Modification of the existing maximum residue level for cyprodinil in Florence fennel

European Food Safety Authority (EFSA), Maria Anastassiadou, Alba Brancato, Daniela Brocca, Luis Carrasco Cabrera, Lucien Ferreira, Luna Greco, Samira Jarrah, Aija Kazocina, Renata Leuschner, Alfonso Lostia, Jose Oriol Magrans, Paula Medina, Ileana Miron, Ragnor Pedersen, Marianna Raczyk, Hermine Reich, Silvia Ruocco, Angela Sacchi, Miguel Santos, Alois Stanek, Jose Tarazona, Anne Theobald and Alessia Verani

Abstract

In accordance with Article 6 of Regulation (EC) No 396/2005, the FPS Health, Food chain safety and Environment of Belgium, submitted an application to modify the existing maximum residue level (MRL) for the active substance cyprodinil in Florence fennel to accommodate the intended use in the northern Europe. The submitted data were found sufficient to derive an MRL proposal of 4 mg/kg for cyprodinil in Florence fennel. 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 long-term intake of residues resulting from the authorised uses of cyprodinil and the intended use on Florence fennel is unlikely to present a risk to consumer health. An indicative acute exposure assessment was performed, considering the acute reference dose (ARfD) proposed by the rapporteur Member State (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 Florence fennel. 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.

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Correspondence: pesticides.mrl@efsa.europa.eu
Summary

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service of Belgium, FPS Health, Food chain safety and Environment submitted an application to modify the existing maximum residue level (MRL) for the active substance cyprodinil in Florence fennel. The FPS Health (evaluating Member State, 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 6 July 2018. To accommodate for the intended use of cyprodinil on Florence fennel in Belgium, the EMS proposed to raise the existing MRL from 0.3 to 5 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 and the data evaluated under previous MRL assessments, including the review of the existing cyprodinil MRLs according to Article 12 of the Regulation (EC) No 396/2005 (MRL review), the following conclusions are derived.

The metabolism of cyprodinil in primary crops was investigated following foliar application in three different crop groups (fruit crops, cereals/grass and root crops). In leafy vegetables, relevant for the application on Florence fennel, no specific metabolism studies are available. In a previous assessment of EFSA, based on the findings of metabolism studies with potatoes and tomatoes where the results on leaves were comparable with the results of fruits and cereal grain, it was concluded that metabolic pathway in leafy vegetables proceeds in the same pathway as in cereals and fruits. Thus, metabolism in leafy crops 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.

In rotational crops, the major residues identified at measurable levels were cyprodinil metabolites CGA321915 and NOA422054. It was therefore concluded that Member States granting authorisations for cyprodinil on Florence fennel should consider the need to take appropriate risk mitigation measures (e.g. definition of a pre-plant interval of at least 120 days) in order to avoid residues of cyprodinil metabolites in rotational crops.

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 Florence fennel 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 Florence fennel according to the enforcement residue definition and the lowest validated limit of quantification (LOQ) of 0.01 mg/kg.

The data submitted in support of this MRL application were found sufficient to derive an MRL proposal of 4 mg/kg in Florence fennel, as extrapolated from northern Europe (NEU) 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 Florence fennel to the total consumer exposure. Residues of cyprodinil in commodities of animal origin were not assessed since fennel is normally not fed to livestock.

The toxicological profile of cyprodinil was assessed in the framework of the European Union (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, the setting of an ARfD of 1.5 mg/kg bw for cyprodinil was proposed by the rapporteur Member State (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, EFSA used the supervised trials median residue (STMR) value as derived for Florence fennel from the residue trials on celery. For the remaining crops the STMR values as reported by the MRL review 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 Florence fennel, in case the proposed ARfD will be confirmed.

No long-term consumer intake concerns were identified for any of the European diets incorporated in EFSA PRIMo. The total calculated intake accounted for 55% of the ADI (NL toddler diet). The contribution of residues in Florence fennel to the total consumer exposure accounted for a maximum of 0.25% of the ADI (IT adult diet). The indicative acute exposure calculation did not identify consumer intake concerns related to residues of cyprodinil in Florence fennels (2% of the ARfD).

EFSA concluded that the proposed use of cyprodinil on Florence fennel will not result in a consumer exposure exceeding the toxicological reference value and therefore is unlikely to pose a risk to consumers’ health.

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

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

Full details of all end points and the consumer risk assessment can be found in Appendices B-D.

| Code<sup>(a)</sup> | Commodity | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification |
|-------------------|-----------|------------------------|-------------------------|-----------------------|
| 0270040           | Florence fennels | 0.3                   | 4                       | The submitted data are sufficient to derive an MRL proposal for the NEU use. A plant-back interval of 120 days shall be considered by Member States granting cyprodinil authorisations. Risk for consumers unlikely |

MRL: maximum residue level; NEU: northern Europe.

(a): Commodity code number according to Annex I of Regulation (EC) No 396/2005.

(F): Fat soluble.
# Table of contents

Abstract................................................................................................................................................... 1  
Summary................................................................................................................................................. 3  
Assessment.............................................................................................................................................. 6  
  1. Residues in plants ........................................................................................................................ 7  
  1.1. Nature of residues and methods of analysis in plants ................................................................. 7  
  1.1.1. Nature of residues in primary crops .......................................................................................... 7  
  1.1.2. Nature of residues in rotational crops ....................................................................................... 7  
  1.1.3. Nature of residues in processed commodities ......................................................................... 8  
  1.1.4. Methods of analysis in plants .................................................................................................. 8  
  1.1.5. Stability of residues in plants ................................................................................................... 8  
  1.1.6. Proposed residue definitions ................................................................................................... 8  
  1.2. Magnitude of residues in plants .................................................................................................. 8  
  1.2.1. Magnitude of residues in primary crops ................................................................................... 8  
  1.2.2. Magnitude of residues in rotational crops ............................................................................... 9  
  1.2.3. Magnitude of residues in processed commodities .................................................................... 9  
  1.2.4. Proposed MRLs ....................................................................................................................... 9  
  2. Residues in livestock ..................................................................................................................... 9  
  3. Consumer risk assessment ............................................................................................................ 9  
  4. Conclusion and Recommendations ................................................................................................. 10  
References............................................................................................................................................... 10  
Abbreviations ........................................................................................................................................... 11  
Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs .............. 12  
Appendix B – List of end points .......................................................................................................... 13  
Appendix C – Pesticide Residue Intake Model (PRIMO) .......................................................... 17  
Appendix D – Input values for the exposure calculations ................................................................. 20  
Appendix E – Used compound codes ............................................................................................. 22
Assessment

The European Food Safety Authority (EFSA) received an application to modify the existing maximum residue level (MRL) for cyprodinil in Florence fennel. The detailed description of the intended use of cyprodinil in Belgium on Florence fennel 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 Council Directive 91/414/EEC1 with France designated as rapporteur Member State (RMS). It was included in Annex I of this Directive by Directive 2006/64/EC2 which entered into force on 1 May 2007 for use as a fungicide. According to Regulation 540/20113, cyprodinil is deemed to be approved under Regulation (EC) No 1107/20094. The representative uses evaluated in the peer review were foliar applications on winter wheat and apples. The draft assessment report (DAR) of cyprodinil has been peer reviewed by EFSA (2006). The renewal of the approval of cyprodinil in accordance with Regulation (EC) No 1107/2009 is currently ongoing.

The European Union (EU) MRLs for cyprodinil are established in Annex 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 by Commission Regulation (EU) 2015/4005. After completion of the MRL review, EU MRLs have been modified, including certain Codex MRLs in the EU MRL legislation (FAO, 2014, 2016, 2017). In 2015, EFSA issued a reasoned opinion on the setting of new MRL for cyprodinil in celery, but since EFSA concluded that the existing MRL was sufficient to cover the intended use (EFSA, 2015), the MRL for celery has not been modified.

In accordance with Article 6 of Regulation (EC) No 396/2005, the Federal Public Service of Belgium, FPS Health, Food chain safety and Environment submitted an application to modify the existing MRL for the active substance cyprodinil in Florence fennel. The FPS Health (evaluating Member State, 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 6 July 2018. To accommodate for the intended use of cyprodinil on Florence fennel in Belgium, the EMS proposed to raise the existing MRL from 0.3 to 5 mg/kg.

EFSA based its assessment on the evaluation report submitted by the EMS (Belgium 2018), the DAR (and its addenda) prepared under Council Directive 91/414/EEC (France, 2003, 2009), the conclusion on the peer review of the pesticide risk assessment of the active substance cyprodinil (EFSA, 2006), the conclusions from the previous EFSA opinion on cyprodinil (EFSA, 2015) and the related evaluation report prepared by the EMS/RMS (France, 2014) as well as the opinion on the review of the existing cyprodinil MRLs (EFSA, 2013).

For this application, the data requirements established in Regulation (EU) No 544/20116 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, 2011, 2013). 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 546/20117.

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 clompyralid, cyprodinil, fosetyl and trinexapac as active substances. OJ L 206, 27.7.2006, p. 107–111.
3 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.
4 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 L 309, 24.11.2009, p. 1–50.
5 Commission Regulation (EU) 2015/400 of 25 February 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for bone oil, carbon monoxide, cyprodinil, dodemorph, iprodione, metaldehyde, metazachlor, paraffin oil (CAS 64742-54-7), petroleum oils (CAS 92062-35-6) and propargite in or on certain products. OJ L 71, 14.3.2015, p. 56–113.
6 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.
7 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.
As the EU pesticides peer review on the renewal of the approval of cyprodinil in accordance with Regulation (EC) No 1107/2009 is ongoing, 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.

The evaluation report submitted by the EMS (Belgium, 2018) and the exposure calculations using the EFSA Pesticide Residues Intake Model (PRIMo revision 3) 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 three crop groups (fruit crops (apple, peach and tomato), root crops (potato) and cereals (wheat)) in the framework of the peer review under Directive 91/414/EEC and was assessed in detail in the framework of the MRL review (EFSA, 2006, 2013).

Cyprodinil was found to be comparatively persistent and up to 60 days after the application remained a dominant residue in all crop groups, except in potato tubers where a different metabolic pattern resulting from the uptake of soil metabolites was observed. Metabolite CGA232449 was the most prevalent metabolite in tomato fruit, where it was found in its conjugated and free form at 0.63 mg/kg (12.6% total radioactive residue (TRR)) and 0.12 mg/kg (2.5% TRR), respectively. In potato foliage at mature harvest, parent cyprodinil was the major component, accounting for 46–48% of the TRR. For residues in potato tubers, the peer review 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 (EFSA, 2006).

For leafy vegetables, no specific metabolism studies are available. In the framework of the MRL review, it was assumed that metabolic pathway in leafy vegetables proceeds in the same pathway as in cereals and fruits (EFSA, 2013). This assumption was confirmed by the finding in metabolism studies with potatoes and tomatoes where the results on leaves were comparable with the results of fruits and cereal grain.

1.1.2. Nature of residues in rotational crops

Fennel can be grown in rotation with other plants and therefore the possible occurrence of residues in succeeding crops resulting from the use of the active substance on primary crops had to be assessed. According to the soil degradation studies evaluated in the framework of the peer review, the highest DT90 value of cyprodinil based on the field study results was 814 days in acidic soils, which exceeds the trigger value of 100 days (EFSA, 2006, 2013).

A study investigating residues in rotational crops was provided where cyprodinil was applied on wheat as primary crop. 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).

In a second study with treatment of the bare soil, four major cyprodinil metabolites were identified in the succeeding crops (wheat, lettuce and radishes) sown at any of the replant plant-back intervals: CGA321915 (lettuce, radish top and wheat straw), CGA2492871 (lettuce, wheat straw and mustard leaves), NOA422054 (major metabolite, representing 12–46% TRR in 29 days after treatment (DAT) lettuce head, 365 DAT radish leaves and 130 DAT wheat straw) and CGA263208 (mustard leaves and wheat straw).

The peer review and the MRL review 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 NOA422054 and CGA321915 which were found at measurable levels at the earliest replanting interval of 30 DAT, while parent cyprodinil occurred rarely (see Section 1.2.2 below). As none of these metabolites were found to be of toxicological concern, it was decided not to include them 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, 2006). The MRL review recommended 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 120 days) in order to avoid the presence of cyprodinil metabolites residues in rotational crops (EFSA, 2013).

EFSA reiterates the previously made recommendation for the intended use on Florence fennel, noting that in the framework of the renewal of the approval for cyprodinil revised recommendations might be derived.

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 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) is 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 oil content, high oil content and in dry commodities (EURL, 2018).

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

1.1.5. Stability of residues in plants

The storage stability of cyprodinil was concluded upon in the EFSA conclusion (EFSA, 2006) and in the MRL review (EFSA, 2013). Residues of cyprodinil were found to be stable at \( \leq -18^\circ C \) for up to 26 months in high water content commodities (peach, apple) and 24 months in high acid content commodities (grape, strawberries) and in dry/high starch content commodities (wheat).

1.1.6. Proposed residue definitions

Based on the primary and rotational crop metabolism studies, the peer review and the MRL review proposed that the residue for enforcement and risk assessment in plant commodities was defined as ‘cyprodinil’ only.

The MRL review proposed that the residue definition should be reconsidered, requesting additional studies for root and tuber vegetables if higher application rates would be requested in the future; this data gap, however, is not pertinent to this intended use on Florence fennel. The current residue definition set in Regulation (EC) No 396/2005 is identical to the residue definition for enforcement derived in the peer review and the MRL review.

If residue definitions will be modified in the framework of the renewal of the approval, the MRL proposal derived in this opinion as well as the risk assessment, need to be reconsidered.

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 Florence fennel, the applicant refers to the residue trials on celery which were submitted previously to EFSA by the EMS France and assessed in the reasoned opinion on the setting of MRLs for cyprodinil in celery (France 2014; EFSA, 2015). The applicant proposes to derive an MRL of 5 mg/kg for Florence fennel on the basis of four NEU and four southern Europe (SEU) celery trials. The residue data extrapolation from celery to Florence fennel is acceptable according to the EU guidance documents (European Commission, 2017).

Since the use of cyprodinil on Florence fennel is intended only in the northern Europe, EFSA derived an MRL proposal of 4 mg/kg from the available four NEU celery trials. Available residue trial data were considered valid both with regard to analytical part and the storage stability (EFSA, 2015).
1.2.2. Magnitude of residues in rotational crops

In addition to the confined rotational crop studies (see Section 1.1.2), five rotational crop field trials performed at application rates ranging from 750 g/ha to 2,240 g/ha (from 1N to 3N of the intended annual dose on Florence fennel) were evaluated in the framework of the peer review (France, 2003, 2009, EFSA, 2006) and in the MRL review (EFSA, 2013).

Based on these studies, it was concluded that significant residue levels of cyprodinil are not expected to be present in rotational crops. For short plant-back intervals (30 days), measurable levels of metabolites CGA321915 and NOA422054 are expected in rotational crops, following the use of cyprodinil at dose rates equivalent to the intended use on Florence fennels.

As recommended in the framework of the MRL review, Member States granting authorisations for cyprodinil on Florence fennel should consider the need to take appropriate risk mitigation measures (e.g. definition of a pre-plant interval of at least 120 days) in order to avoid residues of cyprodinil metabolites CGA321915 and NOA422054 being present in rotational crops.

1.2.3. Magnitude of residues in processed commodities

Studies investigating the effect of processing on the magnitude of cyprodinil residues in processed fennel have not been submitted and not required, considering low contribution of residues in Florence fennel to the total calculated consumer exposure.

1.2.4. Proposed MRLs

The submitted data are sufficient to propose an MRL of 4 mg/kg for cyprodinil in Florence fennel in support of the intended Good Agricultural Practice (GAP) in Belgium.

2. Residues in livestock

Fennel or its by-products is not used as livestock feed item and therefore the assessment of the nature and magnitude of cyprodinil in livestock was not undertaken 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, for Florence fennel EFSA used the STMR value as derived from the residue trials on celery (see Section B.1.2.1). For the remaining crops, the STMR values as reported by the MRL review were used as input values (EFSA, 2013); for Codex MRLs implemented in the EU MRL legislation, the STMR values derived by JMPR were taken into account as well in the risk assessment (FAO, 2014, 2016, 2017). 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.

Currently, no acute reference dose (ARfD) is set formally for cyprodinil. However, in the framework of the renewal of the approval of cyprodinil, an ARfD of 1.5 mg/kg body weight (bw) was proposed by the RMS France (France, 2017). Thus, EFSA also performed an indicative acute exposure assessment, assuming that this proposed ARfD is confirmed by the experts. The indicative acute risk assessment was performed for Florence fennel only, using the highest residue (HR) derived from the valid residue trials.

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

No long-term consumer intake concerns were identified for any of the European diets incorporated in EFSA PRIMo. The total calculated intake accounted for a maximum 55% of the acceptable daily intake (ADI (NL toddler diet)). The contribution of residues in Florence fennel to the total consumer exposure accounted was low (0.25% of the ADI (IT adult diet)). The indicative acute exposure calculation did not identify acute consumer intake concerns related to intended use of cyprodinil in Florence fennels (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 4 mg/kg in Florence fennel, as extrapolated from residue trials on celery, in support of the intended NEU GAP.

Based on the risk assessment results, EFSA concluded that the long-term intake of residues resulting from the authorised uses of cyprodinil and the intended use on Florence fennel is unlikely to present a risk to consumer health. An indicative acute exposure assessment was performed, considering 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 Florence fennel.

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
- 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
- DT90 period required for 90% dissipation (define method of estimation)
- 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
- HPLC-MS/MS high-performance liquid chromatography with tandem mass spectrometry
- HPLC-UVD high-performance liquid chromatography with ultraviolet detector
- 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
- SC suspension concentrate
- SEU southern Europe
- SMILES simplified molecular-input line-entry system
- STMR supervised trials median residue
- TRR total radioactive residue
- WG water-dispersible granule
- WHO World Health Organization
# Appendix A – Summary of intended GAP triggering the amendment of existing EU MRLs

| Crop and/or situation | NEU, SEU, MS or country | F G or I(a) | Pests or group of pests controlled | Preparation | Application | Application rate per treatment |
|----------------------|-------------------------|-------------|----------------------------------|-------------|------------|--------------------------------|
|                      |                         |             |                                  | Type(b) | Conc. a.s. | Method kind | Range of growth stages and season(c) | Number min-max | Interval between application (min) | g a.s./hl min-max | Water L/ha min-max | Rate | Unit | PHI (days)(d) | Remarks |
| Florence fennel (0270040) | NEU (BE) | F | Bortytis cinerea, Sclerotonia sclerotiorum | WG | 375 g/kg | Foliar spray | 1-2 | 10-14 | 375 g/ha | 14 | |

GAP: Good Agricultural Practice; MRL: maximum residue level; NEU: northern European Union; SEU: southern European Union; MS: Member State; WG: water-dispersible granule; a.s.: active substance.
(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/L (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, 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/L | 272 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     | Radish      | Soil, 1.25 kg/L | 29, 124, 365 | Radiolabelling: 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
| Leafy crops                         | Lettuce     | Foliar on wheat, 0.75 + 0.5 kg/L | 43 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     | Soil        | 1.25 kg/L | 29, 124, 365 | Radiolabelling: 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
| Cereal (small grain)                | Wheat       | Foliar on wheat, 0.75 + 0.5 kg/L | 106 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     | Soil        | 1.25 kg/L | 29, 180, 365 | Radiolabelling: 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
|                                     | Maize       | Foliar on wheat, 0.75 + 0.5 kg/L | 302 | Radiolabelling: U-14C-phenyl and 2-14C-pyrimidine cyprodinil (EFSA, 2013) |
Can a general residue definition be proposed for primary crops?

Yes

Any use on potatoes should be considered for metabolism, taking into account the application rates and the actual residue levels expected in tubers. (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, 2005, 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)

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)

B.1.1.2. Stability of residues in plants

| Plant products (available studies) | Category      | Commodity          | T (°C) | Stability period Value | Compounds covered | Comment/source |
|-----------------------------------|---------------|--------------------|--------|------------------------|-------------------|---------------|
|                                    | High water content | Peaches, apples   | –18    | 26 Months              | cyprodinil        | EFSA (2006, 2013) |
|                                    | Dry/High starch   | Wheat              | –18    | 24 Months              | cyprodinil        | EFSA (2006, 2013) |
|                                    | High acid content | Grapes, strawberries | –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/indoor\(^{(a)}\) | Residue levels observed in the supervised residue trials (mg/kg) | Comments/source | Calculated MRL (mg/kg) | HR\(^{(b)}\) (mg/kg) | STMR\(^{(c)}\) (mg/kg) |
|------------|---------------------------|---------------------------------------------------------------|-----------------|------------------------|-----------------|-----------------|
| Fennel     | NEU                       | 0.17; 0.75; 0.79; 1.71                                       | Residue trials on celery compliant with the NEU GAP Extrapolation to fennel supported | 4                      | 1.71            | 0.77            |

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 according to enforcement residue definition.

\(^{(c)}\): Supervised trials median residue according to enforcement residue definition.

#### B.1.2.2. Residues in rotational crops

| Residues in rotational and succeeding crops expected based on confined rotational crop study? | No |
|--------------------------------------------------------------------------------------------|----|
| Yes | EFSA, 2006, 2013 |

| Residues in rotational and succeeding crops expected based on field rotational crop study? | Yes |
|--------------------------------------------------------------------------------------------|-----|
| Following soil treatment at a rate of g/ha, no cyprodinil residues were found above the LOQ Following the treatment of wheat 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 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 (EFSA, 2013) | EFSA, 2006, 2013 |

#### 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**

Highest IESTI, according to EFSA PRIMO Florence fennel: 2 % of ARfD (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 Florence fennels applying the ARfD suggested by the RMS France in the RAR, and using the HR derived from the valid residue trials.

**ADI**

Highest IEDI, according to EFSA PRIMO Florence fennel: 0.25 % of ADI (IT adult diet)

Assumptions made for the calculations

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.

B.4. Recommended MRLs

| Code<sup>(a)</sup> | Commodity          | Existing EU MRL (mg/kg) | Proposed EU MRL (mg/kg) | Comment/justification                                      |
|-------------------|--------------------|-------------------------|-------------------------|------------------------------------------------------------|
| 0270040           | Florence fennels   | 0.3                     | 4                       | The submitted data are sufficient to derive an MRL proposal for the NEU use. A plant-back interval of 120 days shall be considered by Member States granting cyprodinil authorisations. Risk for consumers unlikely |

MRL: maximum residue level; NEU: northern Europe.

<sup>(a)</sup>: Commodity code number according to Annex I of Regulation (EC) No 396/2005.

<sup>(F)</sup>: Fat soluble.
## Appendix C – Pesticide Residue Intake Model (PRIMo)

### Cyprodinil (F)

| Input values | Details – chronic risk assessment | Supplementary results – chronic risk assessment | Details – acute risk assessment/children | Details – acute risk assessment/adults |
|--------------|----------------------------------|-----------------------------------------------|----------------------------------------|---------------------------------------|
| LOQs (mg/kg) range from: to: | | | | |
| ADI (mg/kg bw per day): | | | | |
| ARfD (mg/kg bw): | | | | |
| Source of ADI: | EFSA | | | |
| Source of ARfD: | EFSA | | | |
| EFSA PRIMo revision 3.1; 2018/08/18 | | | | |
| Year of evaluation: | 2018 | | | |
| Year of evaluation: | 2018 | | | |
| No of diets exceeding the ADI : --- | | | | |

### Chronic risk assessment: JMPR methodology (IEDI/TMDI)

#### No of diets exceeding the ADI:

**Exposure resulting from**:  

| Commodity/group of commodities | Exposure (µg/kg bw per day) | Highest contributor to MS diet (in % of ADI) | 2nd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) | 3rd contributor to MS diet (in % of ADI) |
|-------------------------------|-----------------------------|---------------------------------------------|-----------------------------------------|------------------------------------------|------------------------------------------|------------------------------------------|
| MS Diet                       |                             |                                             |                                         |                                          |                                          |                                          |
| 20% NL child                  | 14.60                       | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 20% NL child                  | 8.32                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 20% NL child                  | 7.66                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 20% GEMIS/Food G11            | 6.61                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 20% GEMIS/Food G07            | 5.96                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 20% GEMIS/Food G08            | 5.37                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 20% GEMIS/Food G15            | 5.15                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 19% GEMIS/Food G10            | 5.15                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 19% GEMIS/Food G06            | 4.90                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 18% GEMIS/Food G05            | 4.90                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 18% GEMIS/Food G04            | 4.90                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 17% FR child 3-15 yr          | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 17% FR child 1-2 yr           | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 16% IT child                  | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 15% ES adult                  | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 15% SE general                | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 15% DE women 14-49 yr         | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 15% DE general                | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 15% ES child                  | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 14% PT general                | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 14% RO general                | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 14% FR adult                  | 4.59                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 13% NL general                | 4.65                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 13% FR infant                 | 3.95                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 12% UK infant                 | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 12% UK toddler                | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 12% US toddler                | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 11% FI 3 yr                   | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 9% UK vegetable               | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 9% DK adult                   | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 8% FI 6 yr                    | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 8% PT general                 | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 7% UK adult                   | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 7% LT adult                   | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 6% FR adult                   | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |
| 2% IE child                   | 3.75                        | 42% Apple                                  | 20% Table grapes                       | 3% Apples                                | 2% Wine grapes                          | 2% Lettuce                               |

**Conclusion:** The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI. The long-term intake of residues of Cyprodinil (F) is unlikely to present a public health concern.
## Acute risk assessment/children

The acute risk assessment is based on the ARID. The calculation is based on the large portion of the most critical consumer group.

### Results for children

| Commodity                      | Highest % of ARfD/ADI | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------------------------------|-----------------------|--------------------------|---------------------|
| Celeries                      | 40%                   | 3/0.16                   | 599                 |
| Escaroles/broad-leaved        | 24%                   | 15/8.9                   | 358                 |
| Spinaches                     | 13%                   | 15/8.9                   | 291                 |
| Pears                         | 12%                   | 2/1.3                    | 180                 |
| Table grapes                  | 11%                   | 2/1.7                    | 162                 |
| Peaches                       | 9%                    | 2/1.3                    | 72                  |
| Apples                        | 4%                    | 15/1.7                   | 66                  |
| Plums                         | 5%                    | 15/1.1                   | 64                  |
| Strawberries                  | 4%                    | 5/3.74                   | 61                  |
| Kaki/Japanese persimmons      | 4%                    | 2/1.3                    | 61                  |
| Tomatoes                      | 4%                    | 15/0.97                  | 56                  |
| Melons                        | 4%                    | 0.6/0.36                 | 55                  |
| Sweet peppers/bell peppers   | 3%                    | 1.5/0.78                 | 46                  |
| Beetroot                      | 3%                    | 1.5/1.04                 | 46                  |
| Broccoli                      | 3%                    | 2/1.1                    | 46                  |
| Watermelons                   | 3%                    | 0.6/0.36                 | 44                  |
| Parsnips                      | 3%                    | 1.5/1.41                 | 38                  |
| Salifles                      | 2%                    | 1.5/1.04                 | 32                  |
| Quinces                       | 2%                    | 2/1.3                    | 32                  |
| Avocados                      | 2%                    | 1/0.6                    | 30                  |
| Florence fennels              | 2%                    | 4/1.71                   | 28                  |

### Results for adults

| Commodity                      | Highest % of ARfD/ADI | MRL/Input for RA (mg/kg) | Exposure (µg/kg bw) |
|-------------------------------|-----------------------|--------------------------|---------------------|
| Celeries                      | 17%                   | 3/0.16                   | 296                 |
| Escaroles/broad-leaved        | 12%                   | 15/8.9                   | 179                 |
| Chards/broad-leaved           | 11%                   | 15/8.9                   | 168                 |
| Lettuces                      | 7%                    | 15/8.9                   | 108                 |
| Table grapes                  | 5%                    | 3/0.16                   | 78                  |
| Wine grapes                   | 4%                    | 2/1.3                    | 55                  |
| Red mustard                   | 3%                    | 15/8.9                   | 47                  |
| Pears                         | 3%                    | 2/1.3                    | 40                  |
| Apples                        | 2%                    | 2/1.3                    | 36                  |
| Spinaches                     | 2%                    | 15/8.9                   | 36                  |
| Strawberries                  | 2%                    | 5/3.74                   | 35                  |
| Florence fennels              | 2%                    | 4/1.71                   | 32                  |
| Plums                         | 2%                    | 2/1.7                    | 32                  |
| Kaki/Japanese persimmons      | 2%                    | 2/1.7                    | 30                  |
| Broccoli                      | 2%                    | 2/1.7                    | 29                  |
| Cauliflower                   | 2%                    | 2/1.1                    | 26                  |
| Aubergines/egg plants         | 1%                    | 1.5/0.97                 | 21                  |
| Carrots                       | 1%                    | 1.5/1.04                 | 20                  |
| Quinces                       | 1%                    | 2/1.3                    | 20                  |
| Purslane                      | 1%                    | 15/8.9                   | 17                  |
| Globe artichokes              | 1%                    | 4/1.3                    | 17                  |
| Lamb's lettuce and salads    | 1%                    | 15/8.9                   | 17                  |
### Processed commodities

| Highest % of ARfD/ADI | Processed commodities | Exposure (µg/kg bw) | MRL/input (mg/kg) | Exposure (µg/kg bw) | MRL/input (mg/kg) |
|-----------------------|-----------------------|---------------------|-------------------|---------------------|-------------------|
| 39%                   | Escaroles/broad-leaved endives/boiled | 590                | 15/8.9            | 36%                 | Celeri/boiled     | 540               |
| 19%                   | Spinach/boiled         | 292                | 15/8.9            | 12%                 | Escaroles/broad-leaved endives/boiled | 15/8.9 | 182 |
| 18%                   | Chard/Beet leaves/boiled | 277                | 15/8.9            | 7%                  | Chard/Beet leaves/boiled | 15/8.9 | 111 |
| 8%                    | Broccoli/boiled       | 87                 | 2/1.1             | 5%                  | Spinach/boiled    | 74                |
| 5%                    | Florence fennels/boiled | 78                 | 4/1.71            | 3%                  | Caffiflower/boiled | 46                |
| 5%                    | Cauliflower/boiled    | 77                 | 2/1.1             | 2%                  | Purines/boiled    | 37                |
| 4%                    | Spinach/boiled        | 53                 | 1.5/1.04          | 27%                 | Spinach/boiled    | 4/1.71            |
| 3%                    | Beetroot/boiled       | 46                 | 2/1.1             | 2%                  | Beetroot/boiled  | 1/5.04            |
| 2%                    | Peaches/canned        | 35                 | 2/1.1             | 2%                  | Peaches/canned   | 27.1              |
| 2%                    | Pumpkins/boiled       | 32                 | 0.6/0.36          | 2%                  | Pumpkins/boiled  | 0.6/0.36          |
| 2%                    | Wine grapes/juice     | 29                 | 0.6/0.36          | 2%                  | Pumpkins/boiled  | 0.6/0.36          |
| 2%                    | Babassins/boiled      | 27                 | 1.5/1.04          | 1%                  | Wine grapes/wine | 3.2/3             |
| 2%                    | Apple/boiled          | 26                 | 2/1.1             | 2%                  | Apples/boiled    | 20/4.8            |
| 2%                    | Head cabbages/boiled  | 23                 | 0.7/0.36          | 2%                  | Head cabbages/boiled | 0.7/0.36 | 14 |
| 1%                    | Carrots/boiled        | 20                 | 3/3.69            | 2%                  | Carrots/boiled   | 3/3.69            |
| 1%                    | Pears/juice           | 16                 | 2/1.1             | 1.0%                | Pears/boiled     | 15/8.9            |
| 1%                    | Beans (with pods)/boiled | 14                 | 2/1.1             | 0.9%                | Beans/boiled     | 3/3.69            |
| 0.9%                  | Courgettes/boiled     | 13                 | 0.5/0.36          | 0.8%                | Courgettes/boiled | 0.5/0.36 | 8.2 |
| 0.8%                  | Peaches/juice         | 11                 | 2/1.1             | 0.7%                | Peaches/boiled  | 2/1.1             |
| 0.7%                  | Elderberries/juice    | 11                 | 1.5/1.04          | 0.6%                | Elderberries/boiled | 1.5/1.04 | 14 |
| 0.5%                  | Rasberries/juice      | 8.3                | 0.5/0.36          | 0.6%                | Rasberries/boiled  | 0.5/0.36 | 1.3 |
| 0.5%                  | Plums/juice           | 6.4                | 2/1.1             | 0.4%                | Plums/boiled     | 2/1.1             |
| 0.3%                  | Cranberries/juice     | 4.0                | 3/0.69            | 0.3%                | Cranberries/boiled | 3/0.69 | 0.86 |
| 0.3%                  | Azarole (mediterranean medlar) | 3.8           | 3/0.69            | 0.2%                | Azarole (mediterranean medlar) | 3/0.69 | 0.86 |
| 0.2%                  | Oat/boiled            | 2.7                | 4/0.75            | 0.2%                | Oat/boiled       | 4/0.75            |
| 0.2%                  | Barley/cooked         | 1.3                | 4/0.75            | 0.2%                | Barley/boiled    | 4/0.75            |
| 0.1%                  | Rose hips/jam         | 2.7                | 3/0.69            | 0.1%                | Rose hips/boiled | 3/0.69            |
| 0.1%                  | Wheatmilling (flour)  | 0.16               | 0.5/0.13          | 0.1%                | Wheatmilling (flour) | 0.5/0.13 | 1.6 |
| 0.1%                  | Oatmilling (flakes)   | 0.23               | 4.75/2.3          | 0.1%                | Oatmilling (flakes) | 4.75/2.3 | 6.4 |
| 0.1%                  | Rose hips/jam         | 0.21               | 3/0.69            | 0.1%                | Rose hips/boiled | 3/0.69            |
| 0.1%                  | Quinces/jam           | 1.6                | 0.5/0.13          | 0.1%                | Quinces/boiled   | 0.5/0.13          |
| 0.1%                  | Barley/boiled         | 1.5                 | 0.4/0.20          | 0.1%                | Barley/boiled    | 0.4/0.20          |
| 0.1%                  | Wheatmilling (flour)  | 0.31               | 0.4/0.20          | 0.1%                | Wheatmilling (flour) | 0.4/0.20 | 0.31 |
| 0.1%                  | Oatmilling (flakes)   | 0.31               | 0.4/0.20          | 0.1%                | Oatmilling (flakes) | 0.4/0.20 | 0.31 |
| 0.1%                  | Rose hips/jam         | 0.31               | 3/0.69            | 0.1%                | Rose hips/boiled | 3/0.69            |
| 0.1%                  | Wheatmilling (flour)  | 0.31               | 0.5/0.13          | 0.1%                | Wheatmilling (flour) | 0.5/0.13 | 0.31 |
| 0.1%                  | Oatmilling (flakes)   | 0.31               | 0.4/0.20          | 0.1%                | Oatmilling (flakes) | 0.4/0.20 | 0.31 |

### Conclusion:

No exceedance of the toxicological reference value was identified for any unprocessed commodity. A short-term intake of residues of Cyprodinil (F) is unlikely to present a public health risk. For processed commodities, no exceedance of the ARfD/ADI 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 |                          |                       |                      |                       |
| Florence fennel                          | 0.77                    | STMR                  | 1.71                 | 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, salsifies | 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)     |                       |                       |
| Celeries                                 | 8.45                    | STMR (FAO, 2017)     |                       |                       |
| 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, 2016)     |                       |                       |
| Barley, oat                              | 0.75                    | STMR (EFSA, 2013)     |                       |                       |

The acute exposure assessment was performed only for the crop under consideration.
| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|-------------------------|-----------------------|
|                                               | Input value (mg/kg)     | Comment               |
| Rye, wheat                                    | 0.13                    | STMR (EFSA, 2013)     |
| Herbal infusions (dried roots); Roots         | 0.45                    | STMR (EFSA, 2013)     |
| and rhizome of spices                         |                         |                       |

**Risk assessment residue definition:** sum of cyprodinil and CGA 304075, expressed as cyprodinil

| Commodity                                      | Chronic risk assessment | Acute risk assessment |
|-----------------------------------------------|-------------------------|-----------------------|
|                                               | Input value (mg/kg)     | Comment               |
| 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.
## 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 | ![Structural formula](attachment:image1.png) |
|                               | Cc1cc(nc(Nc2ccccccc1)n1)C3CC3                  |                                 |
|                               | HAORKNGN1CEJBX-UHFFFAOYSA-N                    |                                 |
| CGA2492871                    | 4-cyclopropyl-6-methylpyrimidin-2-amine        | ![Structural formula](attachment:image2.png) |
|                               | Cc1cc(nc(N)n1)C2CC2                           |                                 |
|                               | KPMMRZPKAYBHME-UHFFFAOYSA-N                    |                                 |
| CGA321915                     | 4-cyclopropyl-6-methylpyrimidin-2(1H)-one     | ![Structural formula](attachment:image3.png) |
|                               | CC1=CC(=NC(=O)N1)C2CC2                       |                                 |
|                               | QODMYONMGMOC1-UHFFFAOYSA-N                    |                                 |
| CGA263208                     | 1-phenylguanidine                             | ![Structural formula](attachment:image4.png) |
| CA1139A                       | NC(=N)Nc1ccccc1                               |                                 |
|                               | QRJZGVVKGFG1L1-UHFFFAOYAW                     |                                 |
| NOA422054                     | (2-amino-6-cyclopropylpyrimidin-4-yl)methanol  | ![Structural formula](attachment:image5.png) |
|                               | Nc1nc(cc(CO)n1)C2CC2                         |                                 |
|                               | SPGFTSNGXQXSO-UHFFFAOYAM                      |                                 |
| CGA232449                     | [6-cyclopropyl-2-(phenylamino)pyrimidin-4-yl]methanol | ![Structural formula](attachment:image6.png) |
|                               | OCc2cc(nc(Nc1ccccccc1)n2)C3CC3               |                                 |
|                               | KWORTNPHVKWENH-UHFFFAOYAD                     |                                 |

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 2017.2.1 ACD/Labs 2017 Release (File version N40E41, Build 96719, 6 September 2017).

<sup>(c):</sup> ACD/ChemSketch 2017.2.1 ACD/Labs 2017 Release (File version C40H41, Build 99535, 14 February 2018).