	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	51	79	n.a.	2	10	14	n.a.	0.38	kg a.i./ha	14	SE : BBCH 51-79, 10-14 d. between applications. AT : 10 d. between applications. DE : product = Switch (WG, 375 g/kg). "Application rate" : the value is rounded to 2 numbers after the comma.
Peas (with pods)	*Pisum sativum*	NEU	Outdoor	DE, FR, IE, UK	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.38	kg a.i./ha	14	FR : product = Switch (WG, 375 g/kg). "Application rate" : the value is rounded to 2 numbers after the comma.
Peas (without pods)	*Pisum sativum*	NEU	Outdoor	DE, FR, IE, UK	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.38	kg a.i./ha	14	FR, DE : product = Switch (WG, 375 g/kg). "Application rate" : the value is rounded to 2 numbers after the comma.
Asparagus	*Asparagus officinalis*	NEU	Outdoor	AT, BE, DE, FR, IE	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	10	14	n.a.	0.38	kg a.i./ha	n.a.	PHI : "long (minimum 6 months)" (data applicant). BE, IE : data origin = applicant. AT : 14-21 d. between applications. DE : 10-14 d. between applications, product = Switch (WG, 375 g/kg).
Beans (dry)	*Phaseolus vulgaris*	NEU	Outdoor	IE, UK	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.38	kg a.i./ha	28	Data origin: applicant. "Application rate": the value is rounded to 2 numbers after the comma. BE submitted a more critical GAP during the MSC (1-2 x 375g a.s./ha, BBCH 60-69, 14 day PHI): not supported by data so not conisdered further.
Peas (dry)	*Pisum sativum*	NEU	Outdoor	FR, IE, UK	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.38	kg a.i./ha	28	Data origin: applicant. "Application rate": the value is rounded to 2 numbers after the comma. BE submitted a more critical GAP during the MSC (1-2 x 375g a.s./ha, BBCH 60-69, 14 day PHI): not supported by data so not conisdered further.
Lupins	*Lupinus spp.*	NEU	Outdoor	DE	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	61	79	n.a.	2	14	28	n.a.	0.38	kg a.i./ha	28	"Application rate": the value is rounded to 2 numbers after the comma.
Barley	*Hordeum spp.*	NEU	Outdoor	FR	Erysiphe graminis, Peronospora spp. Pseudocercosporella herpotrichoides, Rhynchosporium secalis	WG	750.0	g/kg	Foliar treatment - spraying	30	65	n.a.	2	n.a.	21	n.a.	0.75	kg a.i./ha	42	Same cGAP for the use "barley straw" (livestock feed). DE has similar GAP but with latest time of application GS 55 (or 49 days). A seed treatment exists too (FR, 1 applic., 5 g/q.).
Oats	*Avena fatua*	NEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	55	n.a.	2	n.a.	n.a.	n.a.	0.60	kg a.i./ha	42	The PHI is not 42 d. but 45d. Same cGAP for the use "oats straw" (fodder for the livestock).
Rye	*Secale cereale*	NEU	Outdoor	FR	Erysiphe graminis, Peronospora spp. Pseudocercosporella herpotrichoides, Rhynchosporium secalis	WG	750.0	g/kg	Foliar treatment - spraying	30	32	n.a.	1	n.a.	n.a.	n.a.	0.75	kg a.i./ha	42	Same cGAP for the use "rye straw" (livestock feed). DE has similar GAP but with application rate of 0.6 kg as/ha and latest time of application GS 61 (or 49 days).
Wheat	*Triticum aestivum*	NEU	Outdoor	FR	Erysiphe graminis, Peronospora spp. Pseudocercosporella herpotrichoides, Rhynchosporium secalis	WG	750.0	g/kg	Foliar treatment - spraying	30	65	n.a.	2	n.a.	21	n.a.	0.75	kg a.i./ha	42	Same cGAP for the use "wheat straw" (livestock feed). DE has similar GAP but with latest time of application GS 61 (or 49 days).
Herbal infusions (roots)	*Not specified*	NEU	Outdoor	UK	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.		3				0.30	kg a.i./ha	7	EFSA Scientific report (2009)240
Spices (roots and rhizome)	*Not specified*	NEU	Outdoor	UK	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.		3				0.30	kg a.i./ha	7	EFSA Scientific report (2009)240

n.a.: not applicable

Critical Outdoor GAPs for Southern Europe																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Apples	*Malus domesticus*	SEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	81	89	1	3	6	10	n.a.	0.30	kg a.i./ha	3	FR's GAP submitted at MSC stage.
Pears	*Pyrus communis*	SEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	81	89	1	3	6	10	n.a.	0.30	kg a.i./ha	3	FR's GAP submitted at MSC stage.
Quinces	*Cydonia oblonga*	SEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	81	89	1	3	6	10	n.a.	0.30	kg a.i./ha	3	FR's GAP submitted at MSC stage.
Apricots	*Prunus armeniaca*	SEU	Outdoor	ES, IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	61	87	n.a.	2	7	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin = applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Cherries	*Prunus cerasus, Prunus avium*	SEU	Outdoor	ES	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant.
Peaches	*Prunus persica*	SEU	Outdoor	ES, IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	61	87	n.a.	2	7	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Plums	*Prunus domestica*	SEU	Outdoor	EL	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.25	kg a.i./ha	7	Data origin : applicant.
Table grapes	*Vitis euvitis*	SEU	Outdoor	PT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	68	88	n.a.	2	21	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Wine grapes	*Vitis euvitis*	SEU	Outdoor	FR	n.a.	WG	37.5	% (w/w)	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.45	kg a.i./ha	21	
Strawberries	*Fragaria x ananassa*	SEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	55	89	n.a.	2	n.a.	10	n.a.	0.38	kg a.i./ha	1	FR GAP submitted at MSC stage. "Application rate" : the value is rounded to 2 numbers after the comma.
Carrots	*Daucus carota*	SEU	Outdoor	FR	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	2	12	n.a.	n.a.	0.30	kg a.i./ha	7	
Salsify	*Tragopogon porrifolius*	SEU	Outdoor	FR	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	2	12	n.a.	n.a.	0.30	kg a.i./ha	7	
Onions	*Allium cepa*	SEU	Outdoor	IT	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	19	47	n.a.	3	14	n.a.	n.a.	0.38	kg a.i./ha	7	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Spring onions	*Allium cepa*	SEU	Outdoor	FR	Botrytis squamosa	WG	375.0	g/kg	Foliar treatment - spraying	20	47	n.a.	3	n.a.	14	n.a.	0.38	kg a.i./ha	14	"Application rate" : the value is rounded to 2 numbers after the comma.
Tomatoes	*Lycopersicum esculentum*	SEU	Outdoor	ES, FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	67	89	n.a.	3	7	14	n.a.	0.38	kg a.i./ha	3	ES GAP: interval and GS at application not stated. Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Peppers	*Capsicum annuum, var grossum and var. longum*	SEU	Outdoor	ES	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.38	kg a.i./ha	7	FR submitted more cGAP during MSC (3 × 0.375 kg as/ha, 3 day PHI): not supported by data so not considered further. Data origin: applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Aubergines (egg plants)	*Solanum melongena*	SEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	67	89	n.a.	3	7	14	n.a.	0.38	kg a.i./ha	3	"Application rate" : the value is rounded to 2 numbers after the comma.
Cucumbers	*Cucumis sativus*	SEU	Outdoor	ES, FR, PT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	71	79	n.a.	3	7	10	n.a.	0.38	kg a.i./ha	3	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Gherkins	*Cucumis sativus*	SEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	71	79	n.a.	3	7	10	n.a.	0.38	kg a.i./ha	3	FR GAP submitted at MSC stage.
Courgettes	*Cucurbita pepo var. melopepo*	SEU	Outdoor	ES, FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	71	79	n.a.	3	7	10	n.a.	0.38	kg a.i./ha	3	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Lamb's lettuce	*Valerianella locusta*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentionned use : "lettuce group". Extrapolation from lettuce. FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.
Lettuce	*Lactuca sativa*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentioned use : "lettuce group". FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.
Scarole (broad-leaf endive)	*Cichorium endiva*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentioned use : "lettuce group". Extrapolation from lettuce. FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.

Cress	*Lepidium sativum*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentioned use : "lettuce group". Extrapolation from lettuce. FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.
Land cress	*Barbarea verna*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentioned use : "lettuce group". Extrapolation from lettuce. FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentioned use : "lettuce group". Extrapolation from lettuce. FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.
Red mustard	*Brassica juncea var. rugosa*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentioned use : "lettuce group". Extrapolation from lettuce. FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.
Leaves and sprouts of Brassica spp	*Brassica spp*	SEU	Outdoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Mentioned use : "lettuce group". Extrapolation from lettuce. FR has a similar GAP: 3 × 0.225 kg as/ha, 14 day PHI.
Spinach	*Spinacia oleracea*	SEU	Outdoor			WG	37.5	% (w/w)	Foliar treatment - spraying				2				0.23	kg a.i./ha	14	EFSA Scientific report (2009)245
Beans (with pods)	*Phaseolus vulgaris,*	SEU	Outdoor	FR, PT	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	51	79	n.a.	2	10	14	n.a.	0.38	kg a.i./ha	14	PT: data origin = applicant. FR : product = Switch (WG, 375 g/kg). "Application rate" : the value is rounded to 2 numbers after the comma.
Peas (with pods)	*Pisum sativum*	SEU	Outdoor	FR	Fungus	WG	37.5	% (w/w)	Foliar treatment - spraying	51	79	n.a.	2	10	14	n.a.	0.38	kg a.i./ha	14	"Application rate" : the value is rounded to 2 numbers after the comma.
Asparagus	*Asparagus officinalis*	SEU	Outdoor	FR	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	61	89	n.a.	3	10	21	n.a.	0.38	kg a.i./ha	n.a.	PHI: "long (minimum 6 months)", although also given as GS 61-89. FR also have this GAP in NEU. "Application rate" : the value is rounded to 2 numbers after the comma.
Fennel	*Foeniculum vulgare*	SEU	Outdoor	FR, IT	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	14	49	n.a.	2	10	n.a.	n.a.	0.30	kg a.i./ha	7	Data origin : applicant.
Beans (dry)	*Phaseolus vulgaris*	SEU	Outdoor	ES	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.38	kg a.i./ha	28	Data origin: applicant. "Application rate" : the value is rounded to 2 numbers after the comma.
Barley	*Hordeum spp.*	SEU	Outdoor	FR	Erysiphe graminis, Peronospora spp. Pseudocercosporella herpotrichoides, Rhynchosporium secalis	WG	750.0	g/kg	Foliar treatment - spraying	30	65	n.a.	2	n.a.	21	n.a.	0.75	kg a.i./ha	42	Same cGAP for the use "barley straw" (fodder for the livestock). A seed treatment exists too (FR, 1 applic., 5 g/q.).
Oats	*Avena fatua*	SEU	Outdoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	n.a.	n.a.	n.a.	0.60	kg a.i./ha	42	The PHI is not 42 d. but 45 d. Same cGAP for the use "oats straw" (fodder for the livestock).
Rye	*Secale cereale*	SEU	Outdoor	FR	Erysiphe graminis, Peronospora spp. Pseudocercosporella herpotrichoides, Rhynchosporium secalis	WG	750.0	g/kg	Foliar treatment - spraying	30	32	n.a.	1	n.a.	n.a.	n.a.	0.75	kg a.i./ha	42	Same cGAP for the use "rye straw" (livestock feed).
Wheat	*Triticum aestivum*	SEU	Outdoor	FR	Erysiphe graminis, Peronospora spp. Pseudocercosporella herpotrichoides, Rhynchosporium secalis	WG	750.0	g/kg	Foliar treatment - spraying	30	65	n.a.	1	n.a.	n.a.	n.a.	0.75	kg a.i./ha	42	Mentioned use: "wheat, triticale". Same cGAP for the use "wheat straw" (livestock feed).

n.a.: not applicable

Critical Indoor GAPs for Northern and Southern Europe (incl. post-harvest treatments)																				
Crop		Region	Outdoor/ Indoor	Member state or Country	Pests controlled	Formulation			Application							Application rate			PHI or wiaiting period (days)	Comments (max. 250 charachters)
Common name	Scientific name					Type	Content		Method	Growth stage		Number		Interval (days)		Min. rate	Max. rate	Rate Unit		
							Conc.	Unit		From BBCH	Until BBCH	Min.	Max.	Min.	Max.					
Table grapes	*Vitis euvitis*	NEU/SEU	Indoor	NL	Botryotinia fuckeliana	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	0.06	0.36	kg a.i./ha	21	NL GAP submitted during MSC stage.
Wine grapes	*Vitis euvitis*	NEU/SEU	Indoor	NL	Botryotinia fuckeliana	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	0.06	0.36	kg a.i./ha	21	NL GAP submitted during MSC stage.
Strawberries	*Fragaria x ananassa*	NEU/SEU	Indoor	NL	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	7	14	n.a.	0.38	kg a.i./ha	1	FR indoor GAP submitted at MSC stage is same as outdoor NEU and SEU GAPs. NL GAP is slightly more critical with 3 applications. "Application rate" : the value is rounded to 2 numbers after the comma.
Blackberries	*Rubus fruticosus*	NEU/SEU	Indoor	FR	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	61	89	n.a.	3	n.a.	10	n.a.	0.38	kg a.i./ha	7	DE has slightly less critical GAP (10 day PHI). "Application rate" : the value is rounded to 2 numbers after the comma.
Raspberries	*Rubus idaeus*	NEU/SEU	Indoor	FR	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	61	89	n.a.	3	n.a.	10	n.a.	0.38	kg a.i./ha	7	DE has slightly less critical GAP (10 day PHI). "Application rate" : the value is rounded to 2 numbers after the comma.
Radishes	*Raphanus sativus var. saitvus*	NEU/SEU	Indoor	NL	Fungi	SC	37.5	% (v/v)	Foliar treatment - spraying	11	49	1	2	n.a.	14	n.a.	0.23	kg a.i./ha	14	EFSA Journal 2013;11(4):3184
Tomatoes	*Lycopersicum esculentum*	NEU/SEU	Indoor	DE, FR	Botrytis cinerea	WG	375.0	g/kg	Foliar treatment - spraying	67	89	n.a.	3	7	14	n.a.	0.38	kg a.i./ha	3	DE GAP: interval and GS at application not stated. "Application rate": the value is rounded to 2 numbers after the comma. NL submitted more cGAP during MSC (3 × 0.9 kg as/ha, 3 day PHI): not supported by data so not considered further.
Peppers	*Capsicum annuum, var grossum and var. longum*	NEU/SEU	Indoor	FR, PT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.38	kg a.i./ha	3	"Application rate" : the value is rounded to 2 numbers after the comma.
Aubergines (egg plants)	*Solanum melongena*	NEU/SEU	Indoor	FR, PT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	67	89	n.a.	3	7	14	n.a.	0.38	kg a.i./ha	3	"Application rate" : the value is rounded to 2 numbers after the comma.
Cucumbers	*Cucumis sativus*	NEU/SEU	Indoor	FR, PT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	71	79	n.a.	3	7	10	n.a.	0.38	kg a.i./ha	3	"Application rate" : the value is rounded to 2 numbers after the comma.
Gherkins	*Cucumis sativus*	NEU/SEU	Indoor	DE, FR	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	61	n.a.	3	5	14	n.a.	0.30	kg a.i./ha	3	DE GAP is given here, FR GAP is slightly different - see gherkins for details.
Courgettes	*Cucurbita pepo var. melopepo*	NEU/SEU	Indoor	FR	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	71	79	n.a.	3	7	10	n.a.	0.38	kg a.i./ha	3	FR GAP submitted at MSC stage.
Melons	*Cucumis melo*	NEU/SEU	Indoor	NL	Fungi	WG	37.5	% (v/v)	Foliar treatment - spraying	11	89	n.a.	2	n.a.	7	n.a.	0.38	kg a.i./ha	3	EFSA Journal 2013;11(4):3184
Pumpkins	*Cucurbita maxima*	NEU/SEU	Indoor	NL	Fungi	WG	37.5	% (v/v)	Foliar treatment - spraying	11	89	n.a.	2	n.a.	7	n.a.	0.38	kg a.i./ha	3	EFSA Journal 2013;11(4):3184
Watermelons	*Citrullus lanatus*	NEU/SEU	Indoor	NL	Fungi	WG	37.5	% (v/v)	Foliar treatment - spraying	11	89	n.a.	2	n.a.	7	n.a.	0.38	kg a.i./ha	3	EFSA Journal 2013;11(4):3184
Lamb's lettuce	*Valerianella locusta*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Lettuce	*Lactuca sativa*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	EFSA Journal 2012; 10(1). NL has a similar GAP: 3 × 0.225 kg as/ha, 7 day PHI.
Scarole (broad-leaf endive)	*Cichorium endiva*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Cress	*Lepidium sativum*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	EFSA Journal 2012; 10(1). NL has a similar GAP: 3 × 0.225 kg as/ha, 7 day PHI.
Land cress	*Barbarea verna*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	
Rocket, Rucola	*Eruca sativa (Diplotaxis spec.)*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	
Red mustard	*Brassica juncea var. rugosa*	NEU/SEU	Indoor	IT	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.26	kg a.i./ha	14	Data origin : applicant. Mentioned use : "lettuce group". Extrapolation from Lettuce.
Leaves and sprouts of Brassica spp	*Brassica spp*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	EFSA Journal 2012; 10(1)

Spinach	*Spinacia oleracea*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Purslane	*Portulaca oleracea*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	GAP submitted by UK during MSC. Extrapolation from lettuce.
Beet leaves (chard)	*Beta vulgaris*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.23	kg a.i./ha	7	EFSA Journal 2012; 10(1)
Witloof	*Cichorium intybus. var. Foliosum*	NEU/SEU	Indoor	FR	n.a.	n.a.	n.a.	n.a.	Local treatment - general (see also comment field)	n.a.	n.a.	n.a.	1	n.a.	n.a.	n.a.	0.03	kg a.i./hL	21	"Application rate" : the value is rounded to 2 numbers after the comma. "Method": root soaking or root shower before conservation or forcing. FR confirmed GAP is authorised and submitted data during MSC.
Chervil	*Anthriscus cerefolium*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Chives	*Allium schoenoprasum*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Celery leaves	*Apium graveolens var. seccalinum*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Parsley	*Petroselinum crispum*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Sage	*Salvia officinalis*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Rosemary	*Rosmarinus officinalis*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Thyme	*Thymus spp.*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Basil	*Ocimum basilicum*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Bay leaves (laurel)	*Laurus nobilis*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Tarragon	*Artemisia dracunculus*	NEU/SEU	Indoor	UK	Fungus	WG	375.0	g/kg	Foliar treatment - spraying	n.a.	n.a.	n.a.	2	10	14	n.a.	0.30	kg a.i./ha	7	EFSA Scientific report (2009); 240
Beans (with pods)	*Phaseolus vulgaris,*	NEU/SEU	Indoor	ES	n.a.	n.a.	n.a.	n.a.	Foliar treatment - spraying	n.a.	n.a.	n.a.	3	n.a.	n.a.	n.a.	0.30	kg a.i./ha	3	Data origin : applicant.
Peas (with pods)	*Pisum sativum*	NEU/SEU	Indoor	PT	n.a.	WG	375.0	g/kg	Foliar treatment - spraying	61	79	n.a.	2	10	14	n.a.	0.38	kg a.i./ha	3	Data origin : applicant. "Application rate" : the value is rounded to 2 numbers after the comma.

n.a.: not applicable

APPENDIX B – PESTICIDE RESIDUES INTAKE MODEL (PRIMO)

Appendix B.1 – EU scenario including all EU MRL proposals resulting from the GAPs reported by the RMS

Appendix B.2 – EU/Codex scenario including demonstrated safe EU MRL proposals and all CXLs

APPENDIX B.1 – EU SCENARIO INCLUDING ALL EU MRL PROPOSALS RESULTING FROM THE GAPS REPORTED BY THE RMS

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

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
5	37
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)
37.1	DE child	19.7	Apples	2.9	Table grapes	2.1	Spinach	
29.2	NL child	10.3	Apples	3.8	Spinach	2.1	Scarole (broad-leaf endive)	
24.6	WHO Cluster diet B	4.0	Wine grapes	3.7	Lettuce	3.7	Wheat	
23.3	FR toddler	7.3	Spinach	4.3	Apples	3.6	Carrots	
19.3	FR infant	4.6	Spinach	4.1	Apples	3.9	Carrots	
18.6	IE adult	3.1	Barley	2.8	Wine grapes	1.3	Apples	
16.0	DK child	3.8	Apples	2.4	Wheat	2.0	Carrots	
15.8	WHO cluster diet E	3.6	Wine grapes	2.0	Barley	1.7	Wheat	
15.2	FR all population	8.9	Wine grapes	1.4	Wheat	0.9	Lettuce	
14.7	ES adult	5.5	Lettuce	1.3	Apples	1.2	Barley	
13.9	ES child	4.3	Lettuce	1.9	Wheat	1.9	Apples	
13.4	WHO regional European diet	3.9	Lettuce	1.3	Wheat	1.1	Apples	
12.8	PT General population	5.6	Wine grapes	1.7	Apples	1.7	Wheat	
12.6	NL general	1.9	Apples	1.5	Spinach	1.4	Wine grapes	
12.2	WHO Cluster diet F	3.1	Lettuce	1.6	Wheat	1.5	Barley	
12.1	IT kids/toddler	3.0	Lettuce	2.9	Wheat	1.4	Apples	
11.9	IT adult	3.9	Lettuce	1.8	Wheat	1.3	Apples	
10.1	WHO cluster diet D	2.8	Wheat	1.1	Apples	0.8	Wine grapes	
9.4	SE general population 90th percentile	1.7	Apples	1.4	Wheat	1.3	Carrots	
9.0	UK Toddler	2.8	Apples	1.7	Wheat	0.8	Carrots	
8.6	UK Infant	2.6	Apples	2.0	Carrots	1.1	Wheat	
7.9	DK adult	3.1	Wine grapes	1.3	Apples	0.9	Wheat	
7.6	UK vegetarian	1.8	Wine grapes	1.5	Lettuce	1.0	Apples	
6.9	LT adult	3.0	Apples	0.7	Lettuce	0.5	Rye	
6.8	PL general population	3.3	Apples	0.7	Table grapes	0.5	Tomatoes	
6.7	UK Adult	2.4	Wine grapes	1.2	Lettuce	0.7	Wheat	
4.7	FI adult	0.8	Lettuce	0.7	Wine grapes	0.7	Apples	

Conclusion:

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

APPENDIX B.2 – EU/CODEX SCENARIO INCLUDING DEMONSTRATED SAFE EU MRL PROPOSALS AND ALL CXLS

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

Prepare workbook for refined calculations

Undo refined calculations

Chronic risk assessment - refined calculations

TMDI (range) in % of ADI minimum - maximum	
5	39
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)
38.6	DE child	19.7	Apples	2.9	Table grapes	2.1	Spinach	
30.0	NL child	10.3	Apples	3.8	Spinach	2.1	Scarole (broad-leaf endive)	
25.7	WHO Cluster diet B	4.0	Wine grapes	3.7	Lettuce	3.7	Wheat	
23.4	FR toddler	7.3	Spinach	4.3	Apples	3.6	Carrots	
20.1	IE adult	3.1	Barley	2.8	Wine grapes	1.3	Apples	
19.4	FR infant	4.6	Spinach	4.1	Apples	3.9	Carrots	
16.4	WHO cluster diet E	3.6	Wine grapes	2.0	Barley	1.7	Wheat	
16.3	DK child	3.8	Apples	2.4	Wheat	2.0	Carrots	
15.6	FR all population	8.9	Wine grapes	1.4	Wheat	0.9	Lettuce	
15.2	ES adult	5.5	Lettuce	1.3	Apples	1.2	Barley	
14.5	ES child	4.3	Lettuce	1.9	Wheat	1.9	Apples	
14.0	WHO regional European diet	3.9	Lettuce	1.3	Wheat	1.1	Apples	
13.4	PT General population	5.6	Wine grapes	1.7	Apples	1.7	Wheat	
13.0	IT kids/toddler	3.0	Lettuce	2.9	Wheat	1.4	Apples	
12.9	NL general	1.9	Apples	1.5	Spinach	1.4	Wine grapes	
12.8	IT adult	3.9	Lettuce	1.8	Wheat	1.3	Apples	
12.4	WHO Cluster diet F	3.1	Lettuce	1.6	Wheat	1.5	Barley	
10.7	WHO cluster diet D	2.8	Wheat	1.1	Apples	0.8	Wine grapes	
9.8	SE general population 90th percentile	1.7	Apples	1.4	Wheat	1.3	Carrots	
9.2	UK Toddler	2.8	Apples	1.7	Wheat	0.8	Carrots	
9.0	UK Infant	2.6	Apples	2.0	Carrots	1.1	Wheat	
8.1	DK adult	3.1	Wine grapes	1.3	Apples	0.9	Wheat	
7.8	UK vegetarian	1.8	Wine grapes	1.5	Lettuce	1.0	Apples	
7.4	PL general population	3.3	Apples	0.7	Table grapes	0.5	Tomatoes	
7.0	LT adult	3.0	Apples	0.7	Lettuce	0.5	Rye	
6.8	UK Adult	2.4	Wine grapes	1.2	Lettuce	0.7	Wheat	
4.8	FI adult	0.8	Lettuce	0.7	Wine grapes	0.7	Apples	

Conclusion:

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

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

Appendix C.1 – Existing EU MRLs

Appendix C.2 – Existing CXLs

APPENDIX C.1 – EXISTING EU MRLS

(Pesticides - Web Version - EU MRLs - File created on (File created on 16/10/2012 13:55)

Code number	Groups and examples of individual products to which the MRLs apply	Cyprodinil [(a)]
100000	1. FRUIT FRESH OR FROZEN; NUTS	
110000	(i) Citrus fruit	0.05*
110010	Grapefruit (Shaddocks, pomelos, sweeties, tangelo (except mineola), ugli and other hybrids)	0.05*
110020	Oranges (Bergamot, bitter orange, chinotto and other hybrids)	0.05*
110030	Lemons (Citron, lemon)	0.05*
110040	Limes	0.05*
110050	Mandarins (Clementine, tangerine, mineola and other hybrids)	0.05*
110990	Others	0.05*
120000	(ii) Tree nuts (shelled or unshelled)	0.05*
120010	Almonds	0.05*
120020	Brazil nuts	0.05*
120030	Cashew nuts	0.05*
120040	Chestnuts	0.05*
120050	Coconuts	0.05*
120060	Hazelnuts (Filbert)	0.05*
120070	Macadamia	0.05*
120080	Pecans	0.05*
120090	Pine nuts	0.05*
120100	Pistachios	0.05*
120110	Walnuts	0.05*
120990	Others	0.05*
130000	(iii) Pome fruit	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
140040	Plums (Damson, greengage, Mirabelle, sloe)	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 cloudberries)	0.05*
153030	Raspberries (Wineberries , arctic bramble/raspberry, (Rubus arcticus), nectar raspberries (Rubus arcticus x idaeus))	10
153990	Others	0.05*
154000	(d) Other small fruit & berries	
154010	Blueberries (Bilberries)	5
154020	Cranberries (Cowberries (red bilberries))	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*
161040	Kumquats (Marumi kumquats, nagami kumquats, limequats (*Citrus aurantifolia x Fortunella spp.*))	0.05*
161050	Carambola (Bilimbi)	0.05*
161060	Persimmon	0.05*
161070	Jambolan (java plum) (Java apple (water apple), pomerac, rose apple, Brazilean cherry (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), mangosteen)	0.05*
162030	Passion fruit	0.05*
162040	Prickly pear (cactus fruit)	0.05*
162050	Star apple	0.05*
162060	American persimmon (Virginia kaki) (Black sapote, white sapote, green sapote, canistel (yellow sapote), and mammey sapote)	0.05*
162990	Others	0.05*
163000	(c) Inedible peel, large	0.05*
163010	Avocados	0.05*
163020	Bananas (Dwarf banana, plantain, apple banana)	0.05*
163030	Mangoes	0.05*
163040	Papaya	0.05*
163050	Pomegranate	0.05*
163060	Cherimoya (Custard apple, sugar apple (sweetsop) , llama and other medium sized Annonaceae)	0.05*
163070	Guava (Red pitaya or dragon fruit (*Hylocereus undatus*)	0.05*
163080	Pineapples	0.05*
163090	Bread fruit (Jackfruit)	0.05*
163100	Durian	0.05*
163110	Soursop (guanabana)	0.05*
163990	Others	0.05*
200000	2. VEGETABLES FRESH OR FROZEN	
210000	(i) Root and tuber vegetables	
211000	(a) Potatoes	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	
213010	Beetroot	1
213020	Carrots	2
213030	Celeriac	0.3
213040	Horseradish (Angelica roots, lovage roots, gentiana roots)	2
213050	Jerusalem artichokes	0.05*
213060	Parsnips	2
213070	Parsley root	2
213080	Radishes (Black radish, Japanese radish, small radish and similar varieties, tiger nut (*Cyperus esculentus*))	0.08[(b)]
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

Code number	Groups and examples of individual products to which the MRLs apply	Cyprodinil [(a)]
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, tree tomato, *Physalis*, gojiberry, wolfberry (*Lycium barbarum and L. chinense*))	1
231020	Peppers (Chilli peppers)	1
231030	Aubergines (egg plants) (Pepino)	1
231040	Okra, lady's fingers	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	0.6[(b)]
233010	Melons (Kiwano)	0.6[(b)]
233020	Pumpkins (Winter squash)	0.6[(b)]
233030	Watermelons	0.6[(b)]
233990	Others	0.6[(b)]
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, Portuguese Kale, Portuguese cabbage, cow cabbage)	0.05*
243990	Others	0.05*
244000	(d) Kohlrabi	0.05*
250000	(v) Leaf vegetables & fresh herbs	
251000	(a) Lettuce and other salad plants including Brassicacea	15
251010	Lamb´s lettuce (Italian cornsalad)	15
251020	Lettuce (Head lettuce, lollo rosso (cutting lettuce), iceberg lettuce, romaine (cos) lettuce)	15
251030	Scarole (broad-leaf endive) (Wild chicory, red-leaved chicory, radicchio, curld leave endive, sugar loaf)	15
251040	Cress	15
251050	Land cress	15
251060	Rocket, Rucola (Wild rocket)	15
251070	Red mustard	15
251080	Leaves and sprouts of Brassica spp (Mizuna, leaves of peas and radish and other babyleaf brassica crops (crops harvested up to 8 true leaf stage))	15
251990	Others	15
252000	(b) Spinach & similar (leaves)	15
252010	Spinach (New Zealand spinach, amaranthus spinach)	15
252020	Purslane (Winter purslane (miner's lettuce), garden purslane, common purslane, sorrel, glassworth, Agretti (*Salsola soda*))	15
252030	Beet leaves (chard) (Leaves of beetroot)	15
252990	Others	15
253000	(c) Vine leaves (grape leaves)	0.05*
254000	(d) Water cress	0.05*
255000	(e) Witloof	0.05*
256000	(f) Herbs	15
256010	Chervil	15
256020	Chives	15
256030	Celery leaves (fennel leaves , Coriander leaves, dill leaves, Caraway leaves, lovage, angelica, sweet cisely and other Apiacea)	15
256040	Parsley	15
256050	Sage (Winter savory, summer savory,)	15
256060	Rosemary	15
256070	Thyme (marjoram, oregano)	15
256080	Basil (Balm leaves, mint, peppermint)	15
256090	Bay leaves (laurel)	15
256100	Tarragon (Hyssop)	15
256990	Others (Edible flowers)	15
260000	(vi) Legume vegetables (fresh)	
260010	Beans (with pods) (Green bean (french beans, snap beans), scarlet runner bean, slicing bean, yardlong beans)	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	0.2
260990	Others	0.05*
270000	(vii) Stem vegetables (fresh)	
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*
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 (Other seeds of *cucurbitacea*)	0.05*
401110	Safflower	0.05*
401120	Borage	0.05*
401130	Gold of pleasure	0.05*
401140	Hempseed	0.05*
401150	Castor bean	0.05*
401990	Others	0.05*
402000	(ii) Oilfruits	0.05*

Code number	Groups and examples of individual products to which the MRLs apply	Cyprodinil [(a)]
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 (Amaranthus, quinoa)	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
500990	Others	0.05*
600000	6. TEA, COFFEE, HERBAL INFUSIONS AND COCOA	
610000	(i) Tea (dried leaves and stalks, fermented or otherwise of Camellia sinensis)	0.05*
620000	(ii) Coffee beans	0.05*
630000	(iii) Herbal infusions (dried)	
631000	(a) Flowers	0.05*
631010	Camomille flowers	0.05*
631020	Hybiscus flowers	0.05*
631030	Rose petals	0.05*
631040	Jasmine flowers (Elderflowers (*Sambucus nigra*)	0.05*
631050	Lime (linden)	0.05*
631990	Others	0.05*
632000	(b) Leaves	0.05*
632010	Strawberry leaves	0.05*
632020	Rooibos leaves (Ginkgo leaves)	0.05*
632030	Maté	0.05*
632990	Others	0.05*
633000	(c) Roots	1
633010	Valerian root	1
633020	Ginseng root	1
633990	Others	1
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	
810000	(i) Seeds	0.05*
810010	Anise	0.05*
810020	Black caraway	0.05*
810030	Celery seed (Lovage seed)	0.05*
810040	Coriander seed	0.05*
810050	Cumin seed	0.05*
810060	Dill seed	0.05*
810070	Fennel seed	0.05*
810080	Fenugreek	0.05*
810090	Nutmeg	0.05*
810990	Others	0.05*
820000	(ii) Fruits and berries	0.05*
820010	Allspice	0.05*
820020	Anise pepper (Japan pepper)	0.05*
820030	Caraway	0.05*
820040	Cardamom	0.05*
820050	Juniper berries	0.05*
820060	Pepper, black and white (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	1
840010	Liquorice	1
840020	Ginger	1
840030	Turmeric (Curcuma)	1
840040	Horseradish	1
840990	Others	1
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 these	0.05*
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*
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*

Code number	Groups and examples of individual products to which the MRLs apply	Cyprodinil [(a)]
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*

(*) Indicates lower limit of analytical determination
(a): The residue definition differs for all of the following: PRODUCTS OF ANIMAL ORIGIN-TERRESTRIAL ANIMALS. For this group, the residue definition is sum of cyprodinil and metabolite CGA 304075.
(b) Value voted during SCFCAH, to be implemented (SANCO 11114/2013).

APPENDIX C.2 – EXISTING CXLS

Summary of CXLs for cyprodinil in plant commodities															
Commodity code	Commodity name	Values adopted by the CCPR		Critical values of the JMPR evaluation					Risk assessment values as calculated by EFSA				Comments on the JMPR evaluation		
		Residue definition	CXL (mg/kg)	Residue definition	STMR (-P) (mg/kg)	HR (-P) (mg/kg)	Default variability factor	Reduced variability factor	STMR (mg/kg)	HR (mg/kg)	Median peeling factor	Median conversion factor	Year	Based on EU GAP only?	Other comments
120010	Almonds	Cyprodinil	0.02 *	Cyprodinil	0.02	n.c.	1	n.c.	0.02	0.02	n.a.	1	2003	No	Trials conducted in the USA according to GAP.
130010	Apples	Cyprodinil	0.05 *	Cyprodinil	0.02	n.c.	1	n.c.	0.02	0.024	n.a.	1	2003	No	Trials conducted in the USA according to GAP.
130020	Pears	Cyprodinil	1	Cyprodinil	0.26	n.c.	1	n.c.	0.26	0.61	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU. USA data were availble but not used to propose the CXL.
140010	Apricots	Cyprodinil	2	Cyprodinil	0.68	n.c.	1	n.c.	0.68	1.7	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU. USA data were availble but not used to propose the CXL.
140020	Cherries	Cyprodinil	2	Cyprodinil	0.68	n.c.	1	n.c.	0.68	1.7	n.a.	1	2003	Yes	
140030	Peaches	Cyprodinil	2	Cyprodinil	0.68	n.c.	1	n.c.	0.68	1.7	n.a.	1	2003	Yes	
140040	Plums	Cyprodinil	2	Cyprodinil	0.68	n.c.	1	n.c.	0.68	1.7	n.a.	1	2003	Yes	
151010	Table grapes	Cyprodinil	3	Cyprodinil	0.79	n.c.	1	n.c.	0.79	2.1	n.a.	1	2003	No	GAP-compliant data from the USA and EU were combined to propose the CXL.
151020	Wine grapes	Cyprodinil	3	Cyprodinil	0.79	n.c.	1	n.c.	0.79	2.1	n.a.	1	2003	No	
152000	Strawberries	Cyprodinil	2	Cyprodinil	0.31	n.c.	1	n.c.	0.31	1.9	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU. USA data were availble but not used to propose the CXL.
153010	Blackberries	Cyprodinil	0.5	Cyprodinil	0.26	n.c.	1	n.c.	0.26	0.38	n.a.	1	2003	No	Trials were conducted in Germany according to Swiss GAP.
153030	Raspberries	Cyprodinil	0.5	Cyprodinil	0.26	n.c.	1	n.c.	0.26	0.38	n.a.	1	2003	No	
220020	Onions	Cyprodinil	0.3	Cyprodinil	0.065	n.c.	1	n.c.	0.065	0.28	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.
231010	Tomatoes	Cyprodinil	0.5	Cyprodinil	0.13	n.c.	1	n.c.	0.13	0.31	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.
231020	Peppers	Cyprodinil	0.5	Cyprodinil	0.16	n.c.	1	n.c.	0.16	0.29	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.
231030	Aubergines (egg plants)	Cyprodinil	0.2	Cyprodinil	0.07	n.c.	1	n.c.	0.07	0.1	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.
232010	Cucumbers	Cyprodinil	0.2	Cyprodinil	0.08	n.c.	1	n.c.	0.08	0.12	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.
232030	Courgettes	Cyprodinil	0.2	Cyprodinil	0.08	n.c.	1	n.c.	0.08	0.12	n.a.	1	2003	Yes	
251020	Lettuce	Cyprodinil	10	Cyprodinil	2.75	n.c.	1	n.c.	2.75	6.4	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.
260010	Beans (fresh, with pods)	Cyprodinil	0.5	Cyprodinil	0.12	n.c.	1	n.c.	0.12	0.29	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU. CXL excludes broad bean and soya bean.
500010	Barley grain	Cyprodinil	3	Cyprodinil	0.58	n.c.	1	n.c.	0.58	2	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.
500090	Wheat grain	Cyprodinil	0.5	Cyprodinil	0.07	n.c.	1	n.c.	0.07	0.32	n.a.	1	2003	Yes	All GAP-compliant trials were conducted in the EU.

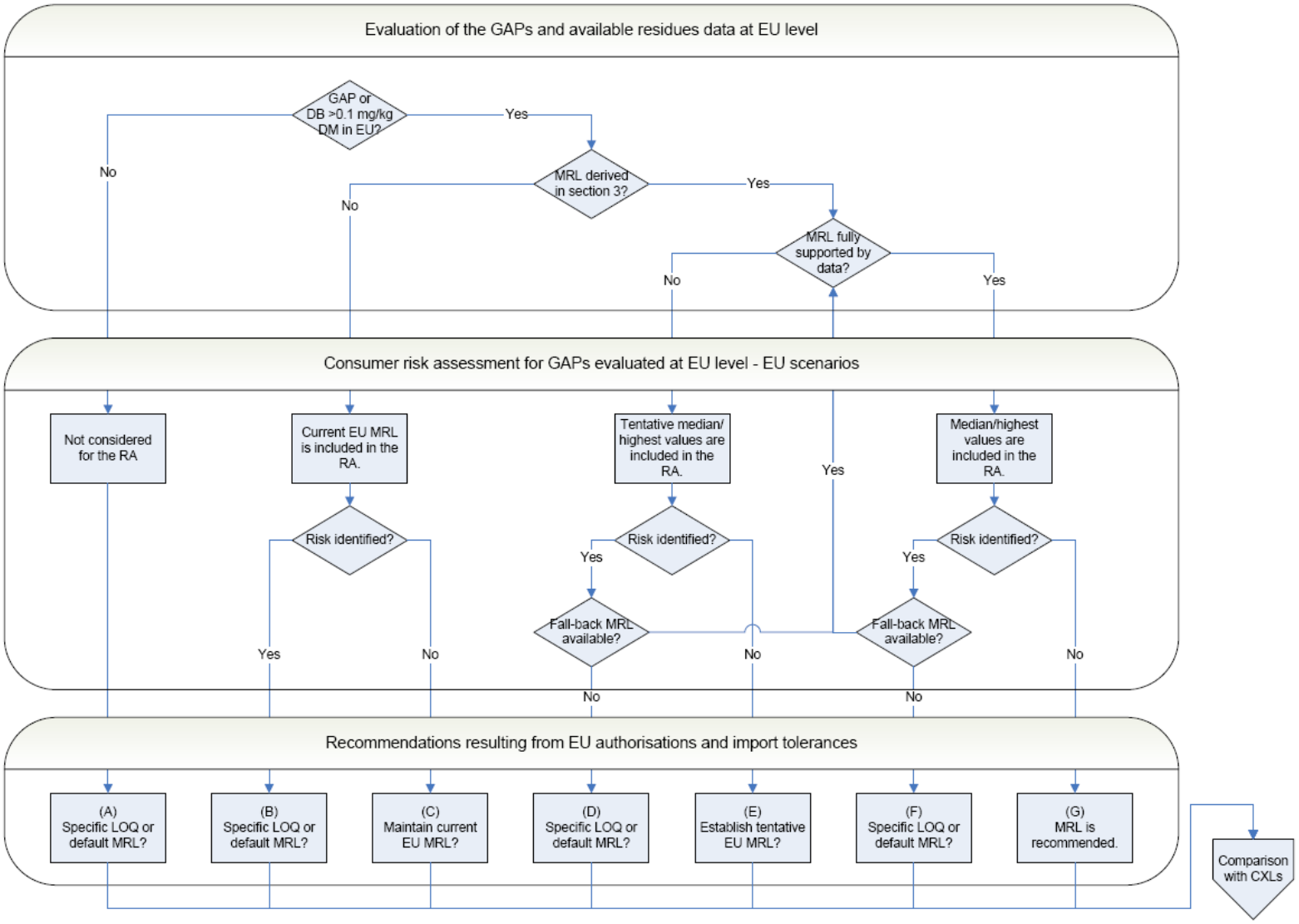
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

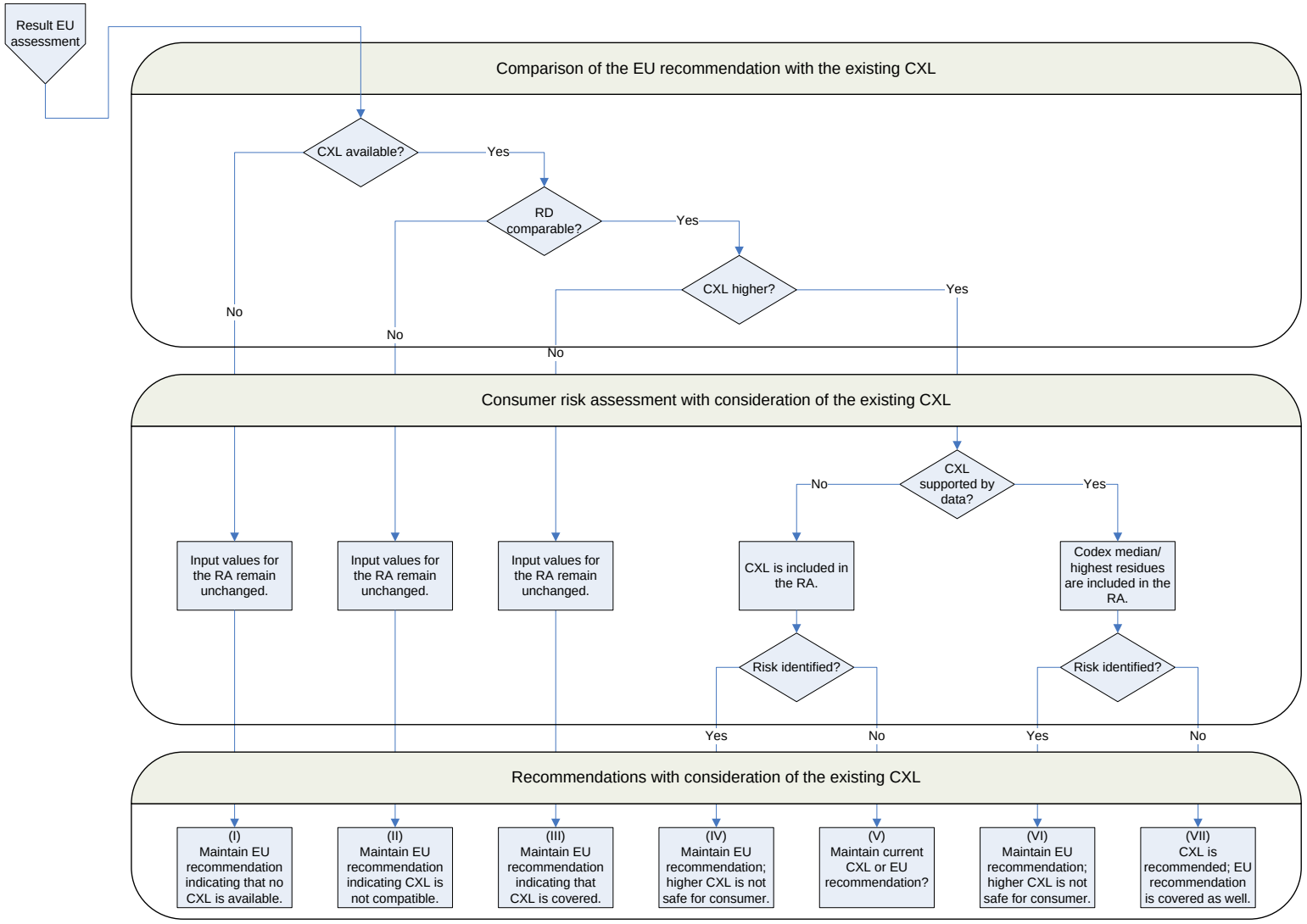
Summary of CXLs for cyprodinil in livestock commodities										
Commodity code	Commodity name	Values adopted by the CCPR			Critical values of the JMPR evaluation			Comment on the JMPR evaluation		
		Residue definition	Expressed as fat?	CXL (mg/kg)	Residue definition	STMR (mg/kg)	HR (mg/kg)	Year	Based on EU GAP only?	Other comments
1011010	Swine meat	Cyprodinil	yes	0.01 *	Cyprodinil	0	n.c.	2003	no	Based on calculated dietary burden for beef cattle of 0.48 and 4.6 mg/kg for STMR and MRL respectively. No residues expected in tissues (0.013 mg/kg in liver at 50 mg/kg).
1011020	Swine fat (free of lean meat)	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	no	
1011030	Swine liver	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1011040	Swine kidney	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1011050	Swine edible offal	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1012010	Bovine meat	Cyprodinil	yes	0.01 *	Cyprodinil	0	n.c.	2003	no	Based on calculated dietary burden for beef cattle of 0.48 and 4.6 mg/kg for STMR and MRL respectively. No residues expected in tissues (0.013 mg/kg in liver at 50 mg/kg).
1012020	Bovine fat	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	no	
1012030	Bovine liver	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1012040	Bovine kidney	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1012050	Bovine edible offal	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1013010	Sheep meat	Cyprodinil	yes	0.01 *	Cyprodinil	0	n.c.	2003	no	Based on calculated dietary burden for beef cattle of 0.48 and 4.6 mg/kg for STMR and MRL respectively. No residues expected in tissues (0.013 mg/kg in liver at 50 mg/kg).
1013020	Sheep fat	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	no	
1013030	Sheep liver	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1013040	Sheep kidney	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1013050	Sheep edible offal	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1014010	Goat meat	Cyprodinil	yes	0.01 *	Cyprodinil	0	n.c.	2003	no	Based on calculated dietary burden for beef cattle of 0.48 and 4.6 mg/kg for STMR and MRL respectively. No residues expected in tissues (0.013 mg/kg in liver at 50 mg/kg).
1014020	Goat fat	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	no	
1014030	Goat liver	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1014040	Goat kidney	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1014050	Goat edible offal	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1015010	Horses, asses, mules or hinnies meat	Cyprodinil	yes	0.01 *	Cyprodinil	0	n.c.	2003	no	Based on calculated dietary burden for beef cattle of 0.48 and 4.6 mg/kg for STMR and MRL respectively. No residues expected in tissues (0.013 mg/kg in liver at 50 mg/kg).
1015020	Horses, asses, mules or hinnies fat	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	no	
1015030	Horses, asses, mules or hinnies liver	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1015040	Horses, asses, mules or hinnies kidney	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1015050	Horses, asses, mules or hinnies edible offal	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	

1016010	Poultry meat	Cyprodinil	yes	0.01 *	Cyprodinil	0	n.c.	2003	yes	Based on calculated dietary burden for poultry of 0.50 and 2.6 mg/kg for STMR and MRL respectively. No residues expected in any tissues including eggs.
1016020	Poultry fat	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	yes	
1016030	Poultry liver	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	yes	
1016040	Poultry kidney	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	yes	
1016050	Poultry edible offal	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	yes	
1017010	Other farm animals meat	Cyprodinil	yes	0.01 *	Cyprodinil	0	n.c.	2003	no	Based on calculated dietary burden for dairy cattle of 0.53 and 8.2 mg/kg for STMR and MRL respectively. No residues expected in milk at these levels.
1017020	Other farm animals fat	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	no	
1017030	Other farm animals liver	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1017040	Other farm animals kidney	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1017050	Other farm animals edible offal	Cyprodinil	n.a.	0.01 *	Cyprodinil	0.01	n.c.	2003	no	
1020010	Cattle milk	Cyprodinil	n.a.	0.0004 *	Cyprodinil	0	n.c.	2003	yes	Based on calculated dietary burden for beef cattle of 0.48 and 4.6 mg/kg for STMR and MRL respectively. No residues expected in tissues (0.013 mg/kg in liver at 50 mg/kg).
1020020	Sheep milk	Cyprodinil	n.a.	0.0004 *	Cyprodinil	0	n.c.	2003	yes	
1020030	Goat milk	Cyprodinil	n.a.	0.0004 *	Cyprodinil	0	n.c.	2003	yes	
1020040	Horse milk	Cyprodinil	n.a.	0.0004 *	Cyprodinil	0	n.c.	2003	yes	
1030000	Birds' eggs	Cyprodinil	n.a.	0.01 *	Cyprodinil	0	n.c.	2003	yes	Based on calculated dietary burden for poultry of 0.50 and 2.6 mg/kg for STMR and MRL respectively. No residues expected in any tissues including eggs.

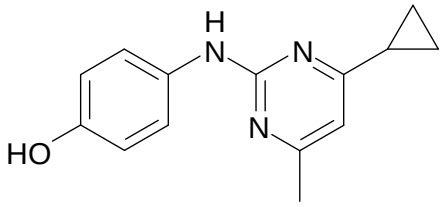
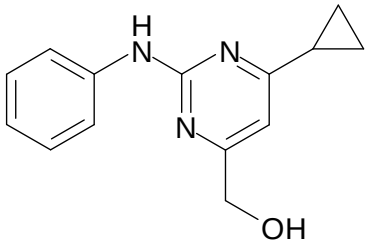
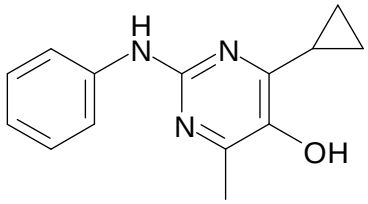
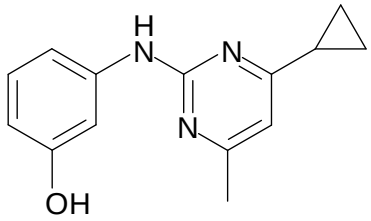
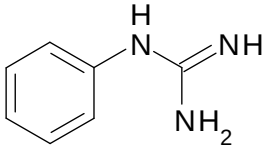
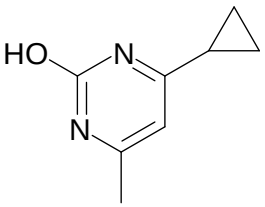
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

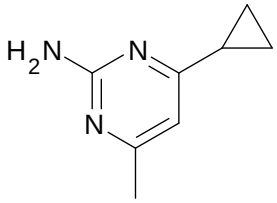
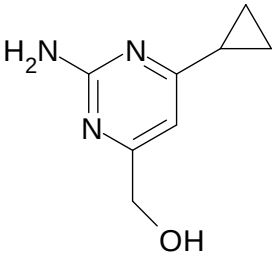
APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




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

APPENDIX E – LIST OF METABOLITES AND RELATED STRUCTURAL FORMULA

Common name	IUPAC name	Structural formula
CGA 304075	4-[(4-cyclopropyl-6-methyl-pyrimidin-2-yl)amino)]phenol	
CGA 232449	(2-anilino-6-cyclopropyl-pyrimidin-4-yl)methanol	
CGA 304076	2-anilino-4-cyclopropyl-6-methyl-pyrimidin-5-ol	
CGA 275535	3-[(4-cyclopropyl-6-methyl-pyrimidin-2-yl)amino)]phenol	
CGA 263208	1-phenylguanidine	
CGA 321915	4-cyclopropyl-6-methyl-pyrimidin-2-ol	

Common name	IUPAC name	Structural formula
CGA 249287	4-cyclopropyl-6-methyl-pyrimidin-2- amine	
NOA 422054	(2-amino-6-cyclopropyl-pyrimidin-4-yl)methanol	

ABBREVIATIONS

a.s.	active substance
ADI	acceptable daily intake
ARfD	acute reference dose
BBCH	growth stages of mono- and dicotyledonous plants
bw	body weight
CAC	Codex Alimentarius Commission
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
DM	dry matter
DT_{90}	period required for 90 percent dissipation (define method of estimation)
EC	European Commission
EFSA	European Food Safety Authority
eq	residue expressed as a.s. equivalent
EU	European Union
FAO	Food and Agriculture Organisation of the United Nations
GAP	good agricultural practice
GC	gas chromatography
GC-MS	gas chromatography with mass spectrometry
ha	hectare
HPLC-MS/MS	high performance liquid chromatography with tandem mass spectrometry
HPLC-UVD	high performance liquid chromatography with ultra-violet detector

ILV	independent laboratory validation
ISO	International Organisation for Standardization
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
LOQ	limit of quantification
MRL	maximum residue limit
MS	Member States
NEU	northern European Union
OECD	Organisation for Economic Co-operation and Development
PF	processing factor
PHI	pre-harvest interval
$P_{o/w}$	partition coefficient n-octanol/water
PRIMo	(EFSA) Pesticide Residues Intake Model
PROFile	(EFSA) Pesticide Residues 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
RMS	rapporteur Member State
SEU	Southern European Union
TRR	total radioactive residue
WHO	World Health Organisation