Modification of the existing maximum residue level for cyprodinil in rhubarbs

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Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) in the United Kingdom submitted a request to the competent national authority to modify the existing maximum residue level (MRL) for the active substance cyprodinil in rhubarbs. The data submitted in support of the request were found to be sufficient to derive an MRL proposal of 2 mg/kg for rhubarbs. Adequate analytical methods for enforcement are available to control the residues of cyprodinil in the plant matrix under consideration at the validated limit of quantification (LOQ) of 0.01 mg/kg. Based on the risk assessment results, EFSA concluded that the short-term and long-term intake of residues resulting from the use of cyprodinil according to the reported agricultural practice is unlikely to present a risk to consumer health.

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Keywords: cyprodinil, rhubarbs, pesticide, MRL, consumer risk assessment

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Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Agriculture and Horticulture Development Board (AHDB) in the United Kingdom submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to modify the existing maximum residue level (MRLs) for the active substance cyprodinil in rhubarbs. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to the European Food Safety Authority (EFSA) on 24 May 2019. To accommodate for the intended use of cyprodinil, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 2 mg/kg.

EFSA assessed the application and the evaluation report as required by Article 10 of the MRL regulation.

Based on the conclusions derived by EFSA in the framework of Directive 91/414/EEC, the data evaluated under previous MRL assessments and the additional data provided by the EMS in the framework of this application, the following conclusions are derived.

The metabolism of cyprodinil following foliar application was investigated in crops belonging to the groups of fruit crops, root crops and cereals. Rhubarb is a leafy crop and no specific metabolism studies are available in leafy vegetables. In the framework of the EFSA MRL review, however, it was assumed that the cyprodinil metabolism in leafy vegetables follows the same pathway as in cereals and fruits. This assumption was confirmed by the findings in metabolism studies with potatoes and tomatoes where the results on leaves were comparable with the results on fruits and cereal grain. Thus, the metabolism in leafy crops and, therefore, in rhubarb is considered to be sufficiently addressed.

Studies investigating the effect of processing on the nature of cyprodinil (hydrolysis studies) demonstrated that the active substance is stable.

As rhubarb is not expected to be grown in rotation with other crops, investigations of residues in rotational crops for rhubarbs are not required.

Based on the metabolic pattern identified in plants, hydrolysis studies and the toxicological significance of metabolites, the residue definitions for plant products were proposed by the peer review and the MRL review as ‘cyprodinil’ for enforcement and risk assessment. These residue definitions are applicable to primary crops, rotational crops and processed products.

EFSA concluded that for rhubarbs the metabolism of cyprodinil in primary and in rotational crops and the possible degradation in processed products has been sufficiently addressed and that the previously derived residue definitions are currently applicable.

Sufficiently validated analytical methods based on high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) are available to quantify residues in rhubarbs according to the enforcement residue definition and the lowest validated LOQ of 0.01 mg/kg. For enforcement purposes, however, a common LOQ of 0.02 mg/kg for cyprodinil was established with Reg. (EC) No 396/2005.

The data submitted in support of this MRL application were found sufficient to derive an MRL proposal of 2 mg/kg in rhubarbs, which was derived by extrapolation from residue trials on celery.

Specific studies investigating the magnitude of cyprodinil residues in processed commodities are not required due to the low contribution of residues in rhubarbs to the total consumer exposure.

Residues of cyprodinil in commodities of animal origin were not assessed since rhubarb is normally not fed to livestock.

The toxicological profile of cyprodinil was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day. An acute reference dose (ARfD) was deemed unnecessary. In the framework of the renewal of the approval of cyprodinil, which is currently ongoing, the setting of an ARfD of 1.5 mg/kg bw for cyprodinil was proposed by the RMS but a formal decision has not yet been taken; the ADI of 0.03 mg/kg bw per day is proposed for confirmation.

The consumer risk assessment was performed with revision 3 of the EFSA Pesticide Residues Intake Model (PRIMO). For the calculation of the chronic exposure to cyprodinil, EFSA used the STMR value from results on celery stems derived by residue trials in celery. For the remaining crops, the STMR values as reported in the MRL review, in the recent EFSA reasoned opinions on the modification of MRLs of cyprodinil in celery and Florence fennels or as available from the JMPR evaluations, were used as input values. The exposure calculation was performed only for those crops for which authorised...
uses were reported in the MRL review and for the accepted Codex MRLs taken over in the EU legislation.

EFSA also performed an indicative acute exposure assessment to identify a potential consumer health concern related to residues in rhubarbs, based on the proposed ARfD.

No long-term consumer intake concerns were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for 48% of the ADI (NL toddler diet). The contribution of residues in rhubarbs to the total consumer exposure accounted for a maximum of 0.4% of the ADI (IE adult diet). The indicative acute exposure calculation did not identify consumer intake concerns related to residues of cyprodinil in rhubarbs (2% of the ARfD).

EFSA concluded that the proposed use of cyprodinil on rhubarbs will not result in a long-term consumer exposure exceeding the ADI value for cyprodinil and therefore is unlikely to pose a risk to consumers’ health. Based on an indicative acute exposure assessment which considers the ARfD proposed by the RMS in the framework of the currently ongoing renewal of the approval of cyprodinil, no acute health concerns were identified with regard to cyprodinil residues in rhubarbs.

The procedure for the renewal of the approval of cyprodinil in accordance with Regulation (EC) No 1107/2009 is currently ongoing. Therefore, the conclusions reported in this reasoned opinion might need to be reconsidered in the light of the outcome of the renewal process.

EFSA proposes to amend the existing MRL as reported in the summary table below.

Full details of all endpoints and the consumer risk assessment can be found in Appendices B–D.

| Code(a) | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---------|-----------|------------------------|------------------------|-----------------------|
| 0270070 | Rhubarbs | 0.02* | 2 | The submitted data are sufficient to derive an MRL proposal for the NEU use by extrapolation from results on celery. Risk for consumers unlikely |

Enforcement residue definition: Cyprodinil(F)

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
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Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for cyprodinil in rhubarbs. The detailed description of the intended use of cyprodinil in rhubarbs, which is the basis for the current MRL application, is reported in Appendix A.

Cyprodinil is the ISO common name for 4-cyclopropyl-6-methyl-N-phenylpyrimidin-2-amine (IUPAC). The chemical structures of the active substance and its main metabolites are reported in Appendix E.

Cyprodinil was evaluated in the framework of Directive 91/414/EEC with France designated as rapporteur Member State (RMS) for the representative use as a foliar application on winter wheat and apples. The draft assessment report (DAR) prepared by the RMS has been peer reviewed by EFSA (EFSA, 2006). Cyprodinil was approved for the use as fungicide on 1 May 2007.

The process of renewal of the first approval in accordance with Regulation (EC) No 1107/2009 is currently ongoing.

The EU MRLs for cyprodinil are established in Annexes II of Regulation (EC) No 396/2005. The review of existing MRLs according to Article 12 of Regulation (EC) No 396/2005 (MRL review) has been performed (EFSA, 2013) and the proposed modifications have been implemented in the MRL legislation. After completion of the MRL review, EFSA has issued two reasoned opinions on the modification of MRLs for cyprodinil for celery and Florence fennels (EFSA, 2015, 2019). The proposals from these reasoned opinions have been considered in recent MRL Regulations. In addition, certain Codex MRLs were recently implemented in the EU MRL legislation (FAO, 2014, 2016b, 2017).

In accordance with Article 6 of Regulation (EC) No 396/2005, AHDB submitted an application to the competent national authority in the United Kingdom (evaluating Member State, EMS) to modify the existing MRLs for the active substance cyprodinil in rhubarbs. The EMS drafted an evaluation report in accordance with Article 8 of Regulation (EC) No 396/2005, which was submitted to the European Commission and forwarded to EFSA on 24 May 2019. To accommodate for the intended use of cyprodinil, the EMS proposed to raise the existing MRL from the limit of quantification (LOQ) to 2 mg/kg, by extrapolating results from four residue trials in celery evaluated by EFSA in 2015.

EFSA based its assessment on the evaluation report submitted by the EMS (United Kingdom, 2019), the DAR (and its addendum) (France, 2003, 2009) prepared under Council Directive 91/414/EEC, the Commission review report on cyprodinil (European Commission, 2006), the conclusion on the peer review of the pesticide risk assessment of the active substance cyprodinil (EFSA, 2006), the renewal assessment report on the active substance cyprodinil (France, 2017), as well as the conclusions from previous EFSA opinions on cyprodinil (EFSA, 2015, 2019), including the opinion on the review of the existing cyprodinil MRLs (EFSA, 2013).

For this application, the data requirements established in Regulation (EU) No 544/2011 and the guidance documents applicable at the date of submission of the application to the EMS are applicable (European Commission, 1997a–g, 2000, 2010a,b, 2017; OECD, 2007, 2011). The assessment is performed in accordance with the legal provisions of the Uniform Principles for the Evaluation and the Authorisation of Plant Protection Products adopted by Commission Regulation (EU) No 546/2011.

As the procedure for the renewal of the approval of cyprodinil in accordance with Regulation (EC) No 1107/2009 is not yet finalised, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review.

A selected list of end points of the studies assessed by EFSA in the framework of this MRL application including the end points of relevant studies assessed previously, are presented in Appendix B.

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1 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.
2 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.
3 Regulation (EC) No 396/2005 of the 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.
4 For an overview of all MRL Regulations on this active substance, please consult: http://ec.europa.eu/food/plant/pesticides/eur-pesticides-database/public/?event=pesticide.residue.selection&language=EN
5 Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances. OJ L 155, 11.6.2011, p. 1–66.
6 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, 11.6.2011, p. 127–175.
The evaluation report submitted by the EMS (United Kingdom, 2019) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo) are considered as supporting documents to this reasoned opinion and, thus, are made publicly available as background documents to this reasoned opinion.

1. **Residues in plants**

1.1. **Nature of residues and methods of analysis in plants**

1.1.1. **Nature of residues in primary crops**

The metabolism of cyprodinil following foliar applications was investigated in the framework of the peer review under Directive 91/414/EEC and assessed in detail in the framework of the MRL review in the following crops: fruit crops (apple, peach and tomato), root crops (potato) and cereals (wheat) (EFSA, 2006, 2013).

Cyprodinil was found to be rather persistent and remained a dominant residue up to 60 days after the application in fruit crops and cereals. For potato tubers, a different metabolic pattern resulting from the uptake of soil metabolites was observed.

No specific metabolism studies for cyprodinil in rhubarbs or other leafy crops are currently available. In the framework of the MRL review, sufficient evidence was available to assume that the cyprodinil metabolism in leafy vegetables follows the same pathway as in cereals and fruits (EFSA, 2013). This assumption was based on the findings in metabolism studies with potatoes and tomatoes where the results on leaves were comparable with the results on fruits and cereal grain.

1.1.2. **Nature of residues in rotational crops**

Rhubarb is not expected to be grown in rotation with other plants and therefore no metabolism studies on the nature of cyprodinil residues in rotational crops are required in the context of this application (OECD, 2007).

1.1.3. **Nature of residues in processed commodities**

The effect of processing on the nature of cyprodinil residues was investigated under standard hydrolysis conditions indicating that cyprodinil is hydrolytically stable under the representative processing conditions of pasteurisation, baking, brewing, boiling and sterilisation (EFSA, 2006, 2013). The relevant residue definition for enforcement and risk assessment in processed commodities is therefore expected to be cyprodinil.

1.1.4. **Methods of analysis in plants**

Various analytical methods for enforcement purposes were assessed by the peer review and further discussed in the MRL review (EFSA, 2006, 2013). The multiresidue QuEChERS method in combination with high-performance liquid chromatography with tandem mass spectrometry (HPLC-MS/MS) was reported by the EU Reference Laboratories for Residues of Pesticides as validated for the analysis of cyprodinil with an LOQ of 0.01 mg/kg in high water content, high acid content and in dry commodities (EURL, 2018). The method can be used for the determination of cyprodinil in rhubarbs, being a high acid content crop.

In the residue trials used in the present evaluation, the analysis of cyprodinil in celery (high water content matrix) is carried out by gas chromatography with tandem mass spectrometry (GC-MS/MS) using the transition m/z 224>208 (see Section 1.2). A full validation package for this method is available in the evaluation report by France in 2014. The estimated LOQ of cyprodinil in celery is 0.01 mg/kg (France, 2014; EFSA, 2015).

EFSA concluded that sufficiently validated analytical enforcement methods are available for the determination of cyprodinil residues in rhubarb which allow quantification of residues at or above the lowest validated LOQ of 0.01 mg/kg.

Based on the above and a number of available residue trials for cyprodinil in high water, acid and dry commodities evaluated in the context of the MRL review, a common LOQ of 0.02 mg/kg for cyprodinil in food of plant origin was set with Reg. (EC) No 396/2005.
1.1.5. Storage stability of residues in plants

The storage stability of cyprodinil was investigated in the context of the peer review (EFSA, 2006) and the MRL review (EFSA, 2013). Residues of cyprodinil were found to be stable at ≤ −18°C for up to 26 months in high water content commodities (peaches, apples) and 24 months in high acid content commodities (grapes, strawberries) and in dry/high starch content commodities (wheat).

For rhubarbs, classified as crop with acid content, sufficient storage stability data are available.

1.1.6. Proposed residue definitions

Based on the primary and rotational crop metabolism studies, the proposed residue definitions in the context of the peer and MRL review for both enforcement and risk assessment purposes were proposed as 'cyprodinil' (EFSA, 2006, 2013). The residue definition set for cyprodinil in Regulation (EC) No 396/2005 is aligned with the EFSA recommendations.

In the framework of the MRL review, EFSA stressed that for root and tuber vegetables the residue definition might need to be reconsidered if new uses are requested for cyprodinil in these crops in the future (EFSA, 2013). This proposal, however, is not relevant for rhubarbs, being a leafy crop.

Future proposals to update the residue definition for cyprodinil in the framework of the on-going renewal of the approval of the active substance might result in the reconsideration of the MRL and risk assessment derived in this opinion.

1.2. Magnitude of residues in plants

1.2.1. Magnitude of residues in primary crops

In support of the intended northern Europe (NEU) outdoor use of cyprodinil on rhubarbs, the applicant referred to residue trials with cyprodinil and fludioxonil on celery which were submitted to EFSA in the framework of a previous MRL application (EFSA, 2012; France, 2012). These trials were also used to derive the current MRLs for cyprodinil in celery (EFSA, 2015). The applicant proposed to derive an MRL proposal for cyprodinil in rhubarbs by extrapolation from celery.

In total, four NEU residue trials in celery, compliant with the intended Good Agricultural Practice (GAP) for rhubarb, are available. The trials were performed in France in 2005, 2009 and 2010.

In one of the trials, the celery (trial number RE05027) stems and the leaves were analysed separately. The residue concentration for the whole product (celery stems plus leaves) was calculated, taking into account the weight of the two fractions. In the remaining three trials, the residue concentration of cyprodinil was measured in the whole product (stems plus leaves).

The trials were valid with regard to the analytical method used and the storage stability. The residue data extrapolation from celery to rhubarbs is acceptable according to the EU guidelines (European Commission, 2017). The EMS proposed to use the residue concentration measured in trial number RE05027 in the stem, instead of the residue calculated for the whole product, as a more realistic result for deriving the MRL proposal for rhubarb. EFSA agrees with this proposed refinement.

EFSA concludes that an MRL of 2 mg/kg for cyprodinil in rhubarb is required in support of the intended GAP in the United Kingdom.

1.2.2. Magnitude of residues in rotational crops

Rhubarb is not expected to be grown in rotation with other plants and therefore no studies on the magnitude of residues of cyprodinil in rotational crops are required in the framework of this application (OECD, 2007).

1.2.3. Magnitude of residues in processed commodities

Studies investigating the magnitude of cyprodinil residues in processed rhubarbs have not been submitted and are not required, considering the low contribution of residues in rhubarbs to the total consumer exposure.

1.2.4. Proposed MRLs

The submitted data are sufficient to propose an MRL of 2 mg/kg for cyprodinil in rhubarbs in support of the intended Good Agricultural Practice (GAP) in the United Kingdom.
2. **Residues in livestock**

Rhubarb is not expected to be fed to livestock, therefore, the nature and magnitude of cyprodinil residues in livestock are not assessed in the framework of this application.

3. **Consumer risk assessment**

The consumer risk assessment was performed with revision 3 of the EFSA PRIMo. This exposure assessment model contains the relevant European food consumption data for different subgroups of the EU population (EFSA, 2017).

For the calculation of the chronic exposure to cyprodinil from rhubarbs, EFSA used the STMR value from results on celery derived by residue trials in celery (see Sections 1.2.1 and B.1.2.1). For the remaining crops, the STMR values as reported by the MRL review and more recent MRL applications on the amendment of the cyprodinil MRLs in various crops were used as input values (EFSA, 2013, 2015, 2019); for Codex MRLs implemented in the EU MRL legislation, the STMR values derived by JMPR were taken into account in the risk assessment process (FAO, 2014, 2016b, 2017).

The details on the input values are presented in Appendix D.1.

The toxicological profile of cyprodinil was assessed in the framework of the EU pesticides peer review under Directive 91/414/EEC and the data were sufficient to derive an acceptable daily intake (ADI) of 0.03 mg/kg body weight (bw) per day (EFSA, 2006). Currently no acute reference dose is set for cyprodinil. However, in the framework of the renewal of the approval of cyprodinil, an ARfD of 1.5 mg/kg bw was proposed by the RMS France (France, 2017). Based on this proposed ARfD, EFSA performed an indicative acute risk assessment for rhubarbs using the HR from results on celery derived from valid residue trials on celery and assuming that the proposed ARfD is confirmed by the experts.

No concerns from long-term exposure to cyprodinil were identified for any of the European diets incorporated in the EFSA PRIMo. The total calculated intake accounted for a maximum 48% of the ADI (NL toddler diet). The contribution of residues in rhubarbs to the total consumer exposure accounted was low (0.4% of the ADI (IE adult diet)). The indicative acute exposure estimate did not identify concerns from acute exposure to cyprodinil via rhubarb consumption (2% of the ARfD).

For further details on the exposure calculations, a screenshot of the Report sheet of the PRIMo is presented in Appendix C.

4. **Conclusion and Recommendations**

The data submitted in support of this MRL application were found to be sufficient to derive an MRL proposal of 2 mg/kg for cyprodinil in rhubarbs, as extrapolated from residue trials on celery, in support of the intended NEU GAP.

EFSA concluded that the proposed use of cyprodinil on rhubarbs will not result in a long-term consumer exposure exceeding the ADI value for cyprodinil and therefore is unlikely to pose a risk to consumers’ health. Based on an indicative acute exposure assessment which considers the ARfD proposed by the RMS in the framework of the currently ongoing renewal of the approval of cyprodinil, no acute health concerns were identified with regard to cyprodinil residues in rhubarbs.

As the peer review on the renewal of the approval of cyprodinil in accordance with Regulation (EC) No 1107/2009 is currently ongoing, the conclusions reported in this reasoned opinion may need to be reconsidered in the light of the outcome of the peer review.

The MRL recommendations are summarised in Appendix B.4.

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Abbreviations

a.s. active substance
ADI acceptable daily intake
AHDB Agriculture and Horticulture Development Board
ARfD acute reference dose
BBCH growth stages of mono- and dicotyledonous plants
bw body weight
CXL Codex maximum residue limit
DAR draft assessment report
DAT days after treatment
EMS evaluating Member State
EURL EU Reference Laboratory (former Community Reference Laboratory (CRL))
FAO Food and Agriculture Organization of the United Nations
GAP Good Agricultural Practice
GC-MS/MS gas chromatography with tandem mass spectrometry
HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
HPLC-UV high-performance liquid chromatography with ultraviolet detection
HR highest residue
IEDI international estimated daily intake
IESTI international estimated short-term intake
InChIKey International Chemical Identifier Key
ISO International Organisation for Standardisation
IUPAC International Union of Pure and Applied Chemistry
JMPR Joint FAO/WHO Meeting on Pesticide Residues
LOQ limit of quantification
MRL maximum residue level
MS Member States
NEU northern Europe
OECD Organisation for Economic Co-operation and Development
PBI plant-back interval
PHI preharvest interval
PRIMo (EFSA) Pesticide Residues Intake Model
QuEChERS Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method)
RA risk assessment
RAR Renewal Assessment Report
RD residue definition
RMS rapporteur Member State
SANCO Directorate-General for Health and Consumers
SEU southern Europe
SMILES simplified molecular-input line-entry system
STMR supervised trials median residue
WG water-dispersible granule
### Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Code   | Crop name | Region/country | Outdoor/indoor(a) | Pests controlled | Active substance (a.s.) | Formulation type(b) | a.s. conc. in formulation | Appl. method | Growth stage(c) | No of appl. | Interval (days) | Water amount | Max. appl. rate | PHI (days)(d) | Comments |
|--------|-----------|----------------|-------------------|------------------|-------------------------|---------------------|------------------------|--------------|----------------|-------------|----------------|--------------|----------------|--------------|----------|
| 270070 | Rhubarbs  | NEU/UK         | Outdoor           | Botrytis cinerea | Cyprodinil              | WG                  | 37.5% (w/w)            | Foliar treatment – broadcast spraying | See comment | 1–2          | 10           | 200–800 L/ha | 375 g a.s./ha | 14           | The formulation contains 25% Fludioxonil 37.5% Cyprodinil. Treatment as soon as first symptoms are observed |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern Europe; SEU: southern Europe; MS: Member State; WG: water-dispersible granule.

(a): Outdoor or field use (F), greenhouse application (G) or indoor application (I).

(b): CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system.

(c): Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including, where relevant, information on season at time of application.

(d): PHI: minimum preharvest interval.
## Appendix B – List of end points

### B.1. Residues in plants

#### B.1.1. Nature of residues and methods of analysis in plants

#### B.1.1.1. Metabolism studies, methods of analysis and residue definitions in plants

| Primary crops (available studies) | Crop groups | Crop(s) | Application(s) | Sampling (DAT) | Comment/source |
|-----------------------------------|-------------|---------|----------------|----------------|---------------|
| Fruit crops                       | Apple       | Foliar, 3 × 0.05 kg/haL (8 and 5 week intervals) | 61 (fruits and foliage at harvest) | Radiolabelling: 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                  | Peach       | Foliar, 4 × 0.27 and 4 × 2.7 kg/ha | 1 (fruits and foliage) | Application to individual branches of separate fruit trees, 21 to 1 day PHI (7 day interval) Radiolabelling: U-14C-phenyl or 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                  | Tomato      | Foliar, 2 × 0.75 kg/ha | 14 (fruits and foliage at harvest) | First application when fruits 2 cm diameter; second application 28 days later. Radiolabelling: U-14C-phenyl or 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
| Root crops                       | Potato      | Foliar, 3 × 0.56 kg/ha (19/20 day interval) | 14 (tuber and foliage at harvest) | Radiolabelling: U-14C-phenyl or 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
| Cereals/grass                    | Wheat       | Foliar, G, 1 × 0.75 g/ha (5–6 leaf stage) | 0-35 (whole plant) | Radiolabelling: U-14C-phenyl cyprodinil (EFSA, 2013) |
|                                  |             | Foliar, 1 × 0.75 + 1 × 0.50 kg/ha (22 day interval) | 41 (straw, husk, grain at harvest) | Radiolabelling: U-14C-phenyl or 2-14C-pyrimidine cyprodinil (EFSA, 2013) |

| Rotational crops (available studies) | Crop groups | Crop(s) | Application(s) | PBI (DAT) | Comment/source |
|--------------------------------------|-------------|---------|----------------|-----------|---------------|
| Root/tuber crops                    | Sugar beet  | Foliar on wheat, 0.75 + 0.5 kg/ha | 272 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     | Radish      | Soil, 1.25 kg/ha | 29, 124, 365 | Radiolabelling: 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
| Leafy crops                         | Lettuce     | Foliar on wheat, 0.75 + 0.5 kg/ha | 43 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     |             | Soil, 1.25 kg/ha | 29, 124, 365 | Radiolabelling: 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
| Cereal (small grain)                | Wheat       | Foliar on wheat, 0.75 + 0.5 kg/ha | 106 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     |             | Soil, 1.25 kg/ha | 29, 180, 365 | Radiolabelling: 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     | Maize       | Foliar on wheat, 0.75 + 0.5 kg/ha | 302 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
## Processed Commodities (hydrolysis study)

| Conditions                                      | Stable? | Comment/source |
|-------------------------------------------------|---------|----------------|
| Pasteurisation (20 min, 90°C, pH 4)             | Yes     | EFSA (2006, 2013) |
| Baking, brewing and boiling (60 min, 100°C, pH 5) | Yes     | EFSA (2006, 2013) |
| Sterilisation (20 min, 120°C, pH 6)             | Yes     | EFSA (2006, 2013) |

Can a general residue definition be proposed for primary crops?

Yes

Further consideration of the residue definition of cyprodinil in root and bulb crops (Allium species) may be required if new uses are requested in the future. (EFSA, 2006, 2013)

Rotational crop and primary crop metabolism similar?

Yes

In rotational crops, two plant metabolites (NOA422054 and CGA321915) were observed; both compounds considered of no toxicological concern (EFSA, 2006, 2013).

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Yes

EFSA (2006, 2013)

Plant residue definition for monitoring (RD-Mo)

Cyprodinil (EFSA, 2006, 2013)

Plant residue definition for risk assessment (RD-RA)

Cyprodinil (EFSA, 2006, 2013)

Methods of analysis for monitoring of residues (analytical technique, crop groups, LOQs)

HPLC-UV with LOQ of 0.01 mg/kg in high water (apples) and high acid (grapes) content matrices, 0.02 mg/kg in dry matrices (wheat grain) and 0.05 mg/kg in wheat straw (EFSA, 2006)

HPLC–MS/MS with LOQ of 0.01 mg/kg in high water (lettuce, radish tuber), high acid (grapes) content matrices, dry matrices (wheat grain and straw) and high oil content matrices (rape seed) (EFSA, 2006). Method validation not fully acceptable for high oil content matrices (EFSA, 2013)

GC–MS/MS with LOQ of 0.01 mg/kg in high water commodities (celery) (EFSA, 2015, France, 2014)

QuEChERS: HPLC–MS/MS with LOQ of 0.01 mg/kg in high water and high acid content matrices, and dry commodities (EFSA, 2013; EURL, 2018)

DAT: days after treatment; PBI: plant-back interval; HPLV-UV: high-performance liquid chromatography with ultraviolet detection; HPLC–MS/MS: high-performance liquid chromatography with tandem mass spectrometry; GC–MS/MS: gas chromatography with tandem mass spectrometry; QuEChERS: Quick, Easy, Cheap, Effective, Rugged, and Safe; LOQ: limit of quantification.
### B.1.1.2. Storage stability of residues in plants

| Plant products (available studies) | Category            | Commodity          | T (°C) | Stability period Value | Compounds covered | Comment/source       |
|-----------------------------------|---------------------|--------------------|--------|------------------------|-------------------|---------------------|
| Peaches, apples                   | High water content  |                    | –18    | 26 Months              | Cyprodinil        | EFSA (2006, 2013)   |
| Wheat                             | Dry/High starch     |                    | –18    | 24 Months              | Cyprodinil        | EFSA (2006, 2013)   |
| Grapes, strawberries              | High acid content   |                    | –18    | 24 Months              | Cyprodinil        | EFSA (2006, 2013)   |
B.1.2. Magnitude of residues in plants

B.1.2.1. Summary of residues data from the supervised residue trials

| Commodity | Region\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/Source | Calculated MRL \(^{(b)}\) (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|-----------|------------------|---------------------------------------------------------------|-----------------|-----------------------------|----------------|-------------------|
| Rhubarbs  | NEU              | 0.17; 0.17\(^{(d)}\); 0.75; 0.79                              | Residue trials on celery compliant with the NEU GAP Extrapolation to rhubarbs is acceptable (European Commission, 2017) | 2              | 0.79           | 0.43              |

MRL: maximum residue level; GAP: Good Agricultural Practice.
\(^{(a)}\): NEU: Outdoor trials conducted in northern Europe, SEU: Outdoor trials conducted in southern Europe, Indoor: indoor EU trials or Country code: if non-EU trials.
\(^{(b)}\): Highest residue. The highest residue for risk assessment refers to the whole commodity.
\(^{(c)}\): Supervised trials median residue. The median residue for risk assessment refers to the whole commodity.
\(^{(d)}\): The result of this trial refers to celery stems.
B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | Yes | EFSA (2006, 2013) |
| Residues in rotational and succeeding crops expected based on field rotational crop study? | Yes | Following treatment of soil planted with lettuce, turnips and wheat as succeeding crops 30, 90, 150 and 210 DAT at a rate of 4 × 0.56 kg/ha, no cyprodinil residues were found above the LOQ. Following one application on soil planted with wheat, lettuce and radishes as succeeding crops ~ 35, 110 and 330 DAT at a rate of 0.75 kg/ha, metabolites NOA422054 and CGA321915 were present at measurable levels in rotational crops at the PBI of 30 days. Residues of NOA422054 were up to 0.14 mg/kg in radish tops, 0.04 mg/kg in lettuces and 0.07 mg/kg in wheat forage (EFSA, 2013). |

DAT: days after treatment; PBI: plant-back interval; LOQ: limit of quantification.

B.1.2.3. Processing factors

No processing studies were submitted in the framework of the present MRL application.

B.2. Residues in livestock

Not relevant.

B.3. Consumer risk assessment

| ARfD | 1.5 mg/kg bw (France, 2017) |
| Highest IESTI, according to EFSA PRIMo | Rhubarbs: 2% of ARfD (UK toddler); indicative result |

Assumptions made for the calculations

Currently no acute reference dose is formally set for cyprodinil. However, in the framework of the renewal of the approval of cyprodinil, the RMS proposed an ARfD of 1.5 mg/kg bw. EFSA performed an indicative acute exposure assessment for rhubarbs applying the ARfD suggested by the RMS France in the RAR, and using the HR derived from the valid residue trials. Calculations were performed with PRIMo rev. 3

| ADI | 0.03 mg/kg bw per day (EFSA, 2006, France, 2017) |
| Highest IEDI, according to EFSA PRIMo | 48% ADI (NL toddler diet) |

Rhubarb: 0.4% of ADI (IE adult diet)
Assumptions made for the calculations

Calculations were performed with PRIMo rev. 3. The calculation is based on the median residue levels derived for raw agricultural commodities for which MRLs have been established in the EU MRL legislation. The contributions of commodities where no GAP was reported in the framework of the MRL review were not included in the calculation.

ARfD: acute reference dose; bw: body weight; IESTI: international estimated short-term intake; PRIMo: (EFSA) Pesticide Residues Intake Model; RMS: rapporteur Member State; RAR: Renewal Assessment Report; ADI: acceptable daily intake; IEDI: international estimated daily intake; MRL: maximum residue level.

B.4. Recommended MRLs

| Code(a) | Commodity  | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|---|---|---|---|---|
| 0270070 | Rhubarbs | 0.02* | 2 | The submitted data are sufficient to derive an MRL proposal for the NEU use by extrapolation from results on celery |

Enforcement residue definition: Cyprodinil(F)

MRL: maximum residue level; NEU: northern Europe.
*: Indicates that the MRL is set at the limit of analytical quantification (LOQ).
(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.
(F): Fat soluble.
LOQs (mg/kg) range from: 0.02 to: 0.10

ADI (mg/kg bw/day): 0.03
ARfD (mg/kg bw): 1.5

Source of ADI: EFSA
Source of ARfD: France

Year of evaluation: 2005
Year of evaluation: 2018

No of diets exceeding the ADI : ---

| Commodity/group of commodities | MRLs set at the LOQ (in % of ADI) | commodities not under assessment (in % of ADI) |
|--------------------------------|-----------------------------------|-----------------------------------------------|
| Pears                          | 48%                               | 48%                                           |
| Spinaches                      | 38%                               | 38%                                           |
| Table grapes                   | 24%                               | 24%                                           |
| Wine grapes                    | 22%                               | 22%                                           |
| Spinaches                      | 18%                               | 18%                                           |
| Lettuces                       | 18%                               | 18%                                           |
| Apples                         | 15%                               | 15%                                           |
| Apples                         | 14%                               | 14%                                           |
| Apples                         | 14%                               | 14%                                           |
| Spinaches                      | 13%                               | 13%                                           |
| Beans (with pods)              | 13%                               | 13%                                           |
| Other lettuce and other salad plants | 13%                       | 13%                                           |
| Wine grapes                    | 13%                               | 13%                                           |
| Carrots                        | 13%                               | 13%                                           |
| Apples                         | 13%                               | 13%                                           |
| Lettuces                       | 13%                               | 13%                                           |
| Lettuces                       | 12%                               | 12%                                           |
| Lettuces                       | 12%                               | 12%                                           |
| Spinaches                      | 11%                               | 11%                                           |
| Carrots                        | 11%                               | 11%                                           |
| Apples                         | 9%                                | 9%                                            |
| Strawberries                   | 8%                                | 8%                                            |
| Lettuces                       | 7%                                | 7%                                            |
| Celeries                       | 6%                                | 6%                                            |
| Apples                         | 5%                                | 5%                                            |
| Lettuces                       | 2%                                | 2%                                            |
| Celeries                       | 2%                                | 2%                                            |

Chronic risk assessment: JMPR methodology (IEDI/TMDI)

Conclusion:
UK vegetarian
PL general
UK adult

Refined calculation mode

Appendix C – Pesticide Residue Intake Model (PRIMo)

The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.

The chronic risk assessment of Cyprodinil in rhabars is unlikely to present a public health concern.
The acute risk assessment is based on the ARfD. The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Commodity                          | MRL/input (mg/kg) | Exposure (µg/kg bw) | Results for adults | No. of commodities for which ARfD/ADI is exceeded |
|-----------------------------------|-------------------|---------------------|--------------------|--------------------------------------------------|
| Unprocessed commodities           |                   |                     |                    |                                                  |
| 40% Celeries                      | 30/16             | 999                 | 17% Celeries       | 30/16                                            |
| 24% Escaroles/broad-leaved         | 15/8.9            | 358                 | 12% Escaroles/broad-leaved | 15/8.9                                           |
| 20% Lettuces                      | 15/8.9            | 339                 | 11% Chardisheet leaves | 15/8.9                                           |
| 13% Spinaches                     | 15/8.9            | 201                 | 7% Lettuces        | 15/8.9                                           |
| 12% Pears                         | 2/1.3             | 180                 | 5% Table grapes    | 3/2.3                                            |
| 11% Tabas grapes                   | 3/2.3             | 168                 | 4% Wine grapes     | 3/2.3                                            |
| 11% Peaches                       | 2/1.7             | 162                 | 3% Red mustards    | 15/8.9                                           |
| 9% Apples                         | 2/1.3             | 140                 | 3% Pears           | 2/1.3                                            |
| 9% Chardisheet leaves             | 15/8.9            | 139                 | 2% Apples          | 2/1.3                                            |
| 6% Plums                          | 2/1.7             | 72                  | 2% Spinaches       | 15/8.9                                           |
| 5% Carrots                        | 1.5/0.4           | 66                  | 2% Strawberries    | 5/3.74                                           |
| 5% Cauliflowers                   | 2/1.1             | 64                  | 2% Florence fennels | 4/1.71                                           |
| 4% Strawberries                   | 5/3.74            | 61                  |                    |                                                  |
| 4% Kaki/Japanese persimmons       | 2/1.3             | 61                  |                    |                                                  |
| 4% Apricots                       | 2/1.7             | 59                  |                    |                                                  |
| 4% Beetroots                      | 1.5/0.4           | 59                  |                    |                                                  |
| 4% Tomatoes                       | 1.5/0.97          | 56                  |                    |                                                  |
| 4% Melons                         | 0.6/0.36          | 55                  |                    |                                                  |
| 3% Sweet peppers/bell peppers     | 1.5/0.78          | 46                  |                    |                                                  |
| 3% Broccoli                       | 2/1.1             | 46                  |                    |                                                  |
| 3% Watermelons                    | 0.6/0.36          | 44                  |                    |                                                  |
| 3% Parsnips                       | 1.5/0.4           | 38                  |                    |                                                  |
| 3% Salads                         | 1.5/0.4           | 32                  |                    |                                                  |
| 2% Quinces                        | 2/1.3             | 32                  |                    |                                                  |
| 2% Avocados                       | 1/0.6             | 30                  |                    |                                                  |
| 2% Rhubarbles                      | 2/0.75            | 29                  |                    |                                                  |
| 2% Florence fennels               | 4/1.71            | 28                  |                    |                                                  |
| 2% Lamb's lettuce/com salads      | 15/8.9            | 25                  |                    |                                                  |
| 2% Aubergines/egg plants          | 1.5/0.97          | 24                  |                    |                                                  |
| 2% Roman rockettucula             | 15/8.9            | 24                  |                    |                                                  |
| 2% Cucumbers                      | 0.5/0.36          | 24                  |                    |                                                  |
| 2% Globe artichokes               | 4/1.3             | 23                  |                    |                                                  |
| 1% Wine grapes                    | 3/2.3             | 21                  |                    |                                                  |
| 1% Cherries                       | 2/1.7             | 21                  |                    |                                                  |
| 1% Chervi                         | 40/16             | 21                  |                    |                                                  |
| 1% Medlar                         | 2/1.3             | 18                  |                    |                                                  |
| 1% Parsley                        | 40/16             | 18                  |                    |                                                  |
| 1% Blackberries                   | 3/1.7             | 16                  |                    |                                                  |
| 1% Cabbage                        | 0.7/0.36          | 16                  |                    |                                                  |
| 1% Carrots                        | 2/1.4             | 15                  |                    |                                                  |
| 1% Sage                           | 40/16             | 12                  |                    |                                                  |
| 0.8% Basil and edible flowers     | 40/16             | 12                  |                    |                                                  |
| 0.8% Guavas                       | 1.5/0.52          | 11                  |                    |                                                  |
| 0.7% Blueberries                  | 3/1.7             | 10                  |                    |                                                  |
| 0.7% Goosberries                 | 3/1.7             | 10                  |                    |                                                  |
| 0.6% Peaches                      | 0.6/0.36          | 9.6                 |                    |                                                  |
| 0.6% Beans (with pods)            | 2/1.15            | 9.4                 |                    |                                                  |
| 0.8% Celery leaves                | 40/16             | 7.7                 |                    |                                                  |
| 0.5% Cranberries                  | 3/1.7             | 7.6                 |                    |                                                  |
| 0.4% Spring onions/green onions   | 0.8/0.43          | 6.7                 |                    |                                                  |
| 0.4% Celery/turnip root           | 0.3/0.11          | 6.1                 |                    |                                                  |
| 0.3% Parsley roots/Hamburg roots  | 0.5/1.04          | 4.7                 |                    |                                                  |
| 0.2% Radishes                     | 0.3/0.14          | 3.4                 |                    |                                                  |
| 0.2% Cress and other sprouts      | 15/8.9            | 2.6                 |                    |                                                  |

### Details – acute risk assessment/children

The calculation is based on the large portion of the most critical consumer group.
Modification of the existing maximum residue level for cyprodinil in rhubarbs

| Processed commodities | MRL/input for RA (µg/kg) | Exposure (µg/kg) |
|-----------------------|---------------------------|-----------------|
| 39% Escarole/cabbage | 15/8.9 1.5 | 15/8.9 | 1.5 |
| 16% Chard/rhubarb | 15/8.9 2.7 | 15/8.9 | 2.7 |
| 8% Spinach/rhubarb, boiled | 15/8.9 124 | 15/8.9 | 124 |
| 6% Broccoli/rhubarb | 2/1.1 87 | 2/1.1 | 87 |
| 5% Florence fennel | 41/7.1 77 | 41/7.1 | 77 |
| 5% Cauliflower | 21/1.1 77 | 21/1.1 | 77 |
| 4% Parsnip/rhubarb | 1.5/0.43 53 | 1.5/0.43 | 53 |
| 3% Beetroot/rhubarb | 1.5/0.43 46 | 1.5/0.43 | 46 |
| 3% Pea/rhubarb, canned | 21/7.1 44 | 21/7.1 | 44 |
| 2% Yosemite/rhubarb | 0.5/0.32 10 | 0.5/0.32 | 10 |
| 2% Rhubarb/sauce/juice | 0.2/0.09 29 | 0.2/0.09 | 29 |
| 2% Wine grape/juice | 2/0.48 29 | 2/0.48 | 29 |
| 2% Salsify/rhubarb | 2/0.48 27 | 2/0.48 | 27 |
| 2% Apple/rhubarb | 2/0.48 26 | 2/0.48 | 26 |
| 1% Carrot, red, black and white | 2/0.48 26 | 2/0.48 | 26 |
| 1% Carrot, yellow | 1.5/0.45 16 | 1.5/0.45 | 16 |
| 1% Peas | 2/0.48 16 | 2/0.48 | 16 |
| 1% Beans, green (with pods) | 2/0.48 14 | 2/0.48 | 14 |
| 0.8% Cabbage/rhubarb | 0.5/0.36 11 | 0.5/0.36 | 11 |
| 0.8% Pea/rhubarb, canned | 0.5/0.36 11 | 0.5/0.36 | 11 |
| 0.7% Endive/rhubarb | 0.8/0.48 11 | 0.8/0.48 | 11 |
| 0.6% Raspberries/rhubarb | 0.3/0.16 9.5 | 0.3/0.16 | 9.5 |
| 0.6% Gherkins/rhubarb | 0.5/0.36 6.3 | 0.5/0.36 | 6.3 |
| 0.4% Plum/rhubarb | 0.8/0.48 4 | 0.8/0.48 | 4 |
| 0.3% Cranberry/rhubarb | 0.3/0.16 4 | 0.3/0.16 | 4 |
| 0.3% Asparagus (mediterranean white) | 0.3/0.16 3.8 | 0.3/0.16 | 3.8 |
| 0.2% Tomato/rhubarb | 1.5/0.45 3.2 | 1.5/0.45 | 3.2 |
| 0.2% Wine/rhubarb, canned | 0.5/0.36 2.7 | 0.5/0.36 | 2.7 |
| 0.1% Rose hip/juice | 0.3/0.16 2.1 | 0.3/0.16 | 2.1 |
| 0.1% Tomatoes/rhubarb, canned | 1.5/0.45 1.6 | 1.5/0.45 | 1.6 |
| 0.1% Quince/rhubarb | 0.3/0.16 1.5 | 0.3/0.16 | 1.5 |
| 0.1% Ginger/rhubarb | 1.5/0.45 1.4 | 1.5/0.45 | 1.4 |
| 0.1% Celery/rhubarb | 0.3/0.16 1.2 | 0.3/0.16 | 1.2 |
| 0.1% Garlic/rhubarb | 0.3/0.16 1.2 | 0.3/0.16 | 1.2 |
| 0.1% Shallots | 0.3/0.16 1.2 | 0.3/0.16 | 1.2 |
| 0.1% Cabbage/rhubarb | 0.3/0.16 1.2 | 0.3/0.16 | 1.2 |
| 0.1% Asparagus/rhubarb | 0.3/0.16 1.2 | 0.3/0.16 | 1.2 |
| 0.06% Thyme/rhubarb | 0.06/0.06 1.2 | 0.06/0.06 | 1.2 |
| 0.06% Horseradish/rhubarb | 0.06/0.06 1.2 | 0.06/0.06 | 1.2 |
| 0.04% Pistachios/rhubarb | 0.04/0.06 0.74 | 0.04/0.06 | 0.74 |
| 0.03% Parsley/rhubarb | 0.03/0.06 0.39 | 0.03/0.06 | 0.39 |
| 0.03% Thyme/rhubarb | 0.03/0.06 0.39 | 0.03/0.06 | 0.39 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |
| 0.02% Mint/rhubarb | 0.02/0.04 0.24 | 0.02/0.04 | 0.24 |

Results for children
No exceedance of the toxicological reference value was identified for any unprocessed commodity.

- For processed commodities, no exceedance of the ARfD was identified.

Conclusion:
No exceedance of the toxicological reference value for cyprodinil was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD was identified.

Results for adults
No exceedance of the toxicological reference value was identified for any unprocessed commodity.

- For processed commodities, no exceedance of the ARfD was identified.

Conclusion:
No exceedance of the toxicological reference value for cyprodinil was identified for any unprocessed commodity. For processed commodities, no exceedance of the ARfD was identified.
Appendix D – Input values for the exposure calculations

D.1. Consumer risk assessment

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|------------------------------------------------|-------------------------|-----------------------|
|                                                | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Risk assessment residue definition: cyprodinil |                         |                       |                      |                       |
| Rhubarb                                        | 0.43 STMR               |                       | 0.79 HR             |                       |
| Almonds                                        | 0.02 STMR (EFSA, 2013)  |                       |                       |                       |
| Other tree nuts (except almonds and pistachios)| 0.02 STMR (FAO, 2017)   |                       |                       |                       |
| Pome fruit                                      | 0.48 STMR (FAO, 2014)   |                       |                       |                       |
| Stone fruit                                     | 0.68 STMR (FAO, 2014)   |                       |                       |                       |
| Table grapes                                    | 0.68 STMR (EFSA, 2013)  |                       |                       |                       |
| Wine grapes                                     | 0.67 STMR (EFSA, 2013)  |                       |                       |                       |
| Strawberries                                    | 0.99 STMR (EFSA, 2013)  |                       |                       |                       |
| Blackberries, raspberries                      | 0.81 STMR (EFSA, 2013)  |                       |                       |                       |
| Other small fruit and berries                  | 0.69 STMR (EFSA, 2013)  |                       |                       |                       |
| Kaki, Japanese persimmon                       | 0.48 STMR (FAO, 2014)   |                       |                       |                       |
| Avocados                                       | 0.26 STMR (FAO, 2014)   |                       |                       |                       |
| Guavas                                         | 0.485 STMR (FAO, 2017)  |                       |                       |                       |
| Beetroot, carrots, horseradish, parsnips, parsley roots, salsifles | 0.45 STMR (EFSA, 2013)  |                       |                       |                       |
| Celeriac                                       | 0.08 STMR (EFSA, 2013)  |                       |                       |                       |
| Radishes                                       | 0.01 STMR (FAO, 2014)   |                       |                       |                       |
| Garlic, shallots                               | 0.02 STMR (EFSA, 2013)  |                       |                       |                       |
| Onions                                          | 0.07 STMR CXL (EFSA, 2013)|                       |                       |                       |
| Spring onions                                  | 0.17 STMR (EFSA, 2013)  |                       |                       |                       |
| Tomatoes, aubergines                           | 0.17 STMR (EFSA, 2013)  |                       |                       |                       |
| Sweet peppers                                  | 0.24 STMR (EFSA, 2013)  |                       |                       |                       |
| Cucurbits (edible peel)                        | 0.13 STMR (EFSA, 2013)  |                       |                       |                       |
| Cucurbits (inedible peel)                      | 0.08 STMR (EFSA, 2013)  |                       |                       |                       |
| Flowering brassica                             | 0.27 STMR (FAO, 2014)   |                       |                       |                       |
| Head cabbages                                  | 0.03 STMR (FAO, 2014)   |                       |                       |                       |
| Lettuce and other salad plants; Spinach and similar leaves | 3.10 STMR (EFSA, 2013)  |                       |                       |                       |
| Witloofs/Belgian endives                       | 0.02 STMR (EFSA, 2013)  |                       |                       |                       |
| Herbs                                          | 5.05 STMR (FAO, 2014)   |                       |                       |                       |
| Beans (with pods), peas (with pods)            | 0.60 STMR (EFSA, 2013)  |                       |                       |                       |
| Beans (without pods), peas (without pods)      | 0.02 STMR (EFSA, 2013)  |                       |                       |                       |
| Lentils                                        | 0.07 STMR (EFSA, 2010)  |                       |                       |                       |
| Asparagus                                      | 0.02 STMR (EFSA, 2013)  |                       |                       |                       |
| Celerics                                       | 8.45 STMR (FAO, 2017)   |                       |                       |                       |
| Florence fennel                                | 0.77 STMR (EFSA, 2019)  |                       |                       |                       |
| Globe artichokes                               | 1.2 STMR (FAO, 2017)    |                       |                       |                       |
| Dry beans                                      | 0.06 STMR (EFSA, 2013)  |                       |                       |                       |
| Dry peas, lupins                               | 0.02 STMR (EFSA, 2013)  |                       |                       |                       |
| Rapeseeds/canola seeds                         | 0.02 STMR (FAO, 2016b)  |                       |                       |                       |
| Barley, oat                                    | 0.75 STMR (EFSA, 2013)  |                       |                       |                       |
| Rye, wheat                                     | 0.13 STMR (EFSA, 2013)  |                       |                       |                       |
| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|-------------------------|-----------------------|
|                                               | Input value (mg/kg)     | Comment               | Input value (mg/kg) | Comment               |
| Herbal infusions (dried roots); Roots and rhizome of spices | 0.45 STMR (EFSA, 2013) |                       |                       |
| **Risk assessment residue definition:** sum of cyprodinil and CGA 304075, expressed as cyprodinil |                       |                       |                       |
| Swine and poultry muscle, fat, liver, kidney  | 0.02 STMR (EFSA, 2013)  |                       |                       |
| Ruminant muscle, fat                         | 0.02 STMR (EFSA, 2013)  |                       |                       |
| Ruminant liver                               | 0.02 STMR (EFSA, 2013)  |                       |                       |
| Ruminant kidney, edible offal                 | 0.02 STMR (EFSA, 2013)  |                       |                       |
| Milk                                          | 0.02 STMR (EFSA, 2013)  |                       |                       |
| Eggs                                          | 0.02 STMR (EFSA, 2013)  |                       |                       |

STMR: supervised trials median residue; HR: highest residue; CXL: codex maximum residue limit.

Consumption figures in the EFSA PRIMo are expressed as meat. Since the a.s. is a fat-soluble pesticide, STMR and HR residue values were calculated considering a 80%/90% muscle and 20%/10% fat content for mammal/poultry meat respectively (FAO, 2016b, 2017).
### Appendix E – Used compound codes

| Code/trivial name<sup>(a)</sup> | IUPAC name/SMILES notation/InChiKey<sup>(b)</sup> | Structural formula<sup>(c)</sup> |
|-------------------------------|---------------------------------------------|--------------------------------|
| cyprodinil                    | 4-cyclopropyl-6-methyl-N-phenylpyrimidin-2-amine |
|                               | Cc1cc(nc(Nc2cccccc2)n1)C3CC3               | ![Structural formula](image1) |
|                               | HAORKGNJCEJBX-UHFFFAOYSA-N                |
| CGA321915                     | 4-cyclopropyl-6-methyl/pyrimidin-2(1H)-one |
|                               | CC1=CC(=NC(=O)N1)C2CC2                  | ![Structural formula](image2) |
|                               | QODMYONMGSOMCI-UHFFFAOYSA-N              |
| NOA422054                     | (2-amino-6-cyclopropyl/pyrimidin-4-yl)methanol |
|                               | Nc1nc(cc(CO)n1)C2CC2                     | ![Structural formula](image3) |
|                               | SPGFTSNGXQXB0-UHFFFAOYAM                |

IUPAC: International Union of Pure and Applied Chemistry; SMILES: simplified molecular-input line-entry system; InChiKey: International Chemical Identifier Key.

<sup>(a)</sup> The metabolite name in bold is the name used in the conclusion.

<sup>(b)</sup> ACD/Name 2015 ACD/Labs 2015 Release (File version N20E41, Build 75170, 19 December 2014).

<sup>(c)</sup> ACD/ChemSketch 2015 ACD/Labs 2015 Release (File version C10H41, Build 75059, 17 December 2014).