**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]

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## ABSTRACT

According to Article 12 of Regulation (EC) No 396/2005, the European Food Safety Authority (EFSA) has reviewed the Maximum Residue Levels (MRLs) currently established at European level for the pesticide active substance 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.



## KEY WORDS

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

[1] On request from EFSA, Question No EFSA-Q-2008-521, approved on 7 October 2013.
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[3] Acknowledgement: EFSA wishes to thank the rapporteur Member State France for the preparatory work on this scientific output.

Suggested citation: European Food Safety Authority, 2013. Reasoned opinion on the review of the existing maximum residue levels (MRLs) for cyprodinil according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2013;11(10):3406, 81 pp. doi:10.2903/j.efsa.2013.3406

Available online: www.efsa.europa.eu/efsajournal

## 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<br>**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<br>**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).

## TABLE OF CONTENTS

## 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.

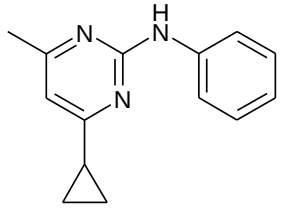
## TERMS OF REFERENCE

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<br>0.27; 0.32; 0.40; 0.56<br>pears<br>0.09; 0.17; 0.25; 0.28 | apples<br>0.27; 0.32; 0.40; 0.56<br>pears<br>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.<br>$R_{max}$ = 0.75<br>$R_{ber}$ = 0.76<br>$MRL_{OECD}$ = 0.88 |
| | SEU | Outdoor | apples<br>0.39; 0.40; 0.49; 0.74<br>pears<br>0.14; 0.26; 0.5; 0.53; 0.88 | apples<br>0.39; 0.40; 0.49; 0.74<br>pears<br>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.<br>$R_{max}$ = 1.17<br>$R_{ber}$ = 1.27<br>$MRL_{OECD}$ = 1.44 |
| Medlar and loquat | NEU | Outdoor | apples<br>0.27; 0.32; 0.40; 0.56<br>pears<br>0.09; 0.17; 0.25; 0.28 | apples<br>0.27; 0.32; 0.40; 0.56<br>pears<br>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.<br>$R_{max}$ = 0.88<br>$R_{ber}$ = 1.03<br>$MRL_{OECD}$ = 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).<br>$R_{max}$ = 0.59<br>$R_{ber}$ = 0.59<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.37<br>$R_{ber}$ = 0.43<br>$MRL_{OECD}$ = 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).<br>$R_{max}$ = 0.32<br>$R_{ber}$ = -<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.67<br>$R_{ber}$ = 0.50<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 2.09<br>$R_{ber}$ = 1.69<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 1.86<br>$R_{ber}$ = 1.96<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 1.95<br>$R_{ber}$ = 1.43<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 1.30<br>$R_{ber}$ = 1.33<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 2.53<br>$R_{ber}$ = 2.45<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 3.58<br>$R_{ber}$ = 3.01<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.06<br>$R_{ber}$ = 0.06<br>$MRL_{OECD}$ = 0.07<br>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.<br>$R_{max}$ = 0.15<br>$R_{ber}$ = 0.16<br>$MRL_{OECD}$ = 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).<br>$R_{max}$ = 0.61<br>$R_{ber}$ = 0.60<br>$MRL_{OECD}$ = 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).<br>$R_{max}$ = 0.15<br>$R_{ber}$ = 0.13<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.83<br>$R_{ber}$ = 0.52<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.91<br>$R_{ber}$ = 0.72<br>$MRL_{OECD}$ = 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<br>0.03; 0.15; 0.17<br>courgette<br>0.10 | cucumber<br>0.03; 0.15; 0.17<br>courgette<br>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).<br>$R_{max}$ = 0.43<br>$R_{ber}$ = 0.33<br>$MRL_{OECD}$ = 0.36 |
| | EU | Indoor | cucumber<br>2 × 0.07; 2 × 0.08; 0.09; 0.11; 3 × 0.13; 0.18; 2 × 0.19; 0.29; 0.36<br>courgette<br>0.07; 0.11; 3 × 0.13; 0.15; 0.17; 0.19 | cucumber<br>2 × 0.07; 2 × 0.08; 0.09; 0.11; 3 × 0.13; 0.18; 2 × 0.19; 0.29; 0.36<br>courgette<br>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.<br>$R_{max}$ = 0.31<br>$R_{ber}$ = 0.37<br>$MRL_{OECD}$ = 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).<br>$R_{max}$ = 0.46<br>$R_{ber}$ = 0.41<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.05<br>$R_{ber}$ = 0.06<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.36<br>$R_{ber}$ = 0.38<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.30<br>$R_{ber}$ = 0.38<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 1.36<br>$R_{ber}$ = 1.58<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.07<br>$R_{ber}$ = 0.08<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.22<br>$R_{ber}$ = 0.22<br>$MRL_{OECD}$ = 0.24 |
| Beans (dry)<br>Peas (dry)<br>Lupins | NEU | Outdoor | beans<br>0.01; 2 × 0.02; 0.03<br>peas<br><0.02; 0.02; 0.03; 0.07 | beans<br>0.01; 2 × 0.02; 0.03<br>peas<br><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.<br>$R_{max}$ = 0.09<br>$R_{ber}$ = 0.06<br>$MRL_{OECD}$ = 0.10 |
| | SEU | Outdoor | beans<br>0.02; 0.03; 0.05; 0.11<br>peas<br>0.04; 2 x 0.06; 0.07 | beans<br>0.02; 0.03; 0.05; 0.11<br>peas<br>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.<br>$R_{max}$ = 0.14<br>$R_{ber}$ = 0.14<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 2.15<br>$R_{ber}$ = 2.44<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 2.95<br>$R_{ber}$ = 2.26<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.38<br>$R_{ber}$ = 0.34<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 0.44<br>$R_{ber}$ = 0.32<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 2.49<br>$R_{ber}$ = 1.21<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 3.79<br>$R_{ber}$ = 3.04<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 2.75<br>$R_{ber}$ = 1.92<br>$MRL_{OECD}$ = 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.<br>$R_{max}$ = 8.50<br>$R_{ber}$ = 5.00<br>$MRL_{OECD}$ = 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).<br>$R_{max}$ = 1.29<br>$R_{ber}$ = 1.05<br>$MRL_{OECD}$ = 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<br>302 | 317 365 398<br>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<br>**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<br>**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) |
| | | | | | | | Content | | | Growth stage | | Number | | Interval (days) | | | | | | |
| Common name | Scientific name | | | | | Type | Conc. | Unit | Method | From BBCH | Until BBCH | Min. | Max. | Min. | Max. | Min. rate | Max. rate | Rate Unit | | |
| 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. |

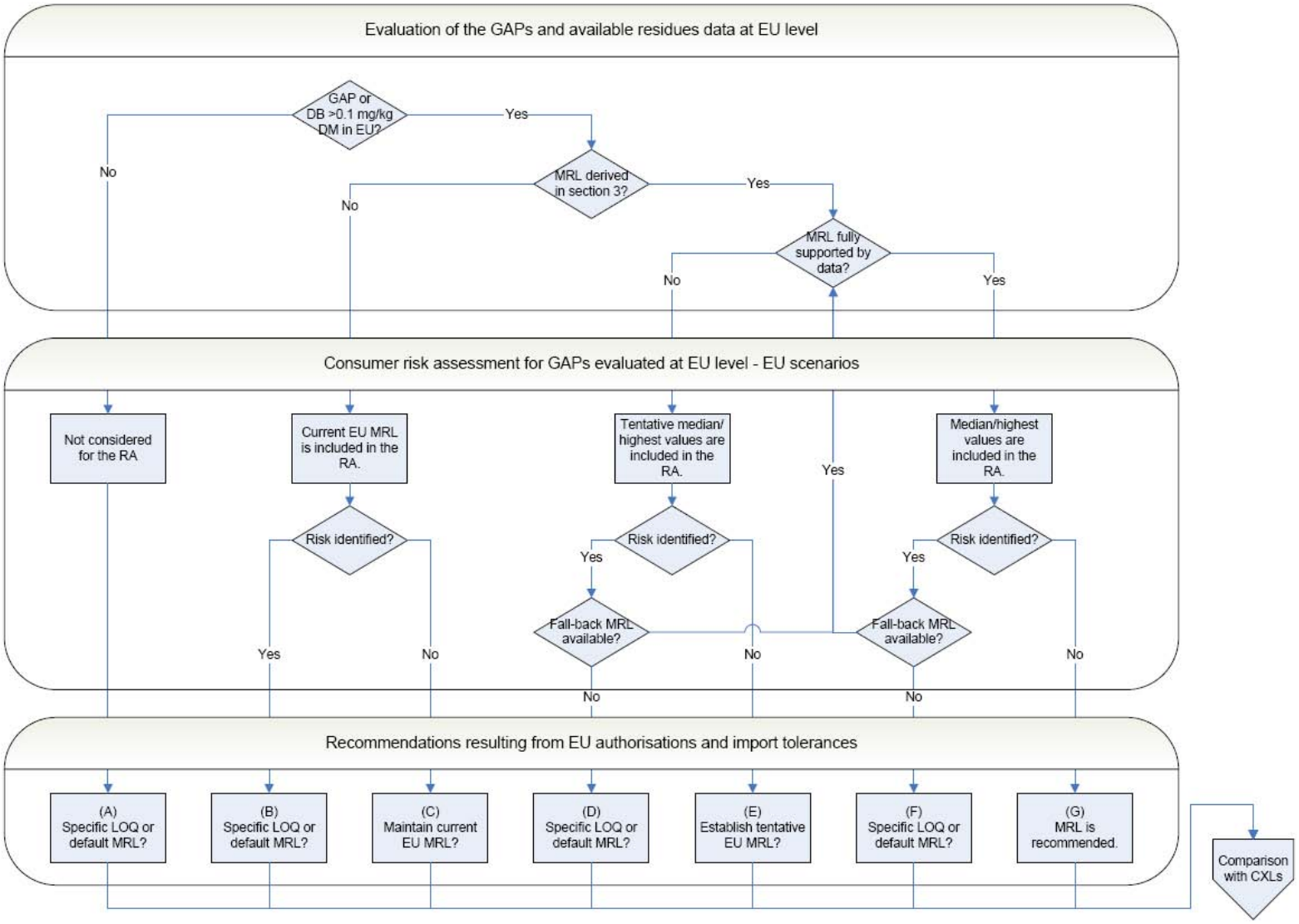
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

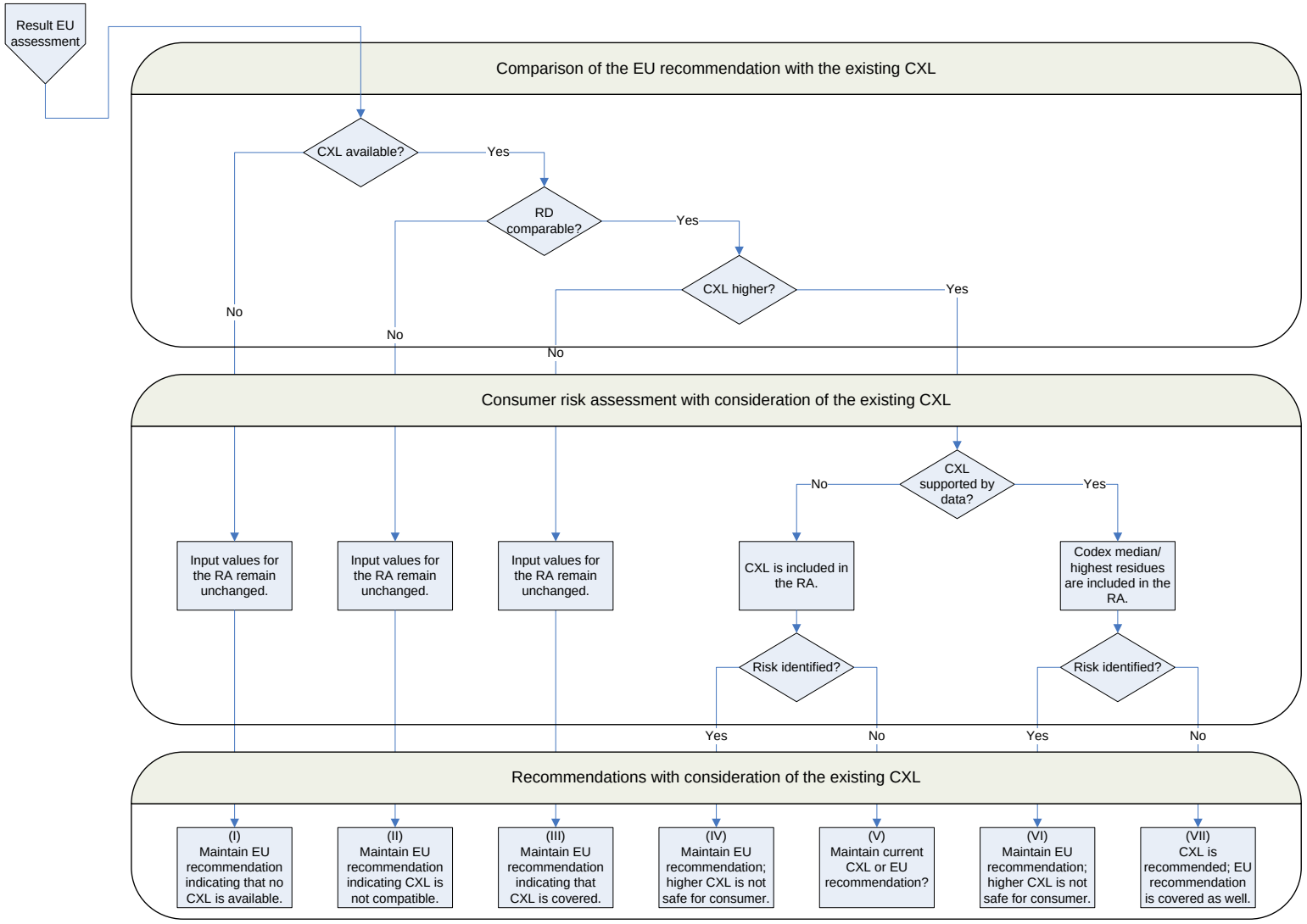
| Summary of CXLs for cyprodinil in livestock commodities | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Commodity code | Commodity name | Values adopted by the CCPR | | | Critical values of the JMPR evaluation | | | Comment on the JMPR evaluation | | |
| | | Residue definition | 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. |

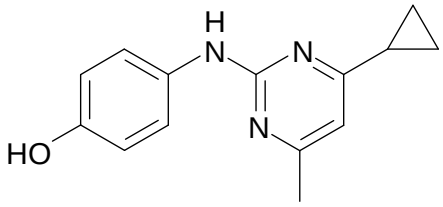
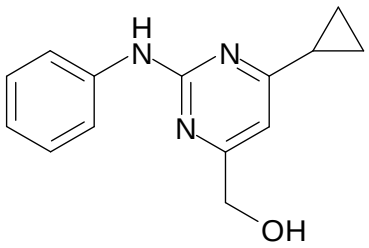
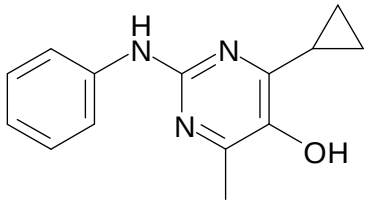
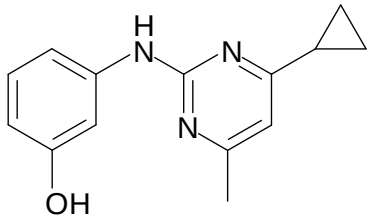
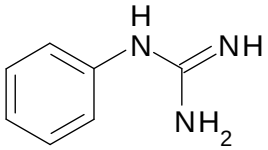
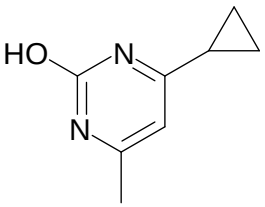
(*) Indicates the lower limit of analytical quantification.
n.a.: not applicable
n.c.: not considered
n.k.: not known

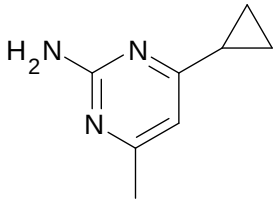
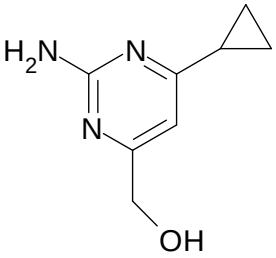
## APPENDIX D – DECISION TREE FOR DERIVING MRL RECOMMENDATIONS




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 |